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, 2023		
or		
☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 1	15(d) OF THE SECURITIES	S EXCHANGE ACT OF 1934
For the transition period from to		
C	Commission File Number 00	01-33462
INSU	LET CORPO	RATION
(Exact na	me of Registrant as specifi	ed in its charter)
Delaware		04-3523891
(State or Other Jurisdiction of Incorporation or Organization)		(I.R.S. Employer Identification No.)
100 Nagog Park Acton (Address of Principal Executive Offi	Massachusetts	01720 (Zip Code)
Registrant's tel	ephone number, including are	ea code: (978) 600-7000
Securities	registered pursuant to Section	n 12(b) of the Act:
<u>Title of Each Class</u> Common Stock, \$0.001 Par Value Per Share	Trading Symbol(s) PODD	Name of Each Exchange on Which Registered The NASDAQ Stock Market, LLC
Securities reg	gistered pursuant to Section 1	2(g) of the Act: None
Indicate by check mark if the registrant is a well-known seasoned issuer, a		
Indicate by check mark if the registrant is not required to file reports pursu	•	
Indicate by check mark whether the registrant (1) has filed all reports requ 12 months (or for such shorter period that the Registrant was required to fi		15(d) of the Securities Exchange Act of 1934 during the preceding n subject to such filing requirements for the past 90 days. Yes ☒ No ☐
Indicate by check mark whether the registrant has submitted electronically this chapter) during the preceding 12 months (or for such shorter period the		uired to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of submit and post such files). Yes \boxtimes No \square
Indicate by check mark whether the registrant is a large accelerated filer, a accelerated filer," "accelerated filer," "smaller reporting company," and "e		ule 12b-2 of the Exchange Act.
Large accelerated filer ⊠		Non-accelerated filer □
Accelerated filer □		Smaller reporting company □
Te and the second secon	1 4 . 1 4 4 4	Emerging growth company □
If an emerging growth company, indicate by check mark if the registrant haccounting standards provided pursuant to Section 13(a) of the Exchange A		ca transition period for complying with any new or revised financial
Indicate by check mark whether the registrant has filed a report on and atteunder Section $404(b)$ of the Sarbanes-Oxley Act $(15~U.S.C.~7262(b))$ by the	_	· ·
If securities are registered pursuant to Section 12(b) of the Act, indicate by an error to previously issued financial statements. \Box	check mark whether the finance	ial statements of the registrant included in the filing reflect the correction o
Indicate by check mark whether any of those error corrections are restatem executive officers during the relevant recovery period pursuant to §240.10	nents that required a recovery an D-1(b). □	nalysis of incentive-based compensation received by any of the registrant's
Indicate by check mark whether the Registrant is a shell company (as defin	ned in Rule 12b-2 of the Act).	Yes □ No ⊠
The aggregate market value of the common stock held by non-affiliates of The NASDAQ Global Market on June 30, 2023 was approximately $\$20.1$		rence to the last reported sale price of the Common Stock as reported on
The number of shares of common stock outstanding as of February 15, 202	24 was 69,925,730.	
	MENTS INCORPORATED BY	
The registrant intends to file a proxy statement pursuant to Regulation 14A are incorporated by reference into Part III of this Annual Report on Form 1		the fiscal year ended December 31, 2023. Portions of such proxy statement

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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 continuous insulin delivery systems for people with insulin-dependent diabetes. The Omnipod platform includes: the Omnipod® 5 Automated Insulin Delivery System ("Omnipod 5"), the Omnipod DASH® Insulin Management System ("Omnipod DASH"), the Omnipod Insulin Management System ("Classic Omnipod") and our latest innovation, Omnipod GOTM, which received U.S. Food and Drug Administration ("FDA") clearance in 2023.

We also produce pods for 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 medications, both oral and injectable, including SGLT2 inhibitors and GLP-1 drugs. As their diabetes advances, some individuals progress to multiple drug therapies, which often include insulin therapy. People with type 2 diabetes who take insulin either require intensive insulin therapy (typically multiple injections of insulin per day) or basal insulin (typically a single injection daily or weekly). We estimate that approximately six million people have insulin-intensive type 2 diabetes in the countries we currently serve and another three million people with type 2 diabetes require only long-acting insulin in the United States.

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 our Omnipod platform 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. 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, 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 injection ("MDI") therapy using syringes or insulin pens and pump therapy using insulin pumps.

MDI therapy involves injecting 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 Platform

The Omnipod platform offers continuous insulin delivery that provides all the benefits of insulin pump therapy in a unique way without the need for external tubing required with conventional pumps. The small, lightweight, self-adhesive disposable tubeless Omnipod device ("Pod"), can be worn in multiple locations, including the abdomen, hip, back of upper arm, upper thigh, or lower back, and delivers insulin into the body through a small flexible tube (called a cannula). We refer to this as "Pod therapy." We believe the Omnipod platform'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 5

Omnipod DASH

Omnipod GO

Omnipod 5

Omnipod 5, which builds on our Omnipod DASH platform, described below, was cleared by the 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") and in 2023, we launched Omnipod 5 in the United Kingdom and Germany.

Omnipod 5 includes a proprietary AID algorithm embedded in the Pod. The Pod integrates with a third-party continuous glucose monitor ("CGM") to obtain glucose values through wireless Bluetooth communication. The embedded algorithm utilizes these glucose values to predict glucose levels into the future and automatically adjusts insulin dosing intended to improve time-in-range 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. In addition, in October 2023, we received FDA clearance for our Omnipod 5 App for iPhone, which allows for control using a compatible iOS smartphone. We expect to launch the iOS app in 2024. The Omnipod 5 Controller and the Omnipod 5 Android and iOS apps 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 Dexcom, Inc.'s G6 CGM and we recently launched a limited market release with Dexcom's G7 CGM. Additionally, we plan to launch Omnipod 5 with Abbott Diabetes Care, Inc.'s FreeStyle Libre 2 Plus sensor ("Libre 2 Plus") in certain international markets in 2024.

Omnipod DASH

Omnipod DASH features a secure Bluetooth enabled Pod that is controlled by a smartphone-like Personal Diabetes Manager ("PDM") with a color touch screen user interface. In the U.S., the PDM has Wi-Fi capabilities to enable 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 (with an IP28 rating for up to 25 feet for 60 minutes), there is no need to remove it when showering, swimming, or performing other activities.

Omnipod Classic

Following the launch of Omnipod 5, the vast majority of our customer base is no longer using our Classic Omnipod product. Accordingly, we are phasing-out our Classic Omnipod product in the U.S. and no longer guarantee the availability of its supplies.

Omnipod GO

Omnipod GO is a standalone, wearable, insulin delivery system that provides a fixed rate of continuous rapid-acting insulin for 72 hours. Omnipod GO has been cleared by the FDA for use by people with type 2 diabetes age 18 and older who would typically take daily injections of long-lasting insulin. The newest addition to the Omnipod brand features a tubeless and waterproof Pod (with an IP28 rating for up to 25 feet for 60 minutes) which is offered in seven different preprogrammed daily rates, ranging from 10 to 40 units per day, and operates without the need for a handheld device to control the Pod. Omnipod GO has been cleared for use with the following U-100 insulins: NovoLog®, Fiasp®, Humalog®, Admelog®, and Lyumjev®.

The product was developed to serve people with type 2 diabetes earlier in their treatment journey by starting them on Pod therapy for their insulin delivery, rather than daily injections. As a patient progresses to requiring additional insulin, including basal and bolus, the transition from Omnipod GO to another Omnipod product will be a natural progression.

We developed Omnipod GO with convenience in mind for both the primary care physician and the user, including with respect to prescribing, getting started, training and using the product. We are currently conducting a pilot program for Omnipod GO in the United States.

Data Management

We have partnered with Glooko Inc. ("Glooko") to connect 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.

Security

Paramount to our ability to deliver full compatible smartphone control is our commitment to cybersecurity and information security. With certifications from the Diabetes Technology Society's "Standard for Wireless Diabetes Device Security" cybersecurity and assurance standard and program as well as from the International Organization for Standardization ("IOS"), Insulet is globally recognized for incorporating the highest standards for cybersecurity, information security and safety, including secure data transfer between the Pod and PDM, as well as secure cloud storage. See Item 1C. "Cybersecurity" for additional information.

Third-Party Reimbursement

In the United States, entities to whom our products are sold (including wholesalers, private healthcare organizations, healthcare facilities, mail order pharmacies, independent retailers, and consumers), 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. Our Omnipod platform's unique patented

design allows us to provide Pod therapy at a relatively low or no up-front investment, which reduces the risk to third-party payors in the U.S.

In our international locations we sell either directly to consumers or through a distributor/intermediary. In all countries where we operate either Insulet or our partners establish appropriate reimbursement contracts with healthcare systems in those countries and provinces. Reimbursement structures vary by country and our unique offering allows us to provide Pod therapy in attractive pricing structures that reduce the risk to payors while expanding access.

Markets and Distribution Methods

Omnipod products are currently available in the following 25 countries:

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

We sell Omnipod products directly to consumers, through distribution partners and in the U.S., also through the pharmacy channel. For the year ended December 31, 2023, 90% of Omnipod product sales globally were through intermediaries.

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

		Years Ended December 31,			
	2023	2022	2021		
Distributor A	28%	19%	*		
Distributor B	24%	16%	*		
Distributor C	19%	17%	12%		

^{*} 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 our Omnipod products. We have a comprehensive sales and marketing approach, which communicates the benefits of the Omnipod platform to users, physicians and providers. This includes three areas of focus:

- Building consumer awareness about the features and benefits that Omnipod products provide to simplify diabetes management.
- Strengthening physician support by demonstrating clinical evidence of how Omnipod products improve 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 Omnipod products offer unique value to the people they insure.

Training

We believe that training consumers on how to use Omnipod products is an important factor to promote successful outcomes and customer retention. We have streamlined and standardized our training by developing online resources and increased our field clinician team to directly train new 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 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. Our Omnipod platform competes for consumers in the insulin delivery market. Because most new Omnipod 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.

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 Omnipod 5, including adding features and functionality that will deliver increased economic value and convenience to users. In October 2023, we received FDA clearance for an iOS app that will enable control of Omnipod 5 Pods using an iPhone and plan to launch a limited market release in the U.S. in 2024. Further, we recently launched a limited market release for Omnipod 5 integration with Dexcom's G7 CGM in the United States. We also recently received CE mark approval under the MDR for the added compatibility of Libre 2 Plus with Omnipod 5 for individuals aged two years and older with type 1 diabetes and expect to launch a limited market release of Omnipod 5 with Libre 2 Plus in the U.K. and the Netherlands in 2024.

We also continue to advance work to improve the Omnipod 5 algorithm and develop next-generation automated insulin delivery products. In 2023, we began our EVOLUTION feasibility trial in New Zealand to test potential enhancements to the Omnipod 5 algorithm in order to further drive simplicity of use. We have completed the first round of study, which included testing the system with both type 1 and type 2 users and are in the process of analyzing the data and making modifications for the next round of study.

In December 2023, we completed enrollment in our pivotal trial for Omnipod 5 with the goal of expanding its indication to individuals with type 2 diabetes. We expect to complete the trial and submit our 510(k) application to the FDA by the end of 2024. Further, in April 2023, we received FDA clearance for Omnipod GO, a basal-only Pod for individuals with type 2 diabetes.

Manufacturing and Quality Assurance

In order to manufacture sufficient volumes of our Pods at high quality while still achieving a cost-effective per unit production price, we have designed our Pods to be manufactured through automation. In 2019, we began producing Pods at our highly automated manufacturing facility in Acton, Massachusetts to increase supply redundancy and add 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 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. In December 2023, we completed construction of our new manufacturing plant in Malaysia to support our international expansion strategy and further ensure product supply. We expect to begin production at this facility in 2024.

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

Raw Materials

We use a broad range of raw materials in the assembly and manufacturing of our products. 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 our products, 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 our products. 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 our products. 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 our products. Our Quality Assurance Department also inspects and tests our products 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 our products 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 our products or obtain and use information that we regard as proprietary.

Patents

As of December 31, 2023, we had over 700 patents in the United States and in certain other countries, with expiration dates ranging from 2024 through 2043 and had over 500 patent applications pending. The issued patents and pending patent applications cover, among other things:

- the basic architecture of our Omnipod products, including the pump and the PDM/Controller;
- the Omnipod drive system;
- the Omnipod cannula insertion system;
- software, such as algorithms and apps, for controlling our current and next generation Omnipod products; and
- · various novel aspects of our current and potential future generations of Omnipod products, 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®, SIMPLIFY LIFE®, Omnipod DASH®, Omnipod GOTM, Omnipod DISPLAY®, Omnipod VIEW®, SmartAdjustTM, Pod Pals®, Podder®, and PodderCentral®.

Government Regulation

United States FDA Regulation

Our products are medical devices that are 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. A 510(k) pre-market notification filing must contain information establishing that the device to be sold is substantially equivalent to a device commercially distributed prior to May 28, 1976 or to a device that has been determined by the FDA to be substantially equivalent. 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 Classic Omnipod, Omnipod DASH, Omnipod 5, and Omnipod GO and expect that regulatory clearances or approvals 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.

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;
- the FDA's Quality System Regulation ("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 clearance of the first generation of our Omnipod product, we have been subject to FDA inspections of our facilities on multiple occasions.

Other Regulations

Licensure. 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, 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.

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We are also 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 Omnipod products may be subject to scrutiny under the law. For example, we may provide the initial training to users necessary for appropriate use of our product either through our own diabetes educators ob y 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 i

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

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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. At least 15 states have enacted various privacy laws of general applicability over the past several years. 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 the delete personal information collected, the right to opt-out of the sale of personal information and the right to non-discrimination in terms of price or service when a consumer exercises a privacy right. The California Privacy Rights Act ("CPRA") amends and expands the CCPA with respect to personal data collected beginning in January 2022. CPRA enforcement is scheduled to begin in March of 2024. 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 in Virginia and the Colorado Privacy Act both became effective in 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. 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 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 Classic Omnipod and Omnipod DASH under the MDD. We can continue to sell Classic Omnipod through 2027 under MDD in the European Union and in other countries that recognize the CE Mark and are awaiting certification under MDR for Omnipod DASH. We have obtained the right to affix the CE Mark to Omnipod 5 under MDR, which allows us to distribute it throughout the European Union and in the United Kingdom. In addition to these countries, Omnipod DASH can be marketed in the Gulf Cooperation Council Countries and in Australia. We also 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. In addition, the European Union Whistleblower Directive (effective in late 2023) and other applicable law around the world impose specific requirements on companies regarding speak up policies and non-retaliation policies.

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.

The European Union has laid out a multi-year plan for additional privacy and data regulation, building upon the GDPR, and has begun to execute on that plan. For example, the Cybersecurity Directive and the Artificial Intelligence Act have been finalized and will impose additional obligations on businesses generally, including those in the medical device industry.

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, 2023, we had approximately 3,000 full-time employees, representing an 18% increase over the prior year. Approximately 75% of our employees are located in the United States and the remainder are located in 15 other countries.

To assess employee retention and engagement and identify potential opportunities for improvement, we conduct periodic 'Your Voice' employee pulse surveys and take timely action to address key areas of employee concern. Our executive leadership team also 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 2023, 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 2023, we continued to embed diversity more formally into our talent acquisition process to attract a diverse pool of candidates. In addition, we continue to provide Conscious Inclusion and Inclusive Hiring diversity training to people managers and employees.

Our Employee Resource Groups ("ERGs") serve as a source of inclusion across the following nine categories: African Descent, Asian and Pacific Islander, Hispanic/Latin, LGBTQ+, Sustainability, Veterans and First Responders, Women, Young Professionals, and Jewish Heritage. 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 and in 2023 we launched our 'Ignite Your Leadership' training program to people managers to support the growth and development of our future leaders and build their capabilities. In addition, we launched LinkedIn Learning to all employees globally providing everyone access to virtual and online learning programs on demand to support their career growth and development. We also offer training for new managers, resources for our experienced leaders, 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. 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.

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,

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- · 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, tuition and professional certification course reimbursement, and employee assistance program. In addition, we offer Pod perks, which provides a free Omnipod 5 or Omnipod DASH product, including PDM/Controller and Pods to benefit eligible employees, interns, or dependents. We also offer summer hours and flexible work arrangements, including the opportunity to work remotely, which allows us to access 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 employees' 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 have trained certain employees to use automated external defibrillators, provide first aid, and perform cardiopulmonary resuscitation (CPR). In 2023, we implemented a text emergency system for our employee base located in our Acton headquarters and Acton manufacturing facility, which advises employees on building closures and emergencies with clear instructions. We also 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 our Omnipod product platform to generate nearly all our revenue.

We expect to continue to derive nearly all our revenue from our Omnipod product platform. Accordingly, our ability to continue to generate revenue is highly reliant on our ability to market and sell our Omnipod products and to retain consumers who currently use the product. Our sales of Omnipod products may be negatively impacted by many factors, including:

- development of an effective patch pump by one or more competitors or breakthrough diabetes treatments not requiring the delivery of insulin;
- failure of our Omnipod products 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 Omnipod products by third-party payors;
- claims that any portion of Omnipod products infringes on intellectual property rights of others;
- adverse regulatory or legal actions relating to our Omnipod products;
- 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 Omnipod products;
- competitive pricing; and
- results of clinical studies relating to Omnipod products or our competitors' products.

If any of these events occur, 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 and maintain our relationships with intermediaries, our business, prospects and brand may be materially and adversely affected.

In addition to promoting, marketing, and selling Omnipod products 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. If we are not able to successfully develop our relationships with third-party intermediaries, 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 our 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. 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, competition 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 our products in a timely manner, which could adversely affect 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 create challenges for 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. In addition, 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 recently implemented a new enterprise resource planning system and plan to 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 our Omnipod products and install additional manufacturing lines, including as a part of our newly constructed facility in Malaysia. 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 our Omnipod products 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 our Omnipod products, which, for Omnipod 5, occur only through the pharmacy channel in the U.S. and for Omnipod DASH, primarily through the pharmacy channel, will be limited unless a substantial portion of their sales price 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 Omnipod products 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 Omnipod products 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 Omnipod products. 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 Omnipod products. 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 Omnipod products 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 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 our products 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:

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- 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 our Omnipod products, 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 our Omnipod products obsolete or less desirable.

The diabetes treatment market is subject to rapid technological change and product innovation. Our Omnipod products are 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. In addition, well-capitalized biopharmaceutical companies like Vertex Pharmaceuticals, 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 breakthroughs in diabetes monitoring, treatment or prevention could reduce the potential market for our products or render our products obsolete altogether, which would significantly reduce our sales or cause our sales to grow at a slower rate than we currently expect. In addition, even the perception that new products may be introduced, or that technological or treatment advancements could occur, could cause consumers to delay the purchase of our products or impact our stock price. In 2023, for example, ongoing adoption of the GLP-1 class of drugs in diabetes and news surrounding the expansion of use of GLP-1 drugs in obesity led to speculation regarding the impact on the insulin therapy market. We believe this speculation was the cause of a decline in our stock price in 2023.

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 our Omnipod products and their 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 our Omnipod products, we have sponsored, and expect to continue to sponsor market studies to assess various aspects of the functionality and relative efficacy of our products. The data obtained from the studies may be unfavorable to our products 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 our products. 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 our products or that our products are 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 our products or otherwise announce positions that are unfavorable to our products. 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. To protect our intellectual property, we may need to assert claims of infringement or misappropriation 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 misappropriated, or are invalid, or unenforceable. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially valuable. Additionally, we may provoke third parties to assert claims against us, and we may not be successful defending against these claims. 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.

We have been involved in patent infringement suits in the past and may be again in the future. 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 be alleged to 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 Classic Omnipod is 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 with Omnipod 5. The loss of any of these rights could impair the functionality of our products 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 our products 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 our products 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 and we do not develop or contract for an alternative data management system, our business could be materially adversely impacted.

Risks Related to Economic Conditions and Operating Internationally

The continuing worldwide macroeconomic and geopolitical uncertainty as well as the impact of the COVID-19 or other global pandemics may adversely affect our business and prospects.

Continued concerns about the systemic impact of potential long-term and wide-spread recession and geopolitical issues, including wars and terrorism, have contributed to increased market volatility and diminished expectations for economic growth in the world. Our business and results of operations may be adversely impacted by changes in macroeconomic conditions, including inflation, bank failures, rising interest rates and availability of capital markets. Uncertainty about global economic conditions, particularly in countries with government-sponsored healthcare systems, may also cause decreased demand for our products, consumers may reduce their spending, new orders for our products 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.

Another global pandemic like COVID-19 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.

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.

Another global pandemic or new variants of COVID-19, and the requirements to take action to help limit the spread of illness, could impact our ability to carry out our business as usual. For example, the COVID-19 pandemic diverted healthcare resources away from the conduct of clinical trials and interrupted the operations of the FDA, which delayed product approval timelines, including 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 our products 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 24% of our revenues in 2023 and we expect international sales to contribute significantly to our future growth as we launch Omnipod 5 in our international markets. 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 products are manufactured by a third-party contract manufacturer 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.

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

While we expect to begin production at our newly constructed manufacturing facility in Malaysia in 2024, currently our products are manufactured 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 inventory in the United States is held at a single location in Massachusetts and our inventory in Europe is maintained by a third-party logistics entity primarily at 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 or at all.

The manufacture of our products 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 our products in the United States, a third-party contract manufacturer in China manufactures and supplies a significant portion of our inventory and we expect to begin additional manufacturing in our new facility in Malaysia during 2024. 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 Pod 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 2028. The marketing and sales initiatives driving this product line differ markedly from those on which we rely for our sales of Omnipod products 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 Pod;
- · our achievement of satisfactory development and pricing terms with the pharmaceutical companies that sell such drugs;
- our development of appropriate modifications to our Omnipod technology to address the needs and parameters required for the respective drug-delivery opportunities;
- manufacturing issues relating to the modified Pod;
- long lead-times associated with the development, regulatory approvals, and ramp up applicable to the use of modified Pods for the delivery of such drugs;
- relatively small number of modified Pods needed to address each drug-delivery opportunity;
- uncertainties regarding the market acceptance of such drugs and the modified Pod 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 Pods as the appropriate delivery devices;

- · intense competition in the drug-delivery industry, including from competitors which have substantially greater resources;
- · 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 negatively 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 regulatory clearance, unless an exemption applies. Obtaining such regulatory clearance can be expensive and lengthy. Delays in obtaining or inability to obtain 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 regulatory clearance of new products, new intended uses or modifications to our Omnipod products;
- · rescinding, suspending or withdrawing clearance that has 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) clearance 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. 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.

We also sell our products 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 will pass any future quality system inspection. If our or our contract manufacturers' facilities fails a quality system inspection or otherwise fails to adhere to QSR requirements, this could delay production of our products and lead to business disruption; failure to take adequate and timely corrective action in response to an adverse quality system inspection or QSR violation could result in business disruption; failure to take adequate and timely corrective action in response to an adverse quality system inspection or QSR violation could result in 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 or litigation 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 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. 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 and could take enforcement action against us for failing to report the recalls when they were conducted. In the event of a product malfunction, 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.

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 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. At least fifteen states have adopted new privacy laws in the past few years. In California, the CCPA, which provides certain privacy rights and consumer protection for residents of the state became effective in 2020, and additional regulation under the CPRA, which amends and expands the CCPA, will take effect in 2024. These consumer rights include the right to know what personal information is 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 laws have served as a model for many subsequently adopted laws in other states. In 2023, similar privacy laws became effective in Colorado and Virginia. 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

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 Classic Omnipod was identified. 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 with Omnipod products. 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. 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, 2023, 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 and 383 of the U.S. Internal Revenue Code imposes an annual limit on the amount of net operating loss and tax carryforwards that may be used to reduce taxes payable when a corporation has undergone significant changes in its stock ownership or equity structure. The issuance of common stock in connection with the conversion of our Convertible Senior Notes, or the consummation of other equity transactions could limit our ability to utilize net operating loss and tax credit carryforwards to offset future U.S. federal and state taxes payable.

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 in the wake of the COVID-19 pandemic and related economic uncertainties may adversely impact job performance and employee retention. Additionally, during the second half of 2023 we introduced a new organizational operating model, which initially may be disruptive or confusing to some employees as job and reporting structures evolve, causing dissatisfaction or resulting in departures. 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 Omnipod products 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. 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.

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. Also, in 2023, ongoing adoption of the GLP-1 class of drugs in diabetes and news surrounding the expansion of use of GLP-1 drugs in obesity led to speculation regarding the impact of GLP-1 drugs on the insulin therapy market. We believe this negatively impacted the stock prices of companies in the medical device industry, including ours. 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.

We have identified control deficiencies that have been determined to be a material weakness in our internal control over financial reporting. This issue, if not remediated, could result in material misstatements in our financial statements and cause us to fail to meet our reporting and financial obligations.

As disclosed in Item 9A, "Controls and Procedures," we have reported a material weakness because we did not maintain effective information technology general controls over systems that support our financial reporting outside of North America. The material weakness will not be considered remediated until the enhanced controls operate for a sufficient period of time and management has concluded, through testing, that the related controls are effective. We cannot assure that the measures we take will remediate the material weakness or that additional material weaknesses will not arise in the future. Any failure to remediate the material weakness, or the development of new material weaknesses in our internal control over financial reporting, could result in material misstatements in our financial statements and cause us to fail to meet our reporting and financial obligations, which in turn could have a negative impact on our financial condition, results of operations or cash flows, restrict our ability to access the capital markets, require significant resources to correct the material weaknesses or deficiencies, subject us to fines, penalties or judgments, harm our reputation or otherwise cause a decline in investor confidence and cause a decline in the market price of our stock.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

We manage cyber risk on a daily basis, as we face a multitude of threats ranging from ransomware and phishing attacks, business email compromise, and a wide array of other cyber-criminal tactics aimed at impacting our operations and compromising our sensitive information. Our customers, suppliers, subcontractors and partners face similar cybersecurity threats, and a cybersecurity incident impacting us or any of these entities could materially adversely affect our operations, performance and results of operations. Accordingly, we have invested in resources (people, process, and technology) aimed at identifying, assessing, and responding to cyber threats.

Our Board of Directors ("Board") oversees management's processes for identifying and mitigating risks, including cybersecurity risks, to help align our risk exposure to our strategic objectives. While the Board reviews the Company's cybersecurity program annually, the Nominating, Governance, and Risk Committee of the Board has primary responsibility for cybersecurity as part of its risk oversight mandate. The Nominating, Governance, and Risk Committee is scheduled to have regular updates on cybersecurity matters from our Chief Information Security Officer ("CISO") and members of the CISO's team at least two times per year. The CISO will discuss management's actions to identify and detect threats and review the structure of and enhancements to the Company's defenses as well as management's progress on its cybersecurity strategic roadmap. The Nominating, Governance, and Risk Committee Chair reports back to the full Board after each Committee meeting, including information relating to the cybersecurity discussions.

Our Cybersecurity organization, which includes corporate and product security, is led by our CISO. Our CISO, reporting directly to our Chief Technology Officer ("CTO"), is responsible for developing and implementing our cybersecurity program, including setting the directional security strategy and continuous improvement plans for the overall security program. Our CISO has over a decade of experience as a leader of cyber-security and technology risk management programs in both healthcare and medical device manufacturing organizations. This experience is coupled with obtaining and maintaining multiple industry certifications, including Certified Information Systems Security Professional certifications (CISSP), and Certified Information Security Manager (CISM). The CTO ensures cyber-security measures are prioritized across research and development, software engineering, and our IT functions.

Assessing, identifying and managing cybersecurity-related risks are also integrated into our overall enterprise risk management ("ERM") process. Cybersecurity-related risks are included in the risk universe that the ERM function evaluates to assess top risks to the enterprise on an annual basis. To the extent the ERM process identifies a heightened cybersecurity-related risk, risk owners are assigned to develop risk mitigation plans, which are then tracked to completion. The ERM annual risk assessment is presented to the Board, with additional reporting during the year to the Nominating, Governance and Risk Committee.

We leverage the National Institute of Standards and Technology ("NIST") Cybersecurity Framework to better manage and respond to cybersecurity risks in protecting our infrastructure and sensitive data. We have mapped our people, process, and technology in alignment with the categories defined in the NIST industry standard framework: Identify, Protect, Detect, Respond, and Recover. Additionally, Insulet's information security management system is ISO 27001 and 27701 certified. For the sixth consecutive year, Insulet received re-certification from the ISO, which is the recognized standard for information security management and privacy best practices that adheres to the highest international data security standards.

We regularly assess the threat landscape and take a holistic view of cybersecurity risks, with a layered cybersecurity strategy based on prevention, detection and mitigation. We maintain a cybersecurity risk register, and cybersecurity team leaders hold monthly meetings to discuss and prioritize risks as well as the status of any remediation activity. Key facets of our cybersecurity program include:

- <u>24/7 cyber monitoring.</u> Our security operations center is located in multiple time zones to ensure around-the-clock coverage and timely threat detection and response.
- External Threat Landscape Assessment. Our integrated privacy, legal, and security teams are continuously monitoring for any external threat that may impact our operations. Third-party threat intelligence feeds are leveraged to monitor Insulet's digital footprint and activity that may cause brand damage.
- <u>Insider Risk Detection.</u> We have targeted tools aimed at detecting insider threats and suspicious data movement.
- <u>Cloud and Vulnerability Management.</u> To enhance cloud and data security, we reduce the attack surface by establishing secure defaults, implementing least privilege, and monitoring configurations continuously. As part of vulnerability and overall security posture management, we have a focused crossfunctional team that meets regularly to address issues identified by security scans and security configuration checks to maintain hygiene of Insulet's computing devices.

- <u>Testing and Audits.</u> Regular penetration testing, incident response tabletop testing, and audits are performed by trusted third-party security consultants. These final reports and gap analysis documents are logged into our risk register as appropriate.
- Operating Technology ("OT") Visibility. As a manufacturer of medical devices, OT is a vital component of our business operations. Interconnectedness between OT technology and other business critical IT infrastructure can create a material cyber risk. Insult deploys segmentation and OT-specific monitoring capabilities to mitigate and monitor this risk as our OT environment continues to expand to meet the needs of our business.
- <u>Vendor Management.</u> Vendors and key partners are subject to Insulet's Vendor Risk assessment process and subsequently monitored by our threat intelligence capability, which tracks our key vendors and suppliers.
- Training and Culture. Training, awareness, and incorporating security into Insulet's culture is key to reducing risk around common threats such as phishing. We have an operational information security training program for all employees. In addition to annual trainings, we have frequent "nanolearning" targeted trainings. These quick trainings encourage participation, provide constant reminders to our employees to be vigilant and give them the tools to recognize and protect against cyber threats. We also conduct phishing simulations to test effectiveness of our training program with the aim of reducing the percentage of employees who click on suspicious emails.

We are intensely focused on protecting the security of our products; our guiding principle of "secure by design" underlies all of our product development. We have a cybersecurity team embedded with our research and development group to deliver on this mission as well as a Product Cybersecurity Risk Management Policy which is aligned with FDA guidance. Omnipod DASH was 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. Omnipod 5 incorporates cybersecurity by design principles, which includes secure data transfer between the Pod, Controller, cloud storage, and compatible continuous glucose monitors. Our Secure Software Development Lifecycle enforces application testing and continuous monitoring to identify security risks. Omnipod 5 is certified by ISO 27001 and the U.K. Cyber Essentials. Omnipod 5 incorporates authentication, encryption, and cybersecurity protection to ensure only trusted devices and authorized people can access the system.

Notwithstanding the extensive approach we take to cybersecurity, we may not be successful in preventing or mitigating a cybersecurity incident that could have a material adverse effect on us. Should a cyber incident occur, we have in place the Insulet Cybersecurity Incident Response Procedure ("CIRP"), which is designed to enable us to respond efficiently to any incidents. Pursuant to the CIRP, cybersecurity incidents are reviewed and rated by our CISO and his team. A cybersecurity incident rated at predefined risk levels will be escalated to CTO, the Chief Compliance Officer, and the General Counsel and assessed for materiality and disclosure to the CEO and the Board. Our internal Disclosure Committee would review any planned public disclosures or filings. CIRP provides the organizational and operational structure to respond to incidents that may affect the confidentiality, integrity or availability of our information systems.

We currently do not believe that risks from cybersecurity threats, including as a result of any previous cybersecurity incidents, have materially affected the Company's business strategy, results of operations, or financial condition. While Insulet maintains cybersecurity insurance, the costs related to cybersecurity threats or disruptions may not be fully insured. See Item 1A. "Risk Factors" for a discussion of cybersecurity and other risks which may impact Insulet.

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, 2023, we leased a total of 13 facilities in 7 countries consisting of approximately 282,000 square feet of office, research and development, and warehousing space and other related facilities, primarily in North America, Asia and Europe. In addition, we leased a 344,000 square foot facility in Malaysia under a finance lease arrangement, which houses our new manufacturing facility and office space. Additional information regarding our leases is provided in Note 15 to the consolidated financial statements included in Item 8 of this Form 10-K.

Item 3. Legal Proceedings

The information required by this Item is provided under "Legal Proceedings" in Note 19 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

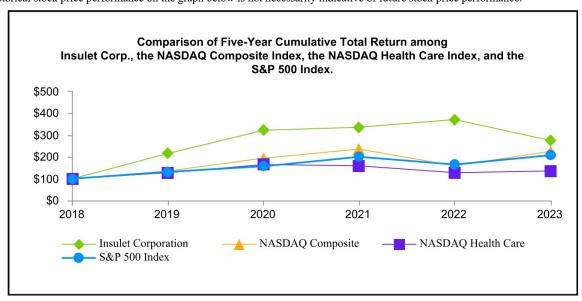
As of February 15, 2024, there were 6 registered holders of record of our common stock.

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, the NASDAQ Health Care Index, and the S&P 500 Index for the five-year period beginning on December 31, 2018, and ending on December 31, 2023, assuming reinvestment of all dividends. The historical stock price performance on the graph below is not necessarily indicative of future stock price performance.



	2	018	2019	2020	2021	2022	2023
Insulet Corporation	\$	100 \$	216 \$	322 \$	335 \$	371 \$	274
NASDAQ Composite	\$	100 \$	135 5	194 \$	236 \$	158 \$	226
NASDAQ Health Care	\$	100 \$	126 \$	164 \$	158 \$	126 \$	134
S&P 500 ⁽¹⁾	\$	100 \$	131 5	156 \$	200 \$	164 \$	207

⁽¹⁾ Our common stock was added to S&P 500 Index in March 2023.

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 continuous insulin delivery system for people with insulin-dependent diabetes. The Omnipod platform, includes: Classic Omnipod, its next generation Omnipod DASH, the most recent generation Omnipod 5, and our latest innovation, Omnipod GO, which received U.S. Food and Drug Administration ("FDA") clearance in 2023, 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 that is controlled by a smartphone-like PDM with a color touch screen user interface. 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. Omnipod GO, for which we are currently conducting a pilot program in the United States, is our basal-only Pod for individuals with type 2 diabetes age 18 and older who require insulin.

Our long-term financial objective is to sustain profitable growth. To achieve this goal, we launched Omnipod 5 in the United States in August 2022 and in the United Kingdom and Germany in June and August 2023, respectively. Subsequent to the launch of Omnipod 5, we began to phase-out our Classic Omnipod in the U.S. in 2023, since the vast majority of our U.S. customer base is no longer using this product.

We are working on further building our international teams and advancing our regulatory, reimbursement, and market development efforts so we can bring Omnipod 5 to additional international markets. We plan to launch Omnipod 5 in more European markets in 2024 starting with the Netherlands. Additionally, in December 2023, we completed enrollment for our pivotal trial for Omnipod 5 with the goal of expanding Omnipod 5's indication to type 2 users. We expect to complete the trial and submit to the FDA for an expanded indication by the end of 2024.

We have completed a randomized control trial in the U.S. and France for Omnipod 5 with DexCom's G6 continuous glucose monitor ("CGM") to support our pricing and market access initiatives. We also continue to expand market access and awareness of Omnipod products 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 upfront investment is required.

We also continue to take steps to strengthen our global manufacturing capabilities. We recently completed construction of 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 smartphone integration and CGM, and enhancing the customer experience through digital product and data capabilities. In February 2024, we began our limited market release of Omnipod 5 with Dexcom's G7 CGM in the United States and received CE mark approval for the added compatibility of Libre 2 Plus with Omnipod 5 for individuals aged two years and older with type 1 diabetes. We expect to launch a limited market release of Omnipod 5 with Libre 2 Plus in the U.K. and the Netherlands in 2024. Additionally, we received FDA clearance for the Omnipod 5 App for iPhone in the fourth quarter of 2023 and plan to launch a limited market release in the U.S. in 2024.

Results of Operations

The discussion of our results of operations for 2021 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, 2022 filed with the Securities and Exchange Commission on February 24, 2023.

Factors Affecting Operating Results

Our Pod is intended to be used continuously for up to three days, after which it is replaced with a new disposable Pod. We recently achieved a milestone of approximately 425,000 estimated active global customers using Omnipod products, including approximately 250,000 global customers using Omnipod 5. Our product's unique patented design allows us to provide Pod therapy at a relatively low or no up-front investment in regions where reimbursement allows for it and our pay-as-you-go

pricing model reduces the risk to third-party payors. As we grow our customer base, we expect to generate an increasing portion of our revenues through recurring sales of our disposable Pods, which provide recurring revenue.

In 2022, we issued two voluntary Medical Device Corrections ("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 its charging port and cable. During 2022, we initially recorded a net charge of \$57.9 million related to these MDCs. During the year ended December 31, 2023, we recorded \$11.5 million of income associated with a change in our estimated liability for the MDCs, primarily due to lower distribution costs.

We continue to experience challenges stemming from the global supply chain disruption; however, while there is no guarantee of future performance, 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 2024, we intend to continue to work to improve productivity to help offset these costs.

Comparison of the Years Ended December 31, 2023 and December 31, 2022

Revenue

	Years Ended	Decemb	er 31,			
(in millions)	 2023		2022	% Change	Currency Impact	Constant Currency(1)
U.S.	\$ 1,251.0	\$	884.8	41.4 %	<u> </u>	41.4 %
International	 410.1		363.0	13.0 %	1.6 %	11.4 %
Total Omnipod Products	1,661.1		1,247.8	33.1 %	0.4 %	32.7 %
Drug Delivery	 36.0		57.5	(37.4)%	— %	(37.4)%
Total	\$ 1,697.1	\$	1,305.3	30.0 %	0.4 %	29.6 %

⁽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 2023 increased \$391.8 million, or 30.0%, to \$1,697.1 million, compared with \$1,305.3 million in 2022. Constant currency revenue growth of 29.6% was primarily driven by higher volume and, to a lesser extent, favorable sales channel mix, partially offset by decreased drug delivery revenue.

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Revenue from the sale of Omnipod products in the U.S. increased \$366.2 million, or 41.4%, in 2023 to \$1,251.0 million, compared with \$884.8 million in 2022. This increase primarily resulted from higher 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, and an increase in estimated inventory days-on-hand at distributors.

Revenue from the sale of Omnipod products in the U.S. includes \$473.7 million of related party revenue in 2023, compared with \$249.9 million in 2022. The \$223.8 million increase primarily resulted from growth through the pharmacy channel. Additional information regarding our related party transactions is provided in Note 5 to our consolidated financial statements.

In 2024, we expect strong U.S. revenue growth driven by continued volume growth of Omnipod 5, continued sales of Omnipod DASH, and the benefits of our recurring revenue model and pharmacy channel access. We expect these increases to be partially offset by lower conversions from Classic Omnipod and Omnipod DASH to Omnipod 5 in the first half of the year compared to 2023 since the vast majority of conversions to Omnipod 5 occurred in 2023.

International

Revenue from the sale of Omnipod products in our international markets increased \$47.1 million, or 13.0%, in 2023 to \$410.1 million, compared with \$363.0 million in 2022. Excluding the 1.6% favorable impact of currency exchange, the remaining 11.4% increase in revenue was primarily due to higher volumes as we continue to expand awareness and access to Omnipod DASH and, to a lesser extent, the timing of revenue recognition related to deferrals associated with our Omnipod DASH MDC and a technology upgrade program, and product mix from the launch of Omnipod 5 in the United Kingdom. These increases were partially offset by a decrease in estimated days-on-hand at distributors and higher attrition in the countries where we have not yet launched Omnipod 5 as we continue to be impacted by competition from AID systems.

In 2024, we expect higher International revenue due to continued volume growth driven by new customers and conversions to Omnipod 5 in the U.K. and Germany and to a lesser extent, the ongoing adoption of Omnipod DASH. We expect these increases to be partially offset by competition from AID systems.

Drug Delivery

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. Drug Delivery revenue for 2023 decreased \$21.5 million, or 37.4%, to \$36.0 million, compared with \$57.5 million in 2022. This decrease primarily resulted from a lower forecast from our partner, partially offset by a higher selling price. In 2024, we expect Drug Delivery revenue to decline \$18 million to \$22 million due to a lower forecast from our partner.

Operating Expenses

	Years Ended December 31,							
	 202	23		2022				
(in millions)	 Amount	Percent of Revenue	Amoun	t	Percent of Revenue			
Cost of revenue	\$ 537.2	31.7 %	\$	499.7	38.3 %			
Research and development expenses	\$ 205.0	12.1 %	\$	180.2	13.8 %			
Selling, general and administrative expenses	\$ 734.9	43.3 %	\$	587.8	45.0 %			

Cost of Revenue

Cost of revenue for 2023 increased \$37.5 million, or 7.5%, to \$537.2 million, compared with \$499.7 million in 2022. Gross margin was 68.3% in 2023, compared with 61.7% in 2022. The 6.6 point increase in gross margin was primarily driven by the \$57.9 million net charge associated with the voluntary MDC notices issued in 2022, which did not repeat in the current period, and an \$11.5 million revision to the voluntary MDC liability in 2023, due to lower than expected distribution costs. The increase was also driven by higher average selling prices primarily due to growth in the pharmacy channel and improved manufacturing efficiencies. These increases were partially offset by higher production costs associated with Omnipod 5 and U.S. manufacturing as it continues to become a larger portion of total production, and to a lesser extent, continued inflation.

We expect gross margin for 2024 to be in the range of 68% to 69%. We anticipate gross margin to be relatively level due to higher average selling prices primarily due to growth in the pharmacy channel and improved manufacturing efficiencies, partially offset by \$11.5 million of income associated with a reduction to our MDC liability in 2023, which will not recur, and higher costs associated with our new product launches.

Research and Development

Research and development expenses for 2023 increased \$24.8 million, or 13.8%, to \$205.0 million, compared with \$180.2 million in 2022. This increase was primarily due to year-over-year headcount additions to support our continued investment in the development of Omnipod products and third-party costs to support clinical trials. Research and development expenses as a percent of revenue declined to 12.1% in 2023, compared with 13.8% in 2022 primarily due to an increase in sustaining costs following the launch of Omnipod 5 in the United States, which are included in selling, general and administrative expenses. We expect research and development spending in 2024 to increase compared with 2023 as we continue to invest in advancing our innovation and clinical pipeline.

Selling, General and Administrative

Selling, general and administrative expenses for 2023 increased \$147.1 million, or 25.0%, to \$734.9 million, compared with \$587.8 million in 2022. This increase was primarily attributable to year-over-year headcount additions, mainly to support international growth and costs associated with our new leadership structure that is designed to accelerate innovation and commercialization. In addition, we had higher direct-to-consumer advertising spend and third-party customer service costs to support Omnipod 5 adoption, and an increase in software license fees driven by investments in new systems due to our growing business and increased headcount. To a lesser extent, the increase was due to higher amortization of cloud computing implementation costs and higher third-party training costs. These increases were partially offset by \$27.3 million of legal costs incurred in the prior year related to the settlement of a patent infringement lawsuit, associated legal fees, and an estimated liability to settle a contract dispute.

We expect selling, general and administrative expenses to increase in 2024 compared with 2023 due to investments in our operating structure, primarily headcount additions, to facilitate continued growth, including customer support. Additionally, we plan to make additional investments to support our Omnipod platform, including market acceptance and access, and the phased launch of Omnipod 5 in our international markets.

Non-Operating Items

Interest Expense and Income

Interest expense of \$36.2 million in 2023 was level with interest expense of \$36.0 million in 2022. Interest income for 2023 increased \$19.3 million to \$28.6 million, compared with \$9.3 million in 2022. This increase was primarily driven by higher interest rates.

Other Income (Expense), Net

Other income of \$2.2 million for 2023 consists primarily of \$2.6 million of gains related to fair value adjustments associated with our strategic debt and equity investments. Other expense of \$1.1 million for 2022 consists primarily of net unrealized and realized foreign currency losses.

Income Tax Expense

Income tax expense was \$8.3 million on pre-tax income of \$214.6 million for 2023 and \$5.2 million on pre-tax income of \$9.8 million for 2022. Our effective tax rate was 3.9% and 53.4% for 2023 and 2022, respectively. The decrease in our effective tax rate was primarily driven by an increase 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. Accordingly, we have not reported any tax benefit relating to the remaining net operating loss carryforwards and income tax credit carryforwards that are available for utilization in future periods.

We maintain a \$202.9 million valuation allowance on net deferred tax assets at December 31, 2023. Given our current earnings and anticipated future earnings, we believe that there is a reasonable possibility that within the next 12 months, sufficient positive evidence may become available to allow us to reach a conclusion that a significant portion of our valuation allowance will no longer be needed. A release of the valuation allowance would result in the recognition of certain deferred tax assets and a decrease to income tax expense in the period the release is recorded. However, the timing and amount of the valuation allowance release, if any, are unknown as this is subject to change on the basis of the level of profitability that we are able to actually achieve in future periods and other evidence that will be considered at the time of the assessment. Refer to Note 23 to our consolidated financial statements for additional information on our income tax expense.

In 2021, the Organization for Economic Co-operation and Development ("OECD") and G20 international forum released the Model Global Anti-Base Erosion (GloBE) rules ("Model Rules") under Pillar Two. These Model Rules set forth the common approach for a Global Minimum Tax at 15% for multinational enterprises with revenue greater than €750 million and is expected to be applicable to Insulet. In December 2022, Pillar Two was adopted by the Council of the European Union for implementation by European Union member states by December 31, 2023, with effect for tax years beginning in calendar year 2024. Similar directives under Pillar Two are already adopted or expected to be adopted by taxing authorities in other countries where Insulet has business operations, with widespread implementation of the Global Minimum Tax in calendar years 2024 and 2025. We are continuing to evaluate the Model Rules for Pillar Two and related legislation, and their potential impact on future periods.

Adjusted EBITDA

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

	Years Ended December 31,				
(in millions)		2023		2022	
Net income	\$	206.3	\$	4.6	
Interest expense, net		7.6		26.7	
Income tax expense		8.3		5.2	
Depreciation and amortization		72.8		63.2	
Stock-based compensation expense		48.3		38.6	
Voluntary medical device corrections ⁽¹⁾		(11.5)		57.9	
Unrealized gains on investments ⁽²⁾		(2.6)		_	
Legal costs ⁽³⁾		_		25.2	
CEO transition costs ⁽⁴⁾		_		3.4	
Adjusted EBITDA	\$	329.2	\$	224.8	

⁽¹⁾ Represents net (income) expense resulting from estimated costs associated with the voluntary MDC notices issued in the fourth quarter of 2022 and adjustments to those costs, which is included in cost of revenue. Refer to Note 14 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 plus net interest expense, income tax expense, depreciation and amortization, stock-based compensation expense and other significant transactions or events, such as legal settlements, medical device corrections, gains (losses) on investments, and loss on extinguishment of debt, which 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.

⁽²⁾ Represents non-operating gains related to fair value adjustments of strategic debt and equity investments.

⁽³⁾ 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 19 to our consolidated financial statements for additional information.

⁽⁴⁾ 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.

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:

		AS OI DO	ecember 3	91,
(in millions)		2023		2022
Cash and cash equivalents	\$	704.2	\$	674.7
Current portion of long-term debt	\$	49.4	\$	27.5
Long-term debt, net	\$	1,366.4	\$	1,374.3
Total debt, net	\$	1,415.8	\$	1,401.8
Total stockholders' equity	\$	732.7	\$	476.4
Debt-to-total capital ratio		66 %	,)	75 %
Net debt-to-total capital ratio		33 %)	39 %

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, 2023, the following notes were outstanding:

		Princ	ipal Outstanding		40	Conversion Price
Issuance Date			Due Date	Conversion Rate ⁽¹⁾	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 \$300 million senior secured revolving credit facility (the "Revolving Credit Facility"), which expires in 2028. At December 31, 2023, 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 Notes 16 and 26 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

	Years Ended December 31,						
(in millions)		2023					
Cash provided by (used in):							
Operating activities	\$	145.7	\$	119.0			
Investing activities		(119.4)		(191.1)			
Financing activities		(13.6)		(40.3)			
Effect of exchange rate changes on cash		1.8		(4.3)			
Net increase (decrease) in cash, cash equivalents, and restricted cash	\$	14.5	\$	(116.7)			

Operating Activities

Net cash provided by operating activities of \$145.7 million in 2023 was primarily attributable to net income, as adjusted for depreciation and amortization and stock-based compensation expense, which was more than offset by a \$190.6 million working capital cash outflow. The working capital outflow was driven by a \$154.2 million increase in accounts receivable, a \$53.6 million increase in inventories and a \$42.1 million increase in prepaid expenses and other assets, partially offset by a \$70.3 million increase in accrued expenses and other liabilities. 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 inventories was primarily driven by a planned inventory build to mitigate supply chain risk and satisfy demand. The increase in prepaid expenses and other assets was driven by an increase in prepaid cloud computing implementation and upgrade costs, subscription renewal costs, and other receivables. Finally, the increase in accrued expenses and other liabilities was primarily driven by an increase in accrued rebates mainly due to revenue growth in the pharmacy channel and an increase in compensation costs due to higher incentive compensation achievement and headcount additions, partially offset by warranty fulfillment associated with the voluntary MDCs issued in 2022.

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.

Investing Activities

We had \$119.4 million of net cash used in investing activities in 2023, compared with \$191.1 million in 2022.

Capital Spending—Capital expenditures were \$75.6 million and \$122.9 million in 2023 and 2022, respectively, and primarily related to the purchase of equipment to increase our manufacturing capacity. We expect capital expenditures for 2024 to increase compared with 2023 given the timing of spending on machinery, equipment and tooling for our new Malaysia manufacturing facility and to support continuous improvement efforts in our other manufacturing locations. To a lesser extent, we expect capital expenditures to increase due to investments in our information technology infrastructure. We expect to fund our capital expenditures using existing cash.

Investments in Developed Software—Investments in developed software were \$8.5 million and \$12.9 million in 2023 and 2022, respectively, and primarily related to investments in projects to support our cloud-based capabilities.

Acquisitions—In 2023, we paid Bigfoot Biomedical, Inc. \$25.1 million, including transaction costs, to acquire patent assets related to pump-based AID technologies. 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 Pods from Dynalloy, Inc. and \$21.5 million to acquire developed technology and patents from Automated Glucose Control LLC. The remaining \$3.0 million purchase price for the Dynalloy acquisition was paid during 2023.

Investments—In 2023 and 2022, we made strategic investments in private companies in the amount of \$7.2 million and \$7.8 million, respectively.

Financing Activities

We had \$13.6 million of net cash used in financing activities in 2023, compared with \$40.3 million in 2022.

Debt Repayments—During 2023, we made principal payments totaling \$27.0 million on our equipment financings, term loan, and mortgage, compared with \$24.5 million of aggregate payments in 2022.

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 15 to the consolidated financial statements for additional information regarding this lease.

Proceeds from Option Exercises and Shares Issued Under Employee Stock Purchase Plan ("ESPP")—Total proceeds from option exercises and issuance of shares under the ESPP were \$26.9 million and \$16.3 million in 2023 and 2022, respectively. The \$10.6 million increase was primarily driven by option exercises by former executives.

Payment of Taxes for Restricted Stock Net Settlements—Payments for taxes related to net restricted and performance stock unit settlements were \$13.2 million and \$16.8 million in 2023 and 2022, respectively. The \$3.6 million decrease was primarily driven by lower achievement of the performance stock units that vested during 2023 (84% achievement in 2023 compared with 101% achievement in 2022).

Commitments and Contingencies

Contractual Obligations—A summary of our contractual obligations and commitments for debt, operating lease obligations and other obligations at December 31, 2023 is presented in the following table:

(in millions)	Short Term	Long Term	Total
Debt obligations	\$ 48.8	\$ 1,395.0	\$ 1,443.8
Interest payments ⁽¹⁾⁽²⁾	58.7	152.7	211.4
Purchase obligations ⁽³⁾	259.3	58.5	317.8
Lease obligations ⁽¹⁾	28.9	47.1	76.0
Total contractual obligations	\$ 395.7	\$ 1,653.3	\$ 2,049.0

⁽¹⁾ Interest on debt and lease obligations are projected for future periods using the interest rates in effect as of December 31, 2023. 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 15 to the consolidated financial statements.

Off-Balance Sheet Arrangements

In 2022, the Company entered into a \$20 million uncommitted letter of credit facility, and concurrently with the execution of an agreement to acquire real estate in Malaysia, a letter of credit of \$16.5 million was issued under the facility to backstop a bank guarantee for the same amount. The bank guarantee serves as security for the building until the Company purchases the property. In 2023, additional letters of credit totaling \$3.5 million were issued under this facility. In aggregate, we had letters of credit totaling \$20.9 million and \$18.6 million as of December 31, 2023 and 2022, respectively. Additional information regarding our letters of credit is provided in Note 19 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 \$465.5 million, \$247.1 million and \$143.3 million in 2023, 2022 and 2021, 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.

⁽²⁾ Excludes the impact of the interest rate swaps discussed in Note 18 to our consolidated financial statements.

⁽³⁾ Purchase obligations include commitments for the purchase of components for our products, 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.

Our Drug Delivery product line includes sales of a modified version of the Pod to pharmaceutical and biotechnology companies who use our technology as a delivery method for their drugs. Revenue from the Drug Delivery product was \$36.0 million for 2023. 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.

Income Taxes

We use the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial statement carrying amount and tax bases of assets and liabilities and are measured using enacted tax rates and laws that will be in effect when the differences are expected to reverse. Deferred tax assets are recognized for deductible temporary differences, and operating loss and tax credit carryforwards. Deferred tax liabilities are recognized for taxable temporary differences. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

Significant judgement is required in determining whether it is probable that sufficient future taxable income will be available against which a deferred tax asset can be utilized. In evaluating our ability to recover our deferred tax assets, we consider all available positive and negative evidence, including cumulative income in recent fiscal years, our forecast of future taxable income exclusive of certain reversing temporary differences and significant risks and uncertainties related to our business. In determining future taxable income, we are responsible for assumptions utilized including the amount of state, federal and international pre-tax operating income, the reversal of certain temporary differences and the implementation of feasible and prudent tax planning strategies. These assumptions require significant judgment about the forecasts of future taxable income in applicable tax jurisdictions, which are based on our commercial experience to date and are consistent with the plans and estimates that we are using to manage our underlying business.

As of December 31, 2023, we recorded a full valuation allowance of \$202.9 million on our net deferred tax assets because realizability is not more likely than not. If we determine that the deferred tax assets are realizable in a future period, it would result in material changes to income tax expense in that period.

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.

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 2023, we charged \$3.7 million to the consolidated statement of operations for excess and obsolete inventory. 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.

Accounting Standards Issued and Not Yet Adopted as of December 31, 2023

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures. ASU 2023-07 requires disclosure of incremental segment information on an annual and interim basis, including enhanced disclosures about significant segment expenses. We are required to comply with these new disclosure requirements beginning with our annual filing for 2024. The guidance is applied retrospectively. We do not plan to early adopt ASU 2023-07.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures.* ASU 2023-09 includes improvements to income tax disclosures primarily related to information about rate reconciliation and income taxes paid. The new guidance requires disclosure of specific categories and greater disaggregation of information in the rate reconciliation and adds a requirement to disaggregate income taxes paid by jurisdiction. The new guidance also requires disclosure of pretax income disaggregated between domestic and foreign, income tax expense (or benefit) disaggregated by federal, state, and foreign, and removes certain existing disclosure requirements. We are required to comply with these new disclosure requirements beginning with our annual filing for 2025. The guidance may be applied on a prospective basis or retrospective basis. We do not plan to early adopt the requirements of ASU 2023-09.

Forward-Looking Statements

This Form 10-K contains forward-looking statements relating to future events or future financial performance that are based on management's current expectations, estimates, and projections. Words 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 or expressions are intended to identify these forward-looking statements. Forward-looking statements are only predictions and involve risks, uncertainties, and assumptions. Certain factors, including but not limited to those identified under "Item 1A. Risk Factors" of this Form 10-K, may cause actual results to differ materially from current expectations, estimates, projections, and forecasts, and from past results. You should not place undue reliance on any forward-looking statements. 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, 2023, 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, 2023 would decrease or increase our annual earnings, respectively, by approximately \$0.1 million.

Market Price Sensitive Instruments

As of December 31, 2023, we had outstanding debt related to our convertible senior notes recorded on our consolidated balance sheet of \$791.8 million, net of unamortized discount and issuance costs totaling \$8.2 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 \$765.6 million as of December 31, 2023, 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 24% of our revenue was denominated in foreign currencies for the year ended December 31, 2023. 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 Malaysia ringgit, 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, Mexican peso, Malaysian ringgit 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

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foreign currency transactions are included in other income (expense), net in the consolidated statement of operations and amounted to a loss of \$0.4 million for the year ended December 31, 2023.

Item 8. Financial Statements and Supplementary Data

Our financial statements as of December 31, 2023 and 2022 and for each of the three years in the period ended December 31, 2023, 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

Opinion on the financial statements

We have audited the accompanying consolidated balance sheets of Insulet Corporation (a Delaware corporation) and subsidiaries (the "Company") as of December 31, 2023 and 2022, 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, 2023, and the related notes and financial statement schedule included under Item 15(a) (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023 in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of December 31, 2023, based on criteria established in the 2013 Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"), and our report dated February 22, 2024 expressed an adverse opinion.

Basis for opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence 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. We believe that our audits provide a reasonable basis for our opinions.

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 a separate opinion on the critical audit matters or on the accounts or disclosures to which they relate.

Variable consideration – Rebates to pharmacy benefit managers

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 in the United States when determining the transaction price at the time of sale. We identified the rebate estimate for pharmacy benefit managers as a critical audit matter.

The principal consideration for our determination that the rebate estimate related to pharmacy benefit managers is a critical audit matter was the high degree of auditor judgment in applying procedures to evaluate the significant estimation made by management. Management's estimate is based on historical experience adjusted for revenue growth, trends, specific known market events, and as available channel inventory data.

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

- Evaluated the significant assumptions and the completeness and accuracy of the underlying data used in management's calculation through inspection of source documents and agreement to other audited schedules.
- · Performed retrospective analysis comparing actual rebates incurred to the previously estimated amounts.
- We tested the design and operating effectiveness of controls related to management's estimate.

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Income taxes – Realizability of the U.S. deferred tax assets

As described further in Note 23 to the financial statements, management records valuation allowances against deferred tax assets when a judgment is made, that it is more likely than not, that a tax benefit will not be realized. The realization of deferred tax assets is dependent upon the generation of future U.S. taxable income during the periods in which those temporary differences will become deductible. We identified the realizability of the Company's U.S. deferred tax assets as a critical audit matter.

The principal consideration for our determination that the realizability of U.S. deferred tax assets is a critical audit matter is the significant judgment regarding the weighting of available positive and negative evidence to determine that the existing valuation allowance on U.S. deferred tax assets remains appropriate. Our audit procedures related to the realizability of the U.S. deferred tax assets included the following, among others. With the involvement of tax professionals, including consultation with national office resources, we assessed the appropriateness of management's evaluation of available positive and negative evidence supporting the valuation allowance position.

/s/ GRANT THORNTON LLP

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

Boston, Massachusetts February 22, 2024

INSULET CORPORATION CONSOLIDATED BALANCE SHEETS

	As of December 31,					
(in millions, except share and per share data)		2023		2022		
ASSETS						
Current Assets						
Cash and cash equivalents	\$	704.2	\$	674.7		
Accounts receivable trade, net		240.2		140.9		
Accounts receivable trade, net — related party		119.5		64.7		
Inventories		402.6		346.8		
Prepaid expenses and other current assets		116.4		86.9		
Total current assets		1,582.9		1,314.0		
Property, plant and equipment, net		664.9		599.9		
Other intangible assets, net		98.7		75.5		
Goodwill		51.7		51.7		
Other assets		190.0		210.0		
Total assets	\$	2,588.2	\$	2,251.1		
LIABILITIES AND STOCKHOLDERS' EQUITY						
Current Liabilities						
Accounts payable	\$	19.2	\$	30.8		
Accrued expenses and other current liabilities		373.7		301.0		
Accrued expenses and other current liabilities — related party		8.9		5.4		
Current portion of long-term debt		49.4		27.5		
Total current liabilities		451.2		364.7		
Long-term debt, net		1,366.4		1,374.3		
Other liabilities		37.9		35.7		
Total liabilities		1,855.5		1,774.7		
Commitments and contingencies (Note 19)						
Stockholders' Equity						
Preferred stock, \$.001 par value, 5,000,000 authorized; none issued and outstanding		_		_		
Common stock, \$.001 par value, 100,000,000 authorized; 69,907,289 and 69,511,286 issued and outstanding		0.1		0.1		
Additional paid-in capital		1,102.6		1,040.6		
Accumulated deficit		(378.0)		(584.3)		
Accumulated other comprehensive income		8.0		20.0		
Total stockholders' equity		732.7		476.4		
Total liabilities and stockholders' equity	\$	2,588.2	\$	2,251.1		

INSULET CORPORATION CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,							
n millions, except share and per share data)		2023				2021		
Revenue	\$	1,223.4	\$	1,055.4	\$	1,040.6		
Revenue from related party		473.7		249.9		58.2		
Total revenue		1,697.1		1,305.3		1,098.8		
Cost of revenue		537.2		499.7		346.7		
Gross profit		1,159.9		805.6		752.1		
Research and development expenses		205.0		180.2		160.1		
Selling, general and administrative expenses		734.9		587.8		466.0		
Operating income		220.0		37.6		126.0		
Interest expense		(36.2)		(36.0)		(61.7)		
Interest income		28.6		9.3		0.5		
Loss on extinguishment of debt		_		_		(42.4)		
Other income (expense), net		2.2		(1.1)		(1.9)		
Income before income taxes		214.6		9.8		20.5		
Income tax expense		(8.3)		(5.2)		(3.7)		
Net income	\$	206.3	\$	4.6	\$	16.8		
Net income per share:								
Basic	\$	2.96	\$	0.07	\$	0.25		
Diluted	\$	2.94	\$	0.07	\$	0.24		
Weighted-average number of common shares outstanding (in thousands):								
Basic		69,751		69,375		67,698		
Diluted		73,633		69,910		68,579		

INSULET CORPORATION

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

	Years Ended December 31,						
(in millions)		2023		2022		2021	
Net income	\$	206.3	\$	4.6	\$	16.8	
Other comprehensive (loss) income, net of tax							
Foreign currency translation adjustment		2.5		(10.3)		(11.9)	
Unrealized (loss) gain on cash flow hedges		(14.2)		32.5		4.5	
Unrealized loss on securities		(0.3)				(0.3)	
Total other comprehensive (loss) income, net of tax		(12.0)		22.2		(7.7)	
Comprehensive income	\$	194.3	\$	26.8	\$	9.1	

INSULET CORPORATION CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock			Additional		Accumulated Other		Total			
(dollars in millions)	Shares (in thousands)	Amount				Paid-in Capital		Accumulated Deficit	Comprehensive Income (Loss)		Stockholders' Equity
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					_	<u> </u>	(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		
Exercise of options to purchase common stock	249		_		16.3	_	_		16.3		
Issuance of shares for employee stock purchase plan	55		_		10.6	_	_		10.6		
Stock-based compensation expense	_		_		48.3	_	_		48.3		
Restricted stock units vested, net of shares withheld for taxes	92		_		(13.2)	_	_		(13.2)		
Net income	_		_		_	206.3	_		206.3		
Other comprehensive loss					_	 	(12.0)		(12.0)		
Balance, December 31, 2023	69,907	\$	0.1	\$	1,102.6	\$ (378.0)	\$ 8.0	\$	732.7		

INSULET CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

		Years Ended December 31,					
(in millions)		2023	2023 2022				
Cash flows from operating activities							
Net income	\$	206.3	\$ 4.6	\$	16.8		
Adjustments to reconcile net income to net cash provided by (used in) operating activities:							
Depreciation and amortization		72.8	63.2		57.4		
Stock-based compensation expense		48.3	40.9		34.4		
Non-cash interest expense		6.7	5.8		40.2		
Loss on extinguishment of convertible debt		_	_		42.4		
Provision for credit losses		2.3	4.2		3.1		
Other		(0.1)	2.8		1.2		
Changes in operating assets and liabilities:							
Accounts receivable		(99.4)	(12.9))	(45.5)		
Accounts receivable — related party		(54.8)	(38.9))	(25.8)		
Inventories		(53.6)	(49.1))	(154.4)		
Prepaid expenses and other assets		(42.1)	(36.8))	(46.7)		
Accounts payable		(11.0)	(2.4))	(15.6		
Accrued expenses and other liabilities		73.8	133.9		22.7		
Accrued expenses and other liabilities — related party		(3.5)	3.7		1.7		
Net cash provided by (used in) operating activities		145.7	119.0		(68.1		
Cash flows from investing activities							
Capital expenditures		(75.6)	(122.9))	(111.9		
Investments in developed software		(8.5)	(12.9)		(10.8		
Acquisition of other intangible assets		(25.1)	(21.5)				
Acquisition of a business		(3.0)	(26.0)		_		
Cash paid for investments		(7.2)	(7.8)		_		
Receipts from the maturity or sale of marketable securities			`		40.0		
Net cash used in investing activities		(119.4)	(191.1)	<u> </u>	(82.7		
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)	(5.0)	,	(2.5		
Proceeds from equipment financings, net			(5.0)		43.1		
Repayment of equipment financings		(19.8)	(17.4)	,	(17.8)		
Repayment of mortgage		(2.2)	(2.1)		(2.0		
Payment of debt issuance costs		(0.3)	(2.1)	/	(4.0)		
Prepayments of financing lease obligation		_	(15.3))			
Proceeds from exercise of stock options		16.3	6.9		15.4		
Proceeds from issuance of common stock under employee stock purchase plan		10.6	9.4		8.1		
Payment of withholding taxes in connection with vesting of restricted stock units		(13.2)	(16.8)	,	(28.2)		
Net cash (used in) provided by financing activities		(13.6)	(40.3)	_	40.7		
Effect of exchange rate changes on cash		1.8	(4.3)		(5.5		
		14.5					
Net increase (decrease) in cash, cash equivalents, and restricted cash			(116.7) 806.4		(115.6)		
Cash, cash equivalents, and restricted cash, beginning of year	Φ.	689.7	-		922.0		
Cash, cash equivalents, and restricted cash, end of year (Note 6) Supplemental cash flow information (Note 25)	\$	704.2	\$ 689.7	\$	806.4		

INSULET CORPORATION NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Nature of the Business

Insulet Corporation (the "Company") is primarily engaged in the development, manufacture, and sale of its proprietary continuous insulin delivery system for people with insulin-dependent diabetes. Currently, the Omnipod platform's revenue generating products include: 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"). Each product 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, Omnipod DASH features a secure Bluetooth enabled Pod that is controlled by a smartphone-like Personal Diabetes Manager ("PDM") with a color touch screen user interface. 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 its Omnipod products, which are sold in the U.S., Europe, Canada, the Middle East, and Australia either directly to end-users or indirectly through intermediaries. Intermediaries include independent distributors who resell Omnipod products 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 gains (losses) from foreign currency transactions are included in other income (expense), net in the consolidated statement of operations and were \$(0.4) million, \$(1.3) million and \$(2.0) million for the years ended December 31, 2023, 2022 and 2021, 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. 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.

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, cash deposited by participating subsidiaries may be in positive or negative cash positions to the extent the overall balance in the cash pool is at least zero. The net cash balance of the notional cash pooling arrangement is included within cash and cash equivalents in the consolidated balance sheets and was insignificant at both December 31, 2023 and 2022.

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 income (expense), net in the Company's consolidated statements of operations.

The Company also has investments in debt securities of privately held companies, which are either classified as available-for-sale securities or for which the Company has elected the fair value option. The available-for-sale securities are recorded 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. The other investment is a debt security that contains embedded derivatives. Unrealized gains and losses for this investment are recorded as a component of other income (loss), net in the consolidated statement of operations. All investments in debt securities are recorded within other assets on the consolidated balance sheet.

The Company may also invest in marketable securities, including term deposits, 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 within other assets on the consolidated balance sheet. The Company reviews investments for other-than-temporary impairment when the fair value of an investment is less than its amortized cost. If an available-for-sale security is other than temporarily impaired, the loss is included in other income (expense), net in the consolidated statement of operations.

Accounts Receivable and Allowance for Credit Losses

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

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

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

Distributor Receivables—The Company measures expected credit losses on distributor receivables using an individual reserve methodology. The risk of loss in this portfolio is low based on the Company's historical experience. The estimate of expected credit losses considers payment history and the financial condition of the distributors.

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.

Judgement is involved in estimating inputs, such as discount rates, used in Level 3 fair value measurements. Changes to these inputs can have a significant effect on fair value measurements and amounts that could be realized.

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.

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 improvements20 to 39 yearsLeasehold improvementsLesser of lease term or useful life of assetMachinery and equipment2 to 15 yearsFurniture and fixtures3 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

Cloud computing arrangements includes services used to support certain internal corporate functions as well as technology platforms that support commercial initiatives. 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 lease liabilities equal to the present value of the future lease payments and lease assets representing the right to use the underlying asset throughout the lease term. Certain leases may contain variable lease payments, including periodic payments that can be avoided by the Company. Variable payments that do not depend on an index or rate are excluded from the right-of-use asset and lease liability and are recognized as expenses in the period in which the obligation for those payments is incurred. Certain of the Company's leases contain options to extend and/or terminate the lease, and/or to purchase the underlying asset. The lease term used to calculate the right-of-use asset and related lease liability includes options to extend or terminate the lease when it is reasonably certain that the Company will exercise the option. The Company's leases do not provide an implicit rate; accordingly, 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. Right-of-use assets are calculated as the initial measurement of the lease liability plus lease payments made prior to lease commencement and initial direct costs incurred, less lease incentives received.

Lease expense is recognized on a straight-line basis over the lease term. For finance leases, the right-of-use asset is amortized to amortization expense and interest expense is recorded in connection with the lease liability.

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. Legal costs associated with loss contingencies are expensed as incurred.

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 Omnipod products to new end-users, either directly to end-users or through intermediaries, primarily consist of the PDM/Controller, the initial and subsequent quantity of Pods ordered, and product training. In the Company's judgment, these performance obligations are capable of being 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 products 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 Omnipod products are 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 Omnipod products 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. Revenue from product training is recognized in the period it is provided. The Company records deferred revenue related to product training as there is generally a lag between when the customer is billed and when the end-user receives product training.

The Company's Drug Delivery product line includes sales of a modified version of the Pod 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 \$12.4 million, \$12.8 million, and \$10.5 million for the years ended December 31, 2023, 2022, and 2021, respectively.

Advertising Costs

The Company expenses advertising costs as they are incurred. Advertising expenses were \$63.1 million, \$41.2 million, and \$44.1 million for the years ended December 31, 2023, 2022, and 2021, 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 by considering all available positive and negative evidence, including 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. The Company has not reclassified income tax effects within accumulated other comprehensive income (loss) to retained earnings due to its full valuation allowance.

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, which exceed Federal Deposit Insurance Corporation limits. See Notes 4 and 7 for customer concentration.

Supply Risk—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 this guidance. The cumulative effect of adopting ASU 2020-06 resulted in a \$207.7 million decrease to the opening balance of additional paid-in-capital upon adoption resulting from the derecognition of the embedded conversion feature and debt issuance costs bifurcated to equity, a \$60.6 million decrease to the opening balance of accumulated deficit representing the cumulative interest expense recognized related to the amortization of the bifurcated conversion option and debt issuance costs, and a \$147.1 million increase in long-term debt resulting from the derecognition of the discount associated with the embedded conversion feature, offset by the remaining debt issuance costs reclassified out of equity. In addition, 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, and assessments are performed by the CODM using consolidated financial information, as the Company's current product offering primarily consists of the Omnipod platform and drug delivery device based on the Omnipod platform.

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

		Years I	Ended December 31,	
(in millions)	2023		2022	2021
U.S.	\$ 1,287.0	\$	942.3	\$ 738.9
International	410.1		363.0	359.9
Total revenue	\$ 1,697.1	\$	1,305.3	\$ 1,098.8

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

	As of December 31,					
(in millions)		2023	2022			
U.S.	\$	461.3	\$	453.2		
China		82.0		87.6		
Malaysia		113.7		51.6		
Other		7.9		7.5		
Total long-lived assets, net	\$	664.9	\$	599.9		

Note 4. Revenue and Contract Acquisition Costs

The following table summarizes the Company's disaggregated revenue:

	Years Ended December 31,							
(in millions)		2023		2022		2021		
U.S.	\$	1,251.0	\$	884.8	\$	651.5		
International		410.1		363.0		359.9		
Total Omnipod Products		1,661.1		1,247.8		1,011.4		
Drug Delivery		36.0		57.5		87.4		
Total revenue	\$	1,697.1	\$	1,305.3	\$	1,098.8		

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

		Years Ended December 31,				
	2023	2022	2021			
Distributor A	28%	19%	*			
Distributor B	24%	16%	*			
Distributor C	19%	17%	12%			

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

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

	As of December 31,				
(in millions)	2023	2022			
Accrued expenses and other current liabilities	\$ 15.4	\$ 16.1			
Other liabilities	1.9	1.6			
Total deferred revenue	\$ 17.3	\$ 17.7			

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

ons)			As of De	cember 31,	
in millions)	2	2023	2	022	2021
eferred revenue recognized	\$	16.0	\$	2.1	\$ 4.4

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

	As of December 31,					
(in millions)		2023		2022		
Prepaid expenses and other current assets	\$	16.6	\$	15.2		
Other assets		32.0		31.3		
Total capitalized contract acquisition costs, net	\$	48.6	\$	46.5		

The Company recognized \$16.3 million, \$14.6 million, and \$12.3 million of amortization of capitalized contract acquisition costs for the years ended December 31, 2023, 2022, and 2021, 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 \$473.7 million, \$249.9 million and \$58.2 million of net revenues from the distributor for the years ended December 31, 2023, 2022, and 2021, respectively.

At each period end, related party transactions recorded on the consolidated balance sheets were as follows:

		ember 31,		
(in millions)		2023		2022
Accounts receivable, net	\$	119.5	\$	64.7
Distribution fees payable ⁽¹⁾	\$	6.1	\$	3.4
Deferred revenue ⁽¹⁾	\$	2.8	\$	2.0

⁽¹⁾ Balances are included in accrued expenses and other current liabilities.

Note 6. Cash and Cash Equivalents

The following table provides a summary of cash and cash equivalents as of December 31, 2023 and 2022:

(in millions)	2023		2022		
Cash	\$	103.7	\$	136.1	
Money market mutual funds		547.0		487.3	
Term deposits		53.5		50.8	
Restricted cash		_		0.5	
Total cash and cash equivalents		704.2		674.7	
Restricted cash included in other assets		_		15.0	
Total cash, cash equivalents, and restricted cash shown in the consolidated statements of cash flows	\$	704.2	\$	689.7	

Restricted cash included in other assets on the consolidated balance sheet as of December 31, 2022 was held as a compensating balance against long-term borrowings.

Note 7. Accounts Receivable

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

	As of December 31,			
(in millions)		2023		2022
Accounts receivable trade, net	\$	234.5	\$	128.6
Unbilled receivable		5.7		12.3
Accounts receivable, net	\$	240.2	\$	140.9

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 OI Dec	aniber 51,
	2023	2022
Distributor A	35%	34%
Distributor B	25%	23%
Distributor C	18%	11%

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

Year Ended December 31						
(in millions)		2023		2022		2021
Credit losses at beginning of year	\$	2.5	\$	2.7	\$	2.9
Provision for expected credit losses		2.3		4.2		3.1
Write-offs charged against allowance		(2.6)		(4.9)		(3.8)
Recoveries of amounts previously reserved		0.3		0.5		0.5
Credit losses at end of year	\$	2.5	\$	2.5	\$	2.7

Note 8. Inventories

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

	As of December 31,						
(in millions)		2023 2022					
Raw materials	\$	118.2	\$	79.1			
Work in process		60.6		84.2			
Finished goods		223.8		183.5			
Total inventories	\$	402.6	\$	346.8			

Amounts charged to the consolidated statements of operations for excess and obsolete inventory for the years ended December 31, 2023, 2022, and 2021 were \$3.7 million, \$8.4 million, and \$2.8 million, respectively.

Note 9. Cloud Computing Costs

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

	As of December 31,						
(in millions)		2023					
Short-term portion	\$	26.4	\$	18.0			
Long-term portion		116.9		87.1			
Total capitalized implementation costs		143.3		105.1			
Less: accumulated amortization		(36.6)		(17.1)			
Capitalized implementation costs, net	\$	106.7	\$	88.0			

Amortization expense is recognized on a straight-line basis over the expected term of the hosting arrangements, which range from three to ten years. Amortization expense was \$20.3 million, \$12.7 million, and \$2.9 million for the years ended December 31, 2023, 2022, and 2021, respectively.

Note 10. Property, Plant and Equipment, Net

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

	As of December 31,						
(in millions)	2023			2022			
$Land^{(1)}$	\$	9.0	\$	2.5			
Building and building improvements ⁽²⁾		205.3		163.9			
Machinery and equipment		572.2		527.0			
Furniture and fixtures		18.1		17.2			
Leasehold improvements		16.0		11.7			
Construction in process		137.5		112.3			
Property, plant and equipment, gross		958.1		834.6			
Less: accumulated depreciation ⁽²⁾		(293.2)		(234.7)			
Property, plant and equipment, net	\$	664.9	\$	599.9			

 $^{^{(1)}}$ Includes \$6.5 million of land at December 31, 2023 related to the finance lease discussed in Note 15.

Capitalized interest expense was \$1.6 million, \$1.3 million, and \$5.6 million for the years ended December 31, 2023, 2022, and 2021, respectively. Depreciation expense related to property and equipment was \$62.6 million, \$56.0 million, and \$50.6 million for the years ended December 31, 2023, 2022, and 2021, respectively. Construction in process primarily consists of manufacturing equipment for our new manufacturing facility being constructed in Malaysia and equipment and tooling for our existing manufacturing lines, most of which is expected to be placed into service during 2024.

⁽²⁾ Includes \$31.7 million of building and building improvements and \$0.4 million of accumulated depreciation at December 31, 2023 related to the finance lease discussed in Note 15.

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:

		Year Ended December 31,					
(in millions)		2023					
Goodwill at beginning of the year	\$	51.7	\$	39.8			
Acquisition (Note 11)		_		12.0			
Foreign currency translation		_		(0.1)			
Goodwill at end of the year	\$	51.7	\$	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:

	As of December 31,											
				2023			2022					
(in millions)	Gross Carrying Accumulated Amount Amortization		N	Net Book Value Gross Carrying Amount			Accumulated Amortization		Net Book Value			
Customer relationships	\$	43.2	\$	(30.9)	\$	12.3	\$	43.2	\$	(27.5)	\$	15.7
Internal-use software		43.1		(13.9)		29.2		34.8		(12.0)		22.8
Developed technology ⁽¹⁾		27.4		(3.0)		24.4		27.4		(1.0)		26.4
Patents ⁽¹⁾		36.2		(3.4)		32.8		11.0		(0.4)		10.6
Total intangible assets	\$	149.9	\$	(51.2)	\$	98.7	\$	116.4	\$	(40.9)	\$	75.5

⁽¹⁾ Includes intangible assets acquired in December 2022. See Note 19 for additional information.

 $Amortization \ expense \ for intangible \ assets \ was \$10.2 \ million, \$7.2 \ million, and \$6.8 \ million \ for the \ years \ ended \ December \ 31, 2023, 2022, and 2021, respectively.$

In February 2023, the Company paid Bigfoot Biomedical, Inc. \$25.1 million, including transaction costs, to acquire patent assets related to pump-based automated insulin delivery technologies. The acquired patent assets have a useful life of 11 years.

Amortization expense associated with the intangible assets included on the Company's consolidated balance sheet as of December 31, 2023 is expected to be as follows:

Years Ending December 31,	(in millions)
2024	\$ 9.8
2025	\$ 13.4
2026	\$ 13.2
2027	\$ 12.0
2028	\$ 11.0

Note 13. Investments

Equity Securities

As of December 31, 2023 and 2022, the total carrying value of the Company's investments in equity securities without readily determinable fair values was \$9.7 million and \$8.7 million, respectively. During 2023, the unrealized gain recorded due to changes in the fair value of equity investments was insignificant. There were no adjustments as of December 31, 2022.

Debt Securities

In 2023, the Company made a strategic investment in debt securities of a privately held entity in the amount of \$5.0 million. The debt securities mature in December 2024, unless converted earlier. The amortized cost basis and fair value of the investment are \$5.0 million and \$4.7 million, respectively, as of December 31, 2023. The unrealized loss recorded due to changes in the fair value of the investment during 2023 was insignificant.

Other

In 2023, the Company made a strategic investment in a privately held entity in the amount of \$2.0 million. The investment is a debt security with embedded derivatives and is accounted for by applying the fair value option, as this approach best reflects the underlying economics of the transaction. The fair value of the investment was calculated using a combination of the market approach and income approach methodologies. During 2023, a \$1.8 million unrealized gain on the investment was recorded in other income (loss), net in the consolidated statement of operations. The fair value of the investment as of December 31, 2023 was \$3.8 million and is reported within other assets on the consolidated balance sheet. The amount of interest earned on the investment in 2023 was insignificant.

Note 14. Accrued Expenses and Other Current Liabilities

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

	As of December 31,						
(in millions)	2023		2022				
Accrued rebates	\$ 144	0 \$	69.6				
Employee compensation and related costs	122.	0	95.9				
Professional and consulting services	34.	1	27.5				
Warranty liability - current portion	4.	8	57.3				
Other	68	8	50.7				
Accrued expenses and other current liabilities	\$ 373	7 \$	301.0				

Product Warranty Costs

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

	Years Ended December 31,					
(in millions)	2023	2023				
Product warranty liability at beginning of year	\$	52.1	\$	6.8		
Warranty expense		8.6		87.0		
Change in estimate	(1.5)		(14.0)		
Warranty fulfillment		8.9)		(17.7)		
Product warranty liability at end of year	\$	0.3	\$	62.1		

During the fourth quarter of 2022, the Company issued two voluntary medical device correction notices ("MDCs"), one for its Omnipod DASH PDM relating to its battery and the other for its Omnipod 5 Controller relating to its charging port and cable. During the year ended December 31, 2022, the Company initially recorded an estimated liability of \$68.9 million related to these MDCs, which was subsequent 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. During the year ended December 31, 2023, the Company revised the estimated liability for these MDCs by an additional \$11.5 million. This change in estimate primarily resulted from lower distribution costs. The Company had a liability of \$0.7 million and \$54.6 million related to the MDCs included in its product warranty liability at December 31, 2023, and 2022, respectively.

Note 15. Leases

As of December 31, 2023, the Company leased certain automobiles and facilities for offices, laboratories, manufacturing, and warehousing, 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. The Company also leases land and a manufacturing building in Malaysia, which are classified as finance leases. The Company has the option to purchase the property at any point after the completion of construction and is contractually obligated to purchase the property nine months after completion, which occurred in December 2023. Because the Company is reasonably certain to purchase the property, the lease term of each finance lease equals the economic life of the underlying asset. As of December 31, 2023, the Company had not exercised the purchase option.

As of December 31, 2023, lease assets and lease liabilities were included in the following consolidated balance sheet accounts in the amounts shown:

	Years Ended December 31,					
(in millions)	2023			2022		
Operating leases						
Operating lease asset:						
Other assets	\$	27.9	\$	26.0		
Operating lease liabilities:				-		
Accrued expenses and other current liabilities	\$	3.5	\$	3.6		
Other liabilities		29.5		27.4		
Total operating lease liabilities	\$	33.0	\$	31.0		
Finance leases						
Finance lease assets:						
Property, plant and equipment, net	\$	37.8	\$			
Finance lease liabilities:						
Current portion of long-term debt and finance leases	\$	22.9	\$			

The Company's operating and financing lease cost was as follows:

	Year Ended December 31,						
(in millions)		023		2022	2021		
Operating lease cost	\$	8.8	\$	8.8	\$	6.0	
Finance lease cost:							
Amortization of leased assets		0.4		_		_	
Interest on lease liabilities		0.6		_		_	
Total finance lease cost		1.0		_		_	
Total operating and financing lease cost	\$	9.8	\$	8.8	\$	6.0	

Maturities of lease liabilities as of December 31, 2023 are as follows:

		,	
(in millions)			

Years Ending December 31,	Operating Leases	Finance Lease ⁽¹⁾		
2024	\$ 5.7	\$	23.2	
2025	4.7		_	
2026	2.8		_	
2027	2.8		_	
2028	3.0		_	
Thereafter	33.8		_	
Total future minimum lease payments	52.8		23.2	
Less: imputed interest	(19.8)		(0.3)	
Present value of future minimum lease payments	\$ 33.0	\$	22.9	

⁽¹⁾ Excludes optional variable lease payments.

As of December 31, 2023, the weighted average remaining lease term and weighted-average discount rate for leases were as follows:

	Operating Leases	Finance Leases
Weighted average remaining lease term	12.4 years	9 months
Weighted-average discount rate used to determine the lease liability	7.1 %	6.0 %

Note 16. Debt

The components of debt consisted of the following:

	As of December 31,								
(in millions)		2023		2022					
Equipment financing due May 2024	\$	2.7	\$	9.5					
Equipment financing due November 2025		15.2		22.5					
5.15% Mortgage due November 2025		63.3		65.5					
0.375% Convertible Senior Notes due September 2026		800.0		800.0					
Equipment financing		12.7		_					
Term loan due May 2028		487.5		492.5					
Revolving Credit Facility expires June 2028		_		_					
Equipment financing due July 2028		29.0		34.4					
Finance lease obligation ⁽¹⁾		22.9		_					
Unamortized debt discount		(6.4)		(7.6)					
Debt issuance costs		(11.1)		(15.0)					
Total debt, net		1,415.8		1,401.8					
Less: current portion		49.4		27.5					
Total long term-debt, net	\$	1,366.4	\$	1,374.3					

 $[\]ensuremath{^{(1)}}$ Refer to Note 15 for information regarding finance lease obligation.

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%.

In May 2023, the Company entered into an arrangement under which the Company may obtain up to \$24.0 million of financing for manufacturing equipment. The Company is involved in the construction of the manufacturing equipment; accordingly, it is included in property, plant and equipment on the consolidated balance sheet at December 31, 2023. The Company's obligation reflects payments made to date by the third-party bank to the equipment manufacturer, net of discount and less repayment of principal. The financing obligation will mature 36 months following completion of construction and has an effective interest rate of 9.4%.

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 cash, shares of the Company's common stock, or the combination of cash and shares of common stock, at the Company's election, 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 at the holder's election, from June 1, 2026 through August 28, 2026 and prior to then under certain circumstances as set forth in the agreement. Additionally, on or after September 6, 2023, the Company may redeem for cash all or a portion of the Notes, if its stock price has been equal to or greater than \$294.75 for at least 20 of the prior 30 consecutive trading days including the date which the Company provides notice of redemption.

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 and are recorded within stockholders' equity on the consolidated balance sheets.

As of December 31, 2023 and 2022, the net carrying amount of the Notes was \$791.8 million and \$788.8 million, respectively, net of unamortized issuance costs of \$8.2 million and \$11.2 million, respectively. As of December 31, 2023, the effective interest rate was 0.76%.

The components of interest expense related to the Notes were as follows:

	Years Ended December 31,								
(in millions)	2023	2022	2021						
Contractual interest expense	\$ 3.0	\$ 3.0	\$ 3.0						
Amortization of debt issuance costs	3.0	3.0	1.9						
Total interest recognized on the Convertible Notes	\$ 6.0	\$ 6.0	\$ 4.9						

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 senior secured revolving credit facility (the "Revolving Credit Facility"). In 2023, the Company increased the borrowing capacity under the Revolving Credit Facility to \$300.0 million and amended the agreement such that outstanding borrowings bear interest at a rate of SOFR plus an applicable margin of 2.625% to 3.25%

based on the Company's net leverage ratio and credit rating and extended the maturity date to the earlier of June 2028 or 91 days prior to the maturity date of the Company's term loan if still outstanding. 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, 2023.

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.

In January 2024, the Company amended its Credit Agreement. Refer to Note 26 for additional information.

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.

Carrying Value

The carrying value amounts of the Company's debt were as follows:

		ember 3	mber 31,		
(in millions)		2023		2022	
Term loan due May 2028	\$	479.2	\$	482.1	
0.375% Convertible Senior Notes		791.8		788.8	
Equipment financings		59.3		66.4	
5.15% Mortgage		62.6		64.5	
Finance lease obligation		22.9		_	
Total debt, net	\$	1,415.8	\$	1,401.8	

Maturity of Debt

The maturity of debt as of December 31, 2023 is as follows:

Years Ending December 31,	<u></u>	(in millions)
2024	\$	49.4
2025	\$	86.4
2026	\$	818.9
2027	\$	17.2
2028	\$	472.5

Note 17. Financial Instruments and Fair Value

Financial Instruments Disclosed at Fair Value

The following tables provide a summary of the significant financial instruments that are disclosed at fair value on a recurring basis as of December 31, 2023 and 2022:

	Fair Value Measurements at December 31, 2023														
(in millions)	Level 1		Level 1 Lev		Level 2		Level 2		Level 2 Lo		Level 2 Level 3			Total	
Term loan due May 2028 ⁽¹⁾	\$	490.2	\$		\$		\$	490.2							
0.375% Convertible Senior Notes ⁽²⁾		_		765.6		_		765.6							
Equipment financings ⁽³⁾		_		_		59.3		59.3							
5.15% Mortgage ⁽³⁾		_		_		62.6		62.6							
Total	\$	490.2	\$	765.6	\$	121.9	\$	1,377.7							

	Fair Value Measurements at December 31, 2022								
(in millions)	Level 1		Level 2		Level 2 Level 3			Total	
Term loan due May 2028 ⁽¹⁾	\$	485.1	\$	_	\$	_	\$	485.1	
0.375% Convertible Senior Notes ⁽²⁾		_		1,038.7				1,038.7	
Equipment financings ⁽³⁾		_		_		66.4		66.4	
5.15% Mortgage ⁽³⁾		_				64.5		64.5	
Total	\$	485.1	\$	1,038.7	\$	130.9	\$	1,654.7	

⁽¹⁾ Fair value of the Term Loan was determined using quoted market prices.

Assets Measured at Fair Value on a Recurring Basis

The following tables provide a summary of assets that are measured at fair value on a recurring basis as of December 31, 2023 and 2022:

	ts at December 31, 202	3				
(in millions)	 Level 1	Level 2		Level 3	Level 3	
Cash ^(I)	\$ 103.7	\$		\$ —	\$	103.7
Money market mutual funds(1)	547.0		_	_		547.0
Term deposits ⁽²⁾	_		53.5	_		53.5
Interest rate swaps ⁽³⁾	_		22.8	_		22.8
Debt securities ⁽⁴⁾	_		_	4.7		4.7
Other investments ⁽⁴⁾	_		<u> </u>	3.8		3.8
Total assets	\$ 650.7	\$	76.3	\$ 8.5	\$	735.5

Fair Value Measurements at Decembe								
(in millions)		Level 1	Level 2		evel 2 Level 3			Total
Cash ⁽¹⁾	\$	136.1	\$		\$		\$	136.1
Money market mutual funds(1)		487.3		_		_		487.3
Term deposits ⁽²⁾		_		50.8		_		50.8
Restricted cash ⁽¹⁾		0.5		_		_		0.5
Interest rate swaps ⁽³⁾		_		36.9		_		36.9
Total assets	\$	623.9	\$	87.7	\$		\$	711.6

⁽¹⁾ Cash and cash equivalents are carried at face amounts, which approximate their fair values.

⁽²⁾ Fair value of the notes was determined using the Company's quoted stock price and the contractual conversion rate.

⁽³⁾ The fair values of the equipment financings and mortgage approximate their carrying values and were determined using their cost basis.

⁽²⁾ Fair value is determined using Level 2 inputs.

⁽³⁾ Fair value represents 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 swaps is included in other assets on the consolidated balance sheets.

⁽⁴⁾ Fair value is determined using industry standard valuation models and market-based unobservable inputs, including credit spread and risk free rate. The range used for the risk free rate is 3.8% - 5.6%.

The following is a reconciliation of changes in fair value of investments, which were acquired during the year ended December 31, 2023:

(in millions)	De	bt Securities	Other Investments	Total
Balance at December 31, 2022	\$		\$ —	\$
Purchases		5.0	2.0	7.0
Unrealized gain included in other income (expense), net		_	1.8	1.8
Unrealized loss on securities included in other comprehensive income		(0.3)		(0.3)
Balance at December 31, 2023	\$	4.7	\$ 3.8	\$ 8.5

Assets Measured at Fair Value on a Non-Recurring Basis

Due to an observable price change in an orderly transaction during 2023, the Company adjusted the carrying value of certain investments in equity securities held as of December 31, 2023, which resulted in an unrealized gain of \$0.8 million. The investments are classified as Level 2 in the fair value hierarchy.

Note 18. 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.

As of December 31, 2023, the Company estimates that \$18.3 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. When recognized, gains and losses on cash flow hedges reclassified from accumulated other comprehensive income are recognized within interest expense, net.

Note 19. 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 million uncommitted letter of credit facility, and concurrently with the execution of the Malaysia Purchase Agreement discussed in Note 15, a \$16.5 million letter of credit was issued under the facility to backstop a bank guarantee for the same amount. The bank guarantee, to which the Company is not a party, serves as security for the building until the Company purchases the property. In 2023, additional letters of credit totaling \$3.5 million were issued under this facility. 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. In aggregate, the Company had letters of credit totaling \$20.9 million and \$18.6 million as of December 31, 2023 and 2022, respectively.

Note 20. 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, 2023, 2.5 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:

	Year Ended December 31,									
(in millions)	2023	2022	2021							
Cost of revenue	\$ 0.4	\$ 0.4	\$ 0.5							
Research and development	11.5	8.9	7.6							
Selling, general and administrative	36.4	31.6	26.3							
Total	\$ 48.3	\$ 40.9	\$ 34.4							

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, 2022	695,588	\$ 109.73		
Granted	72,209	\$ 276.36		
Exercised	(250,192)	\$ 67.30		\$ 52.7
Forfeited and canceled	(81,511)	\$ 250.47		
Outstanding at December 31, 2023	436,094	\$ 135.37	3.8	\$ 43.2
Vested, December 31, 2023	335,862	\$ 95.35	2.4	\$ 43.1
Vested or expected to vest, December 31, 2023	420,190	\$ 130.18	3.6	\$ 43.2

The aggregate intrinsic value of options exercised for the years ended December 31, 2022 and 2021 was \$31.7 million and \$86.5 million, respectively.

The Company uses the Black-Scholes pricing model to determine the fair value of options granted. The assumptions used in the Black-Scholes pricing model are as follows:

• Risk-free Interest Rate—The risk-free interest rate is the implied yield available on U.S. treasury zero-coupon issues with a remaining term equal to the option's expected term on the grant date.

- Expected Term—The expected term of options granted represents the period of time for which the options are expected to be outstanding. The Company
 estimates the expected term using both historical and hypothetical exercise data for outstanding options.
- Dividend Yield—The Company has never declared or paid any cash dividends on any of its capital stock and does not expect to do so in the foreseeable future. Accordingly, the Company uses an expected dividend yield of zero to calculate the grant-date fair value of a stock option.
- Expected Volatility—The expected volatility is a measure of the amount by which the Company's stock price is expected to fluctuate during the expected term of options granted. The Company determines the expected volatility based primarily upon the historical volatility of the Company's common stock over a period commensurate with the option's expected term.

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,			
	2023	2021		
Risk-free interest rate	4.3%	1.8%	0.5% - 0.6%	
Expected life of options (in years)	4.2	4.2	4.2 - 4.4	
Dividend yield	%	%	<u> </u> %	
Expected stock price volatility	45.7%	42.8%	41.4% - 41.6%	
Fair value per option	\$ 115.32	\$ 93.26	\$ 95.92	

As of December 31, 2023, there was \$7.8 million of unrecognized compensation cost related to non-vested stock options. This cost is expected to be recognized over a weighted average period of 2.7 years.

Restricted Stock Units

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

Activity for RSUs is as follows:

	Number of Shares		
Outstanding at December 31, 2022	232,726	\$	249.60
Granted	149,234	\$	259.86
Vested	(98,373)	\$	245.14
Forfeited	(34,393)	\$	266.65
Outstanding at December 31, 2023	249,194	\$	255.31

The weighted-average grant-date fair value per share of RSUs granted was \$248.02 and \$278.68 for the years ended December 31, 2022 and 2021, respectively. The total fair value of RSUs vested was \$24.1 million, \$20.3 million, and \$17.0 million for the years ended December 31, 2023, 2022, and 2021, respectively.

As of December 31, 2023, there was \$41.6 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.

Activity for PSUs is as follows:

	Number of Shares	Weighted Average Fair Value
Outstanding at December 31, 2022	180,301	\$ 249.10
Granted ⁽¹⁾	60,587	\$ 276.36
Vested	(40,023)	\$ 217.34
Forfeited	(78,399)	\$ 272.53
Outstanding at December 31, 2023 ⁽²⁾	122,466	\$ 261.65

⁽¹⁾ Includes a 7,636 share adjustment to awards granted in 2020 for the three-year performance cycle award period ended 2022, based on the actual performance achievement of 84%.

The weighted-average grant-date fair value per share of PSUs granted was \$250.25 and \$273.79 for the years ended December 31, 2022 and 2021, respectively. The total fair value of PSUs vested was \$8.7 million, \$7.8 million, and \$10.3 million for the years ended December 31, 2023, 2022, and 2021, respectively.

As of December 31, 2023, there was \$32.9 million of unrecognized compensation cost related to PSUs, which is expected to be recognized over a weighted-average period of 1.8 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 55,439, 52,724, and 36,103 shares of common stock for the years ended December 31, 2023, 2022, and 2021, respectively, to employees participating in the ESPP. As of December 31, 2023, 364,496 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,		
	2023	2022	2021	
Risk-free interest rate	5.3% - 5.4%	1.6% - 4.7%	0.04% - 0.1%	
Expected term (in years)	0.5	0.5	0.5	
Dividend yield	<u> </u> %	<u> % </u>	<u> %</u>	
Expected stock price volatility	29.1% - 47.0%	44.3% - 50.1%	19.4% - 31.7%	

The weighted average grant date fair value of the six-month option inherent in the ESPP was \$60.67, \$74.50, and \$60.65, for the years ended December 31, 2023, 2022, and 2021, respectively.

As of December 31, 2023, there was \$1.8 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.

⁽²⁾ Based on 111% achievement of the performance metrics, approximately 18,000 shares of Insulet were earned for awards that were granted in 2021 for the performance period ended December 31, 2023. These shares vested in February 2024.

Note 21. 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 (Losses) on Securities	Unrealized Gains on Cash Flow Hedges	Accumulated Other Comprehensive Income (Loss)
Balance, December 31, 2020	\$ 5.2	\$ 0.3	\$	\$ 5.5
Other comprehensive (loss) income	(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
Other comprehensive income (loss) before reclassifications	2.5	(0.3)	6.1	8.3
Amounts reclassified to net income	_	_	(20.3)	(20.3)
Balance, December 31, 2023	\$ (14.5)	\$ (0.3)	\$ 22.8	\$ 8.0

Note 22. 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 \$12.1 million, \$9.8 million, and \$8.5 million for the years ended December 31, 2023, 2022, and 2021, respectively.

Note 23. Income Taxes

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

	Years Ended December 31,					
(in millions)		2023		2022		2021
U.S.	\$	199.5	\$	11.8	\$	25.3
Foreign		15.1		(2.0)		(4.8)
Income before income taxes	\$	214.6	\$	9.8	\$	20.5

Income tax expense consists of the following:

	Years Ended December 31,				
(in millions)	2023		2022	2021	
Current:					
U.S. State	\$	3.7	\$ 1.3	\$	0.5
Foreign		4.1	4.8		2.0
Total current tax expense		7.8	6.1		2.5
Deferred:					
U.S. Federal		0.1	_		_
Foreign		0.4	(0.9)		1.2
Total deferred tax expense (benefit)		0.5	(0.9)		1.2
Total income tax expense	\$	8.3	\$ 5.2	\$	3.7

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

	Years Ended December 31,			
	2023	2022	2021	
U.S. statutory rate	21.0 %	21.0 %	21.0 %	
Foreign rate differential	0.6	13.2	4.8	
State taxes, net of federal benefit	2.4	(5.0)	(9.5)	
Federal and state R&D credits	(5.9)	(49.4)	(26.2)	
Stock-based compensation	(3.2)	(94.8)	(117.0)	
Extinguishment of debt		_	(57.5)	
Capital loss carryforward expirations	_	_	52.1	
Non-deductible officers' compensation	1.3	52.4	45.7	
Permanent items	0.7	6.3	1.9	
Foreign income taxed in the U.S.	0.7	14.5	_	
Change in valuation allowance	(10.8)	124.4	97.9	
Tax rate changes	0.5	(30.9)		
Change to prior year R&D credit	(2.8)	_	_	
Intercompany transfer of intellectual property		_	4.6	
Other	(0.6)	1.7	0.4	
Effective tax rate	3.9 %	53.4 %	18.2 %	

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 \$32.7 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.

During 2023 the Company commenced a multi-year research and development ("R&D") credit study that resulted in an increase to U.S. federal and state R&D credit carryforwards related to the 2022 tax year. This has been reported as a favorable adjustment to prior year taxes in the effective tax rate and a corresponding increase to the valuation allowance.

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 2020 through 2022. In addition, the Company's U.S. net operating loss carryforwards from 2003 and forward may be subject to examination if the losses are utilized in future years.

The following table summarizes the activity related to the Company's unrecognized tax benefits:

(in	mil	llions)

(== ===================================	
Unrecognized tax benefits at December 31, 2022	\$
Additions related to current period tax positions	2.6
Additions related to prior period tax positions	2.4
Unrecognized tax benefits at December 31, 2023	\$ 5.0

As of December 31, 2023, the balance of unrecognized tax benefits, if recognized, would not impact the effective tax rate due to a full valuation allowance against the Company's U.S. deferred tax assets. As of December 31, 2022 and 2021, the Company had no unrecognized tax benefits that would impact the effective tax rates. The Company does not anticipate that the amount of existing unrecognized tax benefits will materially increase or decrease within the next 12 months. No interest and penalties were recognized related to uncertain tax positions for the years ended December 31, 2023, 2022 and 2021 and no interest and penalties were accrued for as of December 31, 2023 and 2022.

The components of the net deferred tax asset at the end of each year consist of the following:

(in millions) Deferred tax assets: Net operating loss carryforwards Tax credits \$	91.4 54.1 53.3 2.2	\$ 143.5 33.6 30.4
Net operating loss carryforwards \$	54.1 53.3	33.6
1 8 9	54.1 53.3	33.6
Tax credits	53.3	
		30.4
Capitalized research and development expenditures	2.2	30.1
Warranty	=:=	14.6
Accrued expenses	22.9	10.2
Amortization of debt discount	7.8	11.0
Inventory capitalization	6.5	4.1
Intangible assets	8.0	12.9
Interest limitation carryforwards	_	1.7
Incentive compensation	13.5	9.4
Stock-based compensation	8.0	6.4
Other	5.4	4.5
Total deferred tax assets	273.1	282.3
Deferred tax liabilities:		
Prepaid assets	(7.7)	(5.3)
Property, plant and equipment	(38.1)	(31.5)
Capitalized contract acquisition costs	(10.4)	(10.4)
Unrealized gains on cash flow hedges	(5.1)	(8.8)
Other	(7.7)	(1.9)
Total deferred tax liabilities	(69.0)	(57.9)
Net deferred tax asset before valuation allowance	204.1	224.4
Valuation allowance	(202.9)	(222.8)
Net deferred tax asset	1.2	\$ 1.6

The Company maintained a valuation allowance of \$202.9 million and \$222.8 million at December 31, 2023 and 2022, respectively, against U.S. federal, state, and certain 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 the weighting of positive and negative evidence, including a history of cumulative tax losses in prior years. The \$19.9 million decrease in the Company's valuation allowance during the year ended December 31, 2023 was primarily due to the utilization of net operating losses and changes in temporary differences in the United States.

As of December 31, 2023, the Company's net operating loss carryforwards were as follows:

(in millions)	Expiration Period	Operating Loss rryforwards
U.S. federal	Indefinite	\$ 192.0
U.S. federal	2032 - 2037	\$ 150.2
State	2024 - 2042	\$ 238.3
Foreign	Indefinite	\$ 23.2

As of December 31, 2023, the Company's tax credit carryforwards were as follows:

(in millions)	Expiration Period	Tax Credit C	arryforwards
U.S. federal	2024 - 2043	\$	40.1
State	2024 - 2043	\$	23.6

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 24. 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 computation of basic and diluted net income per share was as follows:

	Years Ended December 31,				
(in millions, except share and per share data)		2023	2022		2021
Net income	\$	206.3	\$ 4.6	\$	16.8
Add back interest expense, net of tax attributable to assumed conversion of convertible senior notes		10.4	_		_
Net income, diluted	\$	216.7	\$ 4.6	\$	16.8
Weighted average number of common shares outstanding, basic (in thousands)		69,751	69,375		67,698
Convertible Notes		3,528	_		_
Stock options		286	454		686
Restricted stock units		68	81		195
Weighted average number of common shares outstanding, diluted (in thousands)		73,633	69,910		68,579
Net income per share					
Basic	\$	2.96	\$ 0.07	\$	0.25
Diluted	\$	2.94	\$ 0.07	\$	0.24

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:

	Years Ended December 31,							
(in thousands)	2023	2022	2021					
Restricted stock units	322	227	166					
Stock options	163	137	53					
0.375% Convertible Senior Notes	_	3,528	3,528					
1.375% Convertible Senior Notes	_	_	2,024					
Total	485	3,892	5,771					

Note 25. Supplemental Cash Flow Information

Years Ended Decemi			ided December	31,		
(in millions)		2023		2022		2021
Cash paid for interest, net of amount capitalized	\$	49.9	\$	34.2	\$	21.5
Cash paid for taxes	\$	8.1	\$	5.5	\$	7.0
Purchases of property and equipment included in accounts payable and accrued expenses	\$	7.1	\$	3.9	\$	6.1
Purchases of property, plant and equipment included in long-term debt	\$	12.9	\$	_	\$	_
Purchases of developed software included in accounts payable and accrued expenses	\$	0.2	\$	0.4	\$	3.2
Operating lease liabilities arising from obtaining right-of-use assets	\$	5.4	\$	25.5	\$	0.7
Finance lease liability arising from obtaining right-of-use assets	\$	22.3	\$	_	\$	_
Lease payment made for amounts included in the measurement of operating lease liabilities	\$	5.7	\$	4.6	\$	5.7

Note 26. Subsequent Event

In January 2024, the Company amended its Term Loan to bear interest at a rate of SOFR plus 3.00%, with a 0% SOFR floor. At the same time, the Company amended its Revolving Credit Facility such that outstanding borrowings bear interest at a rate of SOFR plus an applicable margin of 2.375% to 3.00% based on the Company's net leverage ratio and credit rating.

SCHEDULE II — VALUATION AND QUALIFYING ACCOUNTS

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

Description	Balance at Beginning of Year	Ac	Additions Charged to Costs and Expenses Othe		Other ⁽¹⁾	.(1) Deductions		Balance at End of Year
(in millions)								
Year Ended December 31, 2023								
Reserve for rebates	\$ 77.3	\$	465.5	\$	_	\$	(385.1)	\$ 157.7
Deferred tax valuation allowance	\$ 222.8	\$	73.5	\$	3.7	\$	(97.1)	\$ 202.9
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

⁽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, 2023. 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, 2023, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were not effective due to the material weakness identified and described below.

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 as of December 31, 2023. 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 this evaluation, our chief executive officer and chief financial officer have concluded that during the period covered by this report, our internal control over financial reporting was not effective, due to a material weakness relating to information technology general controls ("ITGCs"). Specifically, the Company did not design and maintain effective ITGCs around systems that support the Company's financial reporting outside of North America. Automated and manual business process controls that are dependent on the affected ITGCs were also deemed ineffective because they could have been adversely affected to the extent that they rely upon information and configurations from the affected systems.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

Notwithstanding such material weakness in internal control over financial reporting, our management, including our chief executive officer and our chief financial officer, has concluded that our consolidated financial statements present fairly, in all material respects, our financial position, results of our operations and our cash flows for the periods presented in this Form 10-K, in conformity with GAAP.

Management's Annual Report on Internal Control Over Financial Reporting

Management is currently taking actions to remediate the deficiencies in its internal controls over financial reporting and is implementing additional processes and controls designed to address the underlying causes associated with the above-mentioned material weakness.

Management is committed to remediating the deficiencies described above. Internal control remediation efforts are expected to include establishing and maintaining the following:

- · ITGCs over the system used by an outsourced provider, and
- ITGCs over the Company's newly implemented enterprise resource planning system outside of North America related to security access controls.

Management believes that these actions will remediate the material weakness. The weakness will not be considered remediated, however, until the applicable controls operate and management has concluded, through testing, that these controls are operating effectively.

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

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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, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders Insulet Corporation

Opinion on internal control over financial reporting

We have audited the internal control over financial reporting of Insulet Corporation (a Delaware corporation) and subsidiaries (the "Company") as of December 31, 2023, 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, because of the effect of the material weakness described in the following paragraphs on the achievement of the objectives of the control criteria, the Company has not maintained effective internal control over financial reporting as of December 31, 2023, based on criteria established in the 2013 *Internal Control—Integrated Framework* issued by COSO.

A material weakness is a deficiency, or combination of control deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weakness has been identified and included in management's assessment.

The Company did not maintain effective Information Technology General Controls ("ITGCs") around systems that support the Company's financial reporting outside of North America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated financial statements of the Company as of and for the year ended December 31, 2023. The material weakness identified above was considered in determining the nature, timing, and extent of audit tests applied in our audit of the 2023 consolidated financial statements, and this report does not affect our report dated February 22, 2024 which expressed an unqualified opinion on those financial statements.

Basis for opinion

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

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

Definition and limitations of internal control over financial reporting

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

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

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Other information

We do not express an opinion or any other form of assurance on the remediation plans or related actions described in Management's Annual Report on Internal Control Over Financial Reporting.

/s/ GRANT THORNTON LLP

Boston, Massachusetts

February 22, 2024

Item 9B. Other Information

Rule 10b5-1 Plans

On November 23, 2023, Prem Singh, the Company's Senior Vice President, Global Operations, adopted a trading plan intended to satisfy Rule 10b5-1(c) under the Exchange Act to sell up to 775 shares of our common stock between February 23, 2024 and November 22, 2024, the date this plan expires. The trading plan will cease upon the earlier of November 22, 2024 or the sale of all shares subject to the trading plan.

During the fourth quarter of 2023, none of our other executive officers and none of our directors adopted, modified or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement" as defined in Item 408(c) of Regulation S-K.

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 2024 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, 2023.

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⁾	436,094	\$ 135.37	2,524,732 (2)
Equity compensation plans not approved by security holders	_	_	_
Total	436,094	\$ 135.37	2,524,732

⁽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, 2023, 494,126 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 \$135.37. For more information relating to our equity compensation plans, see Note 20 to our consolidated financial statements.

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

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

Item 14. Principal Accounting Fees and Services

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

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

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	<u>Description</u>
3.1	Eighth Amended and Restated Certificate of Incorporation of the Registrant (Incorporated by reference to Exhibit 3.1 to our Registration Statement on Form S-8 (No. 333-144636) filed July 17, 2007)
3.2	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	<u>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).</u>
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*	<u>Insulet Corporation 2017 Stock Option and Incentive Plan (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed May 19, 2017)</u>
10.2*	Form of Insulet Corporation 2017 Stock Option and Incentive Plan Incentive Stock Option Agreement for Employees (Incorporated by reference to Exhibit 10.4 to our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2017, filed August 4, 2017)
10.3*	Form of Insulet Corporation 2017 Stock Option and Incentive Plan Non-Qualified Stock Option Agreement for Employees (Incorporated by reference to Exhibit 10.5 to our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2017, filed August 4, 2017)
10.4*	Form of Insulet Corporation 2017 Stock Option and Incentive Plan Non-Qualified Stock Option Agreement (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed February 24, 2022)
10.5*	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)
10.6*	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)
10.7*	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)
10.8*	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)
10.9*	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)
10.10*	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)
10.11*	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)
10.12*	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)
10.13*	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)

10.14*	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)
10.15*	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)
10.16*	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)
10.17*	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)
10.18*	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)
10.19*	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)
10.20*	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)
10.21*	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)
10.22*	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)
10.23*	Annual Incentive Compensation Plan (Incorporated by reference to Exhibit 10.5 to our Current Report on Form 8-K, filed February 22, 2023)
10.24*	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)
10.25*	<u>Insulet Corporation Employee Stock Purchase Plan (Amended and Restated February 27, 2019) (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed May 30, 2019)</u>
10.26*	Insulet Corporation Deferred Compensation Plan for Non-Employee Directors (incorporated by reference to Exhibit 10.1 to our Registration Statement on Form S-8, filed on November 2, 2023)
10.27*	Form of Inventions, Non-Disclosure, Non-Solicitation, Non-Servicing and Non-Competition Agreement (Executive Officers other than Jim Hollingshead and Dan Manea) (Incorporated by reference to Exhibit 10.30 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed February 24, 2023)
10.28*	Form of Confidentiality, Non-Solicit, Non-Compete, and IP Assignment Agreement, by and between the Company and Employee (Jim Hollingshead and Dan Manea) (Incorporated by reference to Exhibit 10.66 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed February 24, 2023)
10.29*	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).
10.30*	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 for the fiscal year ended December 31, 2020, filed February 24, 2021).
10.31*	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)
10.32*	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)
10.33#	Temporary Acting Up Agreement between Lauren Budden and Insulet Corporation, dated October 30, 2023.
10.34	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)
10.35	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).

10.36	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)
10.37	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)
10.38	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)
10.39	Fourth Amendment to Credit Agreement, dated June 9, 2023, 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 the Company's Current Report on Form 8-K filed June 9, 2023)
10.40	Fifth Amendment to Credit Agreement, dated January 24, 2024, among Insulet Corporation, Insulet MA Securities Corporation, Morgan Stanley Senior Funding, Inc., as administrative agent, and the other lenders party thereto (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed January 25, 2024)
10.41	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)
10.42+	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)
10.43++	Amendment Number 15 to the Supply Agreement by and between Amgen Inc. and Insulet Corporation, dated July 12, 2017 (Incorporated by reference to Exhibit 10.55 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed February 24, 2023)
10.44+	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)
10.45++	Amendment Number 17 to the Supply Agreement by and between Amgen Inc. and Insulet Corporation, dated April 1, 2019 (Incorporated by reference to Exhibit 10.56 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed February 24, 2023)
10.46++	Amendment Number 18 to the Supply Agreement by and between Amgen Inc. and Insulet Corporation, dated August 1, 2019 (Incorporated by reference to Exhibit 10.57 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed February 24, 2023)
10.47++	Amendment Number 19 to the Supply Agreement by and between Amgen Inc. and Insulet Corporation, dated July 13, 2020 (Incorporated by reference to Exhibit 10.58 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed February 24, 2023)
10.48++	Amendment Number 20 to the Supply Agreement by and between Amgen Inc. and Insulet Corporation, dated June 25, 2021 (Incorporated by reference to Exhibit 10.59 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed February 24, 2023)
10.49	Amendment Number 21, dated as of June 1, 2023 to the Supply Agreement by and between Amgen Inc. and Insulet Corporation (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed June 7, 2023)
10.50++	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 for the fiscal year ended December 31, 2021, filed February 24, 2022)
10.51++	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 for the fiscal year ended December 31, 2021, filed February 24, 2022)
10.52++	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)

10.53++	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)
10.54++	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)
10.55++	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)
10.56++#	Amended and Restated Development and Commercialization Agreement by and between Insulet Corporation and Abbott Diabetes Care, Inc., dated September 13, 2021
10.57++#	Amendment No. 1 to the Amended and Restated Development and Commercialization Agreement by and between Insulet Corporation and Abbott Diabetes Care, Inc., dated January 5, 2022
10.58++#	Amendment No. 2 to the Amended and Restated Development and Commercialization Agreement by and between Insulet Corporation and Abbott Diabetes Care, Inc., dated June 6, 2022
10.59++#	Purchase Agreement by and between Insulet Corporation and NXP USA, Inc., dated October 12, 2017
10.60+	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)
10.61	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 (Incorporated by reference to Exhibit 10.52 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed February 24, 2023)
10.62++	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 (Incorporated by reference to Exhibit 10.53 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed February 24, 2023)
10.63++	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)
10.64++#	Amendment, dated November 30, 2019, to the Purchase Agreement dated October 12, 2017 by and between Insulet Corporation and NXP USA, Inc.
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
97.1#	Insulet Corporation Compensation Recoupment Policy
101	The following materials from Insulet Corporation's Annual Report on Form 10-K for the year ended December 31, 2023 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 22, 2024 /s/ James R. Hollingshead

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

February 22, 2024 /s/ Lauren D. Budden

Lauren D. Budden

Interim Chief Financial Officer, Group Vice President, Chief Accounting Officer and Controller

(duly authorized officer and Principal Financial and Accounting Officer)

POWER OF ATTORNEY AND SIGNATURES

We, the undersigned officers and directors of Insulet Corporation, hereby severally constitute and appoint James R. Hollingshead and Lauren D. Budden, 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 22, 2024.

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

Private & Confidential

Lauren Budden [address on file]

Dear Lauren

This letter sets out the temporary change in compensation that will apply for the period of time that you cover the role of Interim Chief Financial Officer, the "Secondment". The allowance will commence on October 23, 2023 and is anticipated to end by March 31, 2024. The Company may, at its discretion, terminate the Secondment at any time prior to the end of that period, whereupon you will resume your normal duties to the Company. Likewise, at the end of your Secondment, you will resume your normal duties and the associated compensation.

Compensation and Benefits

- Base Salary to remain unchanged for the duration of the Secondment, payable via established payroll practices, subject to any year-end salary adjustment (if applicable).
- You will receive a pro-rata allowance for the duration of the Secondment, calculated on a daily basis, and calculated on an annualized figure of USD 70,000.
- Participation in the Company's Annual Incentive Plan with an increased target bonus of **60%** of your Base Salary (on a pro-rata basis) for the duration of the Secondment.
- · Participation in the Company's Long-Term Incentive Plan unchanged.
- Participation in Benefit Plans and Programs will continue unchanged. The temporary allowance will not be considered eligible earnings for benefits plans or leave entitlements, nor for ESPP contributions.

I wish you every success in your new role and please let me know if you have any questions on the above.

Copy: Vanessa Thirion-Cullity, Senior Director, Global HRBP

NASDAQ PODD | Insulet.com

Sincerely,			
/s/ Jim Hollingshead		10/30/2023	
Jim Hollingshead		Date:	
President & CEO, Insulet Co	orporation		
/s/ Vanessa Thirion-Cullity		10/30/2023	
Vanessa Thirion-Cullity		Date:	
Sr. Director – Global HR Bu	siness Partner, Insulet Corporation		
Accepted and agreed by			
/s/ Lauren Budden		10/30/2023	
Lauren Budden		Date:	
	1 (800) 591-3455 100 Nagog Park, Acton, MA 01720	978.600.7000 NASDAQ PODD Insulet.com	

ADDENDUM TO LETTER AGREEMENT DATED OCTOBER 30, 2023

This Addendum to that certain Letter Agreement dated as of October 30, 2023 between Insulet Corporation and Lauren Budden (the "Letter Agreement"), hereby clarifies that the pro-rata allowance paid to Ms. Budden pursuant to the Letter Agreement shall be treated as part of her base salary for purposes of calculating any payments under the Company's Annual Incentive Plan for any period covered by the allowance.

All other provisions of the Letter Agreement remain in full force and effect, other than any provision that conflicts with the terms and spirit of this Addendum, which provision shall be deemed to be amended appropriately in order to be consistent with this Addendum. Terms used herein shall have the same meaning as used in the Letter Agreement unless otherwise noted.

INSULET CORPORATION

By:/s/ James R. Hollingshead	Date: 1/26/2024
James R. Hollingshead	
President and Chief Executive Officer	
By: /s/ Vanessa Thirion-Cullity	Date: 1/26/2024
Vanessa Thirion-Cullity	
Senior Director - Global HR Business Partner	
Agreed and Accepted:	
By: /s/ Lauren Budden	Date: 1/26/2024
Lauren Budden	

1 (800) 591-3455 | 100 Nagog Park, Acton, MA 01720

978.600.7000 NASDAQ **PODD** Insulet.com

CONFIDENTIAL

AMENDED AND RESTATED DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

This AMENDED AND RESTATED DEVELOPMENT AND COMMERCIALIZATION AGREEMENT (the "<u>Agreement</u>") is entered into as of September 13, 2021 (the "<u>Amended Effective Date</u>") by and between Abbott Diabetes Care Inc., a Delaware corporation having its principal place of business at 1420 Harbor Bay Parkway, Alameda, CA 94502 ("<u>ADC</u>"), and Insulet Corporation, a Delaware corporation having its principal place of business at 100 Nagog Park, Acton, MA 01720 ("<u>Insulet</u>"), each of which is referred to as a "<u>Party</u>" and collectively referred to as the "<u>Parties</u>."

RECITALS

WHEREAS, ADC has developed the CGM System and Insulet has developed the Insulin Delivery System;

WHEREAS, on *** (the "<u>Effective Date</u>"), the Parties entered into that certain Development Agreement in connection with (a) the development of the AID System and (b) the sharing of certain data from the CGM System and certain data from the Insulin Delivery System (the "<u>Original Agreement</u>");

WHEREAS, the Parties desire to amend and restate the Original Agreement to, among other things, (a) include additional provisions relating to the commercialization of the AID System; and (b) include the *** as part of the CGM System and

NOW, THEREFORE, in consideration of the foregoing and of the mutual covenants and promises contained in this Agreement, ADC and Insulet agree as follows:

ARTICLE I DEFINITIONS

- 1.1 "ADC ***.
- 1.2 "ADC Indemnitees" means ADC, its Affiliates, and any directors, officers, agents, and employees of the foregoing.
- 1.3 "***" means the *** (and all supporting and related documentation) for the FreeStyle Libre 2 Sensor including the ***; any provided reference/sample code; and the following *** that manage *** and ***, and include the ***used to *** to ***: (a) *** (for use in ***), (b) *** (for use in ***) and (c) *** for use with *** ("***").
- 1.4 "ADC Marks" means the Trademarks listed on Exhibit 1.4, and any other Trademarks as the Parties may stipulate in writing.
 - 1.5 "ADC Sensor" means a FreeStyle Libre 2 Sensor or ***.
- 1.6 "Affiliate" of a Person, means any other Person which controls, is controlled by or is under common control with such Person. For purposes of this definition, "control" shall mean

- (a) in the case of corporate Persons, direct or indirect ownership of at least fifty percent (50%) of the stock or shares entitled to vote for the election of directors; and (b) in the case of non-corporate Persons, direct or indirect ownership of at least fifty percent (50%) of the equity interest with the power to direct the management and policies of the subject Person. However, a Person that is an Excluded Party shall not be an "Affiliate" for purposes of this Agreement, even if such Person would otherwise meet the foregoing definition.
- 1.7 "<u>AID Algorithm</u>" means an algorithm that processes estimated glucose values and any one or more of the following: ***, *** or other factors to automatically control the delivery of insulin to a patient.
 - 1.8 "AID Libre Code" means any source code for the AID System developed by Insulet using the ***.
- **1.9** "<u>AID System</u>" means an automated insulin delivery system, combining the CGM System and Insulin Delivery System, to be developed by the Parties pursuant to the Development Plan. *** and (b) ***.
- 1.10 "AID User Data" means the *** and *** specific to an AID System user that is Processed by the AID System. AID User Data expressly excludes *** and ***.
- 1.11 "Applicable Law" means any national, supranational, multinational, provincial, federal, state or local law (in each case, whether United States or non-United States or otherwise, and whether statutory, common or otherwise), constitution, treaty, convention, ordinance, code, rule, statute, regulation or other similar requirement enacted, issued, adopted, promulgated, entered into or applied by an Authority that may be in effect from time to time during the Term and applicable to a particular activity or country or other jurisdiction hereunder.
- 1.12 "<u>Approved Designee</u>" means (a) with respect to ADC, ADC's Affiliates, those Persons set forth on Part 1 of Exhibit 1.12 and such other Persons as may be approved in writing by Insulet and (b) with respect to Insulet, Insulet's Affiliates, those Persons set forth on Part 2 of Exhibit 1.12, and such other Persons as may be approved in writing by ADC.
- 1.13 "Approved Person" means an employee of either Party who (a) is working on that portion of such Party's development of the AID System for which access to *** of the other Party is required; (b) cannot effectively perform his or her work on the AID System without access to such ***; (c) has been trained by such Party on the procedures for protecting such ***, as set forth in Section 3.6; (d) has agreed in writing to comply with such procedures; and (e) following training and agreement (as required in (c) and (d) above), has been authorized by the *** of Insulet or his or her designee (in the case of Insulet) or the ***, or his or her designee (in the case of ADC) to receive access to such ***. The identity of the *** of Insulet or designee or the *** of ADC or designee shall be disclosed within a reasonable timeframe to either the JSC or an Alliance Manager of Insulet or ADC, as applicable, upon request by either Party.
 - 1.14 "***" means the actual *** during *** of the AID System.

- 1.15 "<u>Authority</u>" means (a) any government regulatory body responsible for granting approvals for the performance of services under this Agreement (if applicable); or (b) any national, supranational, federal, state, international, or local governing or competent body having jurisdiction over a Party with respect to the Party's performance of its obligations under this Agreement.
- **1.16** "Bilateral CDA" means the Confidential Disclosure Agreement Bilateral by and between the Parties effective ***, as amended ***.
 - 1.17 "CGM Algorithm" means an algorithm that processes ***, in order to calculate glucose information including ***.
- 1.18 "CGM Data" means all data generated by (a) the *** or (b) the *** but in each case of (a) and (b), only when they are combined with or used as part of the AID System. "CGM Data" shall include: (i) *** information (***), (i) *** information (***) and (ii) *** information (***).
- 1.19 "<u>CGM System</u>" means an iCGM consisting of an ADC Sensor, LibreView, *** or *** (as applicable), and ADC proprietary software that *** the ***, *** and ***. The CGM System expressly excludes the Insulin Delivery System.
- 1.20 "Change of Control" means with respect to a Party, (a) the sale of all or substantially all of such Party's assets or business relating to this Agreement; or (b) a merger, reorganization, consolidation or similar transaction in which the voting securities of such Party outstanding immediately prior thereto cease to represent at least 50% of the combined voting power of the surviving entity immediately after such merger, reorganization, consolidation or similar transaction; or (c) a Person, or group of Persons, acting in concert acquiring, directly or indirectly, more than 50% of the voting equity securities of, or the power to control the management of, such Party.
 - 1.21 "Closed Loop" means use of the AID System to deliver insulin in an automated mode to the user.
- 1.22 "Claim" means any and all Third Party claims, defenses, demands, causes of action, suits, choses in action, controversies, actions, judgments, liens, indebtedness, damages, losses, attorney's fees, expert's fees, expenses, liabilities, and proceedings of whatever kind and character.
 - 1.23 "Commercially Reasonable Efforts"***.
- **1.24** "Common Vulnerability Scoring System (CVSS)" means an open framework for communicating the characteristics and severity of software vulnerabilities.
- 1.25 "Confidential Information" means all information, including information relating to products (including development or production), customers, suppliers, data, processes, prototypes, samples, plans, marketing plans, reports, forecasts, software (including source code), technical, financial, commercial or personal information or data, research, research results,

strategies, and trade secrets that is disclosed by or on behalf of one Party to the other Party in writing, orally, visually or in another form, including any such information disclosed under the Exploration Agreement or the Bilateral CDA. Confidential Information of ADC includes the ***, the ***, ****, any Pen Testing summaries or reports provided pursuant to Article IX and any other information disclosed by or on behalf of ADC to Insulet related to the CGM System. Confidential Information of Insulet includes information disclosed by or on behalf of Insulet to ADC related to the Insulin Delivery System (or any of its components, including the Insulet AID Algorithm). Confidential Information does not include any ***, AID User Data, CGM Data, or Insulin Delivery System Data (which are protected in accordance with Article VIII and Article IX) or any information that is:

- (a) known to the recipient, as evidenced by its written records, prior to receipt thereof under this Agreement;
- (b) disclosed to the recipient by a Third Party who has no obligations of confidentiality to the disclosing Party;
- (c) in the public domain at the time of disclosure, or becomes part of the public domain other than through breach of this Agreement by recipient (in which instance, the receiving Party's obligations and liabilities for treatment of such information prior to its entering the public domain shall not be affected or diminished); or
- (d) independently developed by or for the recipient as evidenced by its written records, without reference to Confidential Information received from the disclosing Party.
- **1.26** "Consent" means a form of consent that is legally valid under applicable Data Protection Laws.
- 1.27 "Continuous Glucose Monitoring Device Firmware" means software that directly operates the hardware of continuous glucose monitoring devices.
- 1.28 "Data Protection Laws" means all Applicable Law in Canada, the European Economic Area ("EEA"), Switzerland, the United Kingdom, the United States and each Launch Country relating to the Processing or Disclosure of Personal Information, data protection, data security and privacy, including where applicable the guidance, codes of practice and decisions issued by any Authority, as well as all generally applicable industry or self-regulatory standards, in each case, in effect as of the Effective Date, as they become effective, and as amended or superseded, from time to time, which includes, but shall not be limited to, the Canadian Federal Law Personal Information Protection and Electronic Documents Act (S.C. 2000, c. 5) (the "PIPEDA") and any similar data protection laws in applicable Canadian provinces, the General Data Protection Regulation 2016/679 ("GDPR") and any supplemental legislation enacted by an EEA member state, or in the case of the United Kingdom the Data Protection Act 2018 (as amended) ("UK GDPR"), the Swiss Federal Act of 19 June 1992 on Data Protection (as may be amended) ("Swiss GDPR"), the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations, as amended, (collectively, "HIPAA"); the CAN-SPAM Act of 2003; the Telephone Consumer Protection Act and similar laws and regulations governing

telephone calls and text messages; and any other applicable U.S. state and federal data protection laws or regulations.

- 1.29 "<u>Data Security Breach</u>" means any actual or reasonably suspected (a) unauthorized access to, acquisition of, or use of Shared Personal Information; (b) unauthorized or accidental loss, alteration, disclosure, or destruction of Shared Personal Information; (c) compromise, intrusion, interference with, or unauthorized access to networks, systems, databases, servers, or electronic or other media on which Shared Personal Information is Processed or from which Shared Personal Information may be accessed, including those of an agent or subcontractor; or (d) other circumstance that actually or is reasonably suspected of compromising, or could compromise, the privacy, security, confidentiality, availability, or integrity of any Shared Personal Information or the proper functioning of the network resources of ADC or Insulet.
- 1.30 "<u>Direct Market</u>" means, with respect to a Party, a country other than a Distributor Market where such Party or its Affiliates is (a) directly promoting and distributing the Insulin Delivery System (in the case of Insulet and its Affiliates) or the CGM System (in the case of ADC and its Affiliates) to patients, health care providers and payers and (b) is not using one or more Third Parties to manage the majority of its promotion of such products to patients, health care providers and payers, and distribution of such product to patients.
- **1.31** "<u>Disclosure</u>" (including "<u>Disclose</u>") means the release, transfer, provision of, access to, or divulging in any other manner, or by any medium, of Personal Information outside the Party (and its Affiliates) maintaining such information that is not to the other Party (or its Affiliates).
- 1.32 "<u>Distributor Market</u>" means, with respect to a Party, a country where such Party or its Affiliate uses one or more Third Parties to manage the majority of its promotion of the Insulin Delivery System (in the case of Insulet and its Affiliates) or the CGM System (in the case of ADC and its Affiliates) to patients, healthcare providers and payers, and distribution of such product to patients.
- 1.33 "<u>Dosing Algorithm</u>" means an algorithm that processes ***, including ***, in order to ***, including the amount of ***. The *** is an example of a Dosing Algorithm.
 - 1.34 "<u>***</u>.
- 1.35 "Existing Users" means, following regulatory approval of the AID System and the JSC's approval of a Commercialization Plan for a Launch Country, users of the AID System in such Launch Country as of the date of expiration or termination of this Agreement.
 - 1.36 "Exploration Agreement" means the Exploration Agreement by and between the Parties entered into on ***.
 - **1.37** "FDA" means the United States Food and Drug Administration or any successor entity thereto.

- 1.38 "First Commercial Sale" means *** the AID System after regulatory approval for the AID System.
- 1.39 "FOSS" means software or other material that is distributed as free software or open source software ***.
- 1.40 "FreeStyle Libre App" means the continuous glucose monitor application marketed by ADC as ***, as applicable.
- **1.41** "FreeStyle Libre 2 Sensor" means the integrated (as classified by the FDA) in vivo continuous glucose monitoring sensor that is part of the system marketed by ADC as the "Freestyle Libre 2 system".
- 1.42 "*** Documentation" means the specifications provided by or on behalf of ADC to Insulet and its Affiliates which include (i) *** and (ii) ***.
- 1.43 "*** Security Credentials" means the security credentials provided by or on behalf of ADC to Insulet and its Affiliates including *** and *** to enable***.
 - 1.44 "***"
 - 1.45 "***.
 - 1.46 "Glucose***.
- 1.47 "***" means, with respect to ADC, any aspect of the ***, *** and *** that is the Confidential Information of ADC and, with respect to Insulet, any aspect of the *** or *** that is Confidential Information of Insulet.
 - 1.48 "iCGM" means an integrated continuous glucose monitoring system as classified by the FDA.
 - 1.49 "Insulet AID Algorithm" means an AID Algorithm that is owned or otherwise controlled by Insulet.
 - 1.50 "Insulet ***.
 - 1.51 "Insulet Indemnitees" means Insulet, its Affiliates, and any directors, officers, agents, and employees of the foregoing.
- 1.52 "Insulet Marks" means the Trademarks listed on **Exhibit 1.52**, and any other Trademarks as the Parties may stipulate in writing.
- 1.53 "Insulet PDM/App" means an Insulet personal diabetes manager ("PDM") or cellphone application to receive ("Insulet App"), control and display Insulin Delivery System Data and included as part of the Insulin Delivery System.

- 1.54 "Insulin Delivery System" means Insulet's insulin delivery system known on the Amended Effective Date as the "Omnipod" 5 Automated Glucose Control System" including an alternate controller enabled (or "ACE" as classified by the FDA) insulin delivery device(s), an Insulet PDM/App, Insulet cellphone caregiver application, Insulet cloud-based data management platform and Insulet AID Algorithm, in each case such component used in combination or standalone. The Insulin Delivery System includes all components, features and aspects of the AID System, expressly excluding the CGM System.
- 1.55 "Insulin Delivery System Data" means data generated by an Insulin Delivery System that is part of an AID System, including: (a) *** and (b) ***.
- 1.56 "Insulin Metrics" means (a) average units of insulin used per day, by type of insulin, (b) total units of insulin used during the period, by type of insulin, (c) average number of injections per day, by type of insulin, (d) average number of reduced, mis-timed, and missed doses, or (e) average basal to bolus insulin ratio.
 - 1.57 "Insulin Pump" means a continuous subcutaneous insulin infusion pump.
- **1.58** "<u>Insulin Pump Firmware</u>" means software that directly operates the Insulin Pump hardware expressly excluding Dosing Algorithms.
- 1.59 "Intellectual Property" means all patents, patent applications, continuations or continuations-in-part of patents or patent applications, divisionals of patents or patent applications, copyrights, works of authorship, copyrightable subject matter, moral rights, trade secrets, know-how, and all other proprietary and intellectual property rights in discoveries and inventions (whether or not patentable), but not including Trademarks.
- **1.60** "Launch Countries" means the countries set forth on Exhibit 1.60, and such other countries as may be added by execution of one or more Launch Country Addendum.
 - 1.61 "LibreLinkUp" means the caregiver mobile application marketed by ADC as "LibreLinkUp".
 - 1.62 "LibreView" means the cloud-based data management platform that is marketed by ADC or its designee as "LibreView".
 - 1.63 "***.
- **1.64** "Person" means an individual, corporation, partnership, limited liability company, association, company, joint venture, estate, trust, other entity or organization of any kind or nature, including an Authority.
- 1.65 "Personal Information" means any information or set of information relating to an identified or identifiable individual, directly or indirectly, Processed by either Party through the AID System or provided or shared by or on behalf of one Party to the other Party or its designee under this Agreement ("Shared Personal Information"), regardless of the medium in which such information is displayed or contained, which shall include (a) all information that identifies that

individual or could reasonably be used to identify such individual, (b) all "protected health information" as defined by HIPAA, (c) all information, "personal data" as defined by the GDPR such as identification number, location data, an online identifier or one or more factors specific to the physical, physiological, genetic mental, economic, cultural or social identity of a natural individual, as defined by or to which any applicable Data Protection Laws apply, and (d) any information subject to an express written agreement of the Parties to treat such information not otherwise included by applicable Data Protection Laws as Personal Information. For the purposes of this Agreement, Personal Information includes ***, ***, ***, and ***.

- **1.66** "Pod" means the on-body Insulin Pump that is part of the AID System.
- 1.67 "Processing" (including "Process" and "Processed") means any operation or set of operations that is performed on Personal Information within an entity that maintains such information, including use, collection, recording, maintaining, organization, storage, adaptation, modification, retrieval, consultation, retention, alteration, dissemination, transmission, access, transfer, combination, erasure, destruction, deidentification, or pseudonymization or as defined by applicable Data Protection Laws. Processing does not mean Disclosure.
 - 1.68 "***" means the data generated or transmitted by the ***.
 - 1.69 "Restrictive ***" means any *** that is not ***.
 - 1.70 "Senior Officers" means, in the case of ADC, the *** and, in the case of Insulet, the ***.
 - **1.71** "Shared Data" ***.
- 1.72 "Third Party" means any Person other than ADC or Insulet or their respective Affiliates, including Approved Designees, agents and subcontractors.
- 1.73 "Trademarks" means all trademarks, trade names, brand names, domain names, service marks, trade dress, logos, taglines, slogans, certification marks, Internet domain names, social media account or user names (including "handles"), corporate names, business names and all other source indicators, whether registered or unregistered, including all goodwill associated therewith and all applications, registrations and renewals in connection therewith throughout the world, and all rights therein provided by international treaties and conventions.

Additional Definitions. Each of the following definitions is set forth in the Section indicated below:

Definition	Section
" <u>ADC</u> "	Preamble
"ADR"	Exhibit 14.11
"Agreement"	Preamble
"Alliance Manager"	2.7
"Alternate Glucose Devices"	8.3(i)
"Alternate Insulin Delivery Systems"	8.3(j)

"Amended Effective Date"	Preamble
"Android FOSS"	3.9
"Background IP"	5.1
⁶⁶ *** ²⁷	***
"Commercialization Plan"	7.1(a)
"Critical Issues"	9.3(c)
"Data Sharing Exhibit"	8.2(a)
"Development Plan"	3.1(b)
"Effective Date"	Recitals
"***"	***
"GDPR"	1.28
"Global Materials"	7.7(a)
((本本本))	***
" <u>HIPAA</u> "	1.28
"*** [?]	3.9
" <u>Initial Term</u> "	11.1
"Insulet"	Preamble
" <u>JSC</u> "	2.1
" <u>Joint IP</u> "	5.2(b)(i)
"Joint Promotion Agreement"	7.8
"Launch Country Addendum"	7.4
"Local Materials"	7.7(b)
"Mandatory Disclosure"	10.2(b)
"Original Agreement"	Recitals
" <u>Party</u> "	Preamble
"Project Leader"	2.8
"Quality Agreement"	3.1
"Renewal Term"	11.1
"Restriction"	12.2(b)
"Software Protection Provider"	3.6(f)
" <u>Sole IP</u> "	5.2(a)
"Standard Contractual Clauses"	8.4(b)
"Successful Pen Testing Confirmation"	9.3(d)
"System Pen Testing"	9.3(a)
"Target Launch Date"	7.1(a)
" <u>Term</u> "	11.1
"***"	***

ARTICLE II GOVERNANCE

- 2.1 Joint Steering Committee. The joint development committee formed under the Original Agreement is hereby converted into a joint steering committee ("JSC") of expanded size and scope as set forth below. The JSC shall facilitate communications between the Parties and to aid in long-range planning in connection with the development and commercialization of the AID System. The JSC shall consist of four (4) members from each Party and one of the four shall be designated as the lead member by such Party. Each Party shall provide the other Party with a list of its initial members of the JSC within *** after the Effective Date. Each Party may, if needed, (a) replace any or all of its representatives at any time by giving prior written notification to the other Party, or (b) appoint a proxy at any time by giving prior written notification to the other Party.
- 2.2 JSC Meetings. The JSC shall meet at least *** during the Term and within *** of any issue being elevated to them for resolution, or more frequently as agreed to by the Parties, with such meetings alternating between locations designated by ADC and locations designated by Insulet. Upon mutual agreement of the Parties, such meetings may take place telephonically or via videoconference. Any costs and expenses incurred by a Party or its representatives related to a JSC meeting, including, if applicable, travel or telecommunication expenses, shall be borne by such Party. If a representative of a Party is unable to attend a meeting, the Party may designate an alternate to attend such meeting in place of the absent representative. Each Party may, in its reasonable discretion, invite other employees of such Party to attend meetings of the JSC. Each Party shall provide advance notice of any additional attendees it will include at a meeting of the JSC and shall keep the JSC reasonably informed of its progress and activities under this Agreement. Each Party shall be responsible for calling meetings with reasonable advance notice. Any member of the JSC may make proposals for agenda items and shall provide all appropriate information with respect to such proposals reasonably in advance of the applicable meeting.
- **2.3 JSC Responsibilities**. The JSC shall provide oversight for the collaboration between the Parties under this Agreement, including ***. The Parties shall alternate in preparing and circulating for review and approval of the other Party minutes of each meeting within *** after each such meeting.
- 2.4 Procedural Rules. The JSC shall have the right to adopt such standing rules as shall be necessary for its work to the extent that such rules are not inconsistent with this Agreement. A quorum of the JSC shall exist whenever there is present at a meeting at least one (1) member appointed by each Party, and a quorum shall be required for adoption of standing rules. Members of the JSC may attend a meeting either in person or by telephone, video conference or similar means in which each participant can hear what is said by, and be heard by, the other participants. The JSC shall take actions by consensus, with each Party having a single vote irrespective of the number of representatives of such Party in attendance.
- 2.5 **Dispute Resolution**. The JSC shall act in good faith to resolve all issues before it. If the JSC cannot, or does not, reach consensus on an issue, then either Party may refer the

dispute to the Senior Officers of the Parties, who shall meet and discuss in good faith a resolution of the issue. Each Party may designate a JSC member and legal representative to attend such meetings of the Senior Officers. Any final decision mutually agreed to by the Senior Officers of the Parties shall be conclusive and binding on the Parties. If the Senior Officers are not able to agree on the resolution of any such issue within *** of the referral of such matter to the Senior Officers, then (a) if such issue is specific to the Insulin Delivery System (and does not relate to the CGM System), then the Senior Officer of Insulet shall have the final decision with respect to such matter, (b) if such issue is specific to the CGM System (and does not relate to the Insulin Delivery System), then the Senior Officer of ADC shall have the final decision with respect to such matter, and (c) if such issue relates to both the CGM System and the Insulin Delivery System or is otherwise not covered by foregoing clause (a) or (b), then the status quo shall prevail (e.g., if the dispute is regarding approval of a plan or plan update, such plan or update shall not be approved). The Parties shall agree on the minutes of each meeting promptly thereafter. JSC disputes (including such disputes escalated to Senior Officers) shall not be subject to Section 14.11. Disputes arising between the Parties under this Agreement that are outside of the responsibilities of the JSC, shall be resolved pursuant to Section 14.11.

- **2.6 No Binding Powers**. Each Party shall retain the rights, powers, and discretion granted to it under this Agreement, and no such rights, powers, or discretion shall be given to the JSC beyond those in this Article II. The JSC shall have no power to bind the Parties (except for the approval rights expressly provided for in Section 2.3) or modify, or determine or waive compliance with, the terms of this Agreement.
- **2.7 Alliance Managers**. The Parties each appointed an alliance manager pursuant to the Original Agreement (each, an "Alliance Manager"). Each non-member Alliance Manager shall thereafter be permitted to attend meetings of the JSC and any subcommittee as an observer. The Alliance Managers shall be the point of contact for the Parties regarding the contractual and business aspects of the collaboration during the Term. Each Party may replace its Alliance Manager or appoint a proxy at any time by giving prior written notification to the other. Each Party shall pay for its own Alliance Manager's time and activities. The Alliance Managers do not need to be members of the JSC.
- **2.8 Project Leaders**. The Parties each appointed a project leader pursuant to the Original Agreement (each, a "<u>Project Leader</u>"). The Project Leaders shall meet on a *** basis or as mutually agreed by the Parties at such locations or by such means as the Parties agree. The Project Leaders will jointly coordinate the day-to-day work of the Parties under this Agreement and jointly report progress to the JSC. Each Party may replace its Project Leader or appoint a proxy at any time by giving prior written notification to the other Party. Any costs and expenses incurred by a Party or its representatives related to a Project Leaders meeting, including, if applicable, travel or telecommunication expenses, shall be borne by such Party. Project Leaders may attend a meeting either in person or by telephone, video conference or similar means in which each participant can hear what is said by, and be heard by, the other participant. The Parties shall be free to appoint the Project Leader as a member of the JSC, but one person cannot act as Project Leader, Alliance Manager and member of the JSC at the same time.

ARTICLE III DEVELOPMENT PROGRAM

3.1 Development Program Generally.

- (a) Subject to the terms of this Agreement, the Parties shall work together in good faith to develop and approve the AID System as further described in this Agreement and to execute the Development Plan. The final architecture of the AID System shall be mutually agreed by the Parties through the JSC.
- (b) The Parties agreed upon a development plan covering each Party's responsibilities in developing the AID System pursuant to the Original Agreement (the "Original Development Plan"). The Parties shall negotiate in good faith and present to the JSC for approval within the *** after the Amended Effective Date an updated Development Plan *** (the "Updated Development Plan").
- (c) The Development Plan may be updated by the JSC to include or change roles, responsibilities and timelines for any technical work required for development of the AID System. In the event the JSC is unable to reach agreement on any proposed update to the Development Plan, such dispute shall be resolved in accordance with the terms of Section 2.5.
- (d) Subject to the terms of this Agreement, each Party shall use Commercially Reasonable Efforts to complete the activities assigned to it in the Development Plan and will contribute reasonable time, resources, personnel and materials, including for purposes of clinical trials, as specifically set forth in the Development Plan. Each Party shall keep the JSC reasonably informed and updated regarding its progress under the Development Plan.
- (e) If at any time prior to First Commercial Sale, a Party reasonably determines, after any change to the Development Plan that is not initiated by such Party or its Approved Designees, that its remaining obligations under the Development Plan are unduly burdensome it will notify the other Party's members of the JSC in writing of the need to discuss such concerns as an agenda item at the next JSC meeting. If the Parties are not able to come to an agreement at the JSC meeting on how to address such concerns, then the dispute shall be resolved in accordance with the terms of Section 2.5.
- (f) Notwithstanding anything to the contrary herein, neither Party shall be obligated to conduct any development activities related to the AID System until the Development Plan, including any updates thereto, have been approved by the JSC.

3.2 Insulet Development Activities.

(a) Insulet shall be responsible for developing the AID System display; provided that use of the ADC Marks is subject to Section 6.2.

- (b) Insulet shall be responsible for all development, clinical trials, and insulin delivery algorithms for the Insulin Delivery System and AID System, including the AID Algorithm, the features and operation of the AID System, and any changes to the Insulin Delivery System that may be required to combine with the CGM System; ***.
 - (c) Insulet shall provide reasonable assistance to ***.
- (d) Insulet shall ensure that any cloud-based data management platform it uses as part of the AID System is operating in accordance with the principles as outlined in Article VIII.
 - (e) Insulet shall use ***.
 - (f) For the ***.

3.3 ADC Development Activities.

- (a) ADC shall be responsible ***.
- (b) ADC shall ***.

3.4 Regulatory Matters.

- (a) The Parties agree to regularly present and discuss the status of their regulatory activities hereunder at the JSC meetings, or more frequently as needed to keep each other reasonably informed of regulatory matters related to AID System.
- (b) Insulet shall be solely responsible for obtaining and maintaining regulatory approvals and ongoing communication with Authorities for the Insulin Delivery System and AID System and performing all testing (including system, human factors, or clinical) required for such approval; provided that any matters specifically relating to the CGM System shall be subject to ADC's final decision-making authority. When requested by Insulet, ADC shall provide reasonable support, including participation in joint meetings with Authorities, necessary to assist in obtaining and maintaining regulatory approval of the AID System.
- (c) ADC shall be solely responsible for obtaining and maintaining regulatory approvals and ongoing communication with Authorities for the CGM System, and performing all testing (including system, human factors, or clinical) required for such approval, including iCGM approval from the FDA for the CGM System for commercialization in the United States. When requested by ADC, Insulet shall provide reasonable support, including (i) participation in joint meetings with Authorities, necessary to assist in obtaining and maintaining regulatory approval of the CGM System to be used with the AID System, and (ii) for testing and verification of the combination of the CGM System into the AID System.

- (d) If any regulatory approval of the AID System will involve joint approval of both the CGM System and the Insulin Delivery System, the Parties will work in good faith to coordinate their activities to secure such approval; provided that, in connection therewith, ADC shall have final decision-making authority with respect to the CGM System and Insulet shall have final decision-making authority with respect to the Insulin Delivery System and the AID System.
- (e) Each Party shall provide the assistance described in this Section 3.4 and shall otherwise cooperate with the other Party using Commercially Reasonable Efforts to obtain or maintain regulatory approval of the Insulin Delivery System and CGM System, as applicable, to the extent necessary for the AID System, including providing reasonably requested information or documents. Any such information or documents that is non-public shall be used by the receiving Party solely for the purpose of obtaining or maintaining regulatory approval. If the disclosing Party determines in its reasonable discretion that any information or documents requested pursuant to this Section 3.4 contains information of a sensitive nature, the disclosing Party shall have the right to provide such information or documents in confidence directly to the applicable Authorities rather than to the other Party, provided that the disclosing Party timely provides the submission to the applicable Authorities and notifies the other Party of the submission.
- **3.5** Costs. Unless otherwise expressly provided for in this Agreement or the Development Plan, each Party shall be responsible for all costs and expenses it incurs in connection with its development and regulatory activities conducted hereunder.

3.6 Use of ***.

- (a) Both Parties agree to use the *** of the other Party solely for the development and approval of the AID System. Neither Party shall use the *** of the other Party for any other purpose and shall not modify or attempt to reverse engineer the *** of the other Party.
- (b) Neither Party shall provide to the other Party any item of *** unless the disclosing Party provides advance written notice of its need to disclose such *** in connection with the performance of this Agreement and the receiving Party agrees in writing to accept such ***. Insulet and ADC agree that execution of this Agreement constitutes (i) ADC's advance written notice of its need to disclose ADC's *** in connection with the performance of this Agreement and (ii) Insulet's agreement to accept ADC's ***. If and when (but not before) (A) Insulet provides advance written notice to ADC of Insulet's need to disclose its *** in connection with the performance of this Agreement, and (B) ADC agrees in writing to accept such ***, the obligations and duties delineated in this Section 3.6 shall apply to ADC's receipt and use of any such *** of Insulet.
- (c) Neither Party shall provide the *** of the other Party to any Third Parties and shall ensure that only Approved Persons receive access to such ***.

- (d) Subject to the last sentence of Section 3.6(b), each Party shall ensure that:
- (i) it develops protocols to provide the other Party with information about its team who has access to the *** of the other Party;
 - (ii) the *** of the other Party is never checked into any *** such as ***;
 - (iii) all filenames relating to the *** of the other Party are added to *** as soon as they are known;
 - (iv) the *** of the other Party shall never be shared ***;
- (v) every computer with *** of the other Party on an internal hard drive has drive encryption and password protection enabled; and
 - (vi) *** of the other Party is never copied onto a USB or other external hard drive or disk.
- (e) Insulet shall write an abstraction layer around the *** to minimize use of the *** during *** and *** activities and incorporate such other safeguards with respect to the *** and *** as may be set forth in the Development Plan.
- (f) Before distribution of the AID System (or any of its components) to any Third Party (excluding an Approved Person for development purposes hereunder), Insulet shall take any steps that ADC, in its sole discretion, deems necessary to (i) ensure that the *** used by Insulet can be used only with the *** and Insulet PDM/App, and not with any other application, including, unless ADC otherwise agrees in writing, *** such *** to the *** and ***, (ii) protect such ***, the *** and the FreeStyle Libre 3 *** (or any lesser portion thereof to which ADC agrees in writing) using technology provided by either *** or an alternate software protection which is substantially similar thereto (the "Software Protection Provider"), (iii) protect the *** and the AID Libre Code in a reasonable manner and (iv) obtain, at Insulet's sole expense, any necessary licenses from the Software Protection Provider.
- (g) To the extent this Section 3.6 conflicts with any other provision of the Agreement regarding the treatment of ***, this Section 3.6 shall control.
- (h) Each Party agrees that upon request, it shall certify in writing whether it is in compliance with the provisions of this Section 3.6. Within *** after a Party becomes aware of its possible or actual noncompliance with this Section 3.6, such Party shall notify the other Party in writing. Such written notice shall include the nature and period of existence of the possible or actual noncompliance and what action such Party is taking or proposes to take to identify and cure such possible or actual noncompliance. After delivery of such written notice, such Party shall work in good faith with the other Party to address and remediate such possible or actual noncompliance.

- (i) If either Party determines in good faith that the other Party has failed to comply with the provisions of this Section 3.6 or to otherwise sufficiently protect the *** of such Party and that such failure has resulted in unauthorized disclosure or unauthorized use of such ***, such Party shall provide the non-complying Party with written notice of its concerns, including in such notice a description of the basis of its determination. Within *** after receipt of such notice, the non-complying Party shall conduct an investigation into such concerns, its compliance with this Section 3.6 and the sufficiency of its protection of the *** of the other Party, and provide the other Party a written report of the results of such investigation. In addition, the non-complying Party shall (A) use best efforts to identify how the unauthorized disclosure or unauthorized use of such *** occurred, (B) for a period of time as mutually agreed between the Parties (but in no event less than ***), provide to the other Party daily written reports of its findings with respect thereto, and (C) work in good faith with the other Party to ensure that such unauthorized disclosure or unauthorized use does not occur again, including by establishing additional policies and procedures to sufficiently protect the *** of the other Party. If the other Party determines in good faith that its *** remains at risk of future unauthorized disclosure or unauthorized use, then, within *** of written request by the other Party, the non-complying Party shall return or destroy the *** of the other Party.
- 3.7 Pre-Production Environment. ADC shall provide a pre-production environment and any necessary support (including, subject to Section 3.6 and the other terms of this Agreement, access to the *** and *** Technology) to facilitate Insulet's testing and, if necessary, modification of the Insulin Delivery System required for the conduct of the Development Plan. Insulet shall provide a pre-production environment and any necessary support to facilitate ADC's testing and, if necessary, modification of any CGM System required for the conduct of the Development Plan.
- **3.8** Technical Team Meetings. During the conduct of the Development Plan, the relevant technical personnel from each Party will meet as reasonably requested by either Party to discuss the development of the AID System.

3.9 Use of FOSS. ***.

3.10 Quality Agreement. The Parties entered into a Quality Agreement on August 11, 2020 pursuant to the Original Agreement to address adverse event reporting and other regulatory, operational, and quality responsibilities in such Launch Country for the AID System (as may be amended and restated, the "Quality Agreement"). Within *** after the Amended Effective Date, the Parties shall negotiate in good faith any necessary amendments to the Quality Agreement to cover the addition of the *** Sensor. At least *** before the earliest Target Launch Date, the Parties shall commence negotiating in good faith to amend and restate the Quality Agreement to address customer training, service and support, complaint handling, and other regulatory, operational, and quality responsibilities related to the commercialization of the AID System. If the Parties have not amended and restated the Quality Agreement within *** after commencing negotiations, the matter will be addressed at the next JSC meeting and if the JSC is unable to resolve the matter, either Party may refer the matter to the Senior Officers for resolution pursuant Section 2.5.

ARTICLE IV PRODUCT UPDATES

4.1 Update Notices. Each Party shall keep the other Party informed of planned Insulin Delivery System or CGM System updates or any planned cloud-to-cloud data API interface updates, as applicable, (whether software updates or hardware modifications) if such updates will or could impact the integration, features, functions or capabilities of the AID System (e.g. data sharing, data transfer, user experience, etc.).

4.2 Change Management.

- (a) ADC or its Approved Designee shall use Commercially Reasonable Efforts to ensure continued functionality of the AID System with the CGM System. Insulet shall use good faith efforts to provide any reasonable assistance requested by ADC for evaluation testing, design verification, and validation testing necessary to implement any changes ADC anticipates making to the CGM System related to the AID System in accordance with ADC's product development timeline. ADC shall use good faith efforts to provide Insulet with an estimation of resource type, timing and duration for the requested assistance within a reasonable notice period.
- (b) Insulet or its Approved Designee shall use Commercially Reasonable Efforts to ensure continued functionality of the AID System with the Insulin Delivery System (including assisting with implementing any updated versions of the *** on the Insulin Delivery System). ADC shall use good faith efforts to provide any reasonable assistance requested by Insulet for evaluation testing, design verification, and validation testing necessary to implement any changes Insulet anticipates making to the Insulin Delivery System related to the AID System in accordance with Insulet's product development timeline. Insulet shall use good faith efforts to provide ADC with an estimation of resource type, timing and duration for the requested assistance within a reasonable notice period.

ARTICLE V INTELLECTUAL PROPERTY RIGHTS

- **5.1 Background IP.** Each Party shall ***).
- 5.2 Program Intellectual Property
 - (a) Sole IP. Each Party shall ***.
 - (b) Joint IP.
 - (i) The Parties shall ***").
 - (ii) Each Party shall have ***.
 - (iii) Each Party shall ***.

- **5.3 Determination of Inventorship and Authorship.** Inventorship and authorship of Intellectual Property invented, discovered, or created in relation to this Agreement shall be ***.
- **5.4 Documents and Assistance.** Each Party shall execute and shall cause its employees, contractors and agents to execute all documents necessary to effectuate the Parties' rights set forth in this Article V. Each Party shall also provide the other Party with any assistance reasonably necessary for the other Party to obtain or maintain protection on its Intellectual Property.

ARTICLE VI LICENSES

6.1 Intellectual Property Licenses for Activities Under Agreement.

- (a) <u>ADC License to Insulet</u>. During the Term and any survival period provided in Section 11.7, ADC hereby grants to Insulet and its Affiliates and other Approved Designees performing under this Agreement a ***.
- (b) <u>Insulet License to ADC</u>. During the Term and any survival period provided in Section 11.7, Insulet hereby grants to ADC and its Affiliates and other Approved Designees performing under this Agreement a ***.

6.2 Trademark Licenses.

- (a) Subject to compliance with Applicable Law and subject to, and in accordance with, the terms and conditions of this Agreement, ADC hereby grants to Insulet a ***.
- (b) Subject to compliance with Applicable Law and subject to, and in accordance with, the terms and conditions of this Agreement, Insulet hereby grants to ADC a *** license to use ***.
 - (c) ***.
 - (d) ***.
- (e) Except for the limited right to use the ADC Marks granted to Insulet as set forth herein, no right, license or other interest with respect to any ADC Marks is granted under this Agreement.
- (f) Except for the limited right to use the Insulet Marks granted to ADC as set forth herein, no right, license or other interest with respect to any Insulet Marks is granted under this Agreement.

(g) The Parties agree to cooperate in recording these trademark licenses with the local trademark authority and in providing notice to the local trademark authority about the expiration or termination of this Agreement, to the extent such recordation is required under local laws. Neither Party shall take any action to record these trademark licenses without the written consent of the other Party.

6.3 Licenses on Intellectual Property Created with Insulin Delivery System Data or CGM Data.

- (a) ADC License to Insulet. ADC hereby grants to Insulet and its manufacturers, distributors, and customers a ***.
- (b) <u>Insulet License to ADC</u>. Insulet hereby grants to ADC and its Affiliates, manufacturers, distributors, and customers a ***.
- **6.4 No Implied Licenses.** No rights or licenses are granted, by implication or otherwise, to either Party except as expressly set forth in this Agreement.

ARTICLE VII COMMERCIALIZATION, DISTRIBUTION AND MARKETING

7.1 Commercialization Plans.

- (a) At least *** before the anticipated launch date determined by the JSC for each Launch Country (including any new Launch Countries added pursuant to Section 7.4), the Parties shall prepare and present to the JSC for review a preliminary commercialization plan for the AID System in such Launch Country, which plan will include (a) identification of target markets, (b) agreed launch date(s) for the AID System in such country (the "<u>Target Launch Date</u>", for such country), (c) a detailed process for facilitating the approvals contemplated in Section 7.7, (d) type of ADC Sensors *** to be commercialized as part of the AID System in such Launch Country and (e) other actions necessary to achieve commercial launch in such Launch Country and ensure that any such commercial launch activities are coordinated with the activities and deliverables in the Development Plan (as such preliminary plan may be updated and ultimately approved, each a "<u>Commercialization Plan</u>"). Each Commercialization Plan shall be consistent with the terms of this Article VII and include a written plan to comply with Section 8.1. The Parties will present an updated version of each Commercialization Plan to the JSC for approval within *** thereafter, which updated Commercialization Plan shall incorporate any initial feedback and changes based on the input of the JSC.
- (b) If the Parties fail to submit a preliminary Commercialization Plan with respect to a Launch Country within the *** set forth in Section 7.1(a) or if a Commercialization Plan for a Launch Country has not been approved by the JSC at least *** before the First Commercial Sale of the AID System in such Launch Country, then either Party may refer the matter directly to the Senior Officers of the Parties for resolution in accordance with Section 2.5 (without first being addressed by the JSC).

- (c) Notwithstanding anything to the contrary in this Agreement, *** shall have discretion, not to be unreasonably applied, regarding which *** of *** and *** as part of the *** in ***.
- **7.2 Handling of Prescriptions**. In Launch Countries that use forms for prescriptions, *** compliant with Applicable Law *** than ***) ***.

7.3 Commercialization Activities.

- (a) Each Party shall use Commercially Reasonable Efforts to perform its obligations as set forth in each approved Commercialization Plan (including, in the case of ADC, to make the CGM System and, in the case of Insulet, to make the Insulin Delivery System commercially available in the Launch Countries) and shall provide the other Party with *** notice of any occurrence that may substantially affect the Party's ability to perform such obligations.
- (b) In commercializing the AID System and executing each Commercialization Plan, unless otherwise agreed by the Parties:
 - (i) ADC shall (A) retain final decision-making authority with regard to the launch and commercialization of the CGM System ***; and
 - (ii) Insulet shall (A) retain final decision-making authority with regard to the launch and commercialization of the Insulin Delivery System (including pricing), (B) be responsible for the registration, distribution, import, export and sales of the Insulin Delivery System, (C) have the sole right to establish and modify the conditions of sale of the Insulin Delivery System (including market access, pricing, discounts and similar matters), (D) have the sole right to invoice and book all sales of the Insulin Delivery System, and (E) be exclusively responsible for accepting and filling orders and billing for the Insulin Delivery System.
- (c) Notwithstanding anything to the contrary herein, neither Party shall be obligated to conduct any commercialization activities in a Launch Country related to the AID System until a Commercialization Plan for such Launch Country has been approved by the JSC.
- 7.4 Launch Countries. The AID System shall only be launched and commercialized in the Launch Countries. If either Party wishes to propose an additional country that is a Direct Market for inclusion as a Launch Country under this Agreement, then such Party shall prepare and submit to the JSC such proposal for evaluation, which submission shall include a representation that such proposed Launch Country is not a Distributor Market. If the JSC recommends that such country be included as a Launch Country under this Agreement (as documented in the JSC's minutes), then (i) the Parties shall promptly thereafter review the terms of this Agreement to determine if any terms are in conflict with Applicable Law (including the

privacy and data protection implications and obligations under Applicable Law) in any country proposed to be added as a Launch Country and (ii) negotiate in good faith an amendment to this Agreement in the form set forth in **Exhibit 7.4** for such country (each, a "<u>Launch Country Addendum</u>"). Upon execution of a Launch Country Addendum, (A) the corresponding country shall thereafter be a Launch Country and **Exhibit 1.60**shall be amended to include such new Launch Country and (B) the Parties shall negotiate in good faith to prepare a Commercialization Plan for such Launch Country in accordance with Section 7.1. Unless and until a Launch Country Addendum is executed for a proposed new Launch Country, the proposed country shall not be a Launch Country.

7.5 Distributor Markets

- (a) The Parties shall negotiate in good faith for a period of *** commencing on the Amended Effective Date (or such longer time as may be mutually agreed) to amend this Agreement to address the commercialization, registration, sale, and distribution of the AID System in Distributor Markets. No Distributor Markets may be added as Launch Countries to this Agreement until such amendment is executed.
- (b) During the *** period commencing on the Amended Effective Date, neither Insulet nor its Affiliates shall cause, or enter into any agreement or other arrangement to cause, any country to become a Distributor Market.
- (c) Until the amendment contemplated by Section 7.5(a) is executed (and thereafter, subject to such amendment), the Launch Countries shall remain Direct Markets and neither Party nor its Affiliates shall cause a Launch Country to become a Distributor Market.

7.6 Non-Discriminatory Positioning

- (a) Commencing at least *** prior to the First Commercial Sale in a Launch Country, Insulet shall (to the extent consistent with Applicable Law):
 - (i) ***; and (ii) *** develop, ***.
 - (b) Neither Insulet nor its Affiliates ***.
 - (c) Except to the extent required by Applicable Law, *** (through use of ***) *** as a result of ***.
- (d) Commencing at least *** prior to the First Commercial Sale in a Launch Country, ADC shall (to the extent consistent with Applicable Law):
 - (i) ***; and
 - (ii) ***.

- (e) ***.
- (f) Except to the extent required by Applicable Law, *** (through use of ***) *** their Insulin Delivery System with *** as a result of a ***.
 - (g) Neither Party shall *** in a program to *** to *** which includes subcutaneous *** or *** with a ***.

7.7 Marketing Materials

- (a) Global Marketing Materials and Guidelines for AID System. The Parties shall jointly develop marketing and promotion materials and guidelines for the AID System for use throughout the Launch Countries in compliance with (i) Applicable Law, (ii) the regulatory-approved label of the CGM System and Insulin Delivery System and (iii) each Party's internal promotional guidelines for the purpose of publicizing and encouraging interest in the AID System (such materials and guidelines collectively, the "Global Materials"). Such Global Materials must be approved by each Party in *** to use, whether directly or indirectly through Affiliates, distributors or subcontractors, by a Party. The Global Materials can be updated by the Parties from time to time upon the written agreement of the Parties which such agreement shall be provided in ***. Subject to the terms and conditions of this Agreement, each Party shall have sole discretion over its use of the Global Materials.
- (b) <u>Launch Country Marketing Materials for AID System</u>. The Parties shall collaborate in good faith to adapt the Global Materials in compliance with (i) Applicable Law, (ii) the regulatory-approved label of the CGM System and Insulin Delivery System and (iii) each Party's internal promotional guidelines for the purpose of publicizing and encouraging interest in the AID System in each Launch Country (such materials and guidelines collectively, the "<u>Local Materials</u>"). Such Local Materials must be approved by each Party in *** to use, whether directly or indirectly through an Affiliate, distributor or subcontractor, by a Party. The Local Materials can be updated by the Parties from time to time upon the written agreement of the Parties which such agreement shall be provided in ***. Subject to the terms and conditions of this Agreement, each Party shall have sole discretion over its use of the Local Materials.
- (c) <u>Marketing Materials for the CGM System and the Insulin Delivery System</u>. Each Party may, at its own expense, create such global, or country- or region-specific marketing and promotional materials for, in the case of ADC, the CGM System and, in the case of Insulet, the Insulin Delivery System that it considers reasonably necessary to assist with the promotion of such products and the AID System. The Party that created any such country or region-specific promotional or marketing materials shall be responsible to any applicable Authority for such materials. The creating Party may provide any such promotional or marketing materials and translations thereof to the other

Party. The receiving Party may distribute the materials, including such translations, within the Launch Countries solely to promote the AID System.

- (d) <u>License</u>. Subject to the terms and conditions of this Agreement, including the obligations in Section 6.2 and requirements to comply with Applicable Law, each Party hereby grants to the other Party a *** license to *** the marketing and promotional materials created pursuant to Section [7.7(a) through Section 7.7(c)] for the sole purpose of marketing and having marketed the AID System in the Launch Countries.
- (e) <u>Use of Name</u>. Except for Global Materials or Local Materials approved by the other Party, neither Party nor their Affiliates directly, or through a Third Party, shall publish or distribute any written or electronic marketing, promotional, customer services, or other similar materials that mention the other Party's name or products or use the other Party's Trademark without other Party's prior review and written approval, which approval may be ***. The foregoing provision applies to, without limitation, websites, advertising, sales aids, brochures, marketing collateral, emails, social media, and letters or other communications to customers, distributors, healthcare providers, and other Third Parties.
- **7.8 Joint Promotion Activities**. If the Parties mutually decide to either (a) ***, or (b) ***, then the Parties shall negotiate in good faith and agree in advance on the terms for such coordinated and joint activities in a separate promotion agreement or agreements setting forth each Parties responsibilities with respect to such activities (each such agreement, a "Joint Promotion Agreement"). Any such coordinated or joint activities shall be in accordance with all Applicable Law and comply with the Advanced Medical Technology Association (AdvaMed) Code of Ethics on Interactions with Health Care Professionals.
- **7.9 Promotional Communication.** With respect to each Launch Country, following the launch of the AID System in such Launch Country:
 - (a) During the Term, neither Insulet nor any of its Affiliates, may, directly or through a Third Party, issue in such Launch Country *** targeted to ***. Notwithstanding the forgoing, Insulet, may directly or through a Third Party (i) engage in *** that are compatible with ***, (ii) issue *** and (iii) facilitate a ***, if such *** was made (A) in connection with a *** (B) *** or (C) upon the ***.
 - (b) During the Term, neither ADC nor any of its Affiliates, may, directly or through a Third Party, issue in such Launch Country *** targeted to ***. Notwithstanding the forgoing, ADC may, directly or through a Third Party (i) engage in *** that are compatible with ***, (ii) issue *** and (iii) facilitate a ***, if such *** was made (A) in connection with a *** (B) *** or (C) upon the ***.

7.10 Publicity.

- (a) The Parties shall collaborate in good faith to publicize the development of the AID System and shall agree upon the language of news releases or other public announcements regarding the development of the AID System.
- (b) Neither Party shall issue any public announcement, press release or other public disclosure, written or oral, relating to the other Party, the other Party's products, this Agreement, or the existence of an arrangement between the Parties, without the other Party's prior written consent, which shall not be unreasonably withheld, conditioned or delayed, except for a Mandatory Disclosure made in accordance with Section 10.2(b) or a disclosure required by Applicable Law. However, ADC may disclose to *** the existence of this Agreement and any other information included in an issued press release approved by the Parties.
 - (c) ***.
- 7.11 Costs. Unless otherwise expressly provided for in this Agreement or a Commercialization Plan or Joint Promotion Agreement, each Party shall ***.

ARTICLE VIII DATA PROTECTION, SHARING AND USE

8.1 Data Protection.

- (a) Each Party is individually responsible for compliance, and shall comply with all Data Protection Laws applicable to its respective Processing and Disclosure of Shared Personal Information. To the extent the GDPR, Swiss GDPR or UK GDPR applies due to the territoriality or materiality principle of that GDPR, each Party shall furthermore be responsible for compliance with **Exhibit 8.1(a)** ("GDPR Exhibit"), and in the event of conflicting provisions between any of the clauses in this Agreement and the GDPR Exhibit, the provisions included in this Agreement shall be interpreted in a manner consistent with and complementary to the GDPR Exhibit.
- (b) Each Party shall have no influence on the purpose of Processing of Shared Personal Information of the other Party and as such, there is no common purpose jointly determined by both Parties with regard to any such Processing under this Agreement, the Development Plan, any Commercialization Plan or any Joint Promotion Agreement. The Parties are not joint controllers and as such, any provisions relating to joint controllers (or analogous provisions) under applicable Data Protection Laws do not apply.
- (c) The Parties shall cooperate and work in good faith to draft, and incorporate into the AID System, any Consents in a form agreed in writing between the Parties, authorizations, privacy notices, and terms and conditions required by applicable Data Protection Laws to permit the Processing and Disclosure of Shared Personal Information in accordance with this Agreement, the Development Plan, any Commercialization Plan and any Joint Promotion Agreement.

- (d) Each Party shall promptly notify, and in any event within ***, the other Party in the event it receives (i) a request or complaint from a user of the AID System ***.
 - (e) Each Party shall ***.
 - (f) Each Party shall ***.
 - (i) Except with the prior written consent of Insulet, ***.
 - (ii) Except with the prior written consent of ADC, ***.

8.2 Data Use.

- (a) ***, including ***, ***, ***, *** and *** of the Processing, *** and any other additional useful information. ***.

 *** *** be ***, regardless of the method of such data sharing. Insulet shall provide *** notice to ADC ***. *** to ADC

 *** ("***"). If, at any point, Insulet begins to display *** in Insulet's *** at *** ("***"), Insulet will *** any such ***, in addition to the ***, at the *** and at the *** that Insulet *** in *** without ***. ADC may, in its sole discretion, elect to ***. If the *** is *** at *** ("***"), in addition to the restrictions in ***, ADC shall not use *** to *** ADC's, an Affiliate's, or a Third Party's *** or ***, or ***. If Insulet provides *** to ADC, Insulet shall *** in a manner sufficient to allow ADC to *** from *** with *** of greater than ***. If during the Term of this Agreement, Insulet intends to update the ***, it must provide ADC with *** before such plans are implemented and *** prior to implementation in Insulet's ***. The Data Sharing Exhibit may be amended or updated in writing by the Parties during the Term of this Agreement to ensure that it is consistent with the Parties intended data sharing as set out in this Agreement and/or as contemplated in the Development Plan (or Updated Development Plan). ***.
- (b) *** and ***. *** and *** and Consent to share data from *** to ***, *** will be optional. *** and *** and Consented to share data from *** to ***. Insulet will use Commercially Reasonable Efforts to *** (e.g. by means of a ***) ***.
- (c) To the extent not in conflict with applicable Data Protection Laws, ADC and Insulet each have the independent right, title, and interest in and to the *** and to *** for any purpose that is consistent with the terms of this Article VIII.
- (d) This Agreement has no effect on ADC's rights to Process *** and CGM Data, and no effect on Insulet's rights to Process Insulin Delivery System Data.
- (e) ADC has the right to Process Insulin Delivery System Data for any purpose that is consistent with the terms of this Article VIII; provided that without Insulet's prior express written consent, ADC hereby agrees that it may not Process such data:

- (i) to *** ADC's, an Affiliate's, or a Third Party's ***, ***, ADC may ***, other *** and ***, in accordance with the other terms of this Agreement;
 - (ii) *** or *** ***, an ***, or components thereo; or
 - (iii) for ***.
- (f) Insulet has no right to Process, decrypt or reverse-engineer ***. The Pod will receive *** solely for the purpose of providing such *** to the *** therein to generate CGM Data for the AID System, when such AID System is connected to a CGM System using a ***, and for no other purpose.
- (g) Insulet has the right to Process CGM Data for any purpose that is consistent with the terms of this Article VIII; provided that without ADC's prior express written consent, Insulet hereby agrees that it may not Process CGM Data:
 - (i) to *** Insulet's, an Affiliate's, or a Third Party's ;***; ***, other *** and ***, in accordance with the other terms of this Agreement;
 - (ii) *** or *** ***, or components thereof; or
 - (iii) for any ***.
- (h) In addition to the restrictions in Section 8.2(g)(i), Insulet shall not *** to *** Insulet's, an Affiliate's or a Third Party's *** or other *** or *** for use with or in a ***.

8.3 Data Disclosure.

- (a) ADC and Insulet each have the independent right to Disclose *** for any purpose that is consistent with the terms of this Article VIII.
- (b) This Agreement has no effect on ADC's rights to Disclose *** or ***, and no effect on Insulet's rights to Disclose ***
 - (c) ADC may Disclose ***:
 - (i) ***;
 - (ii) ***, of that Person;
 - (iii) in accordance with the terms of this Article VIII, *** provide *** ***, ***); and
 - (iv) an Authority upon request by such Authority (subject to notice to Insulet where allowed by Applicable Law).

(d	ADC may Disclose *** to *** to support ***:
	(i) *** shall be Disclosed to ***.
	(ii) ***.
(e) *** or any *** to data from or derived from Third Party ***.
(f	Insulet may Disclose ***:
	(i) ***;
	(ii) ***, such ***;
	(iii) ***, ***); and
	(iv) an Authority upon request by such Authority (subject to notice to ADC where allowed by Applicable Law).
Notwithstanding	the foregoing, Insulet may ***.
(g	Insulet may *** to *** *** provided that:
	(i) ***, the *** shall be *** to *** together with the same ***;
	(ii) *** as being ***;
(h) ***, ***.
addition,	The Parties acknowledge that *** to ***. If a user selects an ***, *** to such *** under this Agreement. In such *** from an ***.
from an *	The Parties acknowledge that ***. ***, *** or other *** to such *** under this Agreement. In addition, such data ***.
(k	*** Party shall *** to:
ot	(i) *** (and any parent, affiliates, and subsidiaries) "***") *** and *** that *** from (A) *** for any purpose her than *** on the *** (B) *** to *** on the ***.
	(ii) Any ***.
8.4 Cro	oss-Border Personal Information Transfers.
(a	Each Party may ***, when:

- (i) *** pursuant to applicable Data Protection Laws;
- (ii) ***; or
- (iii) *** under applicable Data Protection Laws ***.
- (b) In relation to cross-border or international transfers ***.
- (c) ***. The Parties acknowledge that if ***.
- 8.5 Additional Requirements Under Applicable Data Protection Laws. The Parties shall ***.

ARTICLE IX DATA AND CYBER SECURITY

9.1 Data Security.

- (a) Each Party shall implement and maintain reasonable and appropriate administrative, technical, physical and organizational data security measures and controls for protecting the Personal Information received from the other Party with at least the same degree of care as it uses to protect its own user data and to protect Personal Information against accidental or unlawful destruction, loss, alteration, unauthorized disclosure, or access, as it is transmitted, stored or otherwise Processed and as required by Data Protection Laws and in a manner that also protects the ongoing confidentiality, integrity, availability of Personal Information. Such administrative, technical, physical and organizational security measures must ensure a level of security appropriate to the risk represented by the Processing and the nature of the Personal Information and shall be in accordance with industry standards.
- (b) Notwithstanding any other clause in this Agreement, each Party agrees to *** suffered or incurred by the other Party arising out of or in connection with any Claim made against it arising out of or in connection with any failure by such Party or its employees or Approved Designees to comply with any ***.
- (c) During the Term, upon reasonable written request of a Party and limited to *** period, the other Party shall promptly and accurately complete a written information security questionnaire provided by the requesting Party to confirm compliance with the terms of this Agreement.

a. 9.2 Data Security Breach.

(a) The Development Plan will assign breach notification responsibilities to the Parties, as applicable, for Data Security Breaches affecting the AID System as a whole and for Data Security Breaches affecting the components of the AID System not expressly described in this Section 9.2(a). The Parties agree to provide reasonable

assistance as is necessary to each other to facilitate the handling of any Data Security Breach in an expeditious and compliant manner. ***. Insulet is responsible for the Insulin Delivery System related to Data Security Breaches solely affecting the Insulin Delivery System independent from the AID System (and any notifications and other public statements) and is ***. Except where required by Applicable Law, each Party agrees ***. ***.

(b) It will not be a breach of this Agreement if a Party provides an Authority or user with any Personal Information or Shared Data the Authority requires or which the Party is required to provide to a user in accordance with Applicable Law after the occurrence of a Data Security Breach.

9.3 Penetration Testing and Monitoring Procedures.

- (a) No later than *** before earliest ***, either Party may request that the other Party engage an independent Third Party from the list of penetration testing suppliers set forth in Exhibit 9.3(a) ("Pen Testing Suppliers") to conduct penetration and vulnerability testing of the AID System, ***, or (***.
 - (b) Upon receipt of a System Pen Testing request, ***.
- (c) If the System Pen Testing report provided pursuant to (i) or (ii) above identifies any *** *** ("***"),***. Each Party shall bear its own costs with respect to implementation of such remediation plan. ***.
 - (d) Upon confirmation that all *** have been resolved or if the System Pen Testing report does not reveal any ***, ***.
 - (e) In all cases where either Party receives a System Pen Testing request by the other Party, ***, ***.

9.4 Cyber Security Monitoring.

- (a) During the Term, each Party shall establish and maintain commercially reasonable cybersecurity risk management processes and controls for the purposes of ensuring the security of the other Party's ***, ***. Such processes shall include (i) regular (no less than ***) ***.
 - (b) Each Party agrees that upon request, it shall ***.

ARTICLE X CONFIDENTIAL INFORMATION

10.1 Treatment of Confidential Information. Each Party shall maintain the Confidential Information of the other Party in confidence, and shall not disclose, divulge or otherwise communicate such Confidential Information to any Third Party except as otherwise

permitted hereunder. Neither Party may use any Confidential Information of the other Party for any purpose other than as reasonably necessary to fulfill its obligations under this Agreement. Neither Party shall attempt to reverse-engineer any Confidential Information of the other Party. Each Party hereby agrees to exercise the same standard of care it employs to protect its own Confidential Information (and in no event less than a reasonable standard of care) to prevent and restrain the unauthorized disclosure of such Confidential Information by any of its Affiliates or its or their directors, officers, employees, consultants, subcontractors, sublicensees or agents. Without limiting the foregoing, each Party agrees not to ***.

10.2 Disclosures Required By Law.

- (a) The receiving Party shall not be in violation of this Article X if Confidential Information of the disclosing Party is required to be disclosed by the receiving Party in response to a valid order by a court or other governmental body, provided that the receiving Party provides the disclosing Party with as much prior written notice of such disclosure as practicable, and if possible no less than ***, in order to permit the disclosing Party to seek confidential treatment of such information.
- (b) A Party may disclose Confidential Information or the terms of this Agreement if the Party determines, based on advice from its legal counsel, that it is required to make such disclosure to comply with Applicable Law or the rules of a securities exchange on which such Party is listed (each such disclosure, a "Mandatory Disclosure"). With respect to each Mandatory Disclosure, if permitted in the reasonable opinion of legal counsel, with as much in advance of each such Mandatory Disclosure as practicable, and if possible no less than ***, such Party shall (i) notify the other Party of the proposed content of the Mandatory Disclosure, (ii) give the other Party *** to review and comment on the proposed content of the Mandatory Disclosure, and (iii) in good faith, consider revising the content of the Mandatory Disclosure based on comments received from the other Party. A Party shall include in each Mandatory Disclosure only the information required to be disclosed by Applicable Law or applicable securities rules in the reasonable opinion of legal counsel, and, to the extent possible, shall seek confidential treatment of each Mandatory Disclosure.
- 10.3 Confidential Information Proprietary to Disclosing Party; Return of Confidential Information. The Parties understand and agree that (a) the Confidential Information is and shall remain at all times the sole property of the disclosing Party; (b) the receiving Party shall not obtain any proprietary interest in any Confidential Information; and (c) subject to Section 11.7, all copies of the Confidential Information shall be promptly destroyed or returned to the disclosing Party in their entirety after expiration or termination of this Agreement. Notwithstanding the foregoing, (i) this Agreement and one copy of such Confidential Information necessary to determine the scope of obligations incurred under this Agreement or as otherwise required by law, may be retained in the legal files of the receiving Party and (ii) only to the extent necessary for compliance with an applicable Authority or otherwise as required by Applicable Law, a copy of the *** may be stored in the receiving Party's quality management system.

- 10.4 Breaches of Confidentiality; Assistance in Respect of Same. The receiving Party shall promptly notify the disclosing Party if the receiving Party becomes aware of any breach of confidence by any Person to whom the receiving Party has disclosed any Confidential Information. The receiving Party shall give the disclosing Party all reasonable assistance in connection with any action, demand, claim or proceeding that the disclosing Party may institute against any such Person in respect of such disclosure.
- 10.5 Continuing Obligation. This Article X shall survive for a period of *** after any termination or expiration of this Agreement, provided, however, that the Parties' obligations under this Article X with regard to any Confidential Information identified as a trade secret by the disclosing Party shall survive for as long as the relevant Confidential Information retains its status as a trade secret under Applicable Law.

ARTICLE XI TERM AND TERMINATION

- 11.1 Term. This Agreement shall commence on the Effective Date and continue for an initial term of *** thereafter, unless earlier terminated in accordance with this Agreement (the "<u>Initial Term</u>"). Upon expiration of the Initial Term, this Agreement shall *** for *** of ***, unless earlier terminated in accordance with this Agreement (each a "<u>Renewal Term</u>" and together with the Initial Term, the "<u>Term</u>").
- 11.2 Termination for Material Breach. Either Party may terminate this Agreement in the event of a material breach; provided, however, that such termination shall not become effective unless and until (a) *** have elapsed from the date on which the non-breaching Party gave written notice of such breach to the breaching Party and (b) the breaching Party has not cured such breach within that *** period. If the breaching Party fails to cure such breach, termination of this Agreement shall automatically occur on the *** after the non-breaching Party provided notice of the breach as set forth herein.
- 11.3 Termination for Insolvency. Either Party may terminate this Agreement immediately upon written notice to the other Party, if the other Party (a) files in any court or agency a petition for the opening of bankruptcy or insolvency proceedings or for reorganization or for arrangement or for the appointment of a receiver or trustee of it or its assets under Applicable Law; (b) proposes a written agreement of composition or extension of its debt; (c) is served with an involuntary petition against it, filed in any bankruptcy or insolvency proceeding, and such petition has not been dismissed within *** after the filing thereof; (d) becomes subject to any dissolution or liquidation or resolution thereof; (e) makes an assignment for the benefit of its creditors; or (f) is or is likely to become unable to pay its debts as they fall due in the general course.
- 11.4 Termination for Failure to Launch AID System. If the First Commercial Sale of an AID System has not occurred on or before ***, either Party may elect to terminate this Agreement upon *** written notice to the other Party; provided, however, that, if the First Commercial Sale of an AID System occurs within the *** notice period, then this Agreement shall no longer terminate at the expiration of the notice period.

11.5 Termination ***. At any time after the First Commercial Sale, either Party may terminate this Agreement for *** by giving *** notice to the other Party of the terminating Party's invocation of this Section 11.5. This Agreement shall automatically terminate on the *** anniversaries of such notice.

11.6 Termination ***.

- (a) If (i) Insulet ***, either directly or indirectly through, or in collaboration with, ***, (A) is *** or (B) has ***, or (ii) Insulet ***, (A) is *** or (B) has ***, ADC may terminate this Agreement *** notice to Insulet, which notice must be provided no earlier than *** or event in the foregoing clauses (i), (ii) or (iii), as applicable, and no later than *** thereafter.
- (b) If (i) ADC ***, either directly or indirectly through, or in collaboration with, ***, (A) is *** or (B) has ***, or (ii) ADC ***, (A) *** or (B) has ***, Insulet may terminate this Agreement *** notice to ADC, which notice must be provided no earlier than *** or event in the foregoing clauses (i) or (ii), as applicable, and no later than *** thereafter.
 - (c) Each Party (or its successor) shall provide the other Party with written notice of any such *** following the ***.

11.7 Effect of Termination.

- (a) Upon termination of this Agreement prior to the First Commercial Sale, subject to Applicable Law and the requirements of any ongoing, non-terminable clinical trials set forth in the Development Plan, the licenses set forth in Sections 6.1 and 6.2 shall immediately terminate.
 - (b) Upon termination of this Agreement after the First Commercial Sale:
 - (i) ***; provided that:
 - (1) if termination is due to Section ***, Insulet shall ensure that *** other than the *** includes only the *** or *** of such *** with the ***), *** and ***;
 - (2) if termination is due to Section ***, *** other than the *** *** includes only the *** or *** of such *** with the ***), do not have access to any of *** and ***; and
 - (ii) to the extent permitted by Applicable Law, ***, Insulet shall *** following such termination, and for termination pursuant to ***, *** than *** following such termination.
- 11.8 Survival of Obligations. Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of a Party

prior to such termination or expiration. Notwithstanding anything to the contrary in this Agreement, the following provisions (and the corresponding licenses, covenants and other agreements therein contained) shall survive the expiration of the Term or termination of this Agreement and shall remain in full force and effect thereafter: Article I (to the extent the definitions are used in the other surviving provisions), Section 3.6, Article V, Section 6.2 (other than the license rights therein), Section 6.3, Section 6.4, Article VIII, Article IX, Article X (for the time period set forth in Section 10.5), Section 11.7, this Section 11.8, Article XIII (solely with regard to Claims that accrued prior to such expiration or termination) and Article XIV.

ARTICLE XII REPRESENTATIONS, WARRANTIES AND COVENANTS

- 12.1 Representations by Each Party. Each Party represents and warrants as of the Amended Effective Date, and where applicable, covenants that:
 - (a) such Party is a corporation duly organized, validly existing, and in good standing under the Applicable Law of the State of Delaware;
 - (b) such Party has the full corporate power and authority to execute, deliver, and perform under this Agreement, and has taken all corporate action required by Applicable Law and its organizational documents to authorize the execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement;
 - (c) this Agreement constitutes a valid and binding agreement enforceable against such Party in accordance with its terms;
 - (d) the execution and delivery of this Agreement and the consummation hereof, do not and shall not (i) conflict with or result in a breach of any provision of such Party's organizational documents, (ii) result in a breach of any agreement to which it is a party that would impair the performance of its obligations hereunder, or (iii) violate any Applicable Law;
 - (e) there is no pending or, to such Party's knowledge, threatened action, suit, claim, investigation or proceeding against such Party with respect to its right to enter into and perform its obligations under or that challenges or seeks to prevent or enjoin its entry into or performance of this Agreement;
 - (f) it is not subject to any agreement or order of any Authority that restricts it from granting the rights and licenses to the other Party set forth in this Agreement;
 - (g) such Party is in full compliance at all times and will continue to be in compliance at all times with all Applicable Law (including those related to anti-corruption) and shall not cause the other Party to be in violation of any Applicable Law; and
 - (h) each *** is a *** for such Party and not a ***.

- **12.2** Additional Representation and Warranties. Each Party further represents and warrants, and where applicable covenants, to the other Party that:
 - (a) no components of the AID System will be provided to any customers unless and until all necessary regulatory approvals have been received and thereafter will only be made available in accordance with such regulatory approvals and Applicable Law;
 - (b) on behalf of itself and any of its Affiliates, agents, subcontractors and employees performing activities under this Agreement, that as of the Effective Date they are not, nor have they been within the past *** from the Effective Date, debarred, disqualified, or excluded under any Applicable Law from: (i) providing goods or services to a regulated health care company, (ii) participating in clinical research, (iii) participating in a government procurement or non-procurement program, or (iv) participating in a reimbursed government-funded or financed healthcare program (each, a "Restriction"). Each Party agrees to promptly notify the other Party if any such Restriction is proposed, pending or occurs during the Term. Upon receipt of notice, the receiving Party may elect, in its sole discretion, to immediately terminate this Agreement.

12.3 ***.

- (a) During the Term, Insulet agrees that it shall not ***. Notwithstanding the foregoing, this provision shall not prevent Insulet from ***.
- (b) During the Term, ADC agrees that it shall not ***. Notwithstanding the foregoing, this provision shall not prevent ADC from ***.
- 12.4 Disclaimer. THE PARTIES HEREBY ACKNOWLEDGE THAT, EXCEPT FOR THE REPRESENTATIONS AND WARRANTIES EXPRESSLY SET FORTH IN THIS AGREEMENT, (A) NEITHER PARTY MAKES ANY REPRESENTATION, WARRANTY, OR GUARANTEE OF ANY KIND, EXPRESS OR IMPLIED, AT LAW OR IN EQUITY AND (B) THE PARTIES EXPRESSLY DISCLAIM ALL OTHER REPRESENTATIONS AND WARRANTIES, WHETHER EXPRESS, IMPLIED, OR STATUTORY, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

ARTICLE XIII INDEMNIFICATION

13.1 ADC Indemnification of Insulet. Subject to Section 13.3 and except for claims subject to indemnification under Section ***, if any Claim is brought against the Insulet Indemnitees that (a) is based on or arises out of ***, (b) is based on or arises out of ***, (c) is based on or arises out of ***, (d) asserts that the ***, or (e) is for ***, ADC will *** the Insulet Indemnitees at ADC's expense against such Claim, or at ADC's option, ***, and will *** as a

result of such Claim. Notwithstanding the foregoing, with respect to those Claims for which Insulet, in whole or in part, has an obligation to *** ADC pursuant to Section ***, each Party shall *** the other to the extent of their respective liability for such Claims.

- 13.2 Insulet Indemnification of ADC. Subject to Section 13.3 and except for claims subject to indemnification under Section ***, if any Claim is brought against the ADC Indemnitees that (a) is based on or arises out of ***, (b) is based on or arises out of ***, (c) is based on or arises out of ***, (d) asserts that ***, or (e) is for ***, Insulet will *** the ADC Indemnitees at Insulet's expense against such Claim, or at Insulet's option, ***, and will *** as a result of such Claim. Notwithstanding the foregoing, with respect to those Claims for which ADC, in whole or in part, has an obligation to *** Insulet pursuant to Section ***, each Party shall *** the other to the extent of their respective liability for such Claims.
- 13.3 Obligations of Party Seeking Indemnification. With respect to any Claim for which either Party seeks indemnification from the other Party under this *** or Section ***, the Party seeking indemnification shall (i) provide prompt notice to the other Party of the Claim for which indemnification is sought, (ii) allow the other Party to assume the defense of such Claim, (iii) provide reasonable cooperation and assistance to the other Party in the defense of such Claim, and (iv) not settle or otherwise compromise such Claim without the other Party's prior written consent.

13.4 Limitation of Liability.

- (a) Except for claims under ***, in no event shall a Party's aggregate liability to the other Party for damages of any nature arising out of or in connection with this Agreement, regardless of the form of action, whether for breach of warranty or contract, in tort (including negligence) or otherwise, exceed USD ***.
- (b) Neither Party shall be liable to the other Party or to any Third Party for any special, incidental, indirect, or consequential damages of any kind or for the loss of revenue or profits (even if such Party shall have been advised of or known of or should have known of the possibility of such potential damages or loss), except to the extent that such damages or loss (i) *** or (ii) arise from a ***
- (c) It is agreed that the limitation and exclusions of liability set forth in this 13.4 are intended by the Parties to be a reflection of the agreed allocation of the commercial risks that may arise out of or occur in connection with this Agreement. Further, the Parties hereto agree that the provisions of Section 13.4(a) and 13.4(b) that exclude liability for any consequential damages and limit liability of the Parties for other damages shall in no event be invalidated or deemed unenforceable should any limited warranty or remedy set forth in this Agreement fail of its essential purpose (i.e., provide an insufficient remedy).
- 13.5 Insurance Requirements. During the Term and for *** after the expiration or termination of this Agreement, each Party shall keep in full force and effect and maintain, at its sole cost and expense, insurance coverage in types and amounts commensurate in its industry for the performance of services substantially similar to the services to be performed hereunder by similarly- sized companies, and as otherwise prudent or required by Applicable Law. During the

Term, each Party agrees to provide the other Party with certificates of insurance if requested and on an annual basis. At minimum, Insulet shall maintain the insurance scheme in **Exhibit 13.5**.

ARTICLE XIV MISCELLANEOUS

- **14.1 Assignment.** Except as set forth in Section 14.18, neither Party may assign, delegate, or subcontract this Agreement or any of its rights or duties hereunder, in whole or in part, without the prior written consent of the other Party. Notwithstanding the foregoing, (i) a Party may, without such consent, assign this Agreement to its Affiliate and (ii) a Party may assign this Agreement in connection with *** provided such Person is not ***. Upon assignment of this Agreement to an Affiliate or a Third Party, the assignee must provide to the non-assigning Party a written representation, warranty, and covenant that the assignee has and will commit to the conduct of the Development Plan at least the same amount of resources, labor, capital, and money as the assigning Party had committed to the conduct of the Development Plan as of the assignment date, as reflected in the relevant development plans and budgets. This Agreement will be binding upon and inure to the benefit of the successors and assigns of each Party. Any purported assignment or delegation in violation of the provisions of this Section 14.1 shall be null and void.
- 14.2 Governing Law. This Agreement shall be governed by and interpreted in accordance with the laws of the State of Delaware, without giving effect to the principles of conflicts of law thereof.
- Agreement (except for payment obligations) due to any cause beyond its reasonable control and such Party shall have used Commercially Reasonable Efforts to avoid such occurrence, such Party shall give prompt written notice to the other Party, and thereupon the affected Party's performance shall be excused and the time for performance shall be extended for the period of delay or inability to perform due to such occurrence. The suspension of performance shall be of no greater scope and no longer duration than is necessary and the non-performing Party shall use Commercially Reasonable Efforts to remedy its inability to perform. Such events shall include: acts of god; acts of the public enemy; terrorist acts; insurrections; riots; injunctions; embargoes; labor disputes, including strikes, lockouts, job actions, or boycotts; fires; explosions; floods; earthquakes; shortages of material or energy; delays in the delivery of raw materials; or other unforeseeable causes beyond the reasonable control, and without the fault or negligence, of the Party so affected. The Party so affected shall give prompt notice to the other Party of such cause and shall take whatever reasonable steps are necessary to relieve the effect of such cause as rapidly as reasonably possible.
- 14.4 No Waiver. No waiver will be implied from the Parties' course of conduct or any delay or failure to enforce any rights. No provision of this Agreement shall be deemed waived unless such waiver is in writing and signed by an authorized representative of the Party against whom it is sought to be enforced. Waiver by either Party of any default by the other Party of any provision of this Agreement shall not be deemed a waiver by the waiving Party of any subsequent or other default.

14.5 Notices. Any notice or other communication in connection with this Agreement must be in writing and by certified mail, return receipt requested, or by delivery service that provides a written delivery confirmation. Notice shall be effective and deemed to be given when delivered to the addressee at the address listed below or such other address as the addressee shall have specified in a notice actually received by the addressor.

If to ADC:

Abbott Diabetes Care Inc. 1420 Harbor Bay Parkway Alameda, CA 94502 Attention: Legal Division

with a copy (which shall not constitute notice) to:

Abbott Laboratories Attention: Legal Division 100 Abbott Park Rd. Abbott Park, IL 60064

If to Insulet:

Insulet Corporation 100 Nagog Park Acton, MA 01720

Attention: VP, Corporate Development

with a copy (which shall not constitute notice) to:

Insulet Corporation 100 Nagog Park Acton, MA 01720

Attention: Legal Department

14.6 Relationship Between the Parties.

- (a) **Independent Contractor**. The relationship of the Parties under this Agreement is that of independent contractors. The Parties will not be deemed partners or joint ventures, nor will one Party be deemed an agent or employee of the other Party. Neither Party has any express or implied right under this Agreement to assume or create any obligation on behalf of, or in the name of, the other Party, or to bind the other Party to any contract, agreement, or undertaking with any Third Party, and no conduct of a Party shall be deemed to imply such right.
- (b) **No Exclusivity**. For clarity, the relationship between the Parties under this Agreement is nonexclusive and does not preclude (a) ADC from entering into agreements relating to Third Party insulin delivery devices or systems or (b) Insulet from entering

into agreements relating to Third Party glucose monitoring products or systems, except as set forth in Section 11.6.

- 14.7 Entire Agreement. Each Party acknowledges that in entering into this Agreement it does not rely on any statement, representation, or warranty other than those expressly set forth in this Agreement. This Agreement, the Exhibits hereto (which Exhibits are deemed to be a part of this Agreement for all purposes), the Development Plan, the Commercialization Plans, the Quality Agreement, and any Joint Promotion Agreement contain the entire agreement between the Parties, and supersede all previous agreements, negotiations, discussions, writings, understandings, commitments and conversations with respect to the subject matter hereof. In the event of a conflict between this Agreement and the Development Plan, this Agreement shall control. In the event of a conflict between this Agreement and the Quality Agreement, the Quality Agreement shall control with regard to adverse event reporting and other quality matters, and this Agreement shall control in all other circumstances. The Parties hereby agree and acknowledge that this Agreement amends and restates the Original Agreement in its entirety, and the Original Agreement is replaced with, and superseded by, this Agreement.
- **14.8 Amendments.** No provisions of this Agreement shall be deemed amended, supplemented, or modified unless such amendment, supplement, or modification is in writing and signed by an authorized representative of each Party. The express terms of this Agreement control and supersede any course of performance or dealing inconsistent with any of the terms hereof.
- 14.9 Severability. In the event that any provision of this Agreement is held by a court of competent jurisdiction or the ADR neutral to be unenforceable because it is invalid or in conflict with any law of any relevant jurisdiction, the validity of the remaining provisions shall not be affected, and the rights and obligations of the Parties shall be construed and enforced as if this Agreement did not contain the particular provisions held to be unenforceable.
- 14.10 Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, and all of which together shall constitute one and the same agreement. Each Party acknowledges that an original signature or a copy thereof transmitted by facsimile or by PDF shall constitute an original signature for purposes of this Agreement.
- **14.11 Dispute Resolution.** Subject to Section 2.5, any dispute arising under or related to this Agreement shall be settled by the alternative dispute resolution provisions set forth in **Exhibit 14.11**. Notwithstanding the foregoing sentence, the Parties agree that any request for provisional remedies and any request for injunctive relief, whether preliminary or permanent, shall be decided by a court of competent jurisdiction and not through the alternative dispute resolution provisions set forth in **Exhibit 14.11**.
- 14.12 Venue. If either Party brings any request for provisional remedies or any request for injunctive relief against the other Party in accordance with Section 14.11, that Party may only bring that proceeding in the United States District Court for the District of Delaware or, only if there is no federal subject matter jurisdiction, in any state court of Delaware sitting in New

Castle County, Delaware, and each Party hereby submits to the exclusive jurisdiction of those courts for purposes of any such proceeding.

- 14.3 Equitable Relief. Each Party acknowledges that any breach of the restrictions set forth in ***, and ***, ***, and ***may cause the other Party irreparable harm and significant injury, to which there may not be adequate remedy at law. Each Party further acknowledges that any breach of the restrictions set forth in Section *** and any use or disclosure of the *** of the other Party other than in accordance with this Agreement will cause the other Party irreparable harm and significant injury, to which there is no adequate remedy at law. Accordingly, in the event of a breach or threatened breach of any provision of such Sections or Articles, the non-breaching Party shall be authorized and entitled to seek from any court of competent jurisdiction injunctive relief, whether preliminary or permanent, specific performance, which rights shall be cumulative and in addition to any other rights or remedies to which such non-breaching Party may be entitled in law or equity.
- 14.4 Interpretation. The headings of the Articles and Sections of, and any Exhibits to, this Agreement have been added for the convenience of the Parties and shall not be deemed a part hereof. Words in the singular shall be deemed to include the plural and vice versa, and words of one gender shall be deemed to include the other gender, as the context requires. The terms "hereof," "herein," and "herewith" and words of similar import shall, unless otherwise stated, be construed to refer to this Agreement as a whole (including any and all of the Schedules hereto) and not to any particular provision of this Agreement. Article, Section, and Exhibit references are to the Articles, Sections, and Exhibits to this Agreement, unless otherwise specified. Unless otherwise stated, all references to any agreement shall be deemed to include any and all Exhibits to such agreement. The word "including" and words of similar import when used in this Agreement shall mean "including, without limitation," unless the context otherwise requires or unless otherwise specified. The word "or" shall not be exclusive. Unless otherwise specified in a particular case, the word "days" refers to calendar days. References herein to this Agreement shall be deemed to refer to this Agreement as of the Amended Effective Date and as it may be amended thereafter, unless otherwise specified. References to the performance, discharge, or fulfillment of any liability or obligation in accordance with its terms shall have meaning only to the extent such liability or obligation has terms; if the liability or obligation does not have terms, the reference shall mean performance, discharge, or fulfillment of such liability or obligation.
- 14.15 Joint Negotiation. This Agreement is the joint product of ADC and Insulet, and each provision hereof has been subject to the mutual consultation, negotiation, and agreement of the Parties and their respective legal counsel and advisers, and any rule of construction that a document shall be interpreted or construed against the drafting Party shall not be applicable.
- 14.16 No Other Compensation. Insulet and ADC hereby agree that the terms of this Agreement, (including the Development Plan and Commercialization Plans), the Quality Agreement and any Joint Promotion Agreement fully define all consideration, compensation and benefits, monetary or otherwise, to be paid, granted or delivered by Insulet to ADC and by ADC to Insulet in connection with the transactions contemplated herein. Neither ADC nor Insulet previously has paid or entered into any other commitment to pay, whether orally or in writing,

any ADC or Insulet employee, directly or indirectly, any consideration, compensation or benefits, monetary or otherwise, in connection with the transactions contemplated herein.

- 14.17 Records. Each Party shall, and shall ensure that its Affiliates and its and their employees, agents and subcontractors, maintain, in compliance with Applicable Law, complete and accurate records with respect to its performance of the development and commercialization activities hereunder. Such records shall be retained by each Party for at least *** after the termination of this Agreement, or for such longer period as may be required by Applicable Law.
- 14.18 Performance by Affiliates or other Approved Designees. Notwithstanding anything else set forth herein, any obligation or right of either Party under this Agreement may be fulfilled or exercised, in whole or in part, at such Party's sole option, either by such Party directly or by any Affiliate or other Approved Designee. In such case, such Party shall remain liable for any such obligation or right as if performed directly by such Party itself.
- **14.19** No Third Party Beneficiaries. Nothing in this Agreement, express or implied, is intended to, or shall, confer upon any Third Party any right, benefit, or remedy of any nature whatsoever under, or by reason of, this Agreement.

{Signature Page Follows}

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed in their names by their properly and duly authorized officers or representatives as of the dates set forth below.

ABBOTT DIABETES CARE INC.

By: <u>/s/ Jared Watkin</u> Name: Jared Watkin Title: President

Date: 23 September 2021

INSULET CORPORATION

By: <u>/s/ Eric Benjamin</u>
Name: Eric Benjamin

Title: SVP, Innovation & Strategy

Date: 15 September 2021

EXHIBIT 1.4

ADC MARKS

EXHIBIT 1.12 APPROVED DESIGNEES

EXHIBIT 1.50 ADDITIONAL INSULET EXCLUDED PARTIES

EXHIBIT 1.52 INSULET MARKS

EXHIBIT 1.60 LAUNCH COUNTRIES

EXHIBIT 7.4 LAUNCH COUNTRY ADDENDUM

EXHIBIT 8.1(A)

GDPR EXHIBIT

EXHIBIT 8.2(A) MINIMUM DATA TO BE SHARED BETWEEN CGM SYSTEM AND INSULIN DELIVERY SYSTEM

EXHIBIT 8.4(B) STANDARD CONTRACTUAL CLAUSES

ANNEX A TO THE STANDARD CONTRACTUAL CLAUSES DATA PROCESSING PRINCIPLES

ANNEX B TO THE STANDARD CONTRACTUAL CLAUSES DESCRIPTION OF THE TRANSFER

EXHIBIT 9.3(A) PEN TESTING SUPPLIERS

EXHIBIT 13.5 INSULET INSURANCE REQUIREMENTS

EXHIBIT 14.11 ALTERNATIVE DISPUTE RESOLUTION

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 NO. 1 to the AMENDED AND RESTATED DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

This Amendment No. 1 to the Amended and Restated Development and Commercialization Agreement ("**Amendment**") is dated as of the 5th day of January, 2022 ("**Effective Date**"), by and between Insulet Corporation ("**Insulet**") and Abbott Diabetes Care Inc. ("**ADC**").

WHEREAS, Insulet and ADC are parties to that certain Amended and Restated Development and Commercialization Agreement dated as of September 13, 2021 (the "Agreement"); and

WHEREAS, Insulet and ADC wish to amend the Agreement as set forth herein, effective as of the Effective Date.

NOW, THEREFORE, in consideration of these premises, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

- 1. <u>Definitions</u>. Capitalized terms used herein and not otherwise defined shall have the meaning ascribed to such terms in the Agreement.
- 2. The definition set forth Section 1.13 (Approved Person) is hereby deleted and replaced with the following:

"1.13 "Approved Person" means an employee or *** who (a) is working on that portion of such Party's development of the AID System for which access to *** of the other Party is required; (b) cannot effectively perform his or her work on the AID System without access to such ***; (c) has been trained by such Party on the procedures for protecting such ***, as set forth in Section 3.6; (d) has agreed in writing to comply with such procedures; and (e) following training and agreement (as required in (c) and (d) above), has been authorized by the *** of Insulet or his or her designee (in the case of Insulet) or the ***, or his or her designee (in the case of ADC) to receive access to such ***. The identity of the *** of Insulet or designee or the *** of ADC or designee shall be disclosed within a reasonable timeframe to either the JSC or an Alliance Manager of Insulet or ADC, as applicable, upon request by either Party."

3. Subsection (c) of Section **3.6** (**Use of** ***) is hereby deleted and replaced with the following:

"Each Party shall ensure that only Approved Persons receive access to such *** and, except for Insulet's ***, neither Party shall provide the *** of the other Party to any Third Parties."

- 4. In Exhibit 1.2, Approved Designees, in Part 2, the name "***" is replaced with "***".
- 5. No Other Amendments. Except as modified herein, all other terms of the Agreement and SOW shall remain in full force and effect.
- 6. Conflicts. In the event of a conflict between the Agreement and this Amendment, this Amendment shall govern.
- 7. <u>Counterparts</u>. This Amendment may be executed in counterparts, each of which shall be deemed to be an original and all of which together shall be deemed to be one and the same instrument.

IN WITNESS WHEREOF, this Amendment has been executed by the duly authorized representatives of Insulet and ADC on the date first set forth above.

ABBOTT DIABETES CARE INC.

By: <u>/s/ Jared Watkin</u>
Name: Jared Watkin
Title: President

Date: 2/8/2022

INSULET CORPORATION

By: <u>/s/ Eric Benjamin</u> Name: Eric Benjamin

Title: SVP, Innovation & Strategy

Date: 2/4/2022

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 ***

AMENDMENT NO. 2 TO AMENDED AND RESTATED DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

This Amendment No. 2 ("Amendment") is dated June 6, 2022

BETWEEN

- (1) Abbott Diabetes Care Inc., a Delaware corporation having its principal place of business at 1420 Harbor Bay Parkway, Alameda, CA 94502 ("ADC"); and
- (2) Insulet Corporation, a Delaware corporation having its principal place of business at 100 Nagog Park, Acton, MA 01729 ("Insulet")

Each of which is referred to as a "Party" and collectively referred to as the "Parties".

CONSIDERATIONS

- (A) Following the adoption of the Commission Implementing Decision (EU) 2021/914 of 4 June 2021 on standard contractual clauses ("Standard Contractual Clauses"), Parties agree to amend Exhibit 8.4(b) to the Amended and Restated Development and Commercialization Agreement between ADC and Insulet, entered into as of September 13, 2021 ("Agreement"), regarding the transfer of Personal Information from the EEA to outside the EEA.
- (B) Following the adoption of the Standard Data Protection Clauses by the UK Information Commissioner under S119A(1) Data Protection Act 2018 ("<u>UK Addendum</u>"), parties agree to add an **Exhibit 8.4(c)** to the Agreement regarding the transfer of Personal Information from the UK to outside the UK.

IT IS AGREED:

1. DATA AND CYBER SECURITY ARTICLE IX

1.1 The following will be added to Section 9.2(a) – Data Security Breach:

In the event a Party becomes aware of a Data Security Breach, such Party shall notify the other Party without undue delay but in any case no longer than *** from when such Party becomes aware of the Data Security Breach.

2. AMENDMENT EXHIBIT 8.4(B) – EU STANDARD CONTRACTUAL CLAUSES

2.1 Exhibit 8.4(b) to the Agreement will be replaced by the following:

ANNEX I

ANNEX II

2. ADDITION OF EXHIBIT 8.4(C) – UK ADDENDUM

2.1 The following Exhibit 8.4(c) will be added to the Agreement:

3. No Other Amendments. Except as modified herein, all other terms of the Agreement and SOW shall remain in full force and effect.

Conflicts. In the event of a conflict between the Agreement and this Amendment, this Amendment shall govern.

IN WITNESS WHEREOF, this Amendment has been executed by the duly authorized representatives of Insulet and ADC on the date first set forth above.

ABBOTT DIABETES CARE INC.

By: <u>/s/ Katharine Spayde</u>
Name: Katharine Spayde

Title: DVP, Abbott Diabetes Care

Date: 6/23/2022

INSULET CORPORATION

By: <u>/s/ George Russo</u> Name: George Russ

Title: VP Strategy & Corporate Developmen

Date: 6/20/2022

PURCHASE AGREEMENT

THIS PURCHASE AGREEMENT (this "Agreement"), entered into as of October 12, 2017 ("Effective Date") by and between Insulet Corporation, a Delaware corporation, having a place of business at 600 Technology Park Drive, Suite 200, Billerica, MA 01821 on behalf of itself and its Affiliates ("Purchaser"), and NXP USA, Inc., with an office located at 6501 William Cannon Drive West, Austin, Texas 78735 ("Supplier") on behalf of itself and its Affiliates.

Background

Supplier manufactures certain integrated circuits that Purchaser may choose to use in medical device components and subassemblies. Purchaser is engaged in the marketing and selling medical products. Purchaser desires to purchase from Supplier, and Supplier desires to sell to Purchaser, the Products (as defined below) in accordance with the terms and conditions hereinafter set forth.

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained, the parties mutually agree as follows:

Terms

1. **DEFINITIONS.**

- **1.1.** "Affiliates", (a) with respect to Supplier, (i) any corporation, partnership, limited liability company or other entity Controlled by NXP Semiconductors N.V., or (ii) any corporation, partnership, limited liability company or other entity Controlled by any transferee of all or substantially all of the assets of NXP Semiconductors N.V. and (b) with respect to Purchaser, any corporation, partnership, limited liability company or other entity that directly or indirectly Controls, is Controlled by, or is under common Control with, Purchaser. "Control" means direct or indirect beneficial ownership of more than fifty percent (50%) of the voting stock, or decision-making authority in the event that there is no voting stock, in another entity; provided, any such entity shall be deemed to be an "Affiliate" only for so long as such Control exists.
- **1.2.** "Contract Year" shall mean the twelve-month period commencing on the date first set forth above and each consecutive twelve-month period thereafter during the Term of this Agreement.
- **1.3.** "*Hardware Specifications*" shall mean the Supplier's standard performance specifications for the Products [***], each such specification attached hereto on Exhibit F-1.
- **1.4.** "Performance Specifications" shall mean the Purchaser's specifications set forth on Exhibit F-2 attached hereto, as amended from time to time.
- 1.5. "Product(s)" shall mean hardware goods, as more fully described on Exhibit A attached hereto, [***] (as defined below). Exhibit A may be amended by mutual written agreement of the parties to add additional products to this Agreement from time to time, at which point Specifications for such Products will also be attached.
 - **1.6.** "Specifications" shall mean the Hardware Specifications and the Performance Specifications.

2. APPLICABILITY AND TERM OF AGREEMENT.

- 2.1. <u>Applicability.</u> This Agreement governs all Product purchases made by Purchaser from Supplier. [***].
- **2.2.** <u>Term of Agreement</u>. This Agreement shall commence on the Effective Date and will have an initial term [***]. After the initial term, unless earlier terminated in accordance with this Agreement, [***].

3. SALE AND PURCHASE OF THE PRODUCTS.

3.1. <u>Supply Obligation</u>. Subject to the terms hereof, Supplier agrees to sell Purchaser, and Purchaser agrees to buy from Supplier, the Products, pursuant to certain Purchase Orders (as defined below) issued by Purchaser from time to time.

- 3.2. [***].

 a. [***].
- b. <u>Custom Product</u>. [***]. Supplier shall retain title to and possession of designs, masks, database tapes and source code of any Custom Product. Individual segments or parts of Custom Product designs, including but not limited to standard cells, megacells, base arrays or software libraries, are the property of Supplier and may be used by Supplier in other designs and may not be used by Purchaser except as a part of Custom Product designed and manufactured by Supplier.

3.3. Product Changes and Discontinuation.

a. <u>Product Changes</u>. Supplier may not make any changes to standard (off the shelf) Product that impact Product form, fit or function without providing Purchaser at least [***] written notice. Notwithstanding the foregoing, Supplier reserves the right to make at any time changes to the manufacturing location of any Product that will not negatively affect form, fit or function of the Products or the performance characteristics thereof. Changes to Custom Products that impact the location of manufacture, or the form, fit or function, may only be made by Supplier with the prior written consent of Purchaser, such consent will not be unreasonably withheld or delayed.

b. **Product Discontinuation**.

- i. Subject to the terms of Supplier's Product Longevity Program (the "Longevity Program") in effect as of the Effective Date, which are incorporated herein by reference, the details of which are attached hereto as Exhibit G-1, and which can also be found at http://www.nxp.com/about/about-nxp/technology-leadership/product-longevity:PRDCT_LONGEVITY_HM, Supplier reserves the right to discontinue manufacturing and sale
- of Products at any time. Supplier hereby represents that each of the Products on Exhibit A, that affirmatively indicates inclusion on the Longevity Program, are included therein and shall be subject to its terms.
- ii. If at any time during the term of an agreement under which Supplier sells and Purchaser purchases Products on a regular basis, such regularly sold and purchased Products are to be permanently discontinued ("Discontinued Product"), Supplier shall use its commercially reasonable efforts to give Purchaser prior written notice of such discontinuance [***], all in accordance with Supplier's product discontinuation process and general information related thereto in effect as of the Effective Date, which are incorporated herein by reference, the details of which are attached hereto as Exhibit G-2.

iii. [***].

3.4. Forecasting. On a quarterly basis, Purchaser shall deliver to Supplier, a non-binding, rolling [***] forecast of Purchaser's anticipated purchases of Products. Purchaser's initial non-binding forecast for the first Contract Year of the Term is set forth in Exhibit A. Any forecast quantities set forth on Exhibit A or in any future forecast delivered by Purchaser to Supplier represents the good faith estimates of purchases anticipated by Purchaser during the period set forth in the forecast, but do not impose any binding commitment on Purchaser or Supplier in any way.

3.5. Purchase Orders.

a. All purchases of, and the only binding commitment to purchase, Products shall be made by Purchaser submitting to Supplier purchase order forms ("*Purchase Orders*") specifying (i) the number of units of the Products to be purchased, (ii) the Purchaser's carrier to which the Products will be delivered at Supplier's factory, and (iii) the designated delivery dates, unless otherwise mutually agreed to in writing by the parties. Standard lead time for each Product shall be identified on <u>Exhibit A</u>.

b. <u>Higher Level Suppliers</u>.

i. [***].

ii. If Purchaser asserts a claim against Supplier directly for Products sourced through a Higher-Level Supplier, then the provisions of this Agreement are Purchaser's exclusive remedy for those claims, and Purchaser agrees not to also make a duplicative claim (i.e., a claim with the same cause of action) against the Higher-Level Supplier. If Purchaser has raised a claim against a Higher-Level Supplier with respect to matters addressed in this Agreement, Purchaser agrees not to make a duplicative claim (i.e., a claim with the same cause of action) against Supplier except to the extent it is entitled to a different or greater recovery under this Agreement.

c. [***]Supplier will respond to all Purchase Orders issued by Purchaser within a reasonable time after receipt not to exceed [***]. In the event Supplier has a reasonable basis to reject any Purchase Order, Supplier shall inform Purchaser, and Purchaser shall modify such Purchase Order accordingly. Purchase Orders within the requirements of this Agreement shall be deemed accepted only upon confirmation by Supplier.

- **3.6.** Quality Agreement. The Quality Agreement attached hereto as Exhibit C is an integral part of this Agreement. Supplier shall comply with the provisions of Quality Agreement in all respects. If there is any inconsistency between this Agreement and the Quality Agreement, the terms of this Agreement will prevail with respect to any inconsistency in the commercial terms (e.g. pricing, costs and expenses, delivery terms) and the Quality Agreement will prevail with respect to any inconsistency in the quality terms.
- 3.7. <u>Manufacturing and Delivery Commitment</u>. Supplier shall use commercially reasonable efforts to make all deliveries at the time(s) and in the quantity(ies) specified in the Purchase Order [***]. If Supplier fails to deliver the total quantity of Products ordered by Purchaser in any Purchase Order within [***] of the date of delivery specified therein, then, at Purchaser's option, Purchaser may elect to [***].
 - 3.8. [***]

3.9. Inspection; Defective Products. [***]All Products are subject to Purchaser's (or Higher-Level Supplier's, as the case may be) inspection, testing, approval and acceptance, notwithstanding prior payment for such Products or acknowledgment of receipt of packaging slips or bills of lading. Purchaser, in whole or in part, may reject any Product, revoke any acceptance, cancel any Purchase Order, or return any Products, in the event of: (i) a nonconforming delivery of Products, where nonconforming delivery of Products means the number or timing of the delivery does not match the applicable Purchase Order, except in the case of Custom Product, in which case nonconforming delivery with respect to quantity means quantity that is a maximum amount of [***]than the ordered quantity of any order line item; (ii) delivery of Products that are damaged or defective; or (iii) delivery of Products that do not conform to the required Specifications. Products rejected may, at Supplier's discretion, be returned to Supplier at Supplier's expense. If Purchaser receives Products whose defects or nonconformity are not apparent on examination, Purchaser reserves all rights with respect to the nonconformity of the Products. Nothing contained in this Agreement shall relieve Supplier from its obligations otherwise contained in this Agreement or otherwise limit Purchaser's rights to seek damages caused by the delivery of defective or nonconforming Products.

3.10. [***].

- **3.11. Applicability of FDA.** Supplier represents that the Products will not be adulterated or misbranded within the meaning of the Federal Food, Drug and Cosmetic Act (the "Act"), nor are they goods which may not under the provisions of Section 404, 505 or 512 of the Act be introduced into interstate commerce.
- **3.12.** In some cases, Supplier may promote certain Products for use in safety-related applications. Supplier's goal is to educate customers so that they can design their own end-product solutions to meet applicable functional safety standards and requirements. Purchaser makes the ultimate design decisions regarding its products and is solely responsible for compliance with all legal, regulatory, safety, and security related requirements concerning its products, regardless of any information or support that may be provided by Supplier.
- **3.13.** Supplier designates certain products with specific intended uses (e.g., automotive, military and/or military) which such products are designed and intended for use in only those limited circumstances, applications or environments. If Purchaser uses any designated product in a manner other than it has been designated, Purchaser does so at its own risk.

4. PRICE AND PAYMENT/SHIPMENT TERMS.

- **4.1.** Price. The price of Products hereunder is set forth on Exhibit A hereto. Except as expressly set forth otherwise in this Agreement, [***].
- **4.2.** Payment. Unless otherwise agreed by the parties in writing, payment shall be made by Purchaser separately for each shipment of Products. Purchaser shall pay all undisputed invoice amounts in U.S. dollars [***] from receipt of invoice. Supplier will provide Purchaser with written notice of any past due payment. [***]. Payment by Purchaser of non-recurring charges (as may be made to Supplier for special design, engineering work or production materials) shall not convey title to any design, engineering work or production materials, and title shall remain in Supplier.
 - **4.3** Shipping. The Products sold to Purchaser shall be delivered [***]. Title in the Products shall pass to Purchaser [***].

4.4. <u>Tax.</u> Prices are in United States Dollars and do not include any taxes, duties or similar levies, now or hereafter enacted, applicable to the Products. Supplier will add taxes, duties and similar levies to the sales price where Supplier is required by law to pay or collect them and will be paid by Buyer together with the price.

5. INSURANCE.

5.1. Throughout the Term of this Agreement, Supplier shall carry [***]. Upon the request of Purchaser from time to time during the Term, Supplier shall provide Purchaser with a certificate evidencing such insurance coverage.

6. INTELLECTUAL PROPERTY; OWNERSHIP.

- 6.1. <u>Intellectual Property</u>. Each party's intellectual property including without limitation any patents, trade secrets, processes, knowhow, copyrights, trade dress, trademarks and/or trade names shall remain their exclusive property [***], nothing herein shall be construed as transferring any right, title or interest of any kind or nature whatsoever thereto to the other party hereto. Except as specifically provided herein, neither party shall use in any way, the intellectual property of the other party, and will not do any act which would in any way infringe upon or be in derogation of the validity of such other party's intellectual property and will notify the other party of any conflicting claims that challenge any intellectual property of such party that it is aware of.
- **6.2.** No Transfer. Performance Specifications are owned exclusively by Purchaser and nothing herein shall be construed as transferring any right, title or interest of any kind or nature whatsoever thereto to Supplier. Similarly, the Hardware Specifications are owned exclusively by Supplier and nothing herein shall be construed as transferring any right, title or interest of any kind or nature whatsoever thereto to Purchase.

7. CONFIDENTIALITY.

- 7.1. Confidential Information. Any information that a party obtains regarding the other party in connection with this Agreement ("Confidential Information") shall be maintained in confidence by the receiving party and shall not be used by the receiving party or disclosed to a third party except with the disclosing party's prior written consent. The receiving party shall only disclose the other party's Confidential Information to those of its employees who need to know such Confidential Information in order for the receiving party to fulfill its obligations hereunder. Receiving party shall protect disclosing party's Confidential Information as required hereunder using the same degree of care, but no less than a reasonable degree of care, as receiving party uses to protect its own confidential information of a like nature. The confidentiality obligations in this section shall not apply to Confidential Information that (a) becomes public other than through the receiving party, (b) is already known to the receiving party as evidenced by its written records, (c) becomes lawfully known by the receiving party in the future from another source which is under no obligation of confidentiality to the disclosing party, or (d) is subsequently developed by the receiving party in a manner which it can establish was independent of the disclosure hereunder. The obligations of Supplier and Purchaser pursuant to the provisions of this section shall survive termination of this Agreement for a period of five (5) years.
- **7.2.** Required Disclosures. In the event that the recipient of Confidential Information is requested or becomes legally compelled to disclose any of the Confidential Information (whether by oral questions, interrogatories, requests for information or documents, subpoena, civil investigative demand or similar process or otherwise), such recipient party will provide the disclosing party with prompt notice, (unless prohibited by law) to the extent practicable, so that the disclosing party may seek a protective order or other appropriate remedy and/or waive compliance with the provisions of this section related to

confidentiality. In the event that such protective order or other remedy is not obtained, the disclosing party agrees that such disclosure may be made without liability hereunder; provided that the recipient party

- (a) furnishes only that portion of the Confidential Information which the recipient party is, in the opinion of its counsel, legally required to disclose, and (b) uses its reasonable efforts to obtain reliable assurance that confidential treatment will be accorded the Confidential Information.
- **7.3.** Publicity. Neither party hereto shall make, or permit any of their respective directors, officers, employees, agents, advisors, affiliates or representatives to make any press release, public announcement or other public disclosure with respect to the existence of this Agreement or the terms hereof without the prior consent of the other party hereto.

8. LIMITED WARRANTY AND DISCLAIMER.

8.1. Specifications; Quality; Defects.

- a. Supplier hereby represents and warrants that the Products (and not including Excluded Products as defined below) (i) under normal use (as described in section 8.2 below), shall at the time of delivery to Purchaser, or a Higher-Level Supplier as the case may be, and [***] conform to the Hardware Specifications for off the shelf Product, and the [***], and (ii) be free from defects in material and workmanship.
- b. Supplier further represents and warrants that any die or wafer Products [***]. This warranty will not apply to die or wafers improperly removed from their original shipping container, not stored per Supplier's recommended procedures, or subjected to testing or operational procedures not accepted by Supplier in writing.
- **8.2.** Normal Use. Notwithstanding the warranty contained in Section 8.1, Supplier shall have no obligation for breach of warranty if the alleged defect or non-conformance is found to have occurred outside of normal use. For purposes of this Agreement "normal use" shall mean use of the Products as intended; provided, however, that it does not include environmental or stress testing, neglect, improper installation, accident, improper repair, alteration, modification, improper storage, improper transportation or improper handling of the Products, after the risk of loss of the Products has passed to Purchaser.
- **8.3.** Excluded Products. "Excluded Products" mean: (i) prototypes; (ii) Custom Products manufactured and/or delivered prior to both parties' written acceptance of the prototypes thereof; (iii) experimental Products; (iv) beta testing Products; (v) samples of newly developed Products and/or (vi) software that is (a) licensed under open source software license terms, (b) provided by Purchaser or any of its designees to Supplier, (c) modified by Purchaser or any third party, other than at Supplier's request, and/or (d) not embedded in a Product by Supplier. All Excluded Products are provided AS IS WITHOUT WARRANTY OF ANY KIND.
- **8.4.** RMA Process. Purchaser may ship Products returned under warranty claims to Supplier's designated facility only so long as the returns are in conformance with Supplier's then-current return material authorization policy and are accompanied by a completed return material authorization form issued by Supplier, which such return material authorization shall not be unreasonably withheld or delayed by Supplier. Where warranty adjustment is made, Supplier will pay for freight and agreed to testing for defective Product. Purchaser shall pay for returned Products that are not found to be defective or non- conforming together with the freight, testing and handling associated expenses.
- **8.5.** Warranty Remedy. If any Product sold and delivered hereunder fails to conform to the provisions of Section 8.1 above, [***]. An entire lot may be rejected based on appropriate sampling by

Purchaser as set forth in the Quality Agreement. In the case of such rejection of a lot or shipment, all of the units in the lot or shipment shall be considered non-conformant.

- **8.6.** Subject to the exclusions and limitations set forth in Section 11 ("*Limitation of Liability*"), the remedy contained in Section 8.5 states the entire liability of Supplier in connection with supply of defective or non-conforming Products that do not meet the warranty in this Section 8.
- **8.7. DISCLAIMER.** THE EXPRESS WARRANTY GRANTED ABOVE SHALL EXTEND DIRECTLY TO PURCHASER AND NOT TO PURCHASER'S CUSTOMERS, AGENTS OR REPRESENTATIVES. THE EXPRESS WARRANTY GRANTED ABOVE IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE, MERCHANTABILITY, OR NON-INFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS. ALL OTHER WARRANTIES ARE HEREBY SPECIFICALLY DISCLAIMED BY SUPPLIER.
- 9. [***].

 9.1. [***].

 9.2. [***].

 10. [***].

 10.1. [***].

 a. [***].

 b. [***].

10.2. Purchaser Indemnification.

- **a.** Except as provided in Section 10.2(b) below, Purchaser shall defend, indemnify and hold harmless Supplier from and against any damage, cost or expense, including reasonable attorney's fees and disbursements, arising out of any third-party claim resulting from the gross negligence or willful misconduct of Purchaser in the sale, marketing, or distribution of the Products, except to the extent such claim directly relates to the gross negligence or willful misconduct of Supplier.
- b. Purchaser shall indemnify, defend and hold harmless Supplier and Supplier's directors, officers, employees, representatives, agents and assigns from and against any and all liabilities, losses, costs, damages, judgments and expenses (including, without limitation, claims from Supplier's suppliers, all reasonable costs of investigation, and attorney and paralegal fees) arising out of any claim, demand, lawsuit or cause of action for property damage or personal injury (including without limitation, illness, disease, distress, disability and/or death) to any person as a result of the use of Purchaser's device which includes the Product and is classified as "Class III" according to the Food and Drug Administration's classification system, that contains a Product. THE INDEMNIFICATION CONTAINED IN THIS SECTION 10.2(b) IS ENFORCEABLE REGARDLESS OF WHETHER THE CLAIM IS BASED ON PAST, PRESENT OR FUTURE ACTS, CLAIMS OR LEGAL REQUIREMENTS INCLUDING WITHOUT LIMITATION PRINCIPLES OF PRODUCT LIABILITY REGARDLESS OF WHETHER ANY PERSON ALLEGES OR PROVES THE SOLE, CONCURRENT, CONTRIBUTORY OR COMPARATIVE NEGLIGENCE OF

SUPPLIER OR THE SOLE OR CONCURRENT STRICT LIABILITY IMPOSED ON THE SUPPLIER.

10.3. Survival. The indemnification obligations set forth in this section shall survive the expiration or termination of this Agreement.

11. LIMITATION OF LIABILITY.

- 11.1. EXCEPT FOR DAMAGES THAT MAY ARISE OUT OF A BREACH OF SECTION 7 (CONFIDENTIALITY), UNDER PURCHASER'S OBLIGATIONS UNDER SECTION 10.2(b) (INDEMNIFICATION), OR AS A RESULT OF GROSS NEGLIGENCE OR WILLFUL MISCONDUCT, IN NO EVENT SHALL EITHER PARTY BE LIABLE FOR ANY INCIDENTAL, SPECIAL OR CONSEQUENTIAL LOSS, DAMAGE OR EXPENSE (INCLUDING, WITHOUT LIMITATION, LOST PROFITS) DIRECTLY OR INDIRECTLY ARISING FROM A BREACH OF THIS AGREEMENT WHETHER OR NOT SUCH DAMAGES ARE BASED ON TORT, WARRANTY, CONTRACT OR ANY OTHER LEGAL THEORY, EVEN IF SUCH PARTY HAS BEEN ADVISED, OR IS AWARE, OF THE POSSIBILITY OF SUCH DAMAGES.
- 11.2. [***]. The existence of more than one Purchaser claim, or Purchaser claims involving more than one Product, shall not enlarge or extend the above specified limits.
- 11.3. The limitations and exclusions set forth above in this Section 11 shall only apply to the extent permitted by applicable mandatory law.

12. TERMINATION.

- 12.1 <u>Purchaser Termination.</u> Purchaser may terminate this Agreement prior to its scheduled expiration as follows: (a)[***],(b) upon [***]notice in the event that Supplier breaches any of its material obligations under this Agreement, is given notice of the breach, and fails to cure such breach within such [***], or (c) immediately and without notice upon the institution by or against Supplier of insolvency, receivership or bankruptcy proceedings or any proceedings for the settlement of Supplier's debts or upon Supplier making an assignment for the benefit of its creditors, or Supplier's dissolution or ceasing to do business.
- 12.2. <u>Supplier Termination</u>. Supplier may terminate this Agreement prior to its scheduled expiration as follows: (a) upon [***]notice in the event that Purchaser breaches any of its material obligations under this Agreement, is given written notice of the breach, and fails to cure such breach within such [***], or (b) immediately and without notice upon the institution by or against Purchaser of insolvency, receivership or bankruptcy proceedings or any proceedings for the settlement of Purchaser's debts or upon Purchaser making an assignment for the benefit of its creditors, or Purchaser's dissolution or ceasing to do business.
- **12.3. Effect of Termination.** Following the expiration or termination of this Agreement, all further rights and obligations of the parties shall cease, except that the parties shall not be relieved of
- (a) their respective obligations to pay monies due or which become due as of or subsequent to the date of expiration and (b) any other respective obligations under this Agreement which specifically survive or are to be performed after the date of expiration or termination.
 - **12.4.** [***].

13. MISCELLANEOUS.

13.1. Assignment. Neither party shall assign, transfer or otherwise dispose of this Agreement by operation of law or otherwise, in whole or in part, or any of its obligations hereunder, to a third party without the prior written consent of the other party which approval will not be unreasonably withheld or delayed; provided, however, that no such consent shall be required in connection with the assignment of this Agreement to an affiliate of the party who controls, is controlled by or is under common control with the party or the purchaser of all or substantially all of the assets of the assigning party to which this Agreement pertains. [***].

This Agreement shall be binding on all successors and assigns.

13.2. [***].

- 13.3. Force Majeure. If the performance of any obligation under this Agreement is prevented, restricted or interfered with by reason of war, civil commotion, embargo or any other act which is beyond the reasonable control of the party affected (a "Force Majeure Event"), then the party so affected shall, upon giving written notice to the other party, be excused from such performance to the extent of such prevention, restriction or interference. In the event that either party ceases to perform its obligations under this Agreement due to the occurrence of a Force Majeure Event, such party shall as soon as reasonably practical notify the other party in writing of such Force Majeure Event and its expected duration and take all reasonable steps to recommence performance of its obligations under this Agreement as soon as possible. In the event that any Force Majeure Event delays a party's performance for more than ninety (90) days following notice by such party pursuant to this Agreement, the other party may terminate this Agreement immediately upon written notice to such party.
- 13.4. <u>Compliance with Laws</u>. Each party represents that it will comply at all times with all applicable laws, statutes and regulations governing the manufacture, sale and purchase of the Products and the performance of its obligations hereunder, including, but not limited to those pertaining to the U.S. Foreign Corrupt Practices Act.
- 13.5. Export Controls. Each party shall comply with all applicable export and import control laws and regulations including but not limited to the US Export Administration Regulations (including prohibited party lists issued by other federal governments), catch-all regulations and all national and international embargoes. Each party further agrees that it will not knowingly transfer, divert, export or re- export, directly or indirectly, any product, software, including software source code, or technology restricted by such regulations or by other applicable national regulations, received from the other party under this Agreement, or any direct product of such software or technical data to any person, firm, entity, country or destination to which such transfer, diversion, export or re-export is restricted or prohibited, without obtaining prior written authorization from the applicable competent government authorities to the extent required by those laws. This provision shall survive termination or expiration of this Agreement.
- 13.6. Fair Trade Practices. Each Party represents that it currently does and it will continue to comply with all applicable international conventions relating to fair trade practices to which the United States and/or the country where the Products are produced are signatories, such as prohibitions against bribery, participation in secondary and tertiary boycotts, and comparable conventions, as implemented in national law and regulation.
- 13.7. Entire Agreement; Modification. This Agreement constitutes the entire agreement between the parties hereto and supersedes all previous negotiations, agreements and commitments with respect thereto, and shall not be released, discharged, changed or modified in any manner except by instruments signed by duly authorized representatives of each of the parties hereto. If any provision of this Agreement or the application thereof to any party or circumstance shall be declared void, illegal or

unenforceable, the remainder of this Agreement shall be valid and enforceable to the extent permitted by applicable law. In such event, the parties shall use commercially reasonable efforts to replace the invalid or unenforceable provision by a provision that, to the extent permitted by applicable law, achieves the purposes intended under the invalid or unenforceable provision.

- 13.8. Applicable Law. This Agreement, and any claim or controversy relating hereto, shall be governed by and interpreted exclusively in accordance with the laws of the State of New York without giving effect to the conflict of laws principles thereof. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement. Nothing is this Section 13.6 shall be construed or interpreted as a limitation on either Supplier's or Purchaser's right under applicable law for injunctive or other equitable relief or to take any action to safeguard its possibility to have recourse on the other party.
- 13.9. Waivers. No claim or right arising out of or relating to a breach of any provision of this Agreement can be discharged in whole or in part by a waiver, renunciation or delay of the claim or right unless the waiver or renunciation is in writing signed by the aggrieved party. Any failure by any party hereto to enforce at any time any provision under this Agreement shall not be considered a waiver of that party's right thereafter to enforce each and every provision of this Agreement.
- 13.10. <u>Independent Contractors</u>. Nothing contained in this Agreement shall be construed to constitute either party as a partner, employee or agent of the other party, nor shall either party hold itself out as such. Neither party has any right or authority to incur, assume or create, in writing or otherwise, any warranty, liability or other obligation of any kind, express or implied, in the name or on behalf of the other party, it being intended by Purchaser and Supplier that each shall remain an independent contractor responsible for its own actions. Except as otherwise provided herein, each party shall be responsible for its own expenses incidental to the performance of its obligations hereunder.
- 13.11. Notices. All notices and other communications in connection with this Agreement shall be in writing and shall be sent to the respective parties at the following addresses, or to such other addresses as may be designated by the parties in writing from time to time in accordance with this section, by registered or certified air mail, postage prepaid, or by overnight courier service, service fee prepaid, or by telefax with a hard copy to follow via air mail or overnight courier service in accordance with this section.

If to Supplier: NXP USA Inc.,

6501 William Cannon Drive West Austin, Texas 78735

Attn: General Counsel

If to Purchaser: Insulet Corporation

600 Technology Park Drive, Suite 200

Billerica, MA 01821

Attn: VP, Global Procurement

With a copy to: Insulet Corporation

600 Technology Park Drive, Suite 200 Billerica, MA 01821 Attn: General Counsel

13.12. Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed to be an original and all of which together shall be deemed to be one and the same instrument.

13.13. Government Orders.

- **a.** Supplier makes no representations, certifications, or warranties whatsoever about compliance with government or public entity acquisition statutes or regulations, including, without limitation, statutes or regulations that may relate to pricing, quality, origin or content.
- **b.** Products provided in furtherance of these Terms and Conditions have been developed at private expense and are "Commercial Items" as defined in 48 C.F.R. §2.101. Products include commercial "Technical Data," "Computer Software," and/or "Computer Software Documentation," as such terms are used in 48 C.F.R. §§ 12.211 and 12.212 (or 48 C.F.R. §§ 227.7102 and 227.7202, as applicable) and may only be licensed to or shared with U.S. Government end users with the rights as are set forth in this Section. Purchaser agrees that it will not share Products consisting of "Technical Data," "Computer Software," and/or "Computer Software Documentation," with anyone not covered by these Terms and Conditions, including government customers.

SIGNATURE PAGE FOLLOWS

IN WITNESS WHEREOF, the parties have cathe Effective Date.	aused this Agreement to be executed by their re	spective duly authorized representatives as of
INSULET CORPORATION	[***]	
[***]	[***]	
[***]	[***]	
[***]	[***]	
[***]	[***]	

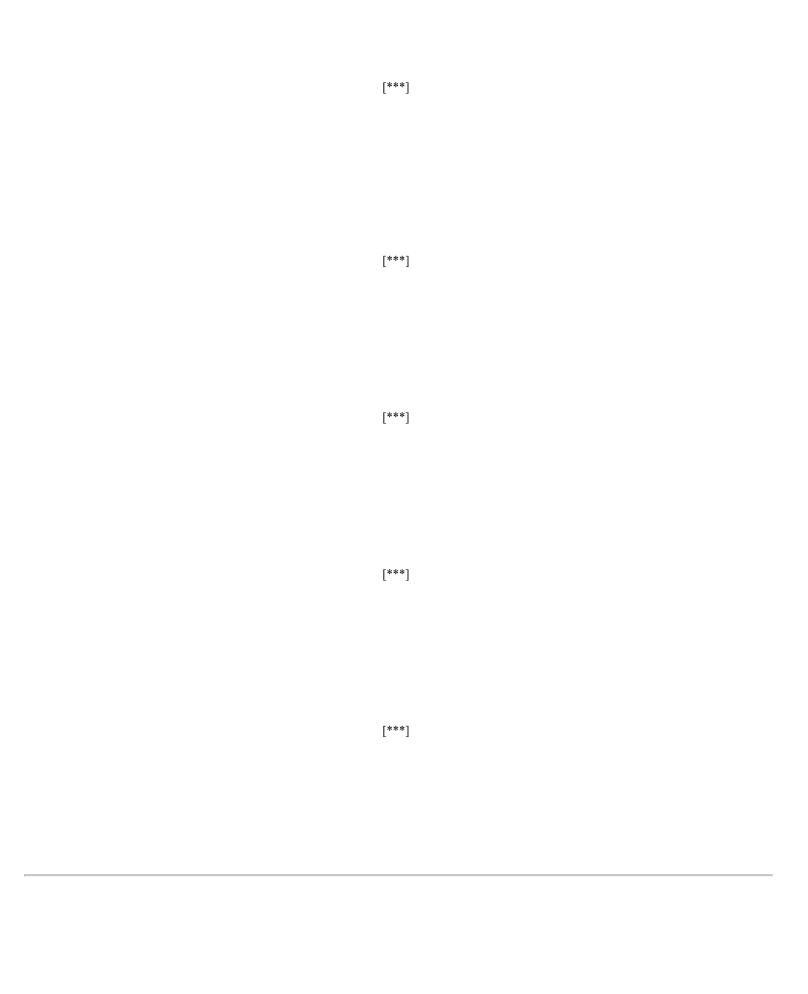


Exhibit A

PRODUCT, PRICING, SPECIFICATIONS, INITIAL FORECAST, LEAD TIME

Exhibit B

FLEXIBILITY TABLE

Exhibit C

QUALITY AGREEMENT

Exhibit D

DISASTER RECOVERY PLAN

Exhibit E

HIGHER LEVEL SUPPLIERS

Exhibit F-1

HARDWARE SPECIFICATIONS

Exhibit F-2

PERFORMANCE SPECIFICATIONS

Exhibit G-1

SUPPLIER'S PRODUCT LONGEVITY PROGRAM

Exhibit G-2

SUPPLIER'S DISCONTINUED PRODUCT PROGRAM

CERTAIN INFORMATION HAS BEEN OMITTED FROM THIS DOCUMENT BECAUSE IT IS (I) NOT MATERIAL AND (II) IS TREATED AS CONFIDENTIAL BY THE COMPANY. OMISSIONS ARE MARKED [***]

AMENDMENT NO. 1 TO PURCHASE AGREEMENT

This Amendment No. 1 to Purchase Agreement (this "Amendment No. 1") is dated as of the 30th day of November, 2019 (the "Amendment Effective Date"), by and between Insulet Corporation, a Delaware corporation, having a place of business at 100 Nagog Park, Acton, Massachusetts 01720 on behalf of itself and its worldwide affiliates ("Purchaser"), and NXP USA, Inc., with an office located at 6501 William Cannon Drive West, Austin, Texas 78735 on behalf of itself and its affiliates ("Supplier").

WHEREAS, Purchaser and Supplier are parties to that certain Purchase Agreement dated as of October 12, 2017 (the "Agreement"); and

WHEREAS, Purchaser and Supplier wish to amend the Agreement as set forth herein, effective as of the Amendment Effective Date.

NOW, THEREFORE, in consideration of these premises, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

- 1. <u>Defined Terms.</u> Capitalized terms used but not defined herein shall have the meanings set forth in the Agreement.
- 2. <u>Exhibit A. Exhibit A</u> of the Agreement is hereby deleted effective as of the Amendment Effective Date and replaced with <u>Exhibit A</u> attached hereto.
- 3. <u>Notices.</u> Section 13.11 of the Agreement is hereby amended so that all notices to Purchaser shall be delivered to the following address: Insulet Corporation, 100 Nagog Park, Acton, MA 01720, Attention: Vice President Procurement, with a copy to Insulet Corporation, 100 Nagog Park, Acton, MA 01720, Attention: Legal Department. All references to Purchaser's office location in Billerica, Massachusetts are hereby deleted and replaced with Purchaser's Acton, Massachusetts address.
- 4. No Other Amendments. Except as modified herein, all other tenns of the Agreement shall remain in full force and effect.
- 5. <u>Conflicts.</u> In the event of a conflict between the Agreement and this Amendment No. 1, this Amendment No. 1 shall govern.
- 6. <u>Counterparts.</u> This Amendment No. 1 may be executed in counterparts, each of which shall be deemed to be an original and all of which together shall be deemed to be one and the same instrument.

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IN WITNESS WHEREOF, the Parties hereto have signed this Amendment No. I as of the Amendment Effective Date.

INSULET CORPORATION

By: <u>/s/ Peter E. Griffin</u>
Name: Peter E. Griffin
Title: VP Global Procurement

Date: 12/18/19

NXP USA, INC.

EXHIBIT A

PRODUCT, PRICING, SPECIFICATIONS, INITIAL FORECAST, LEAD TIME

SUBSIDIARIES OF THE REGISTRANT

Name of Entity State/Country of Organization

Insulet Asia (Singapore) Pte. Ltd. Insulet Austria GmbH Insulet Australia Pty Ltd Insulet Canada Corporation Insulet Consulting (Shenzhen) Co., Ltd.

Insulet France SAS Insulet Germany GmbH

Insulet International Holdings Ltd. Insulet International Ltd.

Insulet MA Securities Corporation

Insulet Malaysia Sdn. Bhd. Insulet Mexico Investments LLC Insulet Mexico, S. de R.L. de C.V.

Insulet Netherlands B.V.

Insulet Netherlands Holdings B.V. Insulet Portugal, Unipessoal Lda Insulet Realty Holdings LLC Insulet Singapore Private Limited Insulet Switzerland GmbH Sub-Q Solutions, Inc.

Singapore Austria Australia Canada China France Germany United Kingdom

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

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our reports dated February 22, 2024, 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, 2023. We consent to the incorporation by reference of said reports in the Registration Statements of Insulet Corporation on Form S-3 (File No. 333-172782) and on Forms S-8 (File No. 333-275271, 333-231860, 333-144636, 333-153176, 333-183166, 333-208387, 333-218125 and 333-208193).

/s/ GRANT THORNTON LLP

Boston, Massachusetts February 22, 2024

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 22, 2024

CERTIFICATION

I, Lauren D. Budden, 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/ Lauren D. Budden

Lauren D. Budden
Interim Chief Financial Officer, Group Vice
President, Chief Accounting Officer and Controller

Date: February 22, 2024

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, 2023, 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 22, 2024

/s/ Lauren D. Budden

Lauren D. Budden Interim Chief Financial Officer, Group Vice President, Chief Accounting Officer and Controller

Date: February 22, 2024

INSULET CORPORATION

COMPENSATION RECOUPMENT POLICY

Recoupment of Incentive-Based Compensation

It is the policy of Insulet Corporation (the "<u>Company</u>") that, in the event the Company is required to prepare an accounting restatement of the Company's financial statements (including any such correction that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period) due to material non-compliance with any financial reporting requirement under U.S. federal securities laws, the Company will recover, on a reasonably prompt basis, the amount of any Incentive-Based Compensation Received by a Covered Executive during the Recovery Period that exceeds the amount that otherwise would have been Received had it been calculated based on the restated financial statements.

Policy Administration and Definitions

This Policy is administered by the Talent and Compensation Committee of the Company's Board of Directors (the "Committee") and is intended to comply with, and as applicable to be administered and interpreted consistent with, and subject to the exceptions set forth in, Listing Rule 5608 adopted by the Nasdaq Stock Exchange ("Nasdaq") to implement Rule 10D-1 under the Securities Exchange Act of 1934, as amended (collectively, "Rule 10D-1").

For purposes of this Policy:

"Incentive-Based Compensation" means any compensation granted, earned or vested based in whole or in part on the Company's attainment of a financial reporting measure that was Received by a person (i) on or after May 23, 2023 and after the person began service as a Covered Executive, and (ii) who served as a Covered Executive at any time during the performance period for the Incentive-Based Compensation. A financial reporting measure is (i) any measure that is determined and presented in accordance with the accounting principles used in preparing the Company's financial statements and any measure derived wholly or in part from such a measure, and (ii) any measure based in whole or in part on the Company's stock price or total shareholder return.

Incentive-Based Compensation is deemed to be "Received" in the fiscal period during which the relevant financial reporting measure is attained, regardless of when the compensation is actually paid or awarded.

"Covered Executive" means any "executive officer" of the Company as defined under Rule 10D-1. This policy shall apply to persons who were Covered Executives during the relevant period but are no longer employees of the Company at the time the determination to recoup compensation is made.

"Recovery Period" means the three completed fiscal years immediately preceding the date that the Company is required to prepare the accounting restatement described in this Policy and any "transition period" as prescribed under Rule 10D-1.

If the Committee determines the amount of Incentive-Based Compensation Received by a Covered Executive during a Recovery Period exceeds the amount that would have been Received if determined or calculated based on the Company's restated financial results, such excess

amount of Incentive-Based Compensation shall be subject to recoupment by the Company pursuant to this Policy. For Incentive-Based Compensation based on stock price or total shareholder return, the Committee will determine the amount based on a reasonable estimate of the effect of the accounting restatement on the relevant stock price or total shareholder return. In all cases, the calculation of the excess amount of Incentive-Based Compensation to be recovered will be determined on a pre-tax basis. Any determinations made by the Committee under this Policy shall be final and binding on all affected individuals.

The Company may effect any recovery pursuant to this Policy by requiring payment of such amount(s) to the Company by setoff, by reducing future compensation, or by such other means or combination of means as the Committee determines to be appropriate.
The Company need not recover the excess amount of Incentive-Based Compensation if and to the extent that the Committee determines
that such recovery is impracticable or not required under Rule 10D-1, including if the Committee determines that the direct expense
paid to a third party to assist in enforcing this Policy would exceed the amount to be recovered after making a reasonable attempt to
recover such amounts. The Company is authorized to take appropriate steps to implement this Policy with respect to Incentive-Based
Compensation arrangements with Covered Executives.

Any right of recoupment or recovery pursuant to this Policy is in addition to, and not in lieu of, any other remedies or rights of recoupment that may be available to the Company pursuant to the terms of any other policy, any employment agreement or plan or award terms, and any other legal remedies available to the Company. The Company shall not indemnify any Covered Executive against the loss of any Incentive-Based Compensation pursuant to this Policy.

This policy shall amend and replace in all respects the Company's existing Policy for Recoupment of Incentive Compensation adopted by the Compensation Committee of the Board of Directors on October 27, 2014.

ADOPTED: May 23, 2023