

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

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2022

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____
Commission File Number 001-33462

INSULET CORPORATION

(Exact name of Registrant as specified in its charter)

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

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

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

<u>Title of Each Class</u>	<u>Trading Symbol(s)</u>	<u>Name of Each Exchange on Which Registered</u>
Common Stock, \$0.001 Par Value Per Share	PODD	The NASDAQ Stock Market, LLC

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

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

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

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

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

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

Large accelerated filer

Non-accelerated filer

Accelerated filer

Smaller reporting company

Emerging growth company

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

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

The aggregate market value of the common stock held by non-affiliates of the registrant computed by reference to the last reported sale price of the Common Stock as reported on The NASDAQ Global Market on June 30, 2022 was approximately \$15.1 billion.

The number of shares of common stock outstanding as of February 16, 2023 was 69,542,257.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a proxy statement pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2022. Portions of such proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K.

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PART I

Item 1. Business

Overview

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 (“Classic Omnipod”), the Omnipod DASH[®] Insulin Management System (“Omnipod DASH”), and the Omnipod[®] 5 Automated Insulin Delivery System (“Omnipod 5”). In addition, substantially all 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 Neulasta 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, 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 approximately five 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 six million people have insulin-intensive type 2 diabetes in the countries we currently serve.

We estimate that approximately 40% of the type 1 diabetes population in the United States and even less of the international type 1 diabetes population use insulin pump therapy. An even smaller portion of the U.S. and international insulin-intensive type 2 diabetes population 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-intensive 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, 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 with multiple daily injections of insulin. 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 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

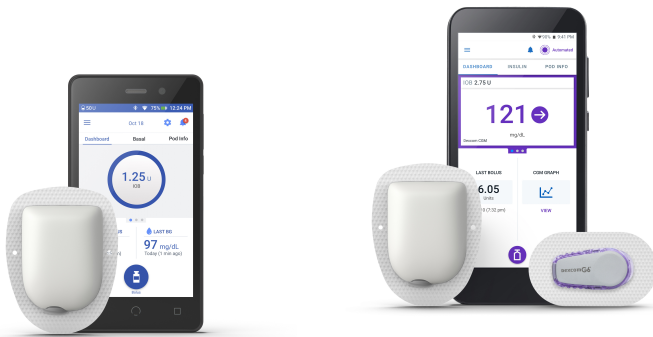
People with insulin-dependent diabetes need a continuous supply of insulin, known as basal insulin, to provide for background metabolic needs. In addition to basal insulin, people with insulin-dependent diabetes require supplemental insulin, known as bolus insulin, to compensate for carbohydrates ingested during meals or snacks or for a high blood glucose level caused by other physiological reasons. 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 perform continuous subcutaneous insulin infusion and typically use a programmable device and an infusion set to administer insulin into the body. Insulin pump therapy has been shown to provide numerous advantages relative to MDI therapy. For example, insulin pump therapy eliminates individual insulin injections, 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, including the use of continuous glucose monitoring technology and automated insulin device (“AID”) algorithms, 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.



Omnipod DASH

Omnipod 5

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 insulin into the body through a small flexible tube (called a cannula); and
- the Personal Diabetes Manager (“PDM”) or Controller, a wireless, handheld device that programs the Pod with the user’s personalized insulin-delivery instructions and wirelessly monitors the Pod’s operation.

Additionally, Omnipod 5 is interoperable with a third-party continuous glucose monitor (“CGM”) sold separately that obtains glucose values and integrates with the Pod.

Further, 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 healthcare providers access to insulin delivery trends, blood glucose levels, and other integrated data.

Omnipod DASH

Omnipod DASH was fully launched in the United States in 2019 and in our international markets starting in 2020. It features a secure Bluetooth enabled Pod and PDM with a color touch screen user interface supported by smartphone connectivity. In the U.S., the PDM has nightly automatic data uploads providing users and their clinicians with cloud access to data, and enhancements for pushing software updates wirelessly to users.

Omnipod DASH 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.

Omnipod DASH delivers 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 Omnipod DASH to fit within the normal daily routines of users. Omnipod DASH communicates wirelessly, provides for virtually pain-free automated cannula insertion, and eliminates the need for MDI therapy or the use of pump and tubing. The Pod can be worn for up to three days at a time and, because it is waterproof up to 25 feet, there is no need to remove it when showering, swimming, or performing other activities. As a result, Omnipod DASH is easy to use, which reduces the training burden on healthcare professionals and users. We believe that Omnipod DASH's overall ease of use and flexibility make it very attractive to people with insulin-dependent diabetes and their healthcare professionals.

Omnipod 5

Omnipod 5, which builds on our Omnipod DASH platform, was cleared by the U.S. Food and Drug Administration ("FDA") in January 2022. Our limited market release of Omnipod 5 in the United States commenced the following month, and in August 2022 we launched our U.S. full market release. In September 2022, we received CE Mark approval for Omnipod 5 under the European Union Medical Device Regulation ("MDR").

Omnipod 5 includes an AID algorithm that is located on the Pod. The Pod integrates with a third-party CGM to obtain glucose values through wireless Bluetooth communication. The embedded algorithm predicts glucose levels into the future and automatically adjusts insulin dosing intended to achieve user selected glucose targets and reduce the occurrence of blood glucose highs and lows. The user can also deliver insulin doses for snacks or meals or to correct high blood glucose through the system. The Pod is controllable by an Insulet-provided handheld device (Controller) or a user-downloaded Android app, which allows for full compatible smartphone control. The Omnipod 5 Controller and Omnipod 5 Android app use cloud-based technology to wirelessly upload data using a built-in SIM card for cellular connectivity or from a secure Wi-Fi connection if established. The Pod currently integrates with a CGM manufactured by Dexcom, Inc.

Subsequent to the launch of Omnipod 5, the vast majority of our customer base is no longer using our Classic Omnipod product. We plan to phase-out our Classic Omnipod product in the U.S. in 2023.

Security

Paramount to our ability to deliver full compatible smartphone control is our commitment to cybersecurity 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, Insulet's information security management system is International Organization for Standardization ("ISO") 27001 and 27701 certified, which are the international standard for best practice in an information security management system globally. With the DTSec and ISO certifications, Insulet is globally recognized for incorporating the highest standards for cybersecurity and information security and safety, including secure data transfer between the Pod and PDM, as well as secure cloud storage.

Insulet continues to advance the cybersecurity capabilities of our medical devices. Omnipod 5 is globally recognized for incorporating the highest standards for information and cyber security by design, which includes secure data transfer between the Pod and the Controller, as well as secure cloud storage. Omnipod 5 is certified by ISO 27001 and the U.K. Cyber Essentials. In addition, Omnipod 5 utilizes state-of-the-art authentication, encryption, and cybersecurity protection that enables the use of approved personal smartphone devices.

Third-Party Reimbursement

In the United States, our products are sold to wholesalers, private healthcare organizations, healthcare facilities, mail order pharmacies, and independent retailers, as well as directly to consumers. These entities, and the Company in some cases, seek reimbursement from health insurance companies and/or government administrative payors. In the United States, consumers generally have commercial insurance, Medicare or Medicaid coverage that pays for the product. The Omnipod System's unique patented design allows 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. In certain international 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 following 24 countries:

Australia	Finland	Italy	Sweden
Austria	France	Kuwait	Switzerland
Belgium	Germany	Netherlands	Turkey
Canada	Greece	Norway	United Arab Emirates
Croatia	Iceland	Qatar	United Kingdom
Denmark	Israel	Saudi Arabia	United States

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, 2022, 84% of our Omnipod System sales were through intermediaries. The Omnipod System is also marketed to physicians.

The percentages of total revenue for customers that represent 10% or more of total revenue was as follows:

	Years Ended December 31,		
	2022	2021	2020
Distributor A	19%	*	*
Distributor B	17%	12%	10%
Distributor C	*	10%	11%
Distributor D	16%	*	*

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

Our sales and marketing efforts are focused on customer acquisition and retention to meet the user, clinician, and payor demands for the Omnipod System. We have a comprehensive sales and marketing approach, which communicates the benefits of the Omnipod System to users, physicians and providers. This includes three areas of focus:

- Building consumer awareness about the features and benefits that the Omnipod System provides to simplify diabetes management.
- Strengthening physician support by demonstrating clinical evidence of how the Omnipod System improves outcomes and quality of life and providing data and insights to physicians offering diabetes care.
- Providing payors with the clinical and economic justifications for why the Omnipod System offers unique value to the people whom they insure.

Training

We believe that training consumers on 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. We created an online training program for Omnipod customers transitioning to Omnipod DASH or Omnipod 5. In addition, our virtual training allows us to onboard new Omnipod customers transitioning from MDI 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. Our customer support systems are integrated with our sales, reimbursement and billing processes, allowing us to provide customers with seamless and reliable support by telephone and through our website.

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 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. We also compete with companies in the insulin pump market, which today consists of tubed pump companies, including Medtronic MiniMed, a division of Medtronic public limited company (“Medtronic”), and Tandem Diabetes Care Inc. (“Tandem”). Medtronic historically has held the

majority share of the tubed insulin pump market. 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 innovation programs are 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.

In addition, our research and development efforts are primarily focused on making improvements to the Omnipod System, including adding features and functionality that will deliver increased economic value and convenience to users. In 2022, we received FDA clearance for Omnipod 5 for individuals aged two years and older with type 1 diabetes and received CE Mark approval for Omnipod 5 under the European Union MDR. We plan to begin a pivotal trial for Omnipod 5 in 2023 with the goal of expanding Omnipod 5's indications to individuals with type 2 diabetes. In addition, we have a development and commercialization agreement to integrate Abbott Diabetes Care, Inc.'s CGM with Omnipod 5 in the future and are also working on developing an iOS app that could be utilized to control Omnipod 5 Pods.

Additionally, in November 2022, we submitted our 510(k) application to the FDA for a basal-only Pod for individuals with type 2 diabetes, which is a version of Omnipod specifically designed for customers on basal-only therapy. The basal-only Pod is designed to deliver a fixed rate of rapid-acting insulin for 72 continuous hours and does not require a PDM/Controller or phone application for use.

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 at high quality 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 and 2021, we began producing on additional lines in this facility. The Acton facility increases supply redundancy and adds capacity closer to our North American customer base to support the growth of our business.

We also produce our devices on manufacturing lines at a facility in Kunshan (Shanghai), China operated by a contract manufacturer. This contract manufacturing agreement expires in October 2025 and is subject to automatic renewal, unless canceled by either party under the terms of the contract. We have optimized our operations in China by consolidating our Omnipod production in that region into this one location. Additionally, in 2022, we broke ground on a new manufacturing plant in Malaysia to support our international expansion strategy and further ensure product supply.

We also continue to invest in supply chain efficiencies, including automation improvements at our suppliers and contract manufacturer. In January 2022, we acquired one of our suppliers to bring key intellectual property and expertise in-house, strengthen our production capabilities and mitigate supply chain risks.

Raw Materials

We use a broad range of raw materials in the assembly and manufacturing of the Omnipod System. We purchase 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 a certain number 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 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 in-house and at the supplier to ensure continuity of supply and lower risk of disruption. We purchase many of our 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 our ISO, European Union MDR, and Medical Device Single Audit Program certifications for our Quality Management System from BSI Group, an accredited Notified Body for CE Marking. 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, 2022, we had over 260 patents in the United States and in certain other countries, with expiration dates ranging from 2023 through 2042 and had over 250 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/Controller;
- the Omnipod drive system;
- the Omnipod cannula insertion system;
- control features of the Omnipod System and next generation products;
- software, such as algorithms and 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 INSULET™, OMNIPOD®, OMNIPOD® 5 Automated Insulin Delivery System, SIMPLIFY LIFE™, Omnipod DASH®, Omnipod DISPLAY®, Omnipod VIEW™, SmartAdjust™, Pod Pals®, Podder®, and PodderCentral®.

Recent Intellectual Property Agreements

Bigfoot. In February 2023, we entered into a Patent Assignment and License Agreement with Bigfoot Biomedical, Inc. (“Bigfoot”), pursuant to which we acquired approximately 400 patents as well as a significant number of global patent applications, and licensed a large number of additional patents and patent applications on a fully paid-up exclusive or non-exclusive basis.

Medtronic. In October 2022, we entered into a mutual agreement with Medtronic, Inc., not to assert our patents against each other for certain technologies in the field of diabetes. With certain exclusions, this agreement applies to the companies’ existing products, as well as new products for at least the next seven years. No payments have been or will be exchanged as part of the agreement. The agreement replaces and terminates the Settlement and Cross License Agreement, dated September 18, 2013, by and between us and Medtronic.

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 pre-market 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, Omnipod DASH, and Omnipod 5 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 12 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 if the FDA disagrees with a manufacturer’s determination, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or PMA is obtained and assess 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 PMA, a new PMA 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.

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 insufficient 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 healthcare 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 healthcare 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 discussed 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 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 to violate 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.

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 statutory and regulatory exceptions protecting certain common business practices, 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 Stark 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 healthcare 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 Healthcare Fraud Statutes. We are also subject to a federal healthcare fraud statutes that, among other things, impose criminal and civil liability for executing a scheme to defraud any healthcare benefit program including non-governmental programs, and prohibit 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 healthcare benefits, items, or services. Violations of these statutes can result in significant civil, criminal, and administrative penalties, fines, damages, and exclusion from federal healthcare 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 compliance with such laws.

Moreover, several states have imposed requirements to disclose payments to healthcare providers, restrictions on marketing and other expenditures, and requirements to adopt a code of conduct or compliance program with specific elements. Liability under such laws could result in fines and penalties and restrictions on our ability to operate in these jurisdictions.

Administrative Simplification of the Health Insurance Portability and Accountability Act of 1996. The Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) mandated the adoption of standards for the exchange of electronic health information to encourage overall administrative simplification and enhance the effectiveness and efficiency of the healthcare industry. Ensuring privacy and security of patient information is one of the key factors driving the legislation. 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.

Privacy Laws. Several states have enacted various privacy laws. For example, 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. 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 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 with respect to personal data collected beginning in January 2022. CPRA enforcement is scheduled to begin on July 1, 2023. If we fail to comply with these regulations, we could be subject to civil sanctions, including fines and penalties for noncompliance. Virginia and Colorado have enacted similar laws. The Consumer Data Protection Act became effective in Virginia on January 1, 2023, and the Colorado Privacy Act is effective July 1, 2023. In addition, general privacy legislation has been filed in Congress, but the final form of the legislation and when it might be enacted is difficult to predict.

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. 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. Applicable manufacturers are also 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 healthcare providers.

Since 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 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 laws.

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.

U.S. Foreign Corrupt Practices Act (“FCPA”). We are subject to FCPA in the U.S. and to similar anti-bribery laws in other jurisdictions, which generally prohibit companies and their intermediaries from making improper payments to foreign 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 replaced MDD in May 2021. Devices that comply with the requirements of the MDD will be entitled to bear the CE conformity marking and, accordingly, can be commercially distributed until May 2024, at which time devices must comply with the MDR, unless certain requirements are met that would allow for an extension until December 2027. 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 under the MDD and to the Omnipod 5 System under MDR, 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 Classic Omnipod and Omnipod DASH in Canada.

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 foreign 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, 2022, we had approximately 2,600 full-time employees, representing a 13% increase over the prior year. Approximately 80% of our employees are located in the United States and the remainder are located in 15 other countries.

To assess and improve employee retention and engagement, we survey employees with the assistance of third-party consultants, and take timely action to address key areas of employee concern. We conduct engagement surveys to gain valuable insight into our employees’ experience and identify areas for improvement. In 2022, instead of conducting an engagement survey once per year, we launched ‘Your Voice’ pulse surveys, which are conducted more often, to better understand opportunities to improve our talent management strategy and gain a more dynamic view of our employees’ needs. Our senior leadership team assesses engagement to understand and identify potential opportunities for improvement.

Our executive leadership team conducts regular Town Hall meetings to ensure our global employees are highly engaged and receive timely business updates. To help our remote employees feel socially connected to their colleagues, we created our “Stay Connected” initiative, which 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 also publish a monthly global employee newsletter, which includes a timely collection of high-level developments and local highlights from across our organization and utilize a social networking tool to ensure our global employees are engaged, motivated, and collaborating with one another.

Diversity, Equity, and Inclusion (“DEI”)

Our success thrives on the diversity of perspective, thought, experience, and background within our workforce. We are committed to creating a diverse and inclusive global culture that reflects the diversity of the customers we serve and creates an environment where all employees feel welcomed, respected, and valued. Accordingly, we are committed to providing equal opportunity in all aspects of our Company culture and workplace. In 2022, we continued to develop a comprehensive, multi-year diversity and social impact strategy that outlines how to implement our greatest opportunities for impact, in alignment with the needs of our stakeholders and diversity maturity model. Our DEI activities focus on four main areas—Attraction, Talent Development, Culture, and External Engagement—which reflect our commitment to integrating DEI within our business processes. In 2022, we worked to embed diversity more formally into our talent acquisition process to attract a diverse pool of candidates. In addition, we launched our flagship diversity training, Conscious Inclusion, to all employees.

Our Employee Resource Groups (“ERGs”) serve as a source of inclusion across the following eight categories: African Descent, Asian and Pacific Islander, Hispanic/Latin, LGBTQ+, Sustainability, Veterans and First Responders, Women, and Young Professionals. These ERGs 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, our culture, and our mission, which is to improve the lives of people with diabetes. In 2022, we launched our ‘Ignite Your Growth’ career development program to employees across the globe. We also offer intensive Customer Care New Hire Training and Sales New Hire Training. In addition, employees have access to monthly learning programs and virtual and online learning programs. Further, during our 2022 annual Compliance Week, employees logged over 7,000 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 our 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, we offer virtual training programs and employee communications designed to support employees and leaders that take advantage of our flexible work policy, 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, 80 hours of COVID-19 paid sick time, accident insurance, critical illness insurance, life insurance, disability insurance, health savings accounts, flexible savings accounts, retirement plans, employee stock purchase plan, legal services, identity theft protection, maternity/paternity leave, and employee assistance program. In addition, we offer Pod perks, which provides a free Omnipod System, including PDM/Controller and Pods to benefit eligible employees, interns, or dependents; summer hours; and a flexible work policy.

In addition to the above, we continued our commitment to flexibility through our Future of Work program. Our Future of Work program and Global Flexible Working Arrangement Policy are rooted in a “choice with responsibility” philosophy. Our sustained commitment to flexibility enables access to a broader, more diverse, and more exceptional talent pool.

Health and Safety

We maintain an occupational health and safety management system that covers all our employees, contractors, and temporary employees because we are committed to the safety and well-being of our workforce. By minimizing risks at our factories and implementing training to enhance awareness of hazards, we are able to promote safe practices and preserve the health of our employees.

Modern manufacturing enables efficiency and automation, which reduces exposure to health and safety risks throughout the production process. At our facilities, the majority of our equipment is fully automated to minimize human involvement in the operations of machines and therefore reduce the risk of injury. We maintain high standards for workplace safety, and our orientation for technicians includes training about safe procedures, such as lockout/tagout.

We have a Health and Safety Compliance Manual to provide employees with the tools needed to identify and report hazards and reduce work-related injuries. Our programs and policies are in compliance with applicable local, regional, and federal laws, including U.S. Occupational Safety and Health Administration requirements. We continuously monitor and adapt to regional regulations as we expand our facilities into new geographies. In addition to hazard recognition, our workplace health and safety programs cover ergonomics, hearing conservation, fall protection, and accident and injury prevention.

We also have formal plans in place to protect our employee's safety in the event of an emergency. In addition, our Acton, Massachusetts facility maintains an Emergency Action Plan that describes procedures that employees should follow when faced with a variety of unexpected health and safety events. As part of this initiative, we trained certain employees to use automated external defibrillators, provide first aid, and perform cardiopulmonary resuscitation (CPR). In addition, we conduct periodic health and safety audits of our facilities to monitor the effectiveness of our programs and drive continuous improvement in our overall safety performance as Insulet expands in size and impact.

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, Talent and 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:

- 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;
- 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;
- results of clinical studies relating to the Omnipod System or our competitors' products; and
- development of an effective patch pump by one or more competitors.

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 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 rapid 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 the number of customers we serve, driven in large part by significant demand for Omnipod 5, 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, including our customer service. In order to manage future growth, we will be required to improve existing, and implement new, sales and marketing efforts, distribution channels, and customer support procedures. The form and function of our enterprise information technology systems will need to change and be improved upon as our business needs change. For example, we are currently working to implement a new enterprise resource planning system and significantly upgrade our customer relationship management system. We will also need to manage our supply chain and manufacturing effectively, including our sourcing of materials such as semiconductor chips. 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, which, in the U.S., occur only through the pharmacy channel for Omnipod 5 and primarily through the pharmacy channel for Omnipod DASH, 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, intermediaries, Medicare, Medicaid 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 and government agencies that provide reimbursement in all 50 states. Medicare Part D Plan Sponsors may provide coverage for the Omnipod System under the Medicare Part D prescription drug program, which requires negotiating with third-party payors in order to provide our product through the pharmacy channel in the United States. While we anticipate entering into additional contracts with other intermediaries and third-party payors, we cannot assure you that our efforts will be successful, which could limit the availability of the Omnipod System. 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 and for payment to be made for such use. 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.

As we expand our Omnipod System sales and marketing efforts internationally, we face additional risks associated with obtaining and maintaining reimbursement from foreign healthcare 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.

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 Competition, Product Development and Intellectual Property

Our failure to compete effectively would negatively impact our revenue.

The competitive landscape in our industry continues to undergo significant change. We compete with companies that produce insulin pumps, such as Medtronic, Tandem, The Ypsomed Group and Roche Diabetes Care, Inc (“Roche”). In addition to the established insulin pump competitors, we compete with companies that provide products and supplies for MDI therapy. MDI therapy, including smart pens, can be substantially less expensive than pump therapy, and 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, which could result in price pressure and decreased revenue.

In addition, some of our competitors, such as Medtronic and Roche, 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.

Our current competitors or other companies may at any time develop additional products for the treatment of diabetes. Several companies are working to develop and market new insulin “patch” pumps, smart pens, and other methods 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, in 2020 Tandem launched an AID system, with which Omnipod 5 competes directly, and which could negatively impact our business. In addition, the National Institutes of Health and other supporters of diabetes research are continually seeking ways to prevent, cure, or improve the treatment of diabetes. Any technological breakthroughs in diabetes monitoring, treatment, or prevention could render the Omnipod System obsolete, which would have a material adverse effect on our business, financial condition, and results of operations.

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

The healthcare industry is characterized by continuous technological change, resulting in changing consumer preferences and requirements. If we are unable to introduce and market new products and keep pace with advances in technology, our business will be negatively impacted. 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 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 develop or acquire commercially valuable intellectual property rights and to protect those rights adequately. 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.

We may not be able to develop additional proprietary technologies that are patentable, and we cannot ensure that our pending patent applications will result in the issuance of patents to us. We also cannot ensure that patents issued to, or licensed by or to, us in the past or in the future will not be challenged or circumvented by competitors. These patents may be found to be invalid or not 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 internationally may be limited in certain circumstances. For example, we may not be able to protect our intellectual property rights effectively in China, where we rely on a third-party contract manufacturer to produce our product.

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.

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.

While not a part of our business plans or operations, we have been involved in patent infringement suits in the past, including as disclosed in Note 17 to the consolidated financial statements included in Item 8. As our revenue increases, the number of companies with whom we compete grows and the functionality of products and technology in different industry segments overlaps, the risk of third-party infringement claims increases. Third parties may currently have, or may eventually be issued, patents on which our current or future products or technologies may infringe. Any of these third parties might make a claim of infringement against us.

Such litigation, regardless of its outcome, could result in the expenditure of significant financial resources and the diversion of management's time and resources. In addition, such litigation could cause negative publicity, adversely affect prospective users, cause product shipment delays, limit or prohibit us from manufacturing, marketing or selling our current or future products, and/or 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 consumers 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.

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 sell 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 System 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 System 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.

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 and worldwide economic issues, such as inflation.

The COVID-19 pandemic and preventative measures taken to contain or mitigate the outbreak have caused, and to some degree are continuing to cause, business slowdown or shutdown in affected areas, supply chain disruptions, labor shortages, inflation and disruption in the financial markets globally. As a result of the pandemic as well as worldwide economic issues such as inflation, consumers may reduce their spending, new orders for our Omnipod System may decline and our user 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, further disruption in China 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, many employees have transitioned to a remote or hybrid work environment, which has increased risks associated with our information technology systems and networks. These increased risks include 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, as it did for Omnipod 5.

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

In addition to the United States, we sell the Omnipod System in Europe, Canada, the Middle East and Australia. Our international operations are subject to risks that are inherent in conducting business under foreign laws, regulations and customs. International sales made up over 25% of our revenues in 2022 and we expect international 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 in other countries. For example, a significant portion of our Omnipod Systems are manufactured at third-party contract manufacturer facility in China.

Our efforts to introduce or expand our current or future products in international 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 international 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 international operations;
- difficulties associated with foreign legal systems, including increased costs associated with enforcing contractual obligations in foreign jurisdictions;
- adapting to the differing laws and regulations, business and clinical practices, and consumer preferences in international markets;
- difficulties in managing international relationships, 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”. While the UK and the European Union entered into a Trade and Cooperation Agreement, a number of areas are still unsettled, and 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 as well as 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 foreign 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 United States. 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 Drug Delivery

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

Our manufacturing of the Omnipod System is conducted in two locations, at our U.S. manufacturing facility in Massachusetts and on manufacturing lines owned by us at a facility located in China that is operated by a third-party contract manufacturer. Political or financial instability, currency fluctuations, the outbreak of pandemics such as 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 of 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 manufacturer and logistics entity safeguard our assets, including maintaining insurance, enacting health and safety protocols, and storing computer data offsite. 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.

We are dependent upon third-party suppliers, making us vulnerable to supply problems and price fluctuations, and we may not be able to obtain sufficient components or raw materials on a timely basis at all.

The manufacture of our product requires the timely delivery of sufficient amounts of quality 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. For example, given the recent worldwide semiconductor chip shortage, we have entered into “take or pay” contracts with suppliers but cannot guarantee our suppliers will meet their obligations under these contracts. We have also seen significant price increases for various components and raw materials, including for semiconductor chips. We do not have long-term supply agreements with all of our suppliers, and, in many cases, we, or our contract manufacturer, make purchases based on individual purchase orders. In some cases, our agreements with suppliers can be terminated by either party upon short notice. Additionally, while efforts are made to diversify our sources of components and materials, in certain instances we acquire components and materials from a sole supplier. Also, due to the stringent regulations and requirements of the FDA and similar regulatory agencies in other countries regarding the manufacture of our products, we may not be able to quickly establish additional or replacement sources for some components or materials.

Our reliance on these third-party suppliers, as well as on our third-party manufacturer, subjects us to other risks that could harm our business, including:

- our suppliers may give other customers’ needs higher priority than ours affecting their ability to deliver products to us in a timely manner, as we are not a major customer of many of our suppliers;
- we may not be able to obtain an adequate supply of materials or components 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);
- 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.

An interruption, delay, or inability to obtain components, products and raw materials from our third-party suppliers at acceptable prices in a timely manner, 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.

Our manufacturing process is highly complex and subject to regulation; as demand for our products increase, we may experience manufacturing difficulties, including not effectively managing the start-up of new manufacturing lines or issues with our third-party contract manufacturer, which could harm our business.

The manufacture of our product is highly exacting and complex, due in part to strict regulatory requirements. While we manufacture Omnipod Systems in the United States, a third-party contract manufacturer in China performs assembly and supplies a significant portion of all finished Omnipod Systems. We and our contract manufacturer may encounter problems during manufacturing for a variety of reasons, including equipment malfunction, failure to follow specific protocols and procedures, defective raw materials, and environmental factors. These issues 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 could have a material adverse effect on our business, results of operations, financial condition, and cash flows. In addition, as we commence operation of new manufacturing lines, we could experience quality issues and unexpected operational delays that decrease our gross margins and cause a shortage of product supply.

Our 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. Substantially all of our commercialized Drug Delivery revenue consists of sales of a customized version of our product for use in Amgen's Neulasta Onpro kit under an agreement that expires in December 2023. 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 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 an 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 or not renewed, 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, and 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. While we have received 510(k) clearance for our Omnipod Insulin Management System as well as modified versions of this device, including Omnipod DASH and Omnipod 5, we may be required to obtain a new 510(k) clearance or PMA for significant further post-market modifications. Obtaining 510(k) clearance or PMA can be expensive and lengthy, and we may not be able to obtain them 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. As described elsewhere in this 10-K, in October and November 2022, we issued voluntary Medical Device Corrections (“MDCs”) relating to the batteries and/or charging of our DASH PDMs and Omnipod 5 Controllers, which are manufactured for us by a third-party.

In addition, the FDA may change its clearance and approval policies, adopt additional regulations, 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 pre- and post-market regulatory processes and requirements associated with infusion pumps and other home use medical devices. As part of this effort, the FDA is reviewing the adverse event reporting and recall processes for insulin pumps. Any change in the laws or regulations that govern the clearance and approval processes relating to our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market, and distribute existing products.

The Omnipod System is also sold in Canada, Australia 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 manufacturer or our component suppliers fail to comply with the FDA’s quality system regulations, the manufacturing and distribution of our devices could be interrupted, and our sales and operating results could suffer.

We and our contract manufacturers’ 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’ facilities would pass any future quality system inspection. If our or our contract manufacturers’ facilities fails a quality system inspection, the manufacturing or distribution of our devices could be interrupted, and our operations disrupted. Failure to take adequate and timely corrective action in response to an adverse quality system inspection could force a suspension or shutdown of our labeling operations or the manufacturing operations of our contract manufacturer, or a recall of our devices.

If we, or our contract manufacturer, 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.

The FDA and similar governmental bodies in other countries have the authority to require the recall of our products if we or our contract manufacturer fails 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. 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, such as our voluntary MDCs issued in October and November 2022, or involuntary, may require the dedication of our time and capital, could distract management from operating our business and potentially harm our reputation and financial results.

In the event of a recall, 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 to the FDA. If the FDA disagrees with our determinations, it 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.

If we fail to comply with Medicare, Medicaid, fraud and abuse, and other healthcare 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 healthcare 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 healthcare 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 healthcare 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 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 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. Colorado and Virginia have enacted similar privacy laws that will also take effect in 2023. California and other states' laws apply more broadly and now or in the future may reach data we hold that relates to employees and healthcare 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 sanctions, including fines and penalties for noncompliance.

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

The increased scope of regulation around the world may require expanded compliance programs and resources. As our efforts to gain insights from data increase for the operation of our products and services and for the improvement of business processes, including sales and marketing, our exposure to increasingly complex privacy regulation may impede our ability to use data in this way.

We rely on the proper function, availability, and security of our product and information technology systems and a successful 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 nature of our business involves the receipt and storage of personal and financial information regarding our customers, including sensitive medical information. We use our information technology systems to manage or support a variety of business processes and activities, including sales, shipping, billing, customer service, procurement, 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. Many of our information systems are cloud-hosted and managed by third-party vendors, some of which may have access to confidential business, employee, healthcare professional, and/or customer information. 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 people with diabetes. After extensive testing and research in conjunction with an independent third-party firm, a potential security vulnerability in the Omnipod was identified. (This vulnerability does not exist in Omnipod DASH or Omnipod 5.) Successful exploitation of this vulnerability may allow an attacker to gain access to the Pod to intercept, modify, or interfere with the wireless radio frequency communications to or from the PDM. This may allow attackers to read sensitive data, change pump settings, or control insulin delivery.

Insulet is aware of a specific group of people with diabetes who have been able to duplicate the Pod communication protocol using a smartphone and a bridge, which in turn allows the Pod to be controlled using an unauthorized device. This practice is commonly referred to as Do-It-Yourself (DIY) and is not the intended use for the Omnipod System. Insulet has not provided the DIY community with any type of information or input on the product, nor has Insulet been provided with any information proving that this form of off-label use is a safe use of the system. This practice does not exist with Omnipod 5.

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 reputation, business, and operating results may be materially adversely affected.

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. We recently experienced a data security incident impacting a subset of our customers in which the impacted customer's IP address, and whether the customer was a Omnipod DASH user and has a PDM, were inadvertently shared with website performance and marketing partners of Insulet through website "cookies" and other trackers. These trackers have since been disabled, and no financial information, social security numbers, email addresses, or passwords were exposed. All affected customers and relevant authorities were notified, and we did not view this as a material event. 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, 2022, we had debt of \$1.4 billion, including \$800 million aggregate principal amount of Convertible Senior Notes, which mature in 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. 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. If we do not generate sufficient cash flow from operations, and additional borrowings, refinancings, or proceeds from asset sales are not available to us, we may not have sufficient cash to enable us to meet all of our obligations.

Our Credit Agreement imposes restrictions on us that may adversely affect our ability to operate our business.

Our Credit Agreement contains covenants that restrict our ability, and that of our subsidiaries, to engage in certain transactions, including, among other things, limitations on our ability to incur additional indebtedness, make asset dispositions, create or permit liens, sell, transfer or exchange assets, guarantee certain indebtedness, and make acquisitions or other investments. These restrictions may impair our ability to respond to changing business and economic conditions and may make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions.

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, conversion of the Convertible Senior Notes 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, our ability to use net operating loss carryforwards to offset U.S. federal taxable income may become subject to limitations.

General Risks

Our success depends on our ability to attract, motivate, and retain key personnel.

Our success depends on our ability to retain our employees and to attract and retain additional qualified personnel in the future. We face intense competition for employees, particularly in light of recent labor shortages and as people are increasingly able to work remotely. We face challenges in maintaining employee well-being, recognizing that the additional financial, family, and health burdens that many employees may be experiencing due to the COVID-19 pandemic and related economic uncertainties may adversely impact job performance and employee retention. Losing 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 and ensuring seamless transitions. 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. For example, in 2022, we acquired one of our suppliers. Additionally, in December 2022 and February 2023, we acquired intangible assets from Automated Glucose Control LLC ("AGC") and Bigfoot, which provided us important intellectual property. We may not complete 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. Acquisitions also present 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. In addition, integration of an acquired business 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 or debt 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 or other debt obligations. 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 inflation and worldwide political unrest, and we may not be able to raise any necessary capital on acceptable terms, or 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 factors related to our operating performance as a high-growth company and 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 medical device and 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, 2022, we leased a total of 22 facilities in 10 countries consisting of approximately 300,000 square feet of office, research and development, and warehousing space and other related facilities, primarily in North America, Asia and Europe.

Item 3. Legal Proceedings

The information required by this Item is provided under “Legal Proceedings” in Note 17 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 Information

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

Holders of Record

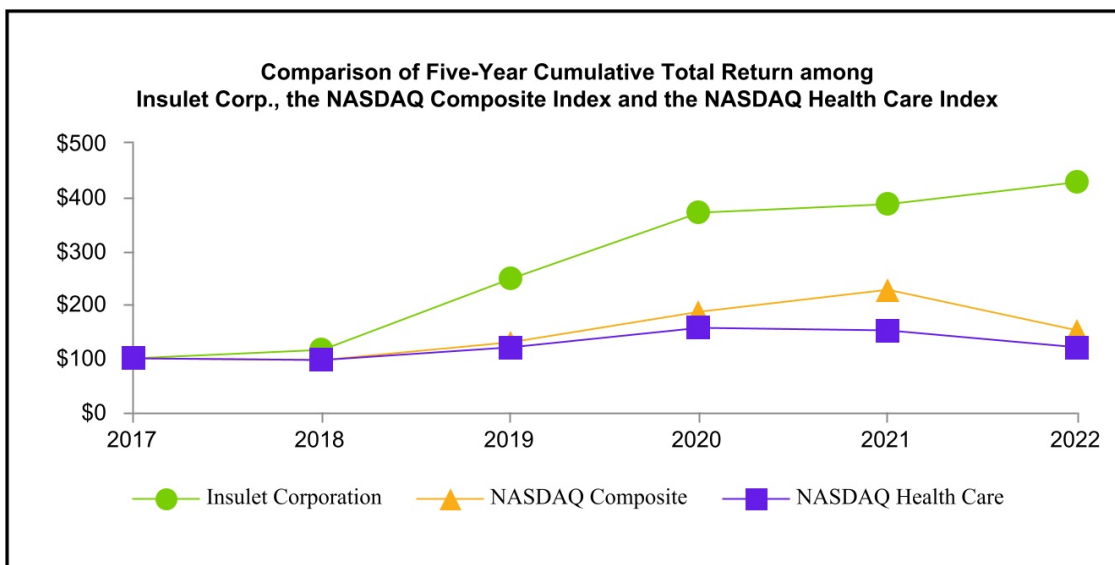
As of February 16, 2023, there were 7 registered holders of record of our common stock.

Recent Sales of Unregistered Securities

None.

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, 2017, and ending on December 31, 2022, assuming reinvestment of all dividends. The historical stock price performance on the graph below is not necessarily indicative of future stock price performance.



	2017	2018	2019	2020	2021	2022
Insulet Corporation	\$ 100	\$ 115	\$ 248	\$ 370	\$ 386	\$ 427
NASDAQ Composite	\$ 100	\$ 96	\$ 130	\$ 187	\$ 227	\$ 152
NASDAQ Health Care	\$ 100	\$ 96	\$ 121	\$ 157	\$ 151	\$ 120

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.

Securities Authorized for Issuance Under Equity Compensation Plans

The information required by this Item is provided under Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Item 6. Reserved

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

Our mission is to improve the lives of people with diabetes. 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 the user fills with insulin and wears directly on the body for up to three days at a time, which delivers personalized doses of insulin, and the PDM or Controller, a wireless handheld device that programs the Pod with the user's personalized insulin-delivery instructions and wirelessly monitors the Pod's operation.

The Omnipod System, includes: Classic Omnipod, its next generation Omnipod DASH, and the most recent generation Omnipod 5, all of which eliminate the need for multiple daily injections using syringes or insulin pens or the use of pump and tubing. Omnipod DASH features a secure Bluetooth enabled Pod and PDM with a color touch screen user interface supported by smartphone connectivity. Omnipod 5, which builds on our Omnipod DASH mobile platform, is a tubeless automated insulin delivery system, that integrates with a continuous glucose monitor ("CGM") to manage blood sugar and is fully controlled by a compatible personal smartphone or Omnipod 5 Controller. The CGM is sold separately by a third party. In addition, substantially all 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 Neulasta to help reduce the risk of infection after intense chemotherapy.

Our long-term financial objective is to sustain profitable growth. To achieve this goal, our efforts have been focused on the launch of Omnipod 5, which in 2022 received FDA clearance for individuals aged two years and older with type 1 diabetes. Our limited market release of Omnipod 5 in the United States began in the first quarter, and in the third quarter we launched our U.S. full market release. We are also working to bring Omnipod 5 to our international markets. We recently received CE Mark approval under the European MDR, and we are currently focused on further building our international teams and advancing our regulatory, reimbursement, and market development efforts. We plan to launch Omnipod 5 in the U.K. and Germany in 2023 and to continue our international roll out more broadly in 2024.

In 2022, we completed our Omnipod 5 type 2 diabetes feasibility study and plan to begin a pivotal trial in 2023 with the goal of expanding Omnipod 5's indication to type 2 users. Additionally, to accelerate our efforts to secure reimbursement for Omnipod 5, we have fully enrolled individuals in a randomized control trial in the U.S. and enrollment will begin soon in France. We also continue to expand market access and awareness of Omnipod through our direct to consumer advertising programs and through growing our presence in the U.S. pharmacy channel, where access to Omnipod 5 and Omnipod DASH is simpler and affordable, as no up-front investment is required. As we continue our growth in the pharmacy channel, we plan to phase-out our Classic Omnipod in the U.S. in 2023, since the vast majority of our customer base is no longer using this product.

Additionally, we continue to increase our presence within our existing markets and expand internationally in a targeted and strategic manner. We opened an office in Dubai to serve as our primary local presence and regional infrastructure in the Middle East, launched Omnipod in Saudi Arabia, and expanded into the United Arab Emirates.

We have also been taking steps to continue strengthening our global manufacturing capabilities. We are optimizing our operations in China by consolidating our production in that region into one location. Further, in 2022 we broke ground on a new manufacturing plant in Malaysia to support our international expansion strategy, further ensure product supply, and drive higher gross margins over time. We expect to begin production at this new manufacturing facility in 2024.

Finally, we continue to focus on our product development efforts, including AID offerings, such as choice of continuous glucose monitor and smartphone integration, and enhancing the customer experience through digital product and data capabilities. We have also developed a basal-only Pod for individuals with type 2 diabetes and submitted our 510(k) application to the FDA in November. We expect commercialization of the basal-only Pod in 2024.

Results of Operations

The discussion of our results of operations for 2020 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, 2021 filed with the Securities and Exchange Commission on February 24, 2022.

Factors Affecting Operating Results

Our Pods are intended to be used continuously for up to three days and then be replaced with a new disposable Pod. We recently achieved a milestone of 360,000 estimated global customers using Omnipod, including over 100,000 U.S. customers using the Omnipod 5. As we grow our customer base, we expect to generate an increasing portion of our revenues through recurring sales of our disposable Pods, which provides recurring revenue. Our recurring revenue business model, alongside the Omnipod System’s unique patented design enables us to provide pump therapy at a low or no up-front investment in regions where reimbursement allows for it. Our pay-as-you-go pricing model also reduces the risk to third-party payors.

During 2022, we issued two voluntary MDCs, one in October for our Omnipod DASH PDM related to its battery and the other in November for our Omnipod 5 Controller related to the charging port and cable. In addition to the estimated liability we recorded in 2022, we have a performance obligation to replace Omnipod DASH PDMs and Omnipod 5 Controllers sold subsequent to the MDC issuances, which is expected to negatively impact gross margins and net income in 2023, most notably in the first half of the year.

We have also experienced and expect to continue to experience challenges stemming from the global supply chain disruption that began during the coronavirus pandemic (“COVID-19”); however, to date we have been able to successfully mitigate this disruption and ensure uninterrupted supply to our customers by increasing our inventory levels and taking other measures. While our mitigation efforts and inflation have and are expected to continue to negatively impact gross margins and net income in 2023, we intend to continue to work to improve productivity to help offset these costs.

Comparison of the Years Ended December 31, 2022 and December 31, 2021

Revenue

(In millions)	Years Ended December 31,		% Change	Currency Impact	Constant Currency ⁽¹⁾
	2022	2021			
U.S. Omnipod	\$ 884.8	\$ 651.5	35.8 %	— %	35.8 %
International Omnipod	363.0	359.9	0.9 %	(11.2)%	12.1 %
Total Omnipod	1,247.8	1,011.4	23.4 %	(3.6)%	27.0 %
Drug Delivery	57.5	87.4	(34.2)%	— %	(34.2)%
Total	\$ 1,305.3	\$ 1,098.8	18.8 %	(3.4)%	22.2 %

⁽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 2022 increased \$206.5 million, or 18.8%, to \$1,305.3 million, compared with \$1,098.8 million in 2021. Constant currency revenue growth of 22.2% was primarily driven by higher volume and, to a lesser extent, favorable sales channel mix.

U.S. Omnipod

U.S. Omnipod revenue for 2022 increased \$233.3 million, or 35.8%, to \$884.8 million, compared with \$651.5 million in 2021. This increase was primarily due to higher Omnipod 5 and Omnipod DASH volumes driven by growing our customer base and, to a lesser extent, growth through the pharmacy channel, where Pods have a higher average selling price due in part to the fact that we offer the PDM/Controller for no charge. Existing customer conversions to Omnipod 5 also contributed to the revenue increase as some users fill both their starter kit and their first month of refills simultaneously.

U.S. Omnipod revenue for 2022 includes \$249.9 million of related party revenue, compared with \$58.2 million in 2021. The \$191.7 million increase primarily resulted from a shift in certain revenues from one distributor to another as we worked to extend our reach through the pharmacy channel. Additional information regarding our related party transactions is provided in Note 5 to our consolidated financial statements.

In 2023, we expect strong Omnipod revenue growth driven by continued volume growth of Omnipod 5 in the pharmacy channel, continued adoption of Omnipod DASH, and the benefits of our recurring revenue model.

International Omnipod

International Omnipod revenue for 2022 increased \$3.1 million, or 0.9%, to \$363.0 million, compared with \$359.9 million in 2021. Excluding the 11.2% unfavorable impact of currency exchange, the remaining 12.1% increase was primarily due to higher volumes as we continue to expand awareness and access to Omnipod DASH, partially offset by increased competition from AID systems. In 2023, we expect higher International Omnipod revenue due to continued volume growth driven by the ongoing adoption of Omnipod DASH, partially offset by competition from AID systems and an unfavorable impact of currency exchange.

Drug Delivery

Drug Delivery revenue for 2022 decreased \$29.9 million, or 34.2%, to \$57.5 million, compared with \$87.4 million in 2021. This decrease was primarily driven by a decline in production volume due to lower demand from our partner. In 2023, we expect Drug Delivery revenue to decline due to a lower demand forecast from our partner.

Operating Expenses

(In millions)	Years Ended December 31,			
	2022		2021	
	Amount	Percent of Revenue	Amount	Percent of Revenue
Cost of revenue	\$ 499.7	38.3 %	\$ 346.7	31.6 %
Research and development expenses	\$ 180.2	13.8 %	\$ 160.1	14.6 %
Selling, general and administrative expenses	\$ 587.8	45.0 %	\$ 466.0	42.4 %

Cost of Revenue

Cost of revenue for 2022 increased \$153.0 million, or 44.1%, to \$499.7 million, compared with \$346.7 million in 2021. Gross margin was 61.7% in 2022, compared with 68.4% in 2021. The 6.7 point decrease in gross margin was primarily driven by a \$57.9 million net charge, or 4.5 points, associated with the voluntary MDCs we issued in 2022. The decrease was also driven by higher expected production costs in the U.S. as manufacturing continues to ramp and become a larger portion of our total production and higher costs associated with Omnipod 5 production. These decreases were partially offset by higher average selling price due to growth in the pharmacy channel, where Pods have a higher average selling price due in part to the fact that we offer the PDM/Controller for no charge.

We expect gross margin for 2023 to be in the range of 65% to 66%. We anticipate gross margin to increase due to significant costs associated with the MDCs in 2022, most of which we do not expect to recur in 2023 and higher volume in the pharmacy channel and favorable geographical sales mix. We believe these increases will be partially offset by continued higher production costs as we further scale U.S. manufacturing, unfavorable product line mix due to higher costs associated with Omnipod 5 production, and higher costs as we contend with inflation.

Research and Development

Research and development expenses for 2022 increased \$20.1 million, or 12.6%, to \$180.2 million, compared with \$160.1 million in 2021. This increase was primarily due to year-over-year headcount additions to support our continued investment in development of Omnipod products, partially offset by lower outside services used for clinical activities. We expect research and development spending in 2023 to increase compared with 2022 as we continue to invest in advancing our innovation and clinical pipeline and contend with inflation.

Selling, General and Administrative

Selling, general and administrative expenses for 2022 increased \$121.8 million, or 26.1%, to \$587.8 million, compared with \$466.0 million in 2021. This increase was primarily attributable to year-over-year headcount additions, mainly to support information technology and commercial operations and \$25.2 million of legal charges related to the settlement of a patent infringement lawsuit, associated legal fees, and the settlement of a contract dispute. To a lesser extent, these increases were due to an increase in investments to expand market acceptance and access to Omnipod, higher travel and entertainment expenses due to increased activity as COVID-19 restrictions have lifted, an increase in software license fees driven by investments in new systems to support our growing business and headcount additions, and higher amortization of cloud computing implementation costs. Additionally, selling, general and administrative expenses include \$3.4 million of costs associated with the retirement and advisory services of our former chief executive officer. These increases were partially offset by a decrease in direct-to-consumer advertising resulting from the timing of spend.

We expect selling, general and administrative expenses to increase in 2023 compared with 2022 due to investments in our operating structure to facilitate operational efficiencies and continued growth, including customer support and a new enterprise

resource planning system. Additionally, we plan to make investments to support the Omnipod System, including market acceptance and access, and the phased launch of Omnipod 5 in our international markets.

Non-Operating Items

Interest Expense, Net

Interest expense, net for 2022 decreased \$34.5 million, or 56.4%, to \$26.7 million, compared with \$61.2 million in 2021. This decrease was primarily driven by the adoption of Accounting Standards Update 2020-06, *Accounting for Convertible Debt Instruments and Contracts in an Entity's Own Equity* (“ASU 2020-06”), which eliminated most of the non-cash interest expense associated with our convertible notes. Refer to *Recently Adopted Accounting Standard* in Note 2 to our consolidated financial statements for additional information.

Loss on Extinguishment of Debt

During 2021, we incurred a \$42.4 million loss on extinguishment of debt related to the repurchase and conversion of all of our outstanding 1.375% Notes. Refer to Note 15 to our consolidated financial statements for additional information.

Other Expense, Net

Other expense, net for 2022 decreased \$0.8 million to \$1.1 million, compared with \$1.9 million in 2021. The decrease was primarily driven by an increase in unrealized foreign currency gains, which was partially offset by realized foreign currency losses.

Income Tax Expense

Income tax expense was \$5.2 million on pre-tax income of \$9.8 million for 2022 and \$3.7 million on pre-tax income of \$20.5 million for 2021. Our effective tax rate was 53.4% and 18.2% for 2022 and 2021, respectively. The increase in our effective tax rate was primarily driven by a decrease in pre-tax income in the U.S. where we have net operating loss carryforwards to reduce taxable profits and a full valuation allowance against deferred tax assets. Refer to Note 22 to our 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”):

(in millions)	Years Ended December 31,	
	2022	2021
Net income	\$ 4.6	\$ 16.8
Interest expense, net	26.7	61.2
Income tax expense	5.2	3.7
Depreciation and amortization	63.2	57.4
Stock-based compensation expense	38.6	34.4
Voluntary MDCs ⁽¹⁾	57.9	—
Legal costs ⁽²⁾	25.2	—
CEO transition costs ⁽³⁾	3.4	—
Loss on extinguishment of debt ⁽⁴⁾	—	42.4
Adjusted EBITDA	\$ 224.8	\$ 215.9

⁽¹⁾ Represents net charge recorded for the estimated costs associated with the voluntary MDCs. Refer to Note 13 to our consolidated financial statements for additional information.

⁽²⁾ Includes a \$20.0 million charge to settle patent infringement litigation with Roche, associated legal fees, and a \$3.6 million charge to settle a contract dispute. Refer to Note 17 to our consolidated financial statements for additional information.

⁽³⁾ Represents costs associated with the retirement and advisory services of our former chief executive officer, including \$2.3 million of accelerated stock-based compensation expense.

⁽⁴⁾ Relates to the repurchase and conversion of all of our outstanding 1.375% Notes. Refer to Note 15 to our consolidated financial statements for additional information.

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 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 expense and other significant transactions or events, such as legal settlements, medical device corrections, and loss on extinguishment of debt, that affect the period-to-period comparability of our operating performances, 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

Capitalization

The following table contains several key measures to gauge our financial condition and liquidity at the end of each year:

(in millions)	As of December 31,	
	2022	2021
Cash and cash equivalents	\$ 674.7	\$ 791.6
Current portion of long-term debt	\$ 27.5	\$ 25.1
Long-term debt, net	\$ 1,374.3	\$ 1,248.8
Total debt, net	\$ 1,401.8	\$ 1,273.9
Total stockholders' equity	\$ 476.4	\$ 556.3
Debt-to-total capital ratio	75 %	70 %
Net debt-to-total capital ratio	39 %	26 %

The increase in debt and the decrease in stockholders' equity was primarily due to the adoption of ASU 2020-06. Refer to *Recently Adopted Accounting Standard* in Note 2 to our consolidated financial statements for additional information.

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, 2022, the following notes were outstanding:

Issuance Date	Coupon	Principal Outstanding (in millions)	Due Date	Conversion Rate ⁽¹⁾	Conversion Price per Share of Common Stock
September 2019	0.375%	\$ 800.0	September 2026	4.4105	\$226.73

⁽¹⁾ Per \$1,000 face value of notes.

In connection with the issuance of the 0.375% Convertible Senior Notes ("0.375% 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 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 our common stock.

Credit Agreement

We have a \$100 million three-year senior secured revolving credit facility ("Revolving Credit Facility"), which expires in 2024. At December 31, 2022, no amount was outstanding under the Revolving Credit Facility. The Revolving Credit Facility contains a covenant to maintain a specified leverage ratio under certain conditions when there are amounts outstanding under the facility.

It also contains other customary covenants, none of which are considered restrictive to our operations. Additionally, we have a seven year term loan, which matures in 2028, that contains covenants restricting or limiting our ability to incur additional indebtedness, make asset dispositions, create or permit liens, sell, transfer or exchange assets, guarantee certain indebtedness, and make acquisitions and other investments. Additional information regarding our debt is provided in Note 15 to the consolidated financial statements.

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.

Summary of Cash Flows

(in millions)	Years Ended December 31,	
	2022	2021
Cash provided by (used in):		
Operating activities	\$ 119.0	\$ (68.1)
Investing activities	(191.1)	(82.7)
Financing activities	(40.3)	40.7
Effect of exchange rate changes on cash	(4.3)	(5.5)
Net decrease in cash, cash equivalents, and restricted cash	\$ (116.7)	\$ (115.6)

Operating Activities

Net cash provided by operating activities of \$119.0 million in 2022 was primarily attributable to net income, as adjusted for depreciation and amortization and stock-based compensation expense, partially offset by a \$2.5 million working capital cash outflow. The working capital outflow was driven by a \$36.8 million increase in prepaid expenses and other assets, a \$51.8 million increase in accounts receivable, and a \$49.1 million increase in inventories, partially offset by a \$137.6 million increase in accrued expenses and other liabilities. The increase in prepaid expenses and other assets was primarily driven by an increase in cloud computing implementation costs. The increase in accounts receivable was primarily due to an increase in sales in the U.S. pharmacy channel, which has longer payment terms, partially offset by a decrease in unbilled accounts receivable related to lower production volumes of our Drug Delivery product. The increase in inventories was primarily driven by a planned inventory build to satisfy demand. Finally, the increase in accrued expenses and other liabilities was primarily driven by the voluntary MDCs issued for our Omnipod DASH PDMs and Omnipod 5 Controllers, an increase in rebates due to growth in the pharmacy channel and an increase in compensation costs due to higher incentive compensation achievement and head count additions.

Net cash used in operating activities of \$68.1 million in 2021 was primarily attributable to net income, as adjusted for depreciation and amortization, loss on extinguishment of debt, non-cash interest, and stock-based compensation expense, partially offset by a \$263.6 million working capital cash outflow. The working capital outflow was driven by a \$154.4 million increase in inventories, a \$71.3 million increase in accounts receivable and a \$46.7 million increase in prepaid expenses and other assets, partially offset by a \$24.4 million increase in accrued expenses and other liabilities. The increase in inventories was primarily driven by a planned inventory build to satisfy demand and the addition of our third highly automated manufacturing line. The increase in accounts receivable was primarily due to an increase in sales in the U.S. pharmacy channel, which has longer payment terms. The increase in prepaid expenses and other assets was primarily driven by an increase in cloud computing implementation costs. Finally, the increase in accrued expenses and other liabilities was primarily driven by an increase in rebates due to growth in the pharmacy channel and higher compensation costs due to an increase in both incentive compensation achievement and head count.

Investing Activities

We had \$191.1 million of net cash used in investing activities in 2022, compared with \$82.7 million in 2021.

Capital Spending—Capital expenditures were \$122.9 million and \$111.9 million in 2022 and 2021, respectively, and primarily related to the purchase of equipment to increase our manufacturing capacity. We expect capital expenditures for 2023 to decrease compared with 2022 given our significant investments to build capacity in 2022, including acceleration of some of our spending on machinery and equipment for our new Malaysia manufacturing facility that is under construction. We expect to fund our capital expenditures using existing cash.

Investments in Developed Software—Investments in developed software were \$12.9 million and \$10.8 million in 2022 and 2021, respectively, and primarily related to investments in projects to support our cloud-based capabilities.

Acquisitions and Investments—In 2022, we paid \$26.0 million to acquire substantially all the assets related to the manufacture and production of shape-memory alloy wire assemblies that are used in the production of Omnipods from Dynalloy, Inc. and \$21.5 million to acquire developed technology and patents from AGC. In addition we paid \$7.8 million for strategic investments in two private companies.

Sales of Marketable Securities—The \$40.0 million decrease in cash receipts from maturities of marketable securities in 2021 was driven by the prior year shift of a portion of our investment portfolio to investments that are classified as cash equivalents.

Financing Activities

We had \$40.3 million of net cash used in financing activities in 2022, compared with \$40.7 million of net cash provided by financing activities in 2021.

Debt Issuance and Repayment—During 2022, we made \$24.5 million in aggregate principal payments on our equipment financings, mortgage, and term loan, compared with \$22.3 million in 2021. The \$2.2 million increase is due to entering the term loan and an additional equipment financing in the second and third quarters of 2021, respectively. During 2021, we received net proceeds of \$489.5 million from the issuance of the term loan and used \$460.9 million of cash to partially fund the repurchase of a portion of our 1.375% Notes. We also received net proceeds of \$43.1 million from the equipment financing transaction entered into in 2021.

Prepayments of Finance Lease Obligation—During 2022, we made \$15.3 million in upfront payments upon entering into an agreement to acquire real estate in Malaysia. Refer to Note 14 to the consolidated financial statements for additional information regarding this lease.

Option Exercises and Employee Stock Purchase Plan Proceeds—Total proceeds from option exercises and issuance of employee stock purchase plan shares were \$16.3 million and \$23.5 million in 2022 and 2021, respectively. The \$7.2 million decrease was primarily driven by option exercises in the prior year by our former chief executive officer who retired in 2018.

Payment of Taxes for Restricted Stock Net Settlements—Payments for taxes related to net restricted and performance stock unit settlements were \$16.8 million and \$28.2 million in 2022 and 2021, respectively. The \$11.4 million decrease was primarily driven by vesting of performance stock units in the prior year by our former chief executive officer who retired in 2018.

Commitments and Contingencies

Contractual Obligations—A summary of our contractual obligations and commitments for debt, operating lease obligations and other obligations at December 31, 2022 is presented in the following table:

(in millions)	Short Term	Long Term	Total
Debt obligations	\$ 26.9	\$ 1,397.6	\$ 1,424.5
Interest payments ⁽¹⁾⁽²⁾	45.9	174.6	220.5
Purchase obligations ⁽³⁾	218.0	42.9	260.9
Lease obligations ⁽¹⁾	6.1	42.3	48.4
Total contractual obligations	\$ 296.9	\$ 1,657.4	\$ 1,954.3

⁽¹⁾ Interest on debt and lease obligations are projected for future periods using the interest rates in effect as of December 31, 2022. Certain of these projected interest payments may differ in the future based on changes in market interest rates. Additional information regarding our leases is provided in Note 14 to the consolidated financial statements.

⁽²⁾ Excludes the impact of the interest rate swaps discussed in Note 16 to our consolidated financial statements.

⁽³⁾ 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.

Off-Balance Sheet Arrangements

As of December 31, 2022, we had various letters of credit totaling \$18.6 million. During 2022, the Company entered into a \$20 million uncommitted letter of credit facility. In conjunction with the execution of an agreement to acquire real estate in Malaysia, including land and building, a letter of credit of \$17.2 million was issued under this facility to backstop a bank guarantee for the same amount. The bank guarantee serves as security for the building while under construction. Additional information regarding our letters of credit is provided in Note 17 to the consolidated financial statements.

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 through distributors, who resell the products to consumers, and directly 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 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, specific known market events and, as available, channel inventory data. Rebates charged against gross sales amounted to \$247.1 million, \$143.3 million and \$82.5 million in 2022, 2021 and 2020, 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 adjust our estimates, which affects 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 \$57.5 million for 2022. Revenue for this product line is recognized as the product is produced. Accounting for Drug Delivery revenue requires us to select a method to measure progress towards the satisfaction of the performance obligation. This election of the most meaningful measure of progress by which to recognize Drug Delivery revenue requires the application of judgment. We elected the input method and selected a blend of cost and time to produce as the measure of progress. Accordingly, revenue is recognized over time using a blend of costs incurred to date relative to total estimated costs at completion and time incurred to date relative to total production time to measure progress toward the satisfaction of our performance obligations. We believe that both incurred cost and elapsed time reflect the value generated, which best depicts the transfer of control to the customer. Contract costs include third-party costs as well as an allocation of manufacturing overhead. Changes from quarter to quarter in quantity and stage of production of in-process inventory could have a significant quarterly impact on revenue.

Product Warranty

We provide a four-year warranty on our PDMs and Controllers sold in the United States and Europe and a five-year warranty on PDMs sold in Canada. In addition, we may replace Pods that do not function in accordance with product specifications. We estimate our warranty obligation at the time the product is shipped based on historical experience and the estimated cost to service the claims, which include the current product cost, reclaim costs, shipping and handling costs and direct and incremental distribution and customer service support costs. Since we continue to introduce new products and versions, the anticipated performance of the product over the warranty period is also considered in estimating warranty reserves. Changes to the actual replacement rates, which are evaluated quarterly, could have a material impact on our estimated warranty reserve.

In 2022, we issued voluntary MDCs for the Omnipod DASH PDM and the Omnipod 5 Controller and accrued an associated warranty reserve of \$68.9 million, which was subsequently reduced by \$11.0 million primarily due to significantly fewer customers requesting a replacement Omnipod DASH PDM prior to our updated PDM being available. The remaining \$54.6 million warranty reserve at December 31, 2022 includes an estimate regarding the number of:

- customers expected to request a replacement Omnipod 5 Controller;
- PDMs/Controllers that will be distributed by third parties and the cost of distribution assistance outside the U.S.;
- additional customer support personnel, their cost and the length of time they will be needed; and
- old PDMs expected to be returned for disposal and the cost of reclaim

Changes in these assumptions could have a material impact on our estimated warranty reserve related to the MDCs.

Intangible Assets

Certain of our intangible assets have been acquired through business combinations or asset purchases that include multiple components, both of which have required us to perform valuations. Our valuations involve assumptions, including, revenue and/or revenue growth rates associated with acquired assets, customer attrition rates, discount rate rates, royalty rates, tax rates, expected product development plans, product lifecycles, and obsolescence.

In 2022, we entered into an Asset Purchase Agreement pursuant to which we made a one-time payment of \$25.0 million for the acquisition of technology and patents and the release of future obligations to AGC, including any future royalty obligations. This amount, together with transaction costs, was allocated between the assets acquired and the settlement component based on estimated relative fair value. The valuation of these intangible assets included assumptions based on future revenues, royalty rates, and obsolescence curves related to our Omnipod 5 product. In addition, since certain of the intangible assets were classified as defensive assets, the valuation included an assumption related to the probability that a claim made by Insulet would be successful. As a result of the relative fair value allocation, values of \$12.0 million and \$9.5 million were assigned to acquired technology and patents, respectively, and the settlement component was estimated to have a value of \$3.6 million. Changes in these assumptions could impact the values assigned to the intangible assets acquired and, accordingly have a material impact on the amount attributed to the settlement component in our results of operations.

Inventory Reserves

We reduce the carrying value of inventories for 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. During 2022, we charged \$8.4 million to the consolidated statement of operations for excess and obsolete inventory, including \$4.8 million related to the phase-out of Classic Omnipod. The determination of this charge involved assumptions regarding the number of PDMs expected to be utilized to satisfy warranty claims during the phase-out period and the length of time we will continue to offer Classic Omnipod outside the United States.

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

Our exposure to changes in interest rates is associated with borrowings under our Revolving Credit Facility and our Term Loan, both of which are variable-rate debt. At December 31, 2022, no amounts were outstanding under our Revolving Credit Facility. In May 2021, we entered into two interest rate swap agreements to effectively convert \$480.0 million of our term loan borrowings from a variable rate to a fixed rate. These interest rate swaps are intended to mitigate the exposure to fluctuations in interest rates and qualify for hedge accounting treatment as cash flow hedges. A 100 basis point increase or decrease in interest rates as of December 31, 2022 would decrease or increase our annual earnings, respectively, by approximately \$0.1 million.

Market Price Sensitive Instruments

As of December 31, 2022, we had outstanding debt related to our convertible senior notes recorded on our consolidated balance sheet of \$788.8 million, net of unamortized discount and issuance costs totaling \$11.2 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 convertible senior notes, which was \$1,038.7 million as of December 31, 2022, is also impacted by changes in our stock price.

In order to reduce potential equity dilution, in connection with the issuance of the \$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 28% of our revenue was denominated in foreign currencies for the year ended December 31, 2022. 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 (expense) income, net in the consolidated statement of operations and amounted to a loss of \$1.3 million for the year ended December 31, 2022.

Item 8. Financial Statements and Supplementary Data

Our financial statements as of December 31, 2022 and 2021 and for each of the three years in the period ended December 31, 2022, and the Report of the Registered Independent Public Accounting Firm are included in this report as listed in the index.

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Report of Independent Registered Public Accounting Firm

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, 2022 and 2021, and the related consolidated statements of operations, comprehensive income, changes in stockholders’ equity, and cash flows for each of the three years in the period ended December 31, 2022, and the related notes and financial statement schedule 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, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022 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, 2022, based on criteria established in the 2013 *Internal Control—Integrated Framework* issued by COSO.

Change in accounting principle

As discussed in Note 2 to the financial statements, the Company changed its method of accounting for convertible debt in 2022 due to the adoption of Accounting Standards Update 2020-06, *Debt – Debt With Conversion and Other Options (Subtopic 470-20)* and *Derivatives and Hedging – Contracts in Entity’s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity*.

Basis for opinions

The Company’s management is responsible for these financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management’s Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company’s financial statements and an opinion on the Company’s internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (“PCAOB”) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the financial statements included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and limitations of internal control over financial reporting

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

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

Critical audit matters

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

Contract Dispute

As described further in note 17 to the financial statements, the Company entered into an Asset Purchase Agreement as part of the resolution to an ongoing contract dispute. Pursuant to this agreement the Company made a one-time payment of \$25.0 million to the counterparty for the acquisition of developed technology, patents, and the release of future obligations. This amount was allocated between the intangible assets acquired and the settlement component based on estimated fair values. We identified the accounting for the resolution of the contract dispute as a critical audit matter.

The principal considerations for our determination that the accounting for the resolution of the contract dispute is a critical audit matter are (1) applying the accounting guidance for allocating the consideration paid, which is complex and requires judgement and (2) estimating the allocation of the fair value of those elements. These considerations heightened the complexity surrounding the design and execution of audit procedures to respond to this risk.

Our audit procedures related to the contract dispute resolution included the following, among others.

- We consulted with our national office resources regarding management’s accounting conclusion that the transaction consisted of multiple elements to be valued and that consideration paid should be allocated using estimated fair values.
- With the assistance of valuation professionals with specialized skills and knowledge, we tested management’s fair value of the identified intangible assets. This included an assessment of the appropriateness of the methodology, inputs and key assumptions used, particularly the selection of the relief from royalty method to value the intangible assets, prospective financial information, royalty rates, the probability factor related to defending the patent asset and the selection of the discount rate.

Variable consideration – Rebates to Intermediaries

As described further in note 2 to the financial statements, the Company provides for certain rebates for sales of its product through intermediaries. The Company estimates variable consideration related to rebates to pharmacy benefit managers based on historical experience adjusted for revenue growth, market trends and events, individual agreements, product mix and, as available, channel inventory data. We identified the rebate estimate as a critical audit matter.

The principal consideration for our determination that the rebate estimate is a critical audit matter is the level of judgement and complexity surrounding the design and execution of audit procedures to respond to this risk due to the subjectivity of the adjustments to historical experience based on recent product variation and volume.

Our audit procedures related to the rebate estimate included the following, among others.

- We tested the design and operating effectiveness of controls related to management’s process to determine rebates, including the completeness and accuracy of the underlying data used in management’s estimation.
- We tested the completeness and accuracy of inputs into the calculation as follows: inspected source documents on a sample basis to test historical rebates, compared revenue growth rates to other audited schedules, and performed sensitivity analyses on the subjective adjustments to historical experience.
- We performed retrospective analysis comparing amounts invoiced to and paid by the Company to previously estimated amounts.

/s/ GRANT THORNTON LLP

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

Boston, Massachusetts
February 23, 2023

INSULET CORPORATION
CONSOLIDATED BALANCE SHEETS

(in millions, except share and per share data)	As of December 31,	
	2022	2021
ASSETS		
Current Assets		
Cash and cash equivalents	\$ 674.7	\$ 791.6
Accounts receivable trade, net	140.9	135.2
Accounts receivable trade, net — related party	64.7	25.8
Inventories	346.8	303.2
Prepaid expenses and other current assets	86.9	74.0
Total current assets	1,314.0	1,329.8
Property, plant and equipment, net	599.9	536.5
Other intangible assets, net	75.5	36.6
Goodwill	51.7	39.8
Other assets	210.0	106.1
Total assets	\$ 2,251.1	\$ 2,048.8
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	\$ 30.8	\$ 37.7
Accrued expenses and other current liabilities	301.0	164.3
Accrued expenses and other current liabilities — related party	5.4	1.7
Current portion of long-term debt	27.5	25.1
Total current liabilities	364.7	228.8
Long-term debt, net	1,374.3	1,248.8
Other liabilities	35.7	14.9
Total liabilities	1,774.7	1,492.5
Commitments and contingencies (Note 17)		
Stockholders' Equity		
Preferred stock, \$.001 par value, 5,000,000 shares authorized; none issued and outstanding	—	—
Common stock, \$.001 par value, 100,000,000 authorized; 69,511,286 and 69,178,691 issued and outstanding	0.1	0.1
Additional paid-in capital	1,040.6	1,207.9
Accumulated deficit	(584.3)	(649.5)
Accumulated other comprehensive income (loss)	20.0	(2.2)
Total stockholders' equity	476.4	556.3
Total liabilities and stockholders' equity	\$ 2,251.1	\$ 2,048.8

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

INSULET CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS

(in millions, except share and per share data)	Years Ended December 31,		
	2022	2021	2020
Revenue	\$ 1,055.4	\$ 1,040.6	\$ 904.4
Revenue from related party	249.9	58.2	—
Total revenue	1,305.3	1,098.8	904.4
Cost of revenue	499.7	346.7	322.1
Gross profit	805.6	752.1	582.3
Research and development expenses	180.2	160.1	146.8
Selling, general and administrative expenses	587.8	466.0	384.0
Operating income	37.6	126.0	51.5
Interest expense, net	(26.7)	(61.2)	(45.1)
Loss on extinguishment of debt	—	(42.4)	—
Other (expense) income, net	(1.1)	(1.9)	3.3
Income before income taxes	9.8	20.5	9.7
Income tax expense	(5.2)	(3.7)	(2.9)
Net income	\$ 4.6	\$ 16.8	\$ 6.8
Net income per share:			
Basic	\$ 0.07	\$ 0.25	\$ 0.11
Diluted	\$ 0.07	\$ 0.24	\$ 0.10
Weighted-average number of common shares outstanding (in thousands):			
Basic	69,375	67,698	64,735
Diluted	69,910	68,579	65,946

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

INSULET CORPORATION
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(in millions)	Years Ended December 31,		
	2022	2021	2020
Net income	\$ 4.6	\$ 16.8	\$ 6.8
Other comprehensive income (loss), net of tax			
Foreign currency translation adjustment	(10.3)	(11.9)	6.8
Unrealized gain on cash flow hedges	32.5	4.5	—
Unrealized loss on available-for-sale securities	—	(0.3)	(0.1)
Total other comprehensive income (loss), net of tax	22.2	(7.7)	6.7
Comprehensive income	\$ 26.8	\$ 9.1	\$ 13.5

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

INSULET CORPORATION
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(dollars in millions)	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive (Loss) Income	Total Stockholders' Equity
	Shares (in thousands)	Amount				
Balance, December 31, 2019	62,685	\$ 0.1	\$ 749.0	\$ (672.0)	\$ (1.2)	\$ 75.9
Adoption of ASU 2016-13 (Note 2)	—	—	—	(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 expense	—	—	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
Exercise of options to purchase common stock	364	—	15.4	—	—	15.4
Issuance of shares for employee stock purchase plan	36	—	8.1	—	—	8.1
Stock-based compensation expense	—	—	34.4	—	—	34.4
Restricted stock units vested, net of shares withheld for taxes	176	—	(28.2)	—	—	(28.2)
Extinguishment of conversion feature on 1.375% Notes, net of issuance costs	—	—	(808.5)	—	—	(808.5)
Issuance of shares for debt extinguishment	2,586	—	722.4	—	—	722.4
Net income	—	—	—	16.8	—	16.8
Other comprehensive loss	—	—	—	—	(7.7)	(7.7)
Balance, December 31, 2021	69,179	0.1	1,207.9	(649.5)	(2.2)	556.3
Adoption of ASU 2020-06 (Note 2)	—	—	(207.7)	60.6	—	(147.1)
Exercise of options to purchase common stock	147	—	6.9	—	—	6.9
Issuance of shares for employee stock purchase plan	53	—	9.4	—	—	9.4
Stock-based compensation expense	—	—	40.9	—	—	40.9
Restricted stock units vested, net of shares withheld for taxes	132	—	(16.8)	—	—	(16.8)
Net income	—	—	—	4.6	—	4.6
Other comprehensive income	—	—	—	—	22.2	22.2
Balance, December 31, 2022	69,511	\$ 0.1	\$ 1,040.6	\$ (584.3)	\$ 20.0	\$ 476.4

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

INSULET CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS

(in millions)	Years Ended December 31,		
	2022	2021	2020
Cash flows from operating activities			
Net income	\$ 4.6	\$ 16.8	\$ 6.8
Adjustments to reconcile net income to net cash provided by (used in) operating activities:			
Depreciation and amortization	63.2	57.4	55.4
Stock-based compensation expense	40.9	34.4	35.9
Non-cash interest expense	5.8	40.2	45.2
Loss on extinguishment of convertible debt	—	42.4	—
Provision for credit losses	4.2	3.1	3.3
Other	2.8	1.2	0.8
Changes in operating assets and liabilities:			
Accounts receivable	(12.9)	(45.5)	(13.7)
Accounts receivable — related party	(38.9)	(25.8)	—
Inventories	(49.1)	(154.4)	(50.5)
Prepaid expenses and other assets	(36.8)	(46.7)	(34.1)
Accounts payable	(2.4)	(15.6)	7.1
Accrued expenses and other liabilities	133.9	22.7	27.8
Accrued expenses and other liabilities — related party	3.7	1.7	—
Net cash provided by (used in) operating activities	119.0	(68.1)	84.0
Cash flows from investing activities			
Capital expenditures	(122.9)	(111.9)	(129.0)
Investments in developed software	(12.9)	(10.8)	(37.5)
Acquisition of a business	(26.0)	—	—
Acquisition of intangible assets	(21.5)	—	—
Cash paid for investments	(7.8)	—	—
Receipts from the maturity or sale of marketable securities	—	40.0	218.4
Cash paid for marketable securities	—	—	(37.9)
Net cash (used in) provided by investing activities	(191.1)	(82.7)	14.0
Cash flows from financing activities			
Repayment of convertible debt	—	(460.9)	—
Proceeds from issuance of term loan, net of issuance costs	—	489.5	—
Repayment of term loan	(5.0)	(2.5)	—
Proceeds from equipment financings, net	—	43.1	60.0
Repayment of equipment financings	(17.4)	(17.8)	(1.4)
Proceeds from mortgage, net of issuance costs	—	—	68.3
Repayment of mortgage	(2.1)	(2.0)	(0.3)
Payment of debt issuance costs	—	(4.0)	(0.5)
Prepayments of financing lease obligation	(15.3)	—	—
Proceeds from issuance of common stock, net	—	—	477.5
Proceeds from exercise of stock options	6.9	15.4	25.7
Proceeds from issuance of common stock under employee stock purchase plan	9.4	8.1	6.0
Payment of withholding taxes in connection with vesting of restricted stock units	(16.8)	(28.2)	(29.8)
Net cash (used in) provided by financing activities	(40.3)	40.7	605.5
Effect of exchange rate changes on cash	(4.3)	(5.5)	4.8
Net (decrease) increase in cash, cash equivalents, and restricted cash	(116.7)	(115.6)	708.3
Cash, cash equivalents, and restricted cash, beginning of year	806.4	922.0	213.7
Cash, cash equivalents, and restricted cash, end of year (Note 6)	\$ 689.7	\$ 806.4	\$ 922.0

Supplemental cash flow information (Note 24)

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

INSULET CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Nature of the Business

Insulet Corporation (the “Company”) is primarily engaged in the development, manufacture, and sale of its 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 (“Pod”) that the user fills with insulin and wears directly on the body for up to three days at a time, which delivers personalized doses of insulin, and the Personal Diabetes Manager (“PDM”) or Controller, a wireless, handheld device that programs the Pod with the user’s personalized insulin-delivery instructions and wirelessly monitors the Pod’s operation.

The Omnipod System includes: the Omnipod Insulin Management System (“Classic Omnipod”), its next generation Omnipod DASH[®] Insulin Management System (“Omnipod DASH”), and its newest generation Omnipod[®] 5 Automated Insulin Delivery System (“Omnipod 5”). Omnipod DASH features a secure Bluetooth enabled Pod and PDM with a color touch screen user interface supported by smartphone connectivity. Omnipod 5, which builds on our Omnipod DASH mobile platform, is a tubeless automated insulin delivery system, that integrates with a continuous glucose monitor (“CGM”) to manage blood sugar and is fully controlled by a compatible personal smartphone or Omnipod 5 Controller. The CGM is sold separately by a third party.

The Company generates most of its revenue from sales of the Omnipod System, which is sold in the U.S., Europe, Canada, the Middle East, and Australia. 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.

Substantially all 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 Neulasta 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.

Foreign Currency Translation

The assets and liabilities of the Company’s foreign subsidiaries are translated into U.S. dollars using exchange rates as of the balance sheet date, while income and expenses of foreign subsidiaries 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 income (loss) within stockholders’ equity on the consolidated balance sheet. Net realized and unrealized (losses) gains from foreign currency transactions are included in other (expense) income, net in the consolidated statement of operations and were \$(1.3) million, \$(2.0) million and \$3.2 million for the years ended December 31, 2022, 2021 and 2020, 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 may 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

The Company has investments in equity securities of privately held companies in which the Company's interest is less than 20%, the Company does not exercise significant influence over the investee, and the investment does not have a readily determinable fair value. These investments are carried at cost less impairment, if any. If an observable price change in orderly transactions for the identical or similar investment in the same issuer is identified, the investment is measured at its fair value as of the date that the observable transaction occurred with the adjustments reflected in other (expense) income, net in the Company's consolidated statements of operations.

In 2022, the Company made strategic investments in two companies in the amount of \$5.0 million and \$2.8 million. As of December 31, 2022 and December 31, 2021, the total carrying value of the Company's investments in equity securities without readily determinable fair values was \$8.7 million and \$0.9 million, respectively. As of December 31, 2022 and 2021, there were no impairments or adjustments to the Company's equity investments without readily determinable fair values.

The Company may also invest in marketable securities, including certificates of deposit, commercial paper, U.S. government and agency bonds, and corporate bonds, which are classified as available-for-sale and carried at fair value with unrealized gains and losses recorded 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 (expense) income, net in the consolidated statement of operations.

Accounts Receivable and Allowance for Credit Losses

Effective January 1, 2020, the Company adopted Accounting Standards Update ("ASU") 2016-13, *Credit Losses (Topic 326)* ("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.

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.

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 on the consolidated balance sheet, net of the short-term portion included in prepaid and other current assets. Costs to obtain a contract are amortized to selling, general and administrative expense on a straight-line basis over the expected period of benefit, which considers future product upgrades. These costs are periodically reviewed for impairment.

Derivative Instruments

The Company is exposed to certain risks relating to its business operations. Risks that relate to interest rate exposure are managed by using interest rate swaps. The Company recognizes derivative instruments as either assets or liabilities at fair value on the consolidated balance sheet. Changes in a derivative financial instrument's fair value are recognized in earnings unless specific hedge criteria are met, in which case changes in fair value are recognized as adjustments to other comprehensive income. The Company has designated its interest rate swap contracts as cash flow hedges.

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.

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; and

Level 3 — significant unobservable inputs for which there are 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 6 and 15 for financial assets and liabilities held at carrying amount on the consolidated balance sheet and Notes 16 for derivative instruments measured at fair value on a recurring basis.

Property, Plant and Equipment

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

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

The Company assesses the recoverability of assets whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable. The Company recognizes an impairment loss if the carrying amount of a long-lived asset is not recoverable based on its undiscounted future cash flows. The impairment loss is measured as the difference between the carrying amount and the fair value of the asset.

Business Combinations

The Company recognizes the assets and liabilities assumed in business combinations based on their estimated fair values at the date of acquisition. The Company allocates the purchase price in excess of net tangible assets acquired to identifiable intangible assets. The Company assesses the fair value of assets, including intangible assets, using a variety of methods and each asset is measured at fair value from the perspective of a market participant. Assets recorded from the perspective of a market participant that are determined to not have economic use for the Company are expensed immediately. Any excess purchase price over the fair value of the net tangible and intangible assets acquired is allocated to goodwill. Transaction costs and restructuring costs associated with a business combination are expensed as incurred.

Goodwill and Other Intangible Assets

Goodwill represents the excess of the purchase price of an acquired entity over the amounts assigned to assets and liabilities assumed in a business combination. The Company performs an assessment of its goodwill for impairment annually on October 1 or whenever events or changes in circumstances indicate there might be impairment. Goodwill is evaluated for impairment at the reporting unit level.

The Company may assess its goodwill for impairment initially using a qualitative approach to determine whether conditions exist that indicate it is more likely than not that the fair value of a reporting unit is less than its carrying value. If management concludes, based on its assessment of relevant events, facts, and circumstances that it is more likely 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. The Company would record an impairment loss to the extent that the carrying value of the reporting unit's goodwill exceeds its fair value.

Intangible assets acquired in a business combination are recorded at fair value, while intangible assets purchased or software developed for internal-use 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
Developed technology	13 to 15 years
Patents	8 to 15 years

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

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 using the straight-line method to the same income statement line as the associated cloud operating expenses. The Company assesses the recoverability of capitalized implementation costs in accordance with the policy disclosed under *Property, Plant and Equipment*.

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 reflects a secured rate that considers 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 and Controllers 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. Costs to service the claims reflect the current product cost, reclaim costs, shipping and handling costs and direct and incremental distribution and customer service support costs. 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. Warranty expense is recorded in cost of revenue in the consolidated statements of operations.

Revenue Recognition

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, 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/Controller 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/Controller and the Pods is separately identifiable in the contract with the customer.
- *Determine Transaction Price.* The price charged for the PDM/Controller and Pods is dependent on the Company's pricing as established with third-party payors and intermediaries. The Company provides a right of return for sales of its Omnipod to new end-users 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 forecasted 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 United States, 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, with an associated unbilled receivable, as the product is produced pursuant to the customer's firm purchase commitments. 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.

Research and Software Development Costs

Internal research and development costs are expensed as incurred. Research and development expenses include salary and benefits, allocated overhead and occupancy costs, clinical trial and related clinical manufacturing costs, contract services, and other costs.

Costs incurred in the research, design, and development of software embedded in products to be sold to customers are charged to expense until technological feasibility of the ultimate product to be sold is established. The Company's policy is that technological feasibility is achieved when a working model, with the key features and functions of the product, is available for customer testing. Software development costs incurred after the establishment of technological feasibility and until the product is available for general release are capitalized, provided recoverability is reasonably assured. Capitalized software development costs are amortized over their estimated useful life and recorded within cost of revenues.

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 \$12.8 million, \$10.5 million, and \$10.1 million for the years ended December 31, 2022, 2021, and 2020, respectively.

Advertising Costs

The Company expenses advertising costs as they are incurred. Advertising expenses were \$41.2 million, \$44.1 million, and \$30.0 million for the years ended December 31, 2022, 2021, and 2020, respectively.

Stock-Based Compensation Expense

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 expense recognized during a period is based on the portion of the awards that are expected to vest. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Income Taxes

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements. Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates that will be in effect in the years in which the differences are expected to reverse. The Company reviews its deferred tax assets for recoverability considering historical profitability, projected future taxable income, and the expected timing of the reversals of existing temporary differences and tax planning strategies. A valuation allowance is provided to reduce the deferred tax assets if, based on the available evidence, it is more likely than not that some or all the deferred tax assets will not be realized. The effect of a change in enacted tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date. Interest and penalties are classified as a component of income tax expense.

Concentration Risk

Credit Risk—Financial instruments that subject the Company to credit risk primarily consist of cash and cash equivalents and accounts receivable. The Company maintains most of its cash, and investments with a limited number of financial institutions that have a high investment grade credit rating. See Notes 4 and 7 for customer concentration.

Supply Risk—The Company's Drug Delivery product is currently produced at a single contract manufacturer. Additionally, the Company uses different types of semiconductor chips, which are sourced from external suppliers, in the manufacturing of its products. While the Company has multiple suppliers of semiconductor chips, each type is typically sourced from a single supplier. Supply chain disruptions, supplier shortages, logistic delays, or quality problems could result in manufacturing delays, increased costs, or a possible loss of sales, which could adversely affect operating results.

Recently Adopted Accounting Standards

Convertible Debt

Effective January 1, 2022, the Company adopted Accounting Standards Update ("ASU") 2020-06, *Debt – Debt With Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* using the modified retrospective method for convertible debt instruments outstanding as of the date of adoption. Under ASU 2020-06, a convertible debt

instrument is generally reported as a single liability at its amortized cost with no separate accounting for embedded conversion features. Consequently, the effective interest rate of convertible debt instruments is closer to the coupon interest rate under the new guidance. The following table shows the adjustments made to the consolidated balance sheet as of January 1, 2022 as a result of adopting the new guidance.

(in millions)	As Reported		As Adjusted	
	Prior to ASU 2020-06		Under ASU 2020-06	
	December 31, 2021	Adjustments	January 1, 2022	January 1, 2022
Long-term debt, net ⁽¹⁾	\$ 1,248.8	\$ 147.1	\$ 1,395.9	
Additional paid-in-capital ⁽²⁾	\$ 1,207.9	\$ (207.7)	\$ 1,000.2	
Accumulated deficit ⁽³⁾	\$ (649.5)	\$ 60.6	\$ (588.9)	

⁽¹⁾ The increase in debt resulted from the derecognition of the discount associated with the embedded conversion feature, offset by the remaining debt issuance costs reclassified out of equity.

⁽²⁾ The decrease in additional paid-in-capital resulted from the derecognition of the embedded conversion feature and debt issuance costs bifurcated to equity.

⁽³⁾ The decrease to accumulated deficit represents the cumulative interest expense recognized related to the amortization of the bifurcated conversion option and debt issuance costs.

In addition to the adjustments in the table above, the Company wrote-off the related deferred tax liabilities with a corresponding adjustment to the valuation allowance, resulting in no net impact to the cumulative adjustment recorded to accumulated deficit. Adoption of this standard had no impact on the Company's diluted earnings per share as the Company historically calculated earnings per share using the if-converted method.

Reference Rate Reform

ASU 2020-04, *Reference Rate Reform (Topic 848) – Facilitation of the Effects of Reference Rate Reform on Reporting* and ASU 2021-01, *Reference Rate Reform (Topic 848) – Scope* allow companies to elect optional expedients and exceptions for applying U.S. GAAP to contracts, hedging relationships, and other transactions affected by reference rate reform (e.g., discontinuation of the London Interbank Offered Rate (“LIBOR”)) if certain criteria are met. During the fourth quarter of 2022, the Company elected to apply optional expedients for contract modifications to all eligible debt instruments and hedging relationships affected by the transition from LIBOR to the Secured Overnight Financing Rate (“SOFR”). Accordingly, the Company did not have to assess whether the contract modification should be accounted for as a debt extinguishment. Additionally, the Company was not required to dedesignate hedging relationships when the contractual terms changed. The adoption of these standards had no impact on our 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 device based on the Omnipod platform.

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

(in millions)	Years Ended December 31,		
	2022	2021	2020
United States ⁽¹⁾	\$ 942.3	\$ 738.9	\$ 596.4
International	363.0	359.9	308.0
Total	\$ 1,305.3	\$ 1,098.8	\$ 904.4

⁽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:

(in millions)	As of December 31,	
	2022	2021
United States	\$ 453.2	\$ 445.4
China	87.6	84.1
Malaysia	51.6	—
Other	7.5	7.0
Total	\$ 599.9	\$ 536.5

Note 4. Revenue and Contract Acquisition Costs

The following table summarizes the Company's disaggregated revenues:

(in millions)	Years Ended December 31,		
	2022	2021	2020
U.S. Omnipod	\$ 884.8	\$ 651.5	\$ 526.9
International Omnipod	363.0	359.9	308.0
Total Omnipod	1,247.8	1,011.4	834.9
Drug Delivery	57.5	87.4	69.5
Total revenue	\$ 1,305.3	\$ 1,098.8	\$ 904.4

The percentages of total revenue for customers that represent 10% or more of total revenue was as follows:

	Years Ended December 31,		
	2022	2021	2020
Distributor A	19%	*	*
Distributor B	17%	12%	10%
Distributor C	*	10%	11%
Distributor D	16%	*	*

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

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

(in millions)	As of December 31,	
	2022	2021
Accrued expenses and other current liabilities	\$ 16.1	\$ 3.5
Other liabilities	1.6	1.5
Total deferred revenue	\$ 17.7	\$ 5.0

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

(in millions)	As of December 31,		
	2022	2021	2020
Deferred revenue recognized	\$ 2.1	\$ 4.4	\$ 1.8

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:

(in millions)	As of December 31,	
	2022	2021
Prepaid expenses and other current assets	\$ 15.2	\$ 13.3
Other assets	31.3	26.1
Total capitalized contract acquisition costs, net	\$ 46.5	\$ 39.4

The Company recognized \$14.6 million, \$12.3 million, and \$10.6 million of amortization of capitalized contract acquisition costs for the years ended December 31, 2022, 2021, and 2020, respectively.

Note 5. Related Party Transactions

In February 2021, the Company entered into a distribution agreement, the terms of which are consistent with those prevailing at arm’s length. The spouse of one of the members of the Company’s Board of Directors is an executive officer of the distributor. The Company recorded \$249.9 million and \$58.2 million of net revenues from the distributor for the years ended December 31, 2022 and 2021, respectively. The Company had \$64.7 million and \$25.8 million of net accounts receivable due from the distributor as of December 31, 2022 and 2021, respectively. In addition, the Company had an aggregate of \$5.4 million and \$1.7 million of distribution fees due to the distributor and deferred revenue, which was included in accrued expenses and other current liabilities on the consolidated balance sheet as of December 31, 2022 and 2021, respectively.

Note 6. Cash and Cash Equivalents

The following table provides a summary of cash and cash equivalents as of December 31, 2022 and 2021:

(in millions)	As of December 31,	
	2022	2021
Cash	\$ 136.1	\$ 159.3
Money market mutual funds	487.3	630.7
Time deposits	50.8	—
Restricted cash	0.5	1.6
Total cash and cash equivalents	674.7	791.6
Restricted cash included in other assets	15.0	14.8
Total cash, cash equivalents, and restricted cash shown in the consolidated statements of cash flows	\$ 689.7	\$ 806.4

All cash and cash equivalents are level 1 in the fair value hierarchy. The restricted cash included in other assets on the consolidated balance sheet is held as a compensating balance against long-term borrowings.

Certain of the Company’s subsidiaries participate in a multi-currency, notional cash pooling arrangement with a third-party bank provider to manage global liquidity requirements. Under this arrangement, which began in 2022, cash deposited by participating subsidiaries may be used to offset amounts owed to the bank by other participating subsidiaries to the extent the overall balance in the cash pool is at least zero, providing legal rights of offset. As of December 31, 2022, the Company had a net cash position of approximately \$0.7 million, consisting of a gross cash position of approximately \$48.7 million less cash borrowings of approximately \$48.0 million by participating subsidiaries, which is reflected as cash and cash equivalents in the consolidated balance sheet.

Note 7. Accounts Receivable

At the end of each period, accounts receivable were comprised of the following:

(in millions)	As of December 31,	
	2022	2021
Accounts receivable trade, net	\$ 128.6	\$ 101.2
Unbilled receivable	12.3	34.0
Accounts receivable, net	\$ 140.9	\$ 135.2

The percentages of total net accounts receivable trade for customers that represent 10% or more of total net accounts receivable trade were as follows:

	As of December 31,	
	2022	2021
Distributor A	34%	21%
Distributor B	11%	*
Distributor D	23%	15%

* Represents less than 10% of total net accounts receivable trade.

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.

(in millions)	Year Ended December 31,		
	2022	2021	2020
Credit losses at beginning of year	\$ 2.7	\$ 2.9	\$ 4.9
Provision for expected credit losses	4.2	3.1	3.3
Write-offs charged against allowance	(4.9)	(3.8)	(5.8)
Recoveries of amounts previously reserved	0.5	0.5	0.5
Credit losses at end of year	\$ 2.5	\$ 2.7	\$ 2.9

Note 8. Inventories

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

(in millions)	As of December 31,	
	2022	2021
Raw materials	\$ 79.1	\$ 70.0
Work in process	84.2	112.6
Finished goods	183.5	120.6
Total inventories	\$ 346.8	\$ 303.2

Amounts charged to the consolidated statements of operations for excess and obsolete inventory, including related to the phase-out of Classic Omnipod for the years ended December 31, 2022, 2021, and 2020 were \$8.4 million, \$2.8 million, and \$2.2 million, respectively.

Note 9. Cloud Computing Costs

Capitalized costs to implement cloud computing arrangements at cost and accumulated amortization were as follows:

(in millions)	As of December 31,	
	2022	2021
Short-term portion	\$ 18.0	\$ 18.4
Long-term portion	87.1	49.2
Total capitalized implementation costs	105.1	67.6
Less: accumulated amortization	(17.1)	(4.4)
Capitalized implementation costs, net	\$ 88.0	\$ 63.2

Amortization expense is recognized on a straight-line basis over the expected term of the hosting arrangements, which range from 3 to 5 years. Amortization expense was \$12.7 million, \$2.9 million, and \$1.4 million for the years ended December 31, 2022, 2021, and 2020, respectively.

Note 10. Property, Plant and Equipment, Net

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

(in millions)	As of December 31,	
	2022	2021
Land	\$ 2.5	\$ 2.5
Building and building improvements	163.9	159.5
Machinery and equipment	527.0	437.2
Furniture and fixtures	17.2	15.9
Leasehold improvements	11.7	5.9
Construction in process	112.3	94.7
Total property, plant and equipment	834.6	715.7
Less: accumulated depreciation	(234.7)	(179.2)
Property, plant and equipment, net	\$ 599.9	\$ 536.5

Depreciation expense related to property and equipment was \$56.0 million, \$50.6 million, and \$38.0 million for the years ended December 31, 2022, 2021, and 2020, respectively. Construction in process primarily consists of manufacturing equipment for our new manufacturing facility being constructed in Malaysia, most of which is expected to be placed into service in 2024. Construction in progress also consists of tooling and other machinery and equipment for our existing manufacturing lines, most of which is expected to be placed into service during 2023.

Note 11. Business Combination

On January 3, 2022, the Company acquired substantially all of the assets related to the manufacture and production of shape-memory alloy wire assemblies that are used in the production of Pods from Dynalloy, Inc., a maker of dynamic alloys. The aggregate purchase price was \$29.0 million, of which \$26.0 million was paid in cash upon closing, and the remaining \$3.0 million was paid in January 2023. Transaction costs were expensed as incurred and were not material.

The following table summarizes the fair value allocation of the assets acquired at the date of acquisition:

(in millions)	
Inventories	\$ 0.5
Property, plant and equipment	0.9
Other assets	0.2
Goodwill (tax deductible)	12.0
Developed technology (15 year useful life)	15.4
Total assets acquired	\$ 29.0

The primary factor that contributed to an acquisition price in excess of the fair value of assets acquired and the establishment of goodwill was the expected cost savings resulting from the integration of a supplier.

Note 12. Goodwill and Other Intangible Assets, Net

Goodwill

The change in the carrying amount of goodwill for the period is as follows:

(in millions)	
Goodwill at December 31, 2021	\$ 39.8
Acquisition (Note 11)	12.0
Foreign currency translation	(0.1)
Goodwill at December 31, 2022	\$ 51.7

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:

(in millions)	As of December 31,					
	2022			2021		
	Gross Carrying Amount	Accumulated Amortization	Net Book Value	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Customer relationships	\$ 43.2	\$ (27.5)	\$ 15.7	\$ 43.4	\$ (23.4)	\$ 20.0
Internal-use software	34.8	(12.0)	22.8	25.5	(10.2)	15.3
Developed technology ⁽¹⁾	27.4	(1.0)	26.4	—	—	—
Patents ⁽¹⁾	11.0	(0.4)	10.6	1.6	(0.3)	1.3
Total intangible assets	\$ 116.4	\$ (40.9)	\$ 75.5	\$ 70.5	\$ (33.9)	\$ 36.6

⁽¹⁾ Includes intangible assets acquired in December 2022. See Note 17 for additional information.

Intangible asset amortization expense was \$7.2 million, \$6.8 million, and \$17.4 million for the years ended December 31, 2022, 2021, and 2020, respectively. As discussed in Note 17, amortization expense for the year ended December 31, 2020 includes \$14.6 million of cumulative amortization associated with customer relationships that were acquired in 2018.

Amortization expense associated with the intangible assets included on the Company's consolidated balance sheet as of December 31, 2022 is expected to be as follows:

Years Ending December 31,	(in millions)
2023	\$ 8.0
2024	\$ 10.3
2025	\$ 9.7
2026	\$ 9.1
2027	\$ 8.2

Note 13. Accrued Expenses and Other Current Liabilities

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

(in millions)	As of December 31,	
	2022	2021
Employee compensation and related costs	\$ 95.9	\$ 70.3
Accrued rebates	69.6	28.7
Warranty liability - current portion	57.3	2.4
Professional and consulting services	27.5	22.8
Other	50.7	40.1
Accrued expenses and other current liabilities	\$ 301.0	\$ 164.3

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

(in millions)	Years Ended December 31,	
	2022	2021
Product warranty liability at beginning of year	\$ 6.8	\$ 6.7
Warranty expense	87.0	10.7
Changes in estimates	(14.0)	—
Warranty fulfillment	(17.7)	(10.6)
Product warranty liability at end of year	\$ 62.1	\$ 6.8

In 2022, the Company issued voluntary Medical Device Corrections (“MDCs”) for its Omnipod DASH PDM related to its battery and for its Omnipod 5 Controller related to its charging port and cable. The Company initially accrued an estimated liability of \$68.9 million related to these MDCs, which was subsequently revised by \$11.0 million, resulting in a net charge of \$57.9 million for the year ended December 31, 2022. The \$11.0 million change in estimate primarily resulted from significantly fewer customers requesting a replacement Omnipod DASH PDM prior to the Company’s updated PDM being available.

Note 14. Leases

As of December 31, 2022, the Company leased certain office spaces, laboratory space, warehouse space, and automobiles, all of which were classified as operating leases. Certain of the Company’s operating leases include escalating rental payments, some include the option to extend for up to 10 years, and some include options to terminate the leases at certain times within the lease term.

As of December 31, 2022, operating lease assets and operating lease liabilities were included in the following consolidated balance sheet accounts in the amounts shown:

(in millions)	Years Ended December 31,	
	2022	2021
Operating lease asset:		
Other assets	\$ 26.0	\$ 9.9
Operating lease liabilities:		
Accrued expenses and other current liabilities	\$ 3.6	\$ 5.0
Other liabilities	27.4	7.6
Total operating lease liabilities	\$ 31.0	\$ 12.6

The Company’s total operating lease cost was \$8.8 million, \$6.0 million, and \$5.4 million for the years ended December 31, 2022, 2021, and 2020, respectively. Cash paid for amounts included in the measurement of lease liabilities was \$4.6 million, \$5.7 million, and \$4.6 million for the years ended December 31, 2022, 2021, and 2020, respectively.

Maturities of lease liabilities as of December 31, 2022 are as follows:

Years Ending December 31,	(in millions)
2023	\$ 6.1
2024	5.5
2025	4.3
2026	1.9
2027	2.0
Thereafter	28.6
Total future minimum lease payments	48.4
Less: imputed interest	(17.4)
Present value of future minimum lease payments	\$ 31.0

As of December 31, 2022, the weighted average remaining lease term for operating leases was 12.2 years and the weighted-average discount rate used to determine the operating lease liability was 6.3%.

In October 2022, the Company made an upfront payment of \$4.0 million upon entering into an agreement to acquire real estate in Malaysia, including land and building to be constructed thereon (“the Malaysia Purchase Agreement”). In December 2022, the Company made an additional \$11.3 million payment upon entering into a change order for additional specifications of the building. The building is expected to be completed no later than January 1, 2024, at which time the Company can either purchase or lease the real estate. The Company will also have the option to purchase the property at any point after the commencement date of the lease and is contractually obligated to purchase the property nine months after the commencement date of the lease. Because the Company is reasonably certain to purchase the real estate, the lease term is equal to the economic life of the underlying asset. The Company is involved in the design of the building but does not control the real estate prior to the lease commencement date. Accordingly, the payments made are included in other assets on the consolidated balance sheet at December 31, 2022. Total undiscounted future lease payments, including the price to purchase the asset, are approximately \$24.6 million as of December 31, 2022.

Note 15. Debt

The components of debt consisted of the following:

(in millions)	As of December 31,	
	2022	2021
Revolving Credit Facility expires May 2024	\$ —	\$ —
Equipment financing due May 2024	9.5	16.0
Equipment financing due November 2025	22.5	29.6
5.15% Mortgage due November 2025	65.5	67.7
0.375% Convertible Senior Notes due September 2026	800.0	800.0
Term loan due May 2028	492.5	497.5
Equipment financing due July 2028	34.4	38.2
Unamortized debt discount	(7.6)	(159.9)
Debt issuance costs	(15.0)	(15.2)
Total debt, net	1,401.8	1,273.9
Less: current portion	27.5	25.1
Total long term-debt, net	\$ 1,374.3	\$ 1,248.8

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%.

In July 2021, the Company entered into a \$43.1 million equipment financing transaction secured by one of the manufacturing lines located at the Company's Acton, Massachusetts manufacturing facility. The equipment financing is payable over 84 months and has an effective interest rate of 4.3%.

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 non-financial customary covenants, none of which are considered restrictive to the Company's operations.

0.375% Convertible Senior Notes

The Company has \$800.0 million aggregate principal amount of 0.375% Convertible Senior Notes due September 2026 (the "0.375% Notes") outstanding. 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 and to purchase the capped call options ("Capped Calls") 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 purchased Capped Calls on the Company’s common stock with certain counterparties 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.

Senior Secured Credit Agreement

In May 2021, the Company entered into a senior secured credit agreement (the “Credit Agreement”), which includes a \$500 million seven year senior secured term loan B (the “Term Loan”) for net proceeds of \$489.5 million, which was used to fund the cash portion of the repurchase of the 1.375% Notes discussed below. On November 30, 2022, the Company amended the Term Loan to bear interest at a rate of SOFR plus 3.25%, with a 0.50% SOFR floor. The Term Loan contains leverage and fixed charge coverage ratio covenants, both of which are measured upon the incurrence of future debt.

Under the same agreement, the Company obtained a three-year senior secured revolving credit facility (the “Revolving Credit Facility”). In 2022, the Company increased the borrowing capacity under the Revolving Credit Facility to \$100.0 million and amended the agreement such that outstanding borrowings bear interest at a rate of SOFR plus an applicable margin of 2.75% to 3.25% based on the Company’s net leverage ratio. The Revolving Credit Facility contains a covenant to maintain a specified leverage ratio under certain conditions when there are amounts outstanding. No amount was outstanding under the Revolving Credit Facility at December 31, 2022.

Borrowings under the Credit Agreement are guaranteed by certain wholly owned domestic subsidiaries of the Company, and are secured by substantially all assets of the Company and of each subsidiary guarantor, subject to certain exceptions. Additionally, borrowings under the Credit Agreement are senior to all of the Company’s unsecured indebtedness, including the convertible notes.

1.375% Convertible Senior Notes

In 2021, the Company repurchased \$370.4 million in principal (\$305.7 million net of discount and issuance costs) of its 1.375% Convertible Senior Notes due November 2024 (“1.375% Notes”) for \$460.8 million in cash and the issuance of 2.2 million shares with a fair value of \$622.7 million. The remaining \$32.1 million in principal of the 1.375% Notes were converted into approximately 0.4 million shares with a fair value of \$99.8 million. The debt repurchase and conversions resulted in a \$42.4 million loss on extinguishment, including cash paid to the note holders as an inducement to convert and transaction costs.

Maturity of Debt

The maturity of debt as of December 31, 2022 is as follows:

Years Ending December 31,	(in millions)
2023	\$ 26.9
2024	\$ 23.3
2025	\$ 79.3
2026	\$ 811.1
2027	\$ 11.4

Fair Value

The carrying amount and the estimated fair value of the Company’s debt were as follows:

(in millions)	As of December 31,			
	2022		2021	
	Carrying Value	Estimated Fair Value	Carrying Value	Estimated Fair Value
Term loan due May 2028 ⁽¹⁾	\$ 482.2	\$ 485.1	\$ 485.2	\$ 498.1
0.375% Convertible Senior Notes ⁽²⁾	788.8	1,038.7	638.8	938.8
Equipment financings ⁽³⁾	66.4	66.4	83.7	83.7
5.15% Mortgage ⁽³⁾	64.5	64.5	66.2	66.2
Total	\$ 1,401.9	\$ 1,654.7	\$ 1,273.9	\$ 1,586.8

⁽¹⁾ Term debt is classified as Level 1 in the fair value hierarchy. Fair value was determined using quoted market prices.

⁽²⁾ The Notes are classified as Level 2 in the fair value hierarchy. Fair value was determined using the Company’s quoted stock price and the contractual conversion rate.

⁽³⁾ The equipment financings and Mortgage are classified as Level 3 in the fair value hierarchy. The fair values were determined using the cost bases of the financial liabilities, which approximate their carrying values.

Note 16. Derivative Instruments

The Company manages interest rate exposure through the use of interest rate swap transactions with financial institutions acting as principal counterparties. Under the Company's interest rate swap agreements that expire on April 30, 2025, the Company receives variable rate interest payments and pays fixed interest rates of 0.95% and 0.96% on a total notional value of \$480.0 million of its Term Loan. The Company has designated the interest rate swaps as cash flow hedges.

The fair value of interest rate swaps, which are classified as Level 2 in the fair value hierarchy, represent the estimated amounts the Company would receive or pay to terminate the contracts and is determined using industry standard valuation models and market-based observable inputs, including credit risk and interest rate yield curves. The fair value of the interest rate swaps was \$36.9 million and \$4.5 million at December 31, 2022 and December 31, 2021, respectively, and was included in other assets on the consolidated balance sheets. As of December 31, 2022, the Company estimates that \$19.8 million of net gains related to the interest rate swaps included in accumulated other comprehensive income will be reclassified into the statement of operations over the next 12 months.

Note 17. Commitments and Contingencies

Legal Proceedings

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, including Pods, PDMs, and other components of the system, and kits in the United States infringed Roche's now-expired U.S. Patent 7,931,613. Roche was seeking monetary damages and attorneys' fees and costs. In July 2022, the Company entered into a Settlement and License Agreement (the "Settlement Agreement") with Roche to settle the pending litigation. Pursuant to the Settlement Agreement, in exchange for a release of claims, mutual covenant not to sue for five years, and license to the patent in suit from Roche, the Company made a one-time payment of \$20.0 million to Roche. On July 12, 2022, following the filing by the parties of a Stipulation of Dismissal, the Court ordered the case dismissed with prejudice. The \$20.0 million charge is included in selling, general and administrative expenses for the year ended December 31, 2022.

The Company is, from time to time, involved in the normal course of business in various legal proceedings, including intellectual property, contract, employment, and product liability suits. The Company does not expect the outcome of these proceedings, either individually or in the aggregate, to have a material adverse effect on its results of operations.

Contract Dispute

Throughout 2022, the Company was engaged in negotiations over a contractual dispute involving in-licensed intellectual property. In December, 2022, the Company entered into an agreement with Automated Glucose Control LLC (the "Asset Purchase Agreement"). Pursuant to the Asset Purchase Agreement, the Company made a one-time payment of \$25.0 million for the acquisition of developed technology and patents and the release of future obligations, including any future royalty obligations. This amount, together with transaction costs, was allocated between the assets acquired and the settlement of the contractual dispute. A value of \$12.0 million was allocated to acquired developed technology and a value of \$9.5 million was allocated to acquired patents. The acquired developed technology and patents are being amortized over their useful lives of 13 years. The remaining \$3.6 million was allocated to the settlement and is included in selling, general and administrative expenses for the year ended December 31, 2022.

Letters of Credit

In 2022, the Company entered into a \$20.0 million uncommitted letter of credit facility. Concurrently with the execution of the Malaysia Purchase Agreement discussed in Note 14, a \$17.2 million letter of credit was issued under this facility to backstop a bank guarantee for the same amount. The bank guarantee, to which the Company is not a party to, serves as security for the building while under construction until the Company purchases the property. The Company pays interest on outstanding borrowings and commitment fees on the maximum amount available to be drawn under the letter of credit at a rate of between 1.65% and 2.25%, depending on the Company's credit rating. The letter of credit includes customary covenants, none of which are considered restrictive to the Company's 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 18. Stock-Based Compensation Expense

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, 2022, 2.7 million shares remain available for future issuance under the 2017 Plan.

Stock-Based Compensation Expense

Compensation expense related to stock-based awards was recorded as follows:

(in millions)	Year Ended December 31,		
	2022	2021	2020
Cost of revenue	\$ 0.4	\$ 0.5	\$ 1.2
Research and development	8.9	7.6	10.9
Selling, general and administrative	31.6	26.3	23.8
Total	\$ 40.9	\$ 34.4	\$ 35.9

Stock Options

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

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

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in millions)
Outstanding at December 31, 2021	765,457	\$ 81.98		
Granted	79,994	\$ 264.69		
Exercised	(147,200)	\$ 47.72		\$ 31.7
Forfeited and canceled	(2,663)	\$ 214.07		
Outstanding at December 31, 2022	695,588	\$ 109.73	5.3	\$ 128.4
Vested, December 31, 2022	517,850	\$ 67.11	4.3	\$ 117.7
Vested or expected to vest, December 31, 2022	645,564	\$ 98.15	5.1	\$ 126.7

The aggregate intrinsic value of options exercised for the years ended December 31, 2021 and 2020 was \$86.5 million and \$115.9 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,		
	2022	2021	2020
Risk-free interest rate	1.8%	0.5% - 0.6%	0.3% - 1.4%
Expected life of options (in years)	4.2	4.2 - 4.4	4.5
Dividend yield	—%	—%	—%
Expected stock price volatility	42.8%	41.4% - 41.6%	39.5% - 41.7%
Fair value per option	\$ 93.26	\$ 95.92	\$ 69.90

As of December 31, 2022, there was \$10.1 million of unrecognized compensation cost related to non-vested stock options. This cost is expected to be recognized over a weighted average period of 1.8 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 RSUs 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, 2021	201,712	\$ 207.97
Granted	166,599	248.02
Vested	(116,906)	173.78
Forfeited	(18,679)	257.23
Outstanding at December 31, 2022	232,726	\$ 249.60

The weighted-average grant-date fair value per share of RSUs granted was \$278.68 and \$211.77 for the years ended December 31, 2021 and 2020, respectively. The total fair value of RSUs vested was \$20.3 million, \$17.0 million, and \$20.7 million for the years ended December 31, 2022, 2021, and 2020, respectively.

As of December 31, 2022, there was \$38.6 million of unrecognized compensation cost related to time-based RSUs, which is expected to be recognized over a weighted-average period of 1.9 years.

Performance Stock Units

Performance stock units (“PSUs”) generally vest over a three-year period from the grant date and include both a service and performance component. Stock-based payments that contain performance conditions are recognized when such conditions are probable of being achieved. Certain of these PSUs could ultimately vest at up to 200% of the target award depending on the achievement of the performance criteria. The Company determines the fair value of PSUs based on the closing price of its common stock on the date of grant.

PSU activity is as follows:

	Number of Shares	Weighted Average Fair Value
Outstanding at December 31, 2021	182,443	\$ 171.02
Granted	83,710	250.25
Vested	(84,526)	93.91
Forfeited	(1,326)	268.58
Outstanding at December 31, 2022 ⁽¹⁾	180,301	\$ 249.10

⁽¹⁾ Based on 84% achievement of the performance metrics, approximately 40,000 shares of Insulet were earned for awards that were granted in 2020 for the performance period ended December 31, 2022. These shares vested in February 2023.

The weighted-average grant-date fair value per share of PSUs granted was \$273.79 and \$202.23 for the years ended December 31, 2021 and 2020, respectively. The total fair value of PSUs vested was \$7.8 million, \$10.3 million, and \$9.1 million for the years ended December 31, 2022, 2021, and 2020, respectively.

As of December 31, 2022, there was \$25.9 million of unrecognized compensation cost related to PSUs, which is expected to be recognized over a weighted-average period of 1.2 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 52,724, 36,103, and 38,313 shares of common stock for the years ended December 31, 2022, 2021, and 2020, respectively, to employees participating in the ESPP. As of December 31, 2022, 419,935 shares remain available for future issuance under the ESPP.

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,		
	2022	2021	2020
Risk-free interest rate	1.6% - 4.7%	0.04% - 0.1%	0.1% - 0.2%
Expected term (in years)	0.5	0.5	0.5
Dividend yield	—%	—%	—%
Expected stock price volatility	44.3% - 50.1%	19.4% - 31.7%	29.7% - 38.5%

The weighted average grant date fair value of the six-month option inherent in the ESPP was \$74.50, \$60.65, and \$55.10, for the years ended December 31, 2022, 2021, and 2020, respectively.

As of December 31, 2022, there was \$1.7 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 19. 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 Gains on Available-for-sale Securities	Unrealized Gains on Cash Flow Hedges	Accumulated Other Comprehensive Income (Loss)
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
Other comprehensive (loss) income before reclassifications	(11.9)	(0.3)	3.0	(9.2)
Amounts reclassified to net income	—	—	1.5	1.5
Balance, December 31, 2021	(6.7)	—	4.5	(2.2)
Other comprehensive (loss) income before reclassifications	(10.3)	—	36.5	26.2
Amounts reclassified to net income	—	—	(4.0)	(4.0)
Balance, December 31, 2022	\$ (17.0)	\$ —	\$ 37.0	\$ 20.0

Note 20. 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 \$9.8 million, \$8.5 million, and \$6.7 million for the years ended December 31, 2022, 2021, and 2020, respectively.

Note 21. Interest Expense, Net

Interest expense, net of portion capitalized was as follows:

(in millions)	Years Ended December 31,		
	2022	2021	2020
Cash interest, net of interest rate swaps	\$ 32.0	\$ 27.1	\$ 9.5
Accretion of debt discount	1.5	36.7	42.3
Amortization of debt issuance costs	4.3	3.5	2.9
Capitalized interest	(1.3)	(5.6)	(6.6)
Interest expense, net of portion capitalized	36.5	61.7	48.1
Interest income	(9.8)	(0.5)	(3.0)
Interest expense, net	\$ 26.7	\$ 61.2	\$ 45.1

Note 22. Income Taxes

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

(in millions)	Years Ended December 31,		
	2022	2021	2020
U.S.	\$ 11.8	\$ 25.3	\$ (1.6)
Foreign	(2.0)	(4.8)	11.3
Income before income taxes	\$ 9.8	\$ 20.5	\$ 9.7

Income tax expense consists of the following:

(in millions)	Years Ended December 31,		
	2022	2021	2020
Current:			
U.S. State	\$ 1.3	\$ 0.5	\$ 0.2
Foreign	4.8	2.0	4.0
Total current expense	6.1	2.5	4.2
Deferred:			
U.S. Federal	—	—	—
Foreign	(0.9)	1.2	(1.3)
Total deferred expense	(0.9)	1.2	(1.3)
Income tax expense	\$ 5.2	\$ 3.7	\$ 2.9

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

	Years Ended December 31,		
	2022	2021	2020
U.S. statutory rate	21.0 %	21.0 %	21.0 %
Foreign rate differential	13.2	4.8	7.0
State taxes, net of federal benefit	10.1	1.8	1.3
Tax credits	(74.1)	(16.8)	(40.5)
Stock-based compensation	(94.8)	(117.0)	(311.1)
Extinguishment of debt	—	(57.5)	—
Capital loss carryforward expirations	—	52.1	—
Non-deductible officers' compensation	52.4	45.7	30.0
Permanent items	6.3	1.9	2.1
Foreign income taxed in the U.S.	14.5	—	(21.0)
Change in valuation allowance	133.9	77.2	336.2
Tax rate changes	(30.9)	—	—
Intercompany transfer of intellectual property	—	4.6	—
Other	1.8	0.4	4.6
Effective income tax rate	53.4 %	18.2 %	29.6 %

For all periods presented, 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 \$27.3 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 Company's U.S. federal and state tax returns are currently open to examination for tax years 2019 through 2021. In addition, the Company's U.S. net operating loss carryforwards from 2002 and forward may be subject to examination if the losses are utilized in future years.

As of December 31, 2022, 2021, and 2020 the Company had no uncertain tax positions.

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

(in millions)	As of December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	\$ 143.4	\$ 170.2
Tax credits	33.6	28.8
Capitalized research and development expenditures	30.4	—
Warranty	14.6	1.6
Amortization of debt discount	11.0	—
Inventory capitalization	4.1	6.5
Intangible assets	12.7	11.6
Interest limitation carryforwards	1.7	7.3
Incentive compensation	15.8	10.4
Other	15.0	9.9
Total deferred tax assets	282.3	246.3
Deferred tax liabilities:		
Prepaid assets	(5.3)	(4.8)
Property, plant and equipment	(31.5)	(22.2)
Amortization of debt discount	—	(22.9)
Capitalized contract acquisition costs	(10.4)	(9.2)
Unrealized gains on cash flow hedges	(8.8)	(1.1)
Other	(1.9)	(2.9)
Total deferred tax liabilities	(57.9)	(63.1)
Net deferred tax asset before valuation allowance	224.4	183.2
Valuation allowance	(222.8)	(182.4)
Net deferred tax asset	\$ 1.6	\$ 0.8

The Company maintained a valuation allowance of \$222.8 million and \$182.4 million at December 31, 2022 and 2021, respectively, against U.S. federal, state, and foreign deferred tax assets, as management has determined that it is more-likely-than-not that these net deferred tax assets will not be realized. These valuation allowances are based on cumulative tax losses in the U.S. and U.K. and the uncertainty of generating future taxable income in these jurisdictions to utilize loss and credit carryforwards. The \$40.4 million increase in the Company's valuation allowance during the year ended December 31, 2022 was primarily due to temporary differences in the United States.

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

(in millions)	Years Ended December 31,	
	2022	2021
U.S. Federal	\$ 573.8	\$ 708.8
State	\$ 278.1	\$ 327.3
Foreign	\$ 30.1	\$ 16.4

As of December 31, 2022, \$190.6 million of the U.S. federal net operating losses and the full amount of the foreign net operating losses have an indefinite carryforward period. The remaining U.S. federal carryforwards, if not utilized, expire from 2028 through 2037, and the state net operating loss carryforwards expire from 2023 through 2042. 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 United States. Research and development and other tax credits were \$37.0 million and \$31.4 million at December 31, 2022 and 2021, respectively. If not utilized, federal research and development credits will expire through 2042. 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 23. 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. The weighted-average number of common shares used in the computation of basic and diluted net income per share were as follows:

(in thousands)	Years Ended December 31,		
	2022	2021	2020
Weighted average number of common shares outstanding, basic	69,375	67,698	64,735
Stock options	454	686	1,025
Restricted stock units	81	195	186
Weighted average number of common shares outstanding, diluted	69,910	68,579	65,946

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

(in thousands)	Years Ended December 31,		
	2022	2021	2020
0.375% Convertible Senior Notes	3,528	3,528	3,528
1.375% Convertible Senior Notes	—	2,024	4,319
Restricted stock units	227	166	282
Stock options	137	53	58
Total	3,892	5,771	8,187

Note 24. Supplemental Cash Flow Information

(in millions)	Years Ended December 31,		
	2022	2021	2020
Cash paid for interest, net of amount capitalized	\$ 34.2	\$ 21.5	\$ 2.6
Cash paid for taxes	\$ 5.5	\$ 7.0	\$ 3.0
Purchases of property, plant and equipment included in accounts payable and accrued expenses	\$ 3.9	\$ 6.1	\$ 6.7
Purchases of intangible assets included in accounts payable and accrued expenses	\$ 0.4	\$ 3.2	\$ —
Lease liabilities arising from obtaining right-of-use assets	\$ 25.5	\$ 0.7	\$ 2.5

Note 25. Subsequent Events

In February 2023, the Company paid \$25 million in cash to acquire insulin pump patents that may be used for automated insulin delivery from Bigfoot Biomedical, Inc. Additionally, the Company made a \$2 million strategic investment in another company.

SCHEDULE II — VALUATION AND QUALIFYING ACCOUNTS

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

Description (in millions)	Balance at Beginning of Year	Additions Charged to Costs and Expenses	Other ⁽¹⁾	Deductions	Balance at End of Year
Year Ended December 31, 2022					
Reserve for rebates	\$ 34.1	\$ 247.1	\$ —	\$ (203.9)	\$ 77.3
Deferred tax valuation allowance	\$ 182.4	\$ 72.5	\$ 37.8	\$ (69.9)	\$ 222.8
Year Ended December 31, 2021					
Reserve for rebates	\$ 16.9	\$ 143.3	\$ —	\$ (126.1)	\$ 34.1
Deferred tax valuation allowance	\$ 143.4	\$ 77.4	\$ —	\$ (38.4)	\$ 182.4
Year Ended December 31, 2020					
Reserve for rebates	\$ 12.1	\$ 82.5	\$ —	\$ (77.7)	\$ 16.9
Deferred tax valuation allowance	\$ 104.4	\$ 61.7	\$ —	\$ (22.7)	\$ 143.4

⁽¹⁾ Represents the increase in deferred tax valuation allowance resulting from the adoption of ASU 2020-06, *Debt — Debt with Conversations and Other Options (Subtopic 470-20)* and *Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*. 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, 2022. 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, 2022, 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, 2022 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, 2022. 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, 2022.

The effectiveness of our internal control over financial reporting as of December 31, 2022 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 2023 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, 2022.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders ⁽¹⁾	695,588	\$ 109.73	2,709,488 ⁽²⁾
Equity compensation plans not approved by security holders	—	\$ —	—
Total	695,588	109.73	2,709,488

⁽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, 2022, 413,027 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 \$109.73. For more information relating to our equity compensation plans, see Note 18 to our consolidated financial statements.

⁽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.

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

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

Item 14. Principal Accounting Fees and Services

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

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) Financial Statements and Schedules

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

(3) Exhibit Index:

Number	Description
3.1	Eighth Amended and Restated Certificate of Incorporation of the Registrant (Incorporated by reference to Exhibit 3.1 to our Registration Statement on Form S-8 (No. 333-144636) filed July 17, 2007).
3.2	Second 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 24, 2022)
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 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).
4.3	Form of 0.375% Convertible Notes due 2026 (included in Exhibit 4.1 to our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2019, filed November 5, 2019)
10.1*	Insulet Corporation 2017 Stock Option and Incentive Plan (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed May 19, 2017)
10.2*	Form of Insulet Corporation 2017 Stock Option and Incentive Plan Incentive Stock Option Agreement for Employees (Incorporated by reference to Exhibit 10.4 to our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2017, filed August 4, 2017)
10.3*	Form of Insulet Corporation 2017 Stock Option and Incentive Plan Non-Qualified Stock Option Agreement for Employees (Incorporated by reference to Exhibit 10.5 to our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2017, filed August 4, 2017)
10.4*	Form of Insulet Corporation 2017 Stock Option and Incentive Plan Restricted Stock Unit Agreement for Employees (Incorporated by reference to Exhibit 10.6 to our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2017, filed August 4, 2017)
10.5*	Form of Insulet Corporation 2017 Stock Option and Incentive Plan Performance Vesting Restricted Stock Unit Agreement for Officers (Incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2017, filed November 3, 2017)
10.6*	Form of Insulet Corporation 2017 Stock Option and Incentive Plan Non-Qualified Stock Option Agreement for Directors (Incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2017, filed August 4, 2017)
10.7*	Form of Insulet Corporation 2017 Stock Option and Incentive Plan Restricted Stock Unit Agreement for Directors (Incorporated by reference to Exhibit 10.3 to our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2017, filed August 4, 2017)
10.8*	Form of Insulet Corporation 2017 Stock Option and Incentive Plan Non-Qualified Stock Option Agreement (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed February 24, 2022)
10.9*	Form of Insulet Corporation 2017 Stock Option and Incentive Plan Performance Shares Agreement (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed March 1, 2022)
10.10*	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)
10.11*	Form of Executive Officer 3 Year Incentive Stock Option Agreement under the Insulet Corporation Third Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to Exhibit 10.7 to our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2017, filed May 9, 2017)
10.12*	Form of International Non-Qualified Stock Option Agreement under the Third Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2016, filed August 4, 2016)
10.13*	Form of Non-Qualified Stock Option Agreement for Non-Employee Directors under the Third Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to Exhibit 10.3 to our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2016, filed August 4, 2016)

- 10.14* [Form of Non-Executive Employee Incentive Stock Option Agreement under the Insulet Corporation Third Amended and Restated 2007 Stock Option and Incentive Plan \(Incorporated by reference to Exhibit 10.60 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, filed February 29, 2016\)](#)
- 10.15* [Form of Section 16 Officer Incentive Stock Option Agreement under the Insulet Corporation Third Amended and Restated 2007 Stock Option and Incentive Plan \(Incorporated by reference to Exhibit 10.62 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, filed February 29, 2016\)](#)
- 10.16* [Form of Vice President Incentive Stock Option Agreement under the Insulet Corporation Third Amended and Restated 2007 Stock Option and Incentive Plan \(Incorporated by reference to Exhibit 10.64 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, filed February 29, 2016\)](#)
- 10.17* [Form of Incentive Stock Option Agreement under the Insulet Corporation Third Amended and Restated 2007 Stock Option and Incentive Plan \(Incorporated by reference to Exhibit 10.4 to our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2015, filed August 12, 2015\)](#)
- 10.18* [Form of Incentive Stock Option Agreement under the Second Amended and Restated 2007 Stock Option and Incentive Plan - 2015 Sales Plan \(Incorporated by reference to Exhibit 10.51 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, filed February 26, 2015\)](#)
- 10.19* [Form of Non-Qualified Stock Option Agreement for Shacey Petrovic under the Second Amended and Restated 2007 Stock Option and Incentive Plan \(Incorporated by reference to Exhibit 10.53 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, filed February 26, 2015\)](#)
- 10.20* [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 \(Incorporated by reference to Exhibit 10.56 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, filed February 26, 2015\)](#)
- 10.21* [Form of Non-Qualified Stock Option Agreement for Company Employees under the Second Amended and Restated 2007 Stock Option and Incentive Plan \(Incorporated by reference to Exhibit 10.4 to our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2014, filed November 5, 2014\)](#)
- 10.22* [Form of Non-Qualified Stock Option Agreement for Non-Employee Directors under the Second Amended and Restated 2007 Stock Option and Incentive Plan \(Incorporated by reference to Exhibit 10.5 to our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2014, filed November 5, 2014\)](#)
- 10.23* [Form of Incentive Stock Option Agreement under the Second Amended and Restated 2007 Stock Option and Incentive Plan \(Incorporated by reference to Exhibit 10.7 to our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2014, filed November 5, 2014\)](#)
- 10.24* [Form of Incentive Stock Option Agreement for Section 16 Officers under the Second Amended and Restated 2007 Stock Option and Incentive Plan \(Incorporated by reference to Exhibit 10.10 to our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2014, filed November 5, 2014\)](#)
- 10.25* [Form of Non-Qualified Stock Option Agreement for Section 16 Officers under the Second Amended and Restated 2007 Stock Option and Incentive Plan \(Incorporated by reference to Exhibit 10.11 to our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2014, filed November 5, 2014\)](#)
- 10.26* [Form of Incentive Stock Option Agreement under the Second Amended and Restated 2007 Stock Option and Incentive Plan - October 2014 New Hires \(Incorporated by reference to Exhibit 10.15 to our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2014, filed November 5, 2014\)](#)
- 10.27* [Form of Non-Qualified Stock Option Agreement for Michael Spears \(Incorporated by reference to Exhibit 10.1 to our Registration Statement on Form S-8 \(No. 333-208387\) filed December 8, 2015\)](#)
- 10.28* [Amended and Restated Executive Severance Plan \(Incorporated by reference to Exhibit 10.4 to our Current Report on Form 8-K filed February 22, 2023\)](#)
- 10.29* [Insulet Corporation Employee Stock Purchase Plan \(Amended and Restated February 27, 2019\) \(Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed May 30, 2019\)](#)
- 10.30*# [Form of Inventions, Non-Disclosure, Non-Solicitation, Non-Servicing and Non-Competition Agreement \(Executive Officers other than Jim Hollingshead and Dan Manea\)](#)
- 10.31* [Offer Letter between Shacey Petrovic and Insulet Corporation, dated September 10, 2018 \(Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed September 14, 2018\)](#)
- 10.32* [Offer Letter between Wayde D. McMillan and Insulet Corporation, dated January 3, 2019 \(Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on January 7, 2019\)](#)
- 10.33+ [Master Equipment and Services Agreement between Insulet Corporation and ATS Automated Tooling Systems Inc., dated August 31, 2016 \(Incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2016, filed November 4, 2016\)](#)

10.34	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))
10.35+	Supply Agreement, dated November 21, 2013, between Amgen and Insulet Corporation, as amended by Amendment No. 1 through Amendment No. 14 (Incorporated by reference to Exhibit 10.18 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2016, filed February 28, 2017)
10.36+	Amendment No. 16, entered into effective as of August 15, 2018, to Supply Agreement, dated November 21, 2013, between Amgen Inc. and Insulet Corporation (Incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2018, filed November 1, 2018)
10.37	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)
10.38*	Offer Letter between John W. Kapples and Insulet Corporation, dated January 22, 2019 (Incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q, filed May 3, 2019)
10.39*	Offer Letter between Dan Manea and Insulet Corporation, dated March 19, 2020 (Incorporated by reference to Exhibit 10.56 to our Annual Report on Form 10-K filed February 24, 2021)
10.40*	Offer Letter between James R. Hollingshead and Insulet Corporation, dated May 4, 2022 (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K, filed May 6, 2022)
10.41*	Retirement and Advisory Agreement between Shacey Petrovic and Insulet Corporation, dated May 4, 2022 (Incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K, filed May 6, 2022)
10.42	Credit Agreement, dated as of May 4, 2021, by and among Insulet Corporation, the lenders and other parties party thereto and Morgan Stanley Senior Funding, Inc., as administrative agent and collateral agent (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed May 5, 2021)
10.43	Incremental Amendment to Credit Agreement, dated June 15, 2022, among Insulet Corporation, Insulet MA Securities Corporation, Morgan Stanley Senior Funding, Inc., as administrative agent, swingline lender, and letter of credit issuer, and the other lenders party thereto (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K, filed June 16, 2022)
10.44	Second Amendment to Credit Agreement, dated November 30, 2022, between Insulet Corporation and Morgan Stanley Senior Funding, Inc., as administrative agent (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K, filed December 1, 2022)
10.45	Third Amendment to Credit Agreement, dated November 30, 2022, between Insulet Corporation, Insulet MA Securities Corporation, the lenders and other parties thereto and Morgan Stanley Senior Funding, Inc., as administrative agent (Incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K, filed December 1, 2022)
10.46++	Materials Supplier Agreement between Insulet Corporation and Sanmina Corporation, dated October 11, 2018. (Incorporated by reference to Exhibit 10.43 to our Annual Report on Form 10-K filed February 24, 2022)
10.47++	First Amendment to Materials Supplier Agreement between Insulet Corporation and Sanmina Corporation, dated October 1, 2020. (Incorporated by reference to Exhibit 10.44 to our Annual Report on Form 10-K filed February 24, 2022)
10.48++	Development Agreement by and between Insulet Corporation and DexCom, Inc, dated December 7, 2016 (Incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2022, filed August 5, 2022)
10.49++	Amendment No.1 to Development Agreement by and between Insulet Corporation and DexCom, Inc, dated November 21, 2019 (Incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2022, filed August 5, 2022)
10.50++	Commercialization Agreement by and between Insulet Corporation and DexCom, Inc, dated November 21, 2019 (Incorporated by reference to Exhibit 10.3 to our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2022, filed August 5, 2022)
10.51++	Data Agreement by and between Insulet Corporation and DexCom, Inc, dated May 7, 2020 (Incorporated by reference to Exhibit 10.4 to our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2022, filed August 5, 2022)
10.52#	First Amendment to the Master Equipment and Services Agreement originally dated August 31, 2016 between Insulet Corporation and ATS Automation Tooling Systems Inc., dated 31 August 2021
10.53++#	Second Amendment to the Master Equipment and Services Agreement originally dated August 31, 2016 between Insulet Corporation and ATS Automation Tooling Systems Inc., dated 31 August 2022

10.54++#	Manufacturing Services and Line Retention Agreement between Insulet Corporation and Flex Medical Sales and Marketing, Ltd., dated July 29, 2022
10.55++#	Amendment Number 15 to the Supply Agreement by and between Amgen Inc. and Insulet Corporation, dated July 12, 2017
10.56++#	Amendment Number 17 to the Supply Agreement by and between Amgen Inc. and Insulet Corporation, dated April 1, 2019
10.57++#	Amendment Number 18 to the Supply Agreement by and between Amgen Inc. and Insulet Corporation, dated August 1, 2019
10.58++#	Amendment Number 19 to the Supply Agreement by and between Amgen Inc. and Insulet Corporation, dated July 13, 2020
10.59++#	Amendment Number 20 to the Supply Agreement by and between Amgen Inc. and Insulet Corporation, dated June 25, 2021
10.60++	Patent Assignment and License Agreement, dated February 9, 2023, between Insulet Corporation, Bigfoot Biomedical, Inc. and Patients Pending, Ltd. (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K, filed February 14, 2023)
10.61*	Form of Insulet Corporation 2017 Stock Option and Incentive Plan Non-Qualified Stock Option Agreement (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K, filed February 22, 2023)
10.62*	Form of Insulet Corporation 2017 Stock Option and Incentive Plan Restricted Stock Unit Agreement (Incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K, filed February 22, 2023)
10.63*	Form of Insulet Corporation 2017 Stock Option and Incentive Plan Performance Stock Unit Agreement (Incorporated by reference to Exhibit 10.3 to our Current Report on Form 8-K, filed February 22, 2023)
10.64*	Annual Incentive Compensation Plan (Incorporated by reference to Exhibit 10.5 to our Current Report on Form 8-K, filed February 22, 2023)
10.65*	Consulting Services Agreement by and between the Company and Charles J. Alpuche (Incorporated by reference to Exhibit 10.6 to our Current Report on Form 8-K, filed February 22, 2023)
10.66*#	Form of Confidentiality, Non-Solicit, Non-Compete, and IP Assignment Agreement, by and between the Company and Employee (Jim Hollingshead and Dan Manea)
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, 2022 formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets; (ii) the Consolidated Statements of Operations; (iii) the Consolidated Statements of Comprehensive Income; (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, 2023

/s/ James R. Hollingshead
James R. Hollingshead
Chief Executive Officer
(Principal Executive Officer)

February 23, 2023

/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 James R. Hollingshead 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, 2023.

<u>Signature</u>	<u>Title</u>
<u>/s/ James R. Hollingshead</u> James R. Hollingshead	Chief Executive Officer (Principal Executive Officer)
<u>/s/ Wayde McMillan</u> Wayde McMillan	Chief Financial Officer (Principal Financial Officer)
<u>/s/ Lauren Budden</u> Lauren Budden	Chief Accounting Officer and Controller (Principal Accounting Officer)
<u>/s/ Luciana Borio, M.D.</u> Luciana Borio, M.D.	Director
<u>/s/ Wayne A.I. Frederick, M.D.</u> Wayne A.I. Frederick, M.D.	Director
<u>/s/ Jessica Hopfield</u> Jessica Hopfield	Director
<u>/s/ Michael R. Minogue</u> Michael R. Minogue	Director
<u>/s/ Corinne H. Nevinny</u> Corinne H. Nevinny	Director
<u>/s/ Shacey Petrovic</u> Shacey Petrovic	Director
<u>/s/ Timothy J. Scannell</u> Timothy J. Scannell	Director
<u>/s/ Elizabeth Weatherman</u> Elizabeth Weatherman	Director

Insulet Corporation

INVENTIONS, NON-DISCLOSURE, NON-SOLICITATION, NON-SERVICING AND NON-COMPETITION AGREEMENT

[Date]

In consideration of my employment by Insulet Corporation, its successors, affiliates, parents, subsidiaries and subdivisions (collectively, the "Company") and the wages, benefits, training opportunities, and other terms and conditions of that employment, I hereby covenant and agree with the Company as follows:

1. Exclusivity of Services: During the period of my employment by the Company, I shall devote my full time and best efforts to the business of the Company and I shall neither pursue, directly or indirectly, alone or as a partner, joint venturer, officer, director, employee, consultant, agent, independent contractor or stockholder of any company or business, any business opportunity outside the Company, nor take any position with any organization other than the Company.

2. Inventions/Developments:

(a) Developments: I will promptly and fully disclose to the Company any and all inventions, improvements, discoveries, methods, processes, developments, software, and works of authorship, whether or not patentable and whether or not they are made, conceived or reduced to practice during working hours or using the Company's data or facilities, which I develop, make, conceive or reduce to practice during my employment by the Company, either solely or jointly with others (collectively the "Developments"). All Developments shall be the sole property of the Company, and I hereby assign to the Company, without further compensation, all my right, title and interest in any and all the Developments and any and all related patents, patent applications, copyrights, copyright applications, trademarks, trademark applications and trade names in the United States and elsewhere. Notwithstanding the foregoing, the term Developments shall not include any invention, discovery or improvement that meets all three of the following criteria: (i) it is not made, conceived or reduced to practice during working hours; (ii) it is not made, conceived or reduced to practice using the Company's information, data or facilities; and (iii) it does not relate to the present business of the Company, any business that is competitive therewith, or any future business in which the Company engages.

(b) Records of Developments: I will keep and maintain adequate and current written records of all Developments (in the form of notes, sketches, drawings and as may be specified by the Company), which records shall be available to and remain the sole property of the Company at all times.

(c) Assistance: I will assist the Company in obtaining and enforcing patent, copyright and other forms of legal protection for the Developments in any country. Upon request, I will sign all applications, assignments, instruments and papers and perform all acts necessary or desired by the Company to assign all such Developments fully and completely to the Company and to enable the Company, its successors, assigns and nominees, to secure and enjoy the full and exclusive benefits and advantages thereof. I understand that my obligations under this subparagraph 2(c) will continue after the termination of my employment with the Company and that during my employment I will perform such obligations without further compensation, except for

reimbursement of expenses incurred at the request of the Company. I further understand that if I am requested to perform any obligations under this subparagraph 2(c) after my employment with the Company terminates, I shall receive for such performance a reasonable per diem fee, as well as reimbursement of any expenses incurred at the request of the Company.

(d) Power of Attorney Regarding Developments: In addition to my agreements set forth in subparagraph 2(c), I hereby constitute and appoint the Company, its successors and assigns, my true and lawful attorney, with full power of substitution for me, and in my name, place and stead or otherwise, but on behalf of and for the benefit of the Company, its successors and assigns, to take all actions and execute all documents on behalf of me necessary to effect the assignment set forth in subparagraph 2(a), and from time to time to institute and prosecute in my name or otherwise, but at the direction and expense and for the benefit of the Company and its successors and assigns, any and all proceedings at law, in equity or otherwise, which the Company, its successors or assigns may deem proper in order to collect, assert or enforce any claim, right or title, of any kind in any and all of the Developments and to defend and compromise any and all actions, suits and proceedings with respect to any of the Developments and to do any and all such acts and things in relation thereto as the Company, its successors or assigns shall deem advisable, and I hereby declare that the appointment hereby made and the powers hereby granted are coupled with an interest and are and shall be irrevocable by me in any manner or for any reason.

(e) Listing of Existing Inventions & Copyrightable Materials: In order to avoid disputes over the application of this assignment to prior inventions or copyrightable materials, I have listed on Schedule A to this Agreement descriptions of patentable inventions and copyrightable materials that I developed and/or reduced to practice prior to my employment with the Company and that I believe are, accordingly, excepted from the provisions of this Paragraph 2.

(f) I acknowledge that all original works of authorship that are made by me (solely or jointly with others) within the scope of my employment and which are protectable by copyright are "works for hire" pursuant to the United States Copyright Act.

3. Proprietary Information/ Non-Disclosure:

(a) Definition of Proprietary Information: I acknowledge that, during my employment, I have been and will continue to be given access to confidential and proprietary information belonging to the Company, its distributors, its customers and/or other third parties. By way of illustration, but not limitation, proprietary information ("**Proprietary Information**") includes trade secrets, processes, data, know-how, marketing plans, forecasts, financial statements, budgets, licenses, prices, costs and employee, customer, distributor and supplier lists. I acknowledge that Proprietary Information has commercial value in the Company's business and is not generally known to the public.

(b) Third Party Information: I recognize that the Company has received and in the future will receive from customers, distributors and other third parties their confidential or proprietary information, subject to a duty on the Company's part to maintain the confidentiality of such information and use it only for limited purposes. All such information is included in the definition of Proprietary Information, and I agree not to disclose it except as necessary in carrying out my work for the Company consistent with the Company's understanding with such third party.

(c) Exclusions from Proprietary Information: Proprietary Information does not include: (i) information that is in the public domain; (ii) information that is disclosed to me by third parties, provided that such disclosure does not violate any confidentiality obligations or agreements

with the Company; (iii) information the Company allows me to disclose; or (iv) information that a Court or government agency requires to be disclosed, provided that I give the Company advance notice that a Court or agency is requiring disclosure of the information and allow the Company an opportunity to object to such disclosure before I provide the information.

(d) Proprietary Information as Company Property: I acknowledge that all Proprietary Information is the sole and exclusive property of the Company or the third party which shared it in confidence to the Company.

(e) Non-Disclosure: At all times, both during my employment with the Company and after its termination for any reason, I will keep in confidence all Proprietary Information. I will not use or disclose any Proprietary Information without the written consent of the Company, except as may be necessary in the ordinary course of properly performing my duties as an employee of the Company and in accordance with all Company policies and procedures. I agree to maintain the confidentiality of Proprietary Information, and I covenant that I will not erase, destroy, discard, use or disclose such information without the Company's express consent.

(f) Termination Certificate: If I am requested to do so by the Company, I will sign a Termination Certificate in which I confirm that I have complied with the requirements of this Paragraph 3, and that I am aware that certain restrictions set forth in this Agreement continue after termination of my employment. I understand, however, that my rights and obligations under this Agreement will continue even if I do not sign a Termination Certificate.

4. Return of Company Property and Proprietary Information: Upon the termination of my employment for any reason or at any time upon the request of the Company, I will promptly return to the Company: (i) all Company property, including but not limited to all documents, records computers, data, files, keys, card passes and equipment; and (ii) all originals and copies of Proprietary Information, whether electronic or in hard copy.

5. Non-Solicitation/Non-Servicing:

(a) The following definitions apply to this Agreement:

(i) **"Restricted Period"** means the period of my employment with the Company and a period of one (1) year following the later of: (a) the end of my employment with the Company, whether my separation from employment is voluntary or involuntary and regardless of the reason for such separation; or (b) the entry of an injunction enforcing any of the provisions of Paragraphs 5 or 6 of this Agreement in whole or part.

(ii) **"Conflicting Product"** means any product that competes with Insulet Corporation. Should the Company enter into or pursue any business other than insulin delivery systems during my employment, the term "Conflicting Product" shall also include: (a) any medical device or other product that serves the same or similar clinical function as any product the Company begins to develop, manufacture, sell, distribute, market, or license during my employment; and (b) any other product or service that competes with the any product or service the Company begins develop, manufacture, sell, distribute, market, or license during my employment.

(iii) **"My Assigned Territory"** means any geographic areas or set of accounts to which I was assigned during the one (1) year preceding the end of my employment with the Company.

(iv) **"Customer"** includes (a) consumers to whom the company sells its products, either through distributors or directly; and (b) other individuals and entities to whom the Company, either directly or through distributors, markets, promotes or educates about its products. The term Customer includes current customers, prospective customers and past customers who purchased Insulet Corporation's products (either through a distributor or directly) during the one (1) year preceding the end of my employment.

(v) **"Distributor"** means any person or entity that sells, markets, or promotes Insulet Corporation products or services on behalf of the Company. The term Distributor includes current distributors, prospective distributors and past distributors who sold, marketed or promoted Insulet Corporation products or services in the one (1) year preceding the end of my employment.

(vi) I will be deemed to have had **"Responsibility"** for each past, present or prospective Customer or Distributor with whom: (i) I directly had contact regarding Insulet Corporation products or services, whether in person, by phone, in writing or otherwise; or (ii) any individual that I supervised or coordinated who had contact about Insulet Corporation products or services, whether in person, by phone, in writing or otherwise.

(vii) I will be deemed to have learned Proprietary Information about Customer or Distributor if I obtained such Proprietary Information as a result of my association with the Company.

(viii) **"Restricted Activities"** means calling upon, soliciting, diverting, taking away, marketing to, promoting a Conflicting Product to, providing information about a Conflicting Product or related medical condition or treatment to, or doing business with any of the Company's Customers or distributors (i) that are in my Assigned Territory (if applicable), (ii) for whom I had Responsibility or (iii) with respect to whom I learned Proprietary Information. However, the term Restricted Activities does not include calling on or doing business with Customers or Distributors after the end of my employment with the Company with respect to anything that is not a Conflicting Product, so long as I certify in writing to the Company that my communications or business with Customers or Distributors does not involve a Conflicting Product and so long as I do not use or disclose any Proprietary Information.

(b) Non-Solicitation/Non-Hire of Employees: During the Restricted Period, I will not: (i) recruit or otherwise solicit any person who is employed by the Company; (ii) in any manner seek to induce any such person to leave his or her employment with the Company; or (iii) hire any person who is employed by the Company or had been employed during the six (6) months preceding the end of my employment with the Company.

(c) Non-Solicitation of Distributors or Customers/Restrictions on Doing Business with Distributors or Customers: I agree that, during the Restricted Period, I will not engage in or attempt to engage in any Restricted Activities in any capacity, including as an employee, consultant, independent contractor, owner or otherwise. I agree that I will not engage or attempt to engage in any of the Restricted Activities either for my own benefit or for the benefit of another person or entity, nor will I assist any other person or entity in engaging in any of the Restricted Activities.

6. Non-Competition:

(a) The following definitions apply to this Paragraph 6:

(i) **"Conflicting Organization"** means any person or organization that is or plans to become engaged in research, development, production, manufacture, distribution, marketing, promoting or selling of a Conflicting Product.

(ii) **"Restricted Area"** means the geographic area in which the Company, during the period of my employment, promoted, licensed, distributed, sold or otherwise made its products or services available (or made plans to do so), either directly or indirectly. I recognize that, as of the date of this Agreement, Insulet Corporation directly or indirectly distributes its products worldwide, and that the Restricted Area is global. I agree that the Restricted Area is reasonable given the global nature of the Company's business and the business of its competitors.

(b) During the term of my employment with the Company, I will not without the express written consent of the Company, directly or indirectly, engage in, participate in, or assist, as owner, part-owner, partner, director, officer, trustee, employee, agent or consultant, or in any other capacity, any business organization or person whose activities or products are directly or indirectly competitive with activities or products of the Company.

(c) In addition to the restrictions contained elsewhere in this Agreement, I agree that, during the Restricted Period and in the Restricted Area, I will not perform any services for or become associated with a Conflicting Organization in any capacity, including as an employee, consultant, independent contractor, owner or otherwise, either for my own benefit or for the benefit of another person or entity. I further agree that, during the Restricted Period and in the Restricted Area, I will not engage on my own behalf in the research, development, production, manufacture, distribution, marketing, promoting or selling of a Conflicting Product.

(d) Notwithstanding the foregoing, I may become associated with or render services to a Conflicting Organization whose business is diversified and that is, as to that part of its business with which I become associated, not a Conflicting Organization, provided that the Company (prior to my acceptance of any such association) receives separate written assurances satisfactory to the Company from such Conflicting Organization and from me that I will not render services (directly or indirectly) in connection with any Conflicting Product.

7. Remedies for Breach: I agree that my breach of any covenant in this Agreement will cause irreparable damage to the Company and that, in the event of such breach, the Company shall have, in addition to any and all remedies of law, the right to an injunction,

specific performance or other equitable relief to prevent the violation of my obligations hereunder.

8. Prior Obligations: I hereby represent that, except as I have disclosed in writing to the Company, I am not a party to, or bound by the terms of, any agreement with or obligation to any previous employer or other party to refrain from using or disclosing any trade secret or confidential or proprietary information in the course of my employment with the Company. I further represent that my performance of all the terms of this Agreement and as an employee of the Company will not require that I violate (and agree that I will not violate) any agreement or obligation to keep in confidence proprietary information, knowledge or data acquired by me in confidence or in trust prior to or during my employment with the Company, and I will not use or disclose to the Company or induce the Company to use any confidential or proprietary information or material belonging to any previous employer or others. By signing below, I acknowledge that the Company has instructed me not to bring to the Company's premises, install on any Company computer, use, or disclose any confidential or proprietary information belonging to a third party during my employment with the Company.

9. Subsequent Employment: I will disclose the existence of this Agreement and its terms to any future employers or other entities or persons with whom I do business during the one (1) year following the end of my employment with the Company. I hereby grant the Company permission to disclose the existence of this Agreement and its terms to any such individuals or entities.

10. Employment at Will: I acknowledge and agree that this Agreement does not constitute an express or implied employment contract and that my employment with the Company will be on an "at-will" basis. Accordingly, I understand that this Agreement does not create an obligation on the Company or any other person or entity to continue my employment and that either the Company or I may terminate my employment at any time, for any or no reason, with or without notice.

11. Modification and Waiver: No modification of or amendment to this Agreement, nor any waiver of any rights under this Agreement will be effective unless in writing signed by an authorized representative of the party to be charged, which in the case of the Company shall be the President. No delay or omission by the Company in exercising any right under this Agreement will operate as a waiver of that or any other right. A waiver or consent given by the Company on any one occasion is effective only in that instance and will not be construed as a bar to or waiver of any right on any other occasion.

12. Reasonableness/ Severability: I acknowledge that, in light of the scope and nature of the Company's business, my job responsibilities and my access to Proprietary Information and/or Distributors and Customers, the restrictions on my activities set forth in this Agreement are reasonable and necessary for the adequate protection of the Company's legitimate business interests in its Proprietary Information and Customer and Distributor goodwill. I further acknowledge that the limitations in this Agreement do not preclude me from pursuing my livelihood. However, if one or more of the provisions contained in this Agreement shall for any reason be held to be excessively broad as to scope, activity or subject so as to be unenforceable at law, such provision or provisions shall be construed by the appropriate judicial body by modifying, limiting and reducing it or them, so as to be enforceable to the maximum extent compatible with the applicable law as it shall then appear. I hereby agree that each provision herein shall be treated as a separate and independent clause, and the unenforceability of any one clause shall in no way impair the enforceability of any of the other clauses herein.

13. Dispute Resolution/Mediation/Jury Waiver: In the event of a "**Dispute**" as that term is defined in this Paragraph, either of us may request that the other participate in a mediation administered by the American Arbitration Association in accordance with its Employment Dispute Resolution Rules ("AAA EDR Rules"), such mediation to occur in the geographic location where I am employed. The party upon whom such request is made shall either agree or decline to participate in such mediation within ten (10) days of such request. In the event that mediation occurs, the Company shall pay the full administrative cost of the mediation including any filing fees and mediator fees, but excluding attorneys' fees, if any, incurred by me, which shall be solely my responsibility.

If a Dispute covered by this Paragraph is not settled through direct negotiation between us or any mediation, then any litigation commenced by either of us shall be resolved by a Judge alone (regardless of the location of such litigation), and both parties hereby waive and forever renounce the right to a trial before a civil jury.

For purposes of this Paragraph, Dispute shall be deemed to include any disputes relating to: (i) the terms and conditions of my employment; (ii) any claimed breach of the covenants set forth in this Agreement, or (iii) any dispute relating to the separation of my employment, whether voluntary or involuntary. Specifically included are any disputes or claims arising under: (i) any local, state or federal discrimination or civil rights statute, regulation or order (including, without limitation, Title VII of the Civil Rights Act of 1964, the Age Discrimination in Employment Act, the Americans With Disabilities Act, and any amendments to the same); (ii) any local, state or federal employment related statute, regulation or order relating to wages, hours, benefits, or other terms and conditions of employment; (iii) any local, state or federal common law theory; or (iv) any other local, state or federal law or regulation now in existence or that hereafter is enacted (and as amended from time to time) concerning in any way the subject of my employment with the Company or its separation.

14. Applicable Law/ Jurisdiction: This Agreement and any issues regarding its enforceability or validity shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts, without regard to the conflicts of laws principles thereof. In addition, any dispute concerning this Agreement shall be brought either by a court of competent jurisdiction in Massachusetts or, if I am employed by the Company primarily in a state other than Massachusetts, by a court of competent jurisdiction in the state where I am primarily employed. I acknowledge that, because the Company is headquartered in Massachusetts, and I will have regular interaction with Company representatives based in Massachusetts, it is appropriate and reasonable for a dispute concerning this Agreement to be heard by a court of competent jurisdiction within Massachusetts. By signing below, I agree to be subject to the personal jurisdiction of the Massachusetts courts in an county where the Company has operations or facilities.

15. Successors and Assigns: The Company shall have the right to assign this Agreement to its successors and assigns, and all covenants and agreements hereunder shall inure to the benefit of and be enforceable by said successors or assigns. I may be transferred without the necessity that this Agreement be re-signed at the time of such transfer.

16. Survival / Changes in Role or Title: I acknowledge that my covenants in this Agreement are given in exchange for my continuing employment and that my covenants are not tied to my present role, title or responsibilities. Therefore, the covenants in this Agreement

shall survive any change in my role, title, responsibilities, compensation, benefits, or any other term or condition of my employment.

17. Entire Agreement / Invalidity of Entire Agreement: This Agreement sets forth the entire agreement and understanding between the Company and me relating to the subject matter herein and merges all prior discussions between us. It supersedes any and all prior agreements (written or oral) relating to the subject matters covered by the Agreement, including and prior agreements covering (i) protection of the Company's intellectual property, or its confidential and proprietary information or documents, and (ii) any dispute resolution process. However, if this entire Agreement is found to be invalid, for whatever reason, and I previously signed an agreement covering the subject matter herein, I acknowledge that the agreement I previously signed will remain in full force and effect.

I HAVE READ ALL OF THE PROVISIONS OF THIS AGREEMENT AND I UNDERSTAND, AGREE TO, AND INTEND TO BE LEGALLY BOUND BY EACH OF SUCH PROVISIONS, EFFECTIVE AS OF THE DATE FIRST ENTERED ABOVE.

Very truly yours,

Signature: _____
Name:

AGREED TO AND ACCEPTED as of
the date first above written:

Insulet Corporation

By: _____
Name:
Title:

THIS AMENDMENT AND RESTATEMENT AGREEMENT to the MASTER EQUIPMENT AND SERVICES AGREEMENT originally dated August 31, 2016 between Insulet Corporation and ATS Automation Tooling Systems Inc., (the "MESA") is made and entered into as of 31 August 2021 by and between:

1. **Insulet Corporation**, with offices at 100 Nagog Park Acton, MA 01720 ("**Insulet**"); and
2. **ATS Automation Tooling Systems Inc.**, a company registered under the laws of Ontario, Canada with its registered office situated at 730 Fountain St N, Cambridge, ON N3H 4R7, Canada (the "**ATS**").

(the "**Parties**").

WHEREAS:

- a) the Parties have previously entered into and executed the MESA;
- b) the MESA is due to expire on August 31, 2021 (the "**Expiry Date**") but the Parties are continuing their business relationship in accordance with, and are acting as bound by, the terms and conditions of the MESA;
- c) in accordance with b) above, the Parties now wish to reflect the continuing working relationship between the Parties under the MESA by extending the term of the MESA past the Expiry Date, and for this extension to be deemed effective prior to the Expiry Date; and
- d) the Parties therefore now wish to amend the MESA as set out below with effect from August 31, 2021 (the "**Amendment Effective Date**").

NOW, THEREFORE, in consideration of the premises, the mutual covenants contained herein and other valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

1. With effect from the Amendment Effective Date, the first sentence of Clause 2 shall be deleted in its entirety and shall be replaced by the following revised first sentence of Clause 2:

"2. This Agreement shall become effective on the Effective Date and shall terminate August 31, 2022, unless earlier terminated in accordance with the termination provisions below (the "Term")."
 2. Except as provided herein, all other terms, conditions and provisions of the MESA shall remain in full force and effect.
-

3. This agreement may be entered into in the form of two or more counterparts, each executed by one or more of the Parties but will not be effective until all Parties have executed and delivered at least one counterpart. Each counterpart will be an original of this agreement and all the counterparts taken together will constitute one instrument.
4. This agreement shall be governed by and construed in accordance with the laws of the State of New York and the United States, excluding its conflicts of law principles.

IN WITNESS OF WHICH, the Parties have caused this agreement to be executed by their duly authorised corporate officers or representatives as of the date first above written.

Insulet Corporation

By:

Name:

Title:

Date:

ATS Automation Tooling Systems Inc.

By:

Name: Paul Hammer

Title: GM, Cambridge, Life Sciences

Date: September 2, 2021

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 [*]**

**MASTER EQUIPMENT AND SERVICES AGREEMENT
AMENDMENT #2**

THIS AMENDMENT AND RESTATEMENT AGREEMENT #2 to the **MASTER EQUIPMENT AND SERVICES AGREEMENT** originally dated August 31, 2016 between Insulet Corporation and ATS Automation Tooling Systems Inc. as amended by the Amendment and Restatement Agreement dated August 31, 2021, (together, the "**MESA**") is made and entered into as of 31 August 2022 by and between:

1. **Insulet Corporation**, with offices at 100 Nagog Park, Acton, MA 01720 ("**Insulet**"); and
2. **ATS Automation Tooling Systems Inc.**, a company registered under the laws of Ontario, Canada with its registered office situated at 730 Fountain St N, Cambridge, ON N3H 4R7, Canada ("**ATS**").

(the "**Parties**").

WHEREAS:

- a) the Parties have previously entered into and executed the MESA;
- b) the MESA is due to expire on August 31, 2022 (the "**Expiry Date**") but the Parties are continuing their business relationship in accordance with, and are acting as bound by, the terms and conditions of the MESA;
- c) in accordance with b) above, the Parties now wish to reflect the continuing working relationship between the Parties under the MESA by extending the term of the MESA past the Expiry Date, and for this extension to be deemed effective prior to the Expiry Date; and
- d) the Parties therefore now wish to amend the MESA as set out below with effect from August 31, 2022 (the "**Amendment Effective Date**").

NOW, THEREFORE, in consideration of the premises, the mutual covenants contained herein and other valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

1. With effect from the Amendment Effective Date, the first sentence of Clause 2 shall be deleted in its entirety and shall be replaced by the following revised first sentence of Clause 2:

"2. This Agreement shall become effective on the Effective Date and shall terminate August 31, 2024, unless earlier terminated in accordance with the termination provisions below (the "**Term**")."

2. The second paragraph of Clause 6 shall be deleted in its entirety and shall be replaced by the following:

"Unless the parties agree otherwise on a case-by-case basis, Seller shall invoice and customer shall make payment based on the following milestone schedule: [***]"

3. Under Clause 27, the Customer notice address shall be changed to: Insulet Corporation, 100 Nagog Park, Acton, MA 01720, Attention: Legal Department.
4. Section 3 of Schedule 1 shall be deleted in its entirety and replaced by the following:


“Customer’s request for the Additional Documentation must be made directly to the ATS Director of Program Management, Life Sciences Division located in Cambridge, Ontario to which access shall be provided within [***] of request.”
5. Section 1 of Schedule 2 shall be deleted in its entirety and replaced with the following:

“During the warranty period defined in Section 14 of the Agreement, Customer shall exclusively purchase from Seller, and Seller shall supply Spare Parts to Customer, based on a priced Spare Parts list to be agreed upon by the parties at FAT.”
6. A new Section 5 will be added to the end of Schedule 2 as follows:


“5. Customer designed spare parts will be updated in the Virtual Manager using the Changes process set out in Clause 8 of the Agreement.”
7. Except as provided herein, all other terms, conditions and provisions of the MESA shall remain in full force and effect.
8. This agreement may be entered into in the form of two or more counterparts, each executed by one or more of the Parties but will not be effective until all Parties have executed and delivered at least one counterpart. Each counterpart will be an original of this agreement and all the counterparts taken together will constitute one instrument.
9. This agreement shall be governed by and construed in accordance with the laws of the State of New York and the United States, excluding its conflicts of law principles.

IN WITNESS OF WHICH, the Parties have caused this agreement to be executed by their duly authorized corporate officers or representatives as of the date first above written.

Insulet Corporation

By: 
 Name: John Bowden
 Title: VP, Global Manufacturing Engineering
 Date: 1-Sep-2022

ATS Automation Tooling Systems Inc.

By: 
 Name: Paul Hammer
 Title: VP Operations, LS North America
 Date: 23-Aug-2022



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 [***]

MANUFACTURING SERVICES AND LINE RETENTION AGREEMENT

July 29, 2022

Insulet Corporation

100 Nagog Park
Acton, Massachusetts 01720

(herein referred to as “INSULET”)

RE: Manufacturing Services Agreement (“Agreement”).

Dear Customer:

We appreciate very much for your choice of Flex Medical Sales and Marketing, Ltd., (“Flex”) as manufacturing partner of Insulet (“Customer”), in accordance with the terms and conditions of this Agreement.

1. Subject to the terms and conditions of this Agreement, Customer hereby engages Flex to procure components, parts and raw material (collectively “Materials”), and to manufacture, assemble, and test inspect, configure and ship certain products (the “Products”) at prices upon which we have agreed (the “Prices”) pursuant to mutually agreed upon written specifications (collectively, such work, the “Services”). In case of any conflict between the specifications and this Agreement, this Agreement prevail.

2. The Products and Prices are listed on Attachment A and the Prices are based on the terms in this Agreement, including the assumptions set forth in Attachment A. Prices are in U.S. Dollars.

3. Customer shall issue a purchase order(s) (“Order”) for the Product set forth in Attachment “A”. Flex will manufacture the Products ordered by Customer in the Order.

4. All Materials will be provided by Customer under buy/sell model [***] (“Buy/Sell Materials”). Flex may use the Buy/Sell Materials solely for manufacturing of the Products. Upon completion of the Order, Customer shall buy back from Flex all Buy/Sell Materials that have not been used for the manufacturing of the Products and remained at Flex’s holdings, at the purchase price agreed by the parties, ExWorks (Incoterms 2020) Flex facility [***]. Title and risk of loss of the Buy/Sell Materials will transfer from one party to the other upon delivery.

5. Customer shall pay Flex [***] expenses as set forth in Attachment “B” (“NRE Charges”). Preparations for providing Services will not commence until the NRE Order of the Customer is received by Flex and the Customer paid for the ordered NRE Charges. If the actual incurred NRE Charges will exceed through no fault of Flex those agreed to, Flex will provide Customer notification and written verification of such additional expenses [***].

6. Flex warrants that the Products shall have been manufactured in accordance with the applicable Specifications and shall be free from defects in workmanship (“Express Limited Warranty”). Flex makes no warranty with respect to (i) the Materials (except that Flex will pass on to Customer all manufacturers’ Materials warranties to the extent that they are transferable but will not independently warrant any Materials), (ii) the specifications and/or the Product design; (iii) Product that has been abused, damaged, altered or misused or mishandled; (iv) prototypes and pre-production units; or (v) defects resulting from tooling, designs or instructions produced or supplied by Customer. Customer shall be liable for costs or expenses incurred by Flex arising out of or related to the foregoing exclusions. Flex shall perform the following tests on Products before delivery to the Customer:

- a. Pre-lot qualification test, and
- b. Thermal cycling process. ((a) and (b) together shall be defined as “Tests”).

The testing protocol, acceptance criteria and cost of the Tests shall be agreed by the parties in writing.

If a Products fails to meet the Express Limited Warranty and to satisfy the agreed acceptance criteria, then, as Flex's sole obligation, and Customer's sole remedy, Flex shall promptly [***] or [***]. Products that passed the Tests shall be deemed accepted by the Customer and shall be delivered by Flex to the Customer "as is", without any further warranty and any and all claims and damages are excluded except in case of gross negligence or wilful intent. **This warranty is the sole warranty given by Flex and is in lieu of any other warranties, either express, implied, or statutory, including but not limited to warranties of merchantability, noninfringement, compliance with RoHS, WEEE and REACH (and other similar applicable legislation), and fitness for a particular purpose, each of which is specifically disclaimed.**

Customer shall be responsible for handling all complaints and inquiries related to the Products made by users of the Products, and any reporting requirements related thereto.

7. If either party believes that a recall, market withdrawal, safety alert or similar corrective action ("Recall") of the Products may be desirable or required by law, it shall immediately notify the other party in writing. If a Recall is necessary or deemed advisable by Customer, each party shall provide reasonable cooperation to the other in recalling the Product. Customer shall be responsible for all Recalls and other corrective actions associated with Products. Flex will not act to initiate a Recall without the express prior written approval of Customer.

8. This Agreement will expire upon the completion of agreed PO and cannot be terminated by either party before that. Any clause contained herein which would be expected to survive expiration shall survive.

Upon (a) expiration or termination of this Agreement for any reason, (b) cancellation of an Order (including a termination or cancellation resulting from a breach by Flex), (c) a reduction in the Ordered quantity by more than [***], or (d) Customer's failure to accept delivery of a shipment made pursuant to its Order within [***], Customer shall pay Flex (i) [***] for all affected finished Products, (ii) [***] of any work in process at the time the cancellation or termination notice was received; and Customer shall buy back from Flex all Buy/Sell Materials at the Material [***]. In addition, [***]. All amounts payable under this paragraph shall be due within thirty (30) days following the date of an invoice.

9. Customer shall defend, indemnify and hold harmless, Flex from and against all claims, actions, losses, expenses, damages or other liabilities, including reasonable attorneys' fees (collectively, "Damages") incurred by or assessed against Flex, but solely to the extent arising out of third-party claims relating to the Products, except to the extent that Flex indemnifies Customer pursuant to the next paragraph.

10. Flex will promptly defend, indemnify, and hold Customer harmless from and against any Damages which relate to any third party claim that Flex's manufacturing process (except to the extent such process is provided or specified by the Customer, in which case Customer shall indemnify Flex) (i) violates the intellectual property rights of a third party; or (ii) has caused personal injury, property damage, or death.

11. Customer acknowledges that, with the exception of its remedies under the warranty clause or the indemnification clause hereunder, [*] shall be the sole and exclusive remedy of the parties for breach of this Agreement. In addition, in no event shall either party be liable to the other party for**

- (i) [***];
- (ii) [***];
- (iii) [***]; or
- (iv) [***]

arising out of or relating to this Agreement or the sale of Products hereunder, whether such liability is asserted on the basis of contract, tort (including the possibility of negligence or strict liability) or otherwise, even if the party has been warned of the possibility of any such loss or damage, and even if any of the limited remedies provided for herein shall fail of their essential purpose. In addition, in no event shall either party's liability for all claims arising out of or relating to this Agreement exceed at any given time an amount determined as follows: [***].

12. Each party owns all background intellectual property rights to any developments (i) prior to this Agreement or (ii) outside of this Agreement. As concerns any new intellectual property created under this Agreement, Insulet will have title to, ownership of, and all proprietary rights in all intellectual property related to the Product, including any new intellectual property created that relates to the manufacturing process of the Product, to the extent such manufacturing process was developed by Flex based on the written instructions or Specifications of the Customer. Customer shall be responsible for obtaining any necessary license or other rights and for paying any royalties or license fees in connection with any third-party intellectual property rights incorporated into the deliverables.

13. Each party agrees to maintain appropriate insurance to cover such party's respective risks and liabilities under this Agreement with coverage amounts commensurate with such risks and liabilities, taking in account each party's capability for self-insurance.

14. This Agreement and its attachments make up the entire Agreement between the parties and supersede prior discussions, except for any related written Agreements concerning confidentiality. Both parties expressly reject any pre-printed terms and conditions of any Order, acknowledgment or any other form or document of either party and any other terms which alter the terms hereof. The terms hereof may be amended only by a writing executed by authorized representatives of both parties. This Agreement will not be assigned by either party without the other party's prior written consent; provided, however, that Customer understands that Flex will engage related legal entities ("Affiliates") to perform all or part of the services contemplated in this Agreement and that Flex may assign, convey or otherwise transfer its rights and obligations under this Agreement, in whole or in part, to any of its Affiliates or to a third party financial institution for the purpose of receivables financing (e.g., factoring).

15. This Agreement shall be governed by and interpreted in accordance with the laws of the state of California. Any dispute, claim or controversy arising from or related in any way to this Agreement or the interpretation, application, breach, termination or validity thereof, including without limitation any claim of inducement of this Agreement by fraud will be submitted for resolution by binding arbitration in accordance with the Comprehensive Arbitration Rules & Procedures of JAMS. The arbitration will be held in Santa Clara County, California and it shall be conducted in the English language. Judgment on any award in arbitration may be entered in any court of competent jurisdiction. Notwithstanding the above, each party shall have the right to file in the Santa Clara, California state court or the federal courts in and for the Northern District of California an application for temporary or preliminary injunctive relief, writ of attachment, writ of possession, temporary protective order, and/or appointment of a receiver on the grounds that the arbitration award to which the applicant may be entitled may be rendered ineffectual in the absence of such relief. In the event of any dispute between

the parties, the parties hereby knowingly and voluntarily agree that any and all matters shall be decided by a judge or arbitrator without a jury to the fullest extent permissible under applicable law.

We look forward to working with you.

Very truly yours,

Flextronics Medical Sales and Marketing, Ltd.

By _____/s/ [***] _____ Name: [***] Title: [***]

August 4, 2022

ACCEPTED AND AGREED TO:

Insulet Corporation

Name: ___/s/ Peter Griffin _____

Title: VP Global Procurement

Date: August 5, 2022

Attachment A.

Additional Assumptions, Products and Prices

[***]

Attachment B

Capital Expenditure and NRE Requirements

[***]

Attachment C

Line Retention Agreement

[***]

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 [*]**

AMENDMENT NUMBER 15
TO THE SUPPLY AGREEMENT
BY AND BETWEEN AMGEN INC. AND INSULET CORPORATION

This Amendment Number 15 ("Amendment"), entered into effective as of July 12, 2017 ("Amendment 15 Effective Date"), by and between Amgen Inc. ("Amgen") and Insulet Corporation ("Insulet") amends the Agreement (defined below).

RECITALS

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

B. Amgen and Insulet desire, and are willing, to amend the Agreement to [***], all as set forth herein.

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

1. **DEFINITIONS**

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

2. **AMENDMENTS TO THE AGREEMENT**

2.1 Section 2.18.3. The first sentence of Section 2.18.3 of the Agreement is hereby amended by replacing the date "June 20, 2017" with the date "July 18, 2017".

3. **CONCLUSION**

This Amendment may be executed in any number of counterparts, each of which shall be an original and all of which together shall constitute one and the same document, binding on the Parties notwithstanding that each of the Parties may have signed different counterparts. A facsimile transmission or PDF of this Amendment bearing a signature on behalf of a Party shall be legal and binding on such Party. Except as amended and supplemented hereby, all of the terms and conditions of the Agreement shall remain and continue in full force and effect and apply hereto. Except as amended and supplemented hereby, all of the terms and conditions of the Agreement shall remain and continue in full force and effect and apply hereto.

IN WITNESS THEREOF, the authorized representatives of the Parties have executed this Amendment to the Agreement effective as of the Amendment 15 Effective Date.

Insulet Corporation

By: /s/ Eric Benjamin
Date: 12 July 2017
Name: Eric Benjamin
Title: Vice President, Global Procurement
and Supplier Development

Amgen Inc.

By: ***
Date: ***
Name: ***
Title: ***

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 [***]

AMENDMENT NUMBER 17
TO THE SUPPLY AGREEMENT
BY AND BETWEEN AMGEN INC. AND INSULET CORPORATION

This Amendment Number 17 ("Amendment"), entered into effective as of April 1, 2019 ("Amendment 17 Effective Date"), by and between Amgen Inc. ("Amgen") and Insulet Corporation ("Insulet") amends the Agreement (defined below).

RECITALS

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

B. Amgen and Insulet desire, and are willing, to amend the Agreement to modify certain terms related to business continuity and manufacturing resiliency related to the manufacture and supply of the Customized Insulet Device, all as set forth herein.

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

1. DEFINITIONS

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

2. AMENDMENTS TO THE AGREEMENT

2.1 Section 2.1.1(v). Section 2.1.1(v) of the Agreement is hereby amended by replacing the reference to June 17, 2018 with April 30, 2019.

2.2 Section 3.1.2(ii)(a). Section 3.1.2(ii)(a) of the Agreement is hereby amended by deleting it in its entirety and replacing it with the following:

"[***]."

3. CONCLUSION

This Amendment may be executed in any number of counterparts, each of which shall be an original and all of which together shall constitute one and the same document, binding on the Parties notwithstanding that each of the Parties may have signed different counterparts. A facsimile transmission or PDF of this Amendment bearing a signature on behalf of a Party shall be legal and binding on such Party. Except as amended and supplemented hereby, all of the terms and conditions of the Agreement shall remain and continue in full force and effect and apply hereto. Except as amended and supplemented hereby, all of the terms and conditions of the Agreement shall remain and continue in full force and effect and apply hereto.

IN WITNESS THEREOF, the authorized representatives of the Parties have executed this Amendment to the Agreement effective as of the Amendment 17 Effective Date.

INSULET CORPORATION

By: /s/ Charles Alpuche
Date: April 1, 2019
Name: Charles Alpuche
Title: EVP & Chief Operations Officer

AMGEN Inc

By: /s/ [***]
Date: May 2, 2019
Name: [***]
Title: Global Category Senior Manager, Global Strategic Sourcing



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**AMENDMENT NUMBER 18
TO THE SUPPLY AGREEMENT
BY AND BETWEEN AMGEN INC. AND INSULET CORPORATION**

This Amendment Number 18 ("Amendment"), entered into effective as of August 1, 2019 ("Amendment 18 Effective Date"), by and between Amgen Inc. ("Amgen") and Insulet Corporation ("Insulet") amends the Agreement (defined below).

RECITALS

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

B. Amgen and Insulet desire, and are willing, to amend the Agreement to provide for the supply of [***], all as set forth herein.

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

1. DEFINITIONS

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

2. AMENDMENTS TO THE AGREEMENT

2.1 Article 1. Article 1 of the Agreement is hereby amended by adding to it a new Section 1.27 and the new Section 1.27 shall read as follows:

1.27 "[***]."

2.2 Article 2. Article 2 of the Agreement is hereby amended by adding to it a new Section 2.1.A immediately before Section 2.1 and this new Section 2.1.A shall read as follows:

2.1.A Manufacture and Supply of [***]. This Agreement sets forth the terms and conditions pursuant to which Amgen will order and purchase from Insulet and Insulet will manufacture and supply to Amgen [***]. With respect to only [***], for ordering, purchasing, manufacturing, supplying, and other terms and conditions of this Agreement, this Agreement shall be amended as follows:

(a) [***].

(b) Section 1.23 of the Agreement is replaced with the following text:

"Specifications" means the specifications and requirements [***].

(c) Section 2.2 of the Agreement is replaced with the following text:

"Quality Agreement. [***].

(d) Section 2.6 of the Agreement is replaced in its entirety with the following text:

"2.6 Ordering. [***]. [***].

(e) Section 3.1 of the Agreement is replaced with the following text:

"[***] Unit Price. [***]."

(f) Section 8.1(iii) of the Agreement is amended by replacing the words "Commercialization of the System" with "[***]."

(g) The following sections of the Agreement shall not apply


1. Section 1.3 (Commercialization or Commercialize)
2. Section 1.6 (Conforming Lot)
3. [***]
4. Section 1.17(ii)
5. [***]
6. [***]
7. Section 2.3 (Person in Plant)
8. Section 2.4 (Specification and Design Changes)
9. Section 2.5 (Audits)
10. [***]

11. Sections 2.7(b) through 2.7(f), inclusive (Purchase Orders)
12. Section 2.8 (Delivery Date Confirmations, Shipping Schedule)
13. [***]
14. [***]
15. Second paragraph of Section 2.11(b) (Insulet Heald Customized Insulet Devices)
16. Section 2.11(c)(v) (Shipment)
17. Section 2.12 (Lot Release Procedure)
18. Section 2.14 (Performance Qualification Lots)
19. [***]
20. [***]
21. [***]
22. [***]
23. [***]
24. Section 3.3 (Person in Plant Production Run)
25. [***]
26. [***]
27. [***]
28. [***]
29. [***]
30. Section 6.9(b) (Manufacture during Person m Plant Production Run Period)
31. Section 9.3(a) (Termination for Cause)
32. Sections 11.3(b), 11.3(c), 11.3(d) and 11.3(e)(Trademarks)
33. Sections 12.1(a), 12.1(c), 12.1(d), and 12.1(e) (Regulatory Support & Submissions)
34. Section 12.2 (Changes)

3. CONCLUSION

This Amendment may be executed in any number of counterparts, each of which shall be an original and all of which together shall constitute one and the same document, binding on the Parties notwithstanding that each of the Parties may have signed different counterparts. A facsimile transmission or PDF of this Amendment bearing a signature on behalf of a Party shall be legal and binding on such Party. Except as amended and supplemented hereby, all of the terms and conditions of the Agreement shall remain and continue in full force and effect and apply hereto. Except as amended and supplemented hereby, all of the terms and conditions of the Agreement shall remain and continue in full force and effect and apply hereto.

IN WITNESS THEREOF, the authorized representatives of the Parties have executed this Amendment to the Agreement effective as of the Amendment 18 Effective Date.

INSULET CORPORATION		AMGEN Inc	
 By:	/s/ Charles Alpuche	By:	/s/ [***]
Date:	July 29, 2019	Date:	July 30, 2019
Name:	Charles Alpuche	Name:	[***]
Title:	EVP & Chief Operations Officer	Title:	Global Category Senior Manager, Global Strategic Sourcing

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 [*]**

AMENDMENT NUMBER 19
TO THE SUPPLY AGREEMENT
BY AND BETWEEN AMGEN INC. AND INSULET CORPORATION

This Amendment Number 18 (“Amendment”), entered into effective as of July 13, 2020 (“Amendment 19 Effective Date”), by and between Amgen Inc. (“Amgen”) and Insulet Corporation (“Insulet”) amends the Agreement (defined below).

RECITALS

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

B. Amgen and Insulet desire, and are willing, to amend the Agreement to modify certain terms related to [***] related to the manufacture and supply of the Customized Insulet Device, all as set forth herein.

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

1. DEFINITIONS

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

1.2 MFC. [***].

2. AMENDMENTS TO THE AGREEMENT

2.1 Section 2.11(b) of the Agreement is hereby amended by adding a new subsection providing that Insulet will hold quantities of Customized Insulet Devices:

“[***].

Insulet will store and manage such Amgen Request Inventory Hold consistent with, and in compliance with, the terms of this Agreement (including the Quality Agreement). Insulet will bear the risk of loss with respect to the Amgen Requested Inventory Hold prior to receipt of the same by Amgen, and without modifying or limiting the requirements set forth in Section 2.11(c).

If Amgen chooses to make changes to the Amgen Requested Inventory Hold such as variation cut over strategy or major ordering changes, Insulet will be required to present a recovery plan and both companies will work together to create a mutually agreeable plan to manage supply.

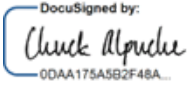
If Insulet fails to meet the Amgen Requested Inventory Hold, then Insulet will put forth a commercially reasonable effort to address the shortage though production volume increases during the next regularly scheduled manufacturing campaign.”

3. CONCLUSION

This Amendment may be executed in any number of counterparts, each of which shall be an original and all of which together shall constitute one and the same document, binding on the Parties notwithstanding that each of the Parties may have signed different counterparts. A facsimile transmission or PDF of this Amendment bearing a signature on behalf of a Party shall be legal and binding on such Party. Except as amended and supplemented hereby, all of the terms and conditions of the Agreement shall remain and continue in full force and effect and apply hereto. Except as amended and supplemented hereby, all of the terms and conditions of the Agreement shall remain and continue in full force and effect and apply hereto.



IN WITNESS THEREOF, the authorized representatives of the Parties have executed this Amendment to the Agreement effective as of the Amendment 19 Effective Date.

Insulet Corporation

By: 
Date: September 15, 2020 | 5:12 PDT
Name: Charles Alpuche
EVP / COO

Amgen Inc.

By: [***]
Date: September 15, 2020 | 5:38 PDT
Name: [***]
Global Sr. Category Manager

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 [***]

**AMENDMENT NUMBER 20
TO THE SUPPLY AGREEMENT
BY AND BETWEEN AMGEN INC. AND INSULET CORPORATION**

This Amendment Number 20 (“Amendment”), entered into effective as of June 25, 2021 (“Amendment 20 Effective Date”), by and between Amgen Inc. (“Amgen”) and Insulet Corporation (“Insulet”) amends the Agreement (defined below).

RECITALS

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

B. Amgen and Insulet desire, and are willing, to amend the Agreement to provide additional terms for, among other thing, [***], all as set forth herein.

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

1. DEFINITIONS

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

2. AMENDMENTS TO THE AGREEMENT

2.1 Agreement Section 3.1. Section 3.1 of the Agreement is hereby amended and replaced in its entirety with the following text:

3.1 Unit Price Amounts.

Customized Insulet Device Unit Price Amounts. [***]

“[***] Unit Price Amounts. [***].”

3.1.1 Intentionally Omitted.

3.1.2 Additional Compensation; Unit Price Adjustments for Customized Insulet Device.

(i) [***].

(ii) On and after December 20, 2016, the Unit Price will change by the amount specified upon the occurrence, if ever, of the following:

(a) [***].

(b) [***].

(c) [***].

(iii) [***].

2.2 Agreement Section 2.1.A(g)8. Section 2.1(A)(g)8 is amended and replaced in its entirety with the following text: “(intentionally omitted)”.

2.3 Agreement Section 2.1.A(g)9. Section 2.1(A)(g)9 is amended and replaced in its entirety with the following text: “(intentionally omitted)”.

3. CONCLUSION

This Amendment may be executed in any number of counterparts, each of which shall be an original and all of which together shall constitute one and the same document, binding on the Parties notwithstanding that each of the Parties may have signed different counterparts. A facsimile transmission or PDF of this Amendment bearing a signature on behalf of a Party shall be legal and binding on such Party. Except as amended and supplemented hereby, all of the terms and conditions of the Agreement shall remain and continue in full force and effect and apply hereto. Except as amended and supplemented hereby, all of the terms and conditions of the Agreement shall remain and continue in full force and effect and apply hereto.

IN WITNESS THEREOF, the authorized representatives of the Parties have executed this Amendment to the Agreement effective as of the Amendment 20 Effective Date.

Insulet Corporation

Amgen Inc.

By: 

By: [***]

Date: June 24, 2021 | 6:15 PDT

Date: June 24, 2021 | 6:43 PDT

Name: Kimberly Ruzek

Name: [***]

Title: VP Quality Systems and Operation

Title: Global Sr. Category Manager

Insulet Corporation, Confidentiality, Non-Solicit, Non-Compete, and IP Assignment Agreement

This Confidentiality, Non-Solicit, Non-Compete, and IP Assignment Agreement (“**Agreement**”) is entered into between the undersigned individual (“**I**”, “**me**”, or “**Employee**”) and Insulet Corporation (collectively, the “**Company**”). I understand the Company is engaged in the business of designing, developing and marketing medical devices and related software (the Company’s “**Business**” or “**Line of Business**”). I understand that the Company seeks to employ me in a position of trust and confidence related to this Line of Business, and I wish to be employed in such a position. In consideration of my employment and the compensation and other benefits received as a consequence thereof, and the other mutual promises and representations of the parties made herein, the parties agree as follows:¹

1. **Position of Trust and Confidence.** In reliance upon the promises made by me in this Agreement, the Company will provide me with access to Confidential Information (including trade secrets) related to my position, and may also provide me with specialized training related to the Company’s Business and/or the opportunity to develop relationships with the Company’s employees, business contacts (customers and others) and agents for the purpose of developing goodwill for the Company. I agree that my receipt of the foregoing would give me an unfair competitive advantage if my activities during employment, and for a reasonable period thereafter, were not restricted as provided for in this Agreement.

2. **Confidential Information and Company Property.** Subject to Paragraph 7, I agree to use the Company’s Confidential Information only in the performance of my duties, to hold such information in confidence and trust, and not to engage in any unauthorized use or disclosure of such information during my employment and for so long thereafter as such information qualifies as Confidential Information. “**Confidential Information**” means an item of information or compilation of information in any form (tangible or intangible) related to the Company’s Business that I acquire or gain access to during my employment that the Company has not authorized public disclosure of, and that is not readily available to the public or persons outside the Company. By way of example and not limitation, Confidential Information is understood to include: lists and records, contact information, private contract terms, business preferences, and historical transaction data regarding existing and prospective customers; non-public records and data regarding the Company’s financial performance; business plans and strategies, forecasts and analyses; internal business methods and systems, know how, and innovations; marketing plans, research and analysis; unpublished pricing information, and variables such as costs, discounting options, and profit margins; business sale and acquisition opportunities identified by the Company and related analysis; records of private dealings with vendors, suppliers, and distributors; and Company trade secrets. I acknowledge that items of Confidential Information are the Company’s valuable assets and have economic value because they are not generally known by the public or others who could use them to their own economic benefit and/or to the competitive disadvantage of the Company. I agree that all records, in any form (such as email, database, correspondence, notes, files, contact lists, drawings, specifications, spreadsheets, manuals, and calendars) that contain Confidential Information or otherwise relate to the Company’s Business, with the exception of wage and benefit related materials provided to me as an employee for my own use as an employee, are the property of the Company (collectively “**Company Records**”). I will follow all Company policies regarding use or storage of Company Records, and return all such records (including all copies) when my employment with the Company ends or sooner if requested.

Confidential Information does not include information lawfully acquired by a non-management employee about wages, hours or other terms and conditions of employment when used for purposes protected by Section 7 of the National Labor Relations Act (NLRA) such as joining or forming a union,

¹ Important state-specific modifications to this Agreement are contained in Appendix A hereto.

engaging in collective bargaining, or engaging in other concerted activity for mutual aid or protection of laborers. For purpose of clarity, it shall still be a violation of this Agreement for a non-management employee to wrongfully compete by sharing Confidential Information with a competitor about other employees' compensation and benefits which was obtained through the course of employment with the Company for purposes of assisting such competitor in soliciting Company employees.

3. **Protective Covenants.** In order to protect the Company's Confidential Information (including trade secrets) and key business relationships, I agree that, during the Restricted Period (as defined below), I will not (directly or through the direction or control of others):

- (a) solicit any Covered Employee (as defined below) to leave the employment of the Company; or
- (b) hire, attempt to hire, or assist in hiring any Covered Employee on behalf of a Competing Business; or,
- (c) solicit, or attempt to solicit a Covered Customer or Key Relationship (as defined below) for the purpose of doing any business that would compete with the Company's Business; or
- (d) knowingly engage in any conduct that is intended to cause, or could reasonably be expected to cause the Covered Customer or Key Relationship to stop or reduce doing business with the Company, or that would involve diverting business opportunities away from the Company; or
- (e) provide services for the benefit of a Competing Business within the Territory (as defined below) that are the same or similar in function or purpose to those I provided to the Company during the Look Back Period (as defined below); or
- (f) take on any other responsibilities for a Competing Business that would involve the probable use or disclosure of Confidential Information or the conversion of Covered Customers or Key Relationships to the benefit of a Competing Business or detriment of the Company.

Nothing herein is intended or to be construed as a prohibition against general advertising such as "help wanted" ads that are not targeted at the Company's employees. This Agreement is not intended to prohibit: (i) employment with a non-competitive independently operated subsidiary, division, or unit of a family of companies that include a Competing Business, so long as the employing independently operated business unit is truly independent and my services to it do not otherwise violate this Agreement; or, (ii) a passive and non-controlling ownership of less than 2% of the stock in a publicly traded company. This provision also does not preclude conduct protected by Section 7 of the NLRA such as joining or forming a union, engaging in collective bargaining, or engaging in other concerted activity for mutual aid and protection.

"**Restricted Period**" means the period while Employee is employed by the Company and for one (1) year after Employee's employment ends, irrespective of which party ends the relationship or why it ends. "**Covered Employee**" means any employee that Employee supervised, worked with, or received Confidential Information about during the Look Back Period. "**Competing Business**" means any person or entity that engages in (or is planning to engage in) a business that competes with a portion of the Company's Business that I had involvement with or access to Confidential Information about during the last two years of my employment (or such shorter period of time as I am employed) (the "**Look Back Period**"). "**Covered Customer**" means a customer or potential customer that I had material business-related contact or dealings with or access to Confidential Information about during the Look Back Period. "**Key Relationship**" refers to a person or entity with an ongoing business relationship with the Company (including vendors, agents, and contractors) that I had material business-related contact or dealings with during the Look Back Period. "**Territory**" means the

geographic territory(ies) assigned to me by the Company during the Look Back Period (by state, county, or other recognized geographic boundary used in the Company's Business); and, if I have no such specifically assigned geographic territory then: (i) those states and counties in which I participated in the Company's Business and/or about which I was provided access to Confidential Information during the Look Back Period; and, (ii) the state and county where I reside and the states and counties contiguous thereto. If I am a Vice President or other executive, then I agree that I will be deemed to have participated in the Company's Business and/or had Confidential Information about the Company's Business throughout the United States (including state and state-equivalents and county and county-equivalents therein). I am responsible for seeking clarification from the Company's Human Resources department if it is unclear to me at any time what the scope of the Territory is. State and county references include equivalents.

4. **Assignment of Intellectual Property.** Employee is expected to use his or her inventive and creative capacities for the benefit of the Company and to contribute, where possible, to the Company's intellectual property in the ordinary course of employment.

(a) **"Inventions"** mean any inventions, discoveries, improvements, designs, processes, machines, products, innovations, business methods or systems, know how, ideas or concepts of commercial value or utility, and related technologies or methodologies, whether or not shown or described in writing or reduced to practice and whether patentable or not. **"Works"** mean original works of authorship, including, but not limited to: literary works (including all written material), mask works, computer programs, formulas, tests, notes, data compilations, databases, artistic and graphic works (including designs, graphs, drawings, blueprints, and other works), recordings, models, photographs, slides, motion pictures, and audio visual works; whether copyrightable or not, and regardless of the form or manner in which documented or recorded. **"Trademarks"** mean any trademarks, trade dress or names, symbols, special wording or devices used to identify a business or its business activities whether subject to trademark protection or not. The foregoing is collectively referred to in this Agreement as **"Intellectual Property."**

(b) Employee assigns to the Company or its nominee Employee's entire right, title and interest in and to all Inventions that are made, conceived, or reduced to practice by Employee, alone or jointly with others, during Employee's employment with the Company (whether during working hours or not) that either (i) relate to the Company's Business, or actual or demonstrably anticipated research or development of the Company, or (ii) involve the use or assistance of any tools, time, material, personnel, information, or facility of the Company, or (iii) result from or relate to any work, services, or duties undertaken by Employee for the Company.

(c) Employee recognizes that all Works and Trademarks conceived, created, or reduced to practice by Employee, alone or jointly with others, during Employee's employment shall to the fullest extent permissible by law be considered the Company's sole and exclusive property and "works made for hire" as defined in the U.S. Copyright Laws for purposes of United States law and the law of any other country adhering to the "works made for hire" or similar notion or doctrine, and will be considered the Company's property from the moment of creation or conception forward for all purposes without the need for any further action or agreement by Employee or the Company. If any such Works, Trademarks or portions thereof shall not be legally qualified as a work made for hire in the United States or elsewhere, or shall subsequently be held to not be a work made for hire or not the exclusive property of the Company, Employee hereby assigns to the Company all of Employee's rights, title and interest, past, present and future, to such Works or Trademarks. Employee will not engage in any unauthorized publication or use of such Company Works or Trademarks, nor will Employee use same to compete with or otherwise cause damage to the business interests of the Company.

(d) It is the purpose and intent of this Agreement to convey to the Company all of the rights (inclusive of moral rights) and interests of every kind, that Employee may hold in Inventions, Works, Trademarks and other intellectual property that are covered by Paragraphs 4(a) – (c) above (“**Company Intellectual Property**”), past, present and future; and, Employee waives any right that Employee may have to assert moral rights or other claims contrary to the foregoing understanding. It is understood that this means that in addition to the original work product (be it invention, plan, idea, know how, concept, development, discovery, process, method, or any other legally recognized item that can be legally owned), the Company exclusively owns all rights in any and all derivative works, copies, improvements, patents, registrations, claims, or other embodiments of ownership or control arising or resulting from an item of assigned Company Intellectual Property everywhere such may arise throughout the world. The decision whether or not to commercialize or market any Company Intellectual Property is within the Company's sole discretion and for the Company's sole benefit and no royalty will be due to Employee as a result of the Company's efforts to commercialize or market any such Invention. In the event that there is any Invention, Work, Trademark, or other form of intellectual property that is incorporated into any product or service of the Company that Employee retains any ownership of or rights in despite the assignments created by this Agreement, then Employee hereby grants to the Company and its assigns a nonexclusive, perpetual, irrevocable, fully paid-up, royalty-free, worldwide license to the use and control of any such item that is so incorporated and any derivatives thereof, including all rights to make, use, sell, reproduce, display, modify, or distribute the item and its derivatives. All assignments of rights provided for in this Agreement are understood to be fully completed and immediately effective and enforceable assignments by Employee of all intellectual property rights in Company Intellectual Property. When requested to do so by the Company, either during or subsequent to employment with the Company, Employee will (i) execute all documents requested by the Company to affirm or effect the vesting in the Company of the entire right, title and interest in and to the Company Intellectual Property at issue, and all patent, trademark, and/or copyright applications filed or issuing on such property; (ii) execute all documents requested by the Company for filing and obtaining of patents, trademarks and/or copyrights; and (iii) provide assistance that the Company reasonably requires to protect its right, title and interest in the Company Intellectual Property, including, but not limited to, providing declarations and testifying in administrative and legal proceedings with regard to Company Intellectual Property. Power of Attorney: Employee hereby irrevocably appoints the Company as its agent and attorney in fact to execute any documents and take any action necessary for applications, registrations, or similar measures needed to secure the issuance of letters patent, copyright or trademark registration, or other legal establishment of the Company's ownership and control rights in Company Intellectual Property in the event that Employee's signature or other action is necessary and cannot be secured due to Employee's physical or mental incapacity or for any other reason.

(e) Employee will make and maintain, and not destroy, notes and other records related to the conception, creation, discovery, and other development of Company Intellectual Property. These records shall be considered the exclusive property of the Company and are covered by Paragraphs 4(b)-(d) above. During employment and for a period of one (1) year thereafter, Employee will promptly disclose to the Company (without revealing the trade secrets of any third party) any Intellectual Property that Employee creates, conceives, or contributes to, alone or with others, that involve, result from, relate to, or may reasonably be anticipated to have some relationship to the Line of Business the Company is engaged in or its actual or demonstrably anticipated research or development activity.

(f) Employee will not claim rights in, or control over, any Invention, Work, or Trademark as something excluded from this Agreement because it was conceived or created prior to being employed by the Company (a “**Prior Work**”) unless such item is identified on Appendix B and signed by Employee as of the date of this Agreement. Employee will not incorporate any such

Prior Work into any work or product of the Company without prior written authorization from the Company to do so; and, if such incorporation does occur, Employee grants the Company and its assigns a nonexclusive, perpetual, irrevocable, fully paid-up, royalty-free, worldwide license to the use and control of any such item that is so incorporated and any derivatives thereof, including all rights to make, use, sell, reproduce, display, modify, or distribute the item and its derivatives.

(g) This Agreement's assignment provisions are limited to only those Inventions that can be lawfully assigned by an employee to an employer. Some examples of state laws limiting the scope of assignable inventions are: Delaware Code, Title 19, Section 805; North Carolina General Statutes, Article 10A, Chapter 66, Commerce and Business, Section 66-57.1; Minnesota Statutes, 13A Section 181.78; Kansas Statutes, Section 44-130; Utah Code, Sections 34-39-1 through 34-39-3, "Employee Inventions Act"; and Washington Revised Code, Title 49 RCW: Labor Regulations Chapter 49.44.140. NOTICE: I acknowledge notice that, to the extent one of the foregoing laws applies, my invention assignment agreement will not apply to an Invention for which no equipment, supplies, facility, or trade secret information of the Company was used and which was developed entirely on my own time, unless: (1) the Invention relates directly to the Line of Business the Company is engaged in or its actual or demonstrably anticipated research or development activity; or (2) the Invention results from any work performed by me for the Company. Similarly, to the extent California Labor Code Section 2870, or Illinois Compiled Statutes, 765 ILCS 1060/1-3, "Employees Patent Act," controls, then the same notice will apply, but without the word "directly" in part (1).

5. **Severability and Special Remedies.** Each of my obligations under this Agreement shall be considered a separate and severable obligation. If a court or arbitrator determines that a restriction in this Agreement cannot be enforced as written due to an overbroad limitation (such as time, geography, or scope of activity), the parties agree that the court or arbitrator shall reform or modify the restrictions or enforce the restrictions to such lesser extent as is allowed by law. If, despite the foregoing, any provision contained in this Agreement is determined to be void or unenforceable, in whole or in part, then the other provisions of this Agreement will remain in full force and effect. The parties agree that the Company will suffer irreparable harm, in addition to any damages that can be quantified, by a breach of this Agreement by me. Accordingly, in the event of such a breach or a threatened breach, the Company will be entitled to all remedies that may be awarded by a court of competent jurisdiction or arbitrator, recovery of its attorneys' fees and expenses (including not only costs of court, but also expert fees, travel expenses, and other expenses incurred), and any other legal or equitable relief allowed by law.

6. **Choice of Law.** The laws of the state in which the Employee last regularly resided and worked shall govern the interpretation, application, and enforcement of this Agreement, without regard to any choice of law rules of that or any other state.

7. **Agreement Limitations.** Nothing in this Agreement prohibits me from reporting an event that I reasonably and in good faith believe is a violation of law to the relevant law-enforcement agency (such as the Securities and Exchange Commission or Department of Labor), requires notice to or approval from the Company before doing so, or prohibits me from cooperating in an investigation conducted by such a government agency. This may include a disclosure of trade secret information provided that it must comply with the restrictions in the Defend Trade Secrets Act of 2016 (DTSA). The DTSA provides that no individual will be held criminally or civilly liable under Federal or State trade secret law for the disclosure of a trade secret that: (i) is made in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney; and made solely for the purpose of reporting or investigating a suspected violation of law; or, (ii) is made in a complaint or other document if such filing is under seal so that it is not made public. Also, an individual who pursues a lawsuit for retaliation by an employer for reporting a suspected violation of the law may disclose the trade secret to the attorney of the individual and use the trade secret information in the court proceeding, if the individual files any document containing the trade secret under seal, and does not disclose the trade secret, except as permitted by court order. To the extent that I am covered by Section 7 of the National Labor Relations Act (NLRA) because I am not in a supervisor or management role, nothing in this Agreement shall be construed to prohibit me from using information I acquire regarding the wages, benefits, or other terms and conditions of employment at the Company for any purpose protected under the NLRA. I understand that under the NLRA, covered employees have a right to self-organization, to form, join, or assist labor organizations, to bargain collectively through representatives of their own choosing, and to engage in other concerted activities for the purpose of collective bargaining or other mutual aid or protection, and to refrain from any or all of such activities.

8. **Survival, All Duties and At-Will Status Preserved.** Nothing in this Agreement limits or reduces any common law or statutory duty I owe to the Company, nor does this Agreement limit or eliminate any remedies available to the Company for a violation of such duties. This Agreement will survive the expiration or termination of Employee's employment with the Company and/or any assignee pursuant to Paragraph 10 and shall, likewise, continue to apply and be valid notwithstanding any change in the Employee's duties, responsibilities, position, or title. Nothing in this Agreement creates a contract for term employment or limits either party's right to end the employment relationship between them.

9. **Tolling.** If Employee fails to comply with a timed restriction in this Agreement, the time period for that will be extended by one day for each day Employee is found to have violated the restriction, up to a maximum of twelve (12) months.

10. **Assignment.** This Agreement, including the restrictions on Employee's activities set forth herein, also apply to any parent, subsidiary, affiliate, successor and assign of the Company to which Employee provides services or about which Employee receives Confidential Information. The Company shall have the right to assign this Agreement at its sole election without the need for further notice to or consent by Employee.

11. **Entire Agreement.** This instrument contains the entire agreement between the Parties with respect to the subject matter hereof. All representations, promises, and prior or contemporaneous understandings are merged into, and expressed in this instrument; however, should Employee be subject to a prior agreement with the Company containing confidentiality, nonsolicitation, noncompetition and/or invention assignment provisions and this Agreement is found to be unenforceable, for any reason, then such prior agreement(s) shall remain in place and survive to afford the Company the greatest protection allowed by law. This Agreement shall not be amended, modified, or supplemented without the written agreement of the Parties at the time of such amendment, modification, or supplement and must be signed by an officer of the Company (unless such

amendment, modification, or supplementation is by order of a court or arbitrator). The headings herein are for convenience only and shall not affect the terms of the Agreement.

AGREED:

INSULET CORPORATION

By:  _____

Its: Chief Human Resource Officer

Employee: _____

(signature) _____

(name printed)

Date: _____

SUBSIDIARIES OF THE REGISTRANT

<u>Name of Entity</u>	<u>State/Country of Organization</u>
Insulet Asia (Singapore) Pte. Ltd.	Singapore
Insulet Austria GmbH	Austria
Insulet Australia Pty Ltd	Australia
Insulet Canada Corporation	Canada
Insulet Consulting (Shenzhen) Co., Ltd.	China
Insulet France SAS	France
Insulet Germany GmbH	Germany
Insulet International Holdings Ltd.	United Kingdom
Insulet International Ltd.	United Kingdom
Insulet MA Securities Corporation	Massachusetts
Insulet Malaysia Sdn. Bhd.	Malaysia
Insulet Mexico Investments LLC	Delaware
Insulet Mexico, S. de R.L. de C.V.	Mexico
Insulet Netherlands B.V.	Netherlands
Insulet Netherlands Holdings B.V.	Netherlands
Insulet Realty Holdings LLC	Delaware
Insulet Singapore Private Limited	Singapore
Insulet Switzerland GmbH	Switzerland
Sub-Q Solutions, Inc.	Delaware

Consent of Independent Registered Public Accounting Firm

We have issued our report dated February 23, 2023, with respect to the consolidated financial statements and internal control over financial reporting included in the Annual Report of Insulet Corporation on Form 10-K for the year ended December 31, 2022. 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 on Forms S-8 (No. 333-231860, 333-144636, 333-153176, 333-183166, 333-202689, 333-208387, 333-218125 and 333-208193).

/s/ GRANT THORNTON LLP

Boston, Massachusetts

February 23, 2023

CERTIFICATION

I, James R. Hollingshead, 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/ James R. Hollingshead

James R. Hollingshead
Chief Executive Officer

Date: February 23, 2023

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, 2023

**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, 2022, 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/ James R. Hollingshead

James R. Hollingshead
Chief Executive Officer

Date: February 23, 2023

/s/ Wayde McMillan

Wayde McMillan
Chief Financial Officer

Date: February 23, 2023