Risk Factors Comparison 2024-02-23 to 2023-02-24 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text Moved Text Section

Risks Related to Our Business and Industry We currently rely on sales of ~~the~~ **our** Omnipod ~~System, and tailored versions of the Omnipod System in our Drug Delivery~~ product **platform** ~~line,~~ to generate nearly all our revenue. **We** ~~Our main product is the Omnipod System, from which 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 ~~the~~ **our** Omnipod ~~System~~ **products** and to retain consumers who currently use the product. Our sales of ~~the~~ Omnipod ~~System~~ **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 ~~the~~ **our** Omnipod ~~System~~ **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 ~~the~~ Omnipod ~~System~~ **products** by third- party payors; • claims that any portion of ~~the~~ Omnipod ~~System~~ **products** infringes on intellectual property rights of others; • adverse regulatory or legal actions relating to ~~the~~ **our** Omnipod ~~System~~ **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 ~~the~~ Omnipod ~~System~~ **products**; • competitive pricing; **and** • results of clinical studies relating to ~~the~~ Omnipod ~~System~~ **products** or our competitors' products ~~; and • development of an effective patch pump by one or more competitors~~. If any of these events ~~occurs~~ **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 ~~the~~ Omnipod ~~System~~ **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 cannot assure you that~~ we ~~will be~~ **are not** able to successfully develop our relationships with third- party intermediaries ~~. If we fail to do so~~, our sales could fail to grow or could decline, and our ability to grow our business could be adversely affected. Intermediaries that are in the business of selling other medical products may not devote a sufficient level of resources and the support required to generate awareness of our products and grow or maintain **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. ~~We have developed retention programs aimed at both healthcare professionals and consumers, which include appeals assistance, ongoing customer communications, newsletters, support, training, and an automatic re- order program for certain customers. We have had a satisfactory customer retention rate; however, we cannot assure you that we will maintain this retention rate in the future.~~ Current uncertainty in global economic conditions, competition, higher levels of unemployment, changes in insurance reimbursement levels, and negative financial news may negatively affect product demand. If demand for our products fluctuates as a result of economic conditions **, 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** ~~the Omnipod System~~ in a timely manner, which could ~~harm~~ **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 ~~provide~~ **create** challenges ~~to~~ **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. ~~The~~ **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** ~~are currently working to implement~~ **implemented** a new enterprise resource planning system and ~~significantly~~ **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 ~~the~~ **our** Omnipod ~~System~~ **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 ~~the~~ **our** Omnipod ~~System~~ **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 ~~the~~ **our** Omnipod ~~System~~ **products**, which, **for Omnipod 5** ~~in the U. S.~~, occur only through the pharmacy channel **in** ~~for Omnipod 5 and primarily through~~ the ~~pharmacy channel~~ **U. S. and** for Omnipod DASH **, primarily through the pharmacy channel**, will be limited unless a substantial portion of ~~the~~ **their** sales price ~~of the Omnipod System~~ is paid for by third- party payors, including private insurance companies, health maintenance organizations, preferred provider organizations, federal and state government healthcare agencies, intermediaries, Medicare, Medicaid and other managed care providers. In the United States, we currently have contracts establishing reimbursement for ~~the~~ Omnipod ~~System~~ **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 ~~the~~ Omnipod ~~System~~ **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 ~~the~~ Omnipod ~~System~~ **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 ~~the~~ Omnipod ~~System~~ **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 ~~the~~ Omnipod ~~System~~ **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 ~~Omnipod System~~ sales and marketing efforts internationally, we face additional risks associated with obtaining and maintaining reimbursement from foreign healthcare payment systems on a timely basis or at all. Failure to secure or retain adequate coverage or reimbursement for **our products** ~~the Omnipod System~~ by third- party payors could have a material adverse effect on our business, financial condition, and results of operations. Healthcare reform laws could adversely affect our revenue and financial condition. During the past several years, the U. S. healthcare industry has been subject to an increase in governmental regulation at both the federal and state levels. Efforts to control healthcare costs, including limiting access to care, alternative delivery models, and changes in the methods used to determine reimbursement scenarios and rates, are ongoing at the federal and state government levels. It is unclear how the ACA and its implementation, as well as efforts to repeal or replace, or invalidate, the ACA, or portions thereof, will affect our business. Additional legislative changes, regulatory changes, and judicial challenges related to the ACA remain possible. It is possible that the ACA, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future, could have an adverse effect on our industry and on our ability to maintain or increase sales of any of our products. Risks Related to Competition, Product Development and Intellectual Property Our failure to compete effectively would negatively impact our revenue. The competitive landscape in our industry continues to undergo significant change. We compete with companies that produce insulin pumps, such as Medtronic, Tandem, The Ypsomed Group and Roche Diabetes Care, Inc (“ Roche ”). In addition to the established insulin pump competitors, we compete with companies that provide products and supplies for MDI therapy. MDI therapy, including smart pens, can be substantially less expensive than pump therapy, and improvements in the effectiveness of MDI therapy may result in fewer people with insulin- dependent diabetes converting from MDI therapy to pump therapy than we expect, which could result in price pressure and decreased revenue. In addition, some of our competitors, such as Medtronic and Roche, are large, well- capitalized companies with more resources than we have. These companies may have competitive advantages over us, including: • significantly greater name recognition; • different and more complete reimbursement profiles; • established relations with healthcare professionals, customers, and third- party payors; • larger and more established distribution networks; • greater experience in conducting research and development, clinical trials, manufacturing, marketing, and obtaining regulatory approval; and • greater financial and human resources for product development, sales and marketing, and patent litigation. As a result, we may not be able to compete effectively against these companies or their products, which may adversely impact our business. Our current competitors or other companies may at any time develop additional products for the treatment of diabetes. Several companies are working to develop and market new insulin “ patch ” pumps, smart pens, and other methods for the treatment of diabetes. If an existing or future competitor develops a product that competes with or is superior to ~~the~~ **our** Omnipod ~~System~~ **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 ~~the~~ **our** Omnipod ~~System~~ **products** obsolete **or less desirable**. The diabetes treatment market is subject to rapid technological change and product innovation. ~~The~~ **Our** Omnipod ~~System is~~ **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. ~~For example, in 2020 Tandem launched an AID system, with which Omnipod 5 competes directly, and which could negatively impact our business.~~ 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 ~~technological~~ breakthroughs in diabetes monitoring, treatment ~~,~~ or prevention could **reduce the potential market for our products or** render **our products** ~~the Omnipod System~~ obsolete **altogether**, which would ~~have~~ **significantly reduce our sales or cause our sales to grow at** a ~~material adverse effect~~ **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 ~~our business, financial condition, and results~~ **the insulin therapy market. We believe this speculation was the cause** of ~~operations~~ **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 ~~the~~ **our** Omnipod ~~System~~ **products** and ~~its~~ **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 ~~the~~ **our** Omnipod ~~System~~ **products** , we have sponsored, and expect to continue to sponsor market studies to assess various aspects of the ~~Omnipod System's~~ functionality and ~~its~~ relative efficacy **of our products** . The data obtained from the studies may be unfavorable to **our products** ~~the Omnipod System~~ or may be inadequate to support satisfactory conclusions. In addition, in the future we may sponsor clinical trials to assess certain aspects of the efficacy of **our products** ~~the Omnipod System~~ . If future clinical trials fail to support the efficacy of our current or future products, our sales may be adversely affected and we may lose an opportunity to secure clinical preference from prescribing clinicians, which may have a material adverse effect on our business, financial condition, and results of operations. In addition, future clinical studies or articles regarding our existing products or any competing products may be published that either support a claim, or are perceived to support a claim, that a competitor's product is clinically more effective or easier to use than **our products** ~~the Omnipod System~~ or that **our products are** ~~the Omnipod System is~~ not as effective or easy to use as we claim. Additionally, diabetes associations, healthcare providers that focus on diabetes, or other organizations that may be viewed as authoritative could endorse products or methods that compete with **our products** ~~the Omnipod System~~ or otherwise announce positions that are unfavorable to **our products** ~~the Omnipod System~~ . Any of these events may negatively affect our sales efforts and result in decreased revenue. We may be unable to adequately protect our intellectual property rights. Our success depends in part on our ability to develop or acquire commercially valuable intellectual property rights and to protect those rights adequately. We rely on a combination of patents, trade secrets, copyright and trademark laws, confidentiality, non- disclosure and assignment of invention agreements, and other contractual provisions and technical measures to protect our intellectual property rights. Despite these measures, any of our intellectual property rights could be challenged, invalidated, circumvented, or misappropriated. We may not be able to develop additional proprietary technologies that are patentable, and we cannot ensure that our pending patent applications will result in the issuance of patents to us. **To** ~~We also cannot ensure that patents issued to, or licensed by or to, us in the past or in the future will not be challenged or circumvented by competitors. These patents may be found to be invalid or not sufficiently broad to preclude our competitors from introducing technologies similar to those covered by our patents and patent applications. In addition, our ability to enforce and~~ protect our intellectual property ~~rights internationally may be limited in certain circumstances. For example, we may not be able to protect our intellectual property rights effectively in China, where we rely on a third- party contract manufacturer to produce our product. Our efforts to safeguard our unpatented and unregistered intellectual property rights, including requiring employees, consultants, and other third parties to sign confidentiality, non- disclosure, or assignment of invention agreements, may not be successful. The agreements may be breached and trade secrets and other proprietary information could be disclosed to our competitors. Further, we may have inadequate remedies for any breach. In addition, others may independently develop substantially equivalent or superior proprietary information and techniques or gain access to our trade secrets or disclose such technologies. To protect our intellectual property~~ , we may need to assert claims of infringement **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 ~~. We may not prevail in any lawsuits that we initiate~~ , and **we** ~~the damages or other remedies awarded, if any,~~ may not be ~~commercially valuable~~ **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** ~~While not a part of~~

~~our business plans or operations, we~~ have been involved in patent infringement suits in the past ~~, including as disclosed~~ **and may be again** in ~~Note 17 to~~ the **future** ~~consolidated financial statements included in Item 8~~. As our revenue increases, the number of companies with whom we compete grows **,** and the functionality of products and technology in different industry segments overlaps, the risk of third- party infringement claims increases. Third parties may currently have, or may eventually be issued, patents on which our current or future products or technologies may **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 ~~the~~ **Classic** Omnipod ~~are~~ **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 ~~into~~ **with** Omnipod 5. The loss of any of these rights could impair the functionality of **our products** ~~the Omnipod System~~ or prevent us from selling our products without significant development and regulatory activities that may not be completed in time to prevent an interruption in the availability of **our products** ~~the Omnipod System~~ to consumers. This could result in a material adverse effect on our business, financial condition, and results of operations. We also have a partnership with Glooko that allows **our products** ~~the Omnipod System~~ to connect with Glooko' s cloud- based diabetes data management system so that users and healthcare providers can monitor user data, including insulin delivery trends and blood glucose levels. Our agreement with Glooko expires in December 2025. If this agreement is not renewed in the future **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** ~~Our financial condition and results of operations have been and may to continue~~ **continuing** ~~to be adversely affected by~~ **worldwide macroeconomic and geopolitical uncertainty as well as the impact of** the COVID- 19 **or other global** ~~pandemic~~ **pandemics may adversely affect our business** and ~~worldwide~~ **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 ~~issues~~ **growth in the world. Our business and results of operations may be adversely impacted by changes in macroeconomic conditions**, **including** ~~such as~~ inflation **, bank failures, rising interest rates and availability of capital markets**. ~~The COVID~~ **Uncertainty about global economic conditions, particularly in countries with government** - **sponsored healthcare systems** ~~19 pandemic and preventative measures taken to contain or mitigate the outbreak have caused~~, **may also** ~~and to some degree are continuing to~~ cause **decreased demand** ~~, business slowdown or~~ **for our products** ~~shutdown in affected areas, supply chain disruptions, labor shortages, inflation and disruption in the financial markets globally. As a result of the pandemic as well as worldwide economic issues such as inflation~~, consumers may reduce their spending, new orders for our **products** ~~Omnipod System~~ may decline and our user attrition rate may increase, which could have a material adverse effect on our business, sales, financial condition, and results of operations. ~~The~~ **Another global pandemic like** COVID- 19 ~~pandemic also~~ has the potential to significantly impact our supply chain if the manufacturing plants that produce our products or product components, the distribution centers where we manage our inventory, or the operations of our logistics and other service providers, including third parties that sterilize our products, are disrupted, temporarily closed or experience worker shortages for a sustained period of time ~~. Although China, where we manufacture a significant portion of our product, has experienced a recovery and we are currently producing at pre- COVID- 19 levels, further disruption in China could hinder our ability to produce product and have a material adverse effect on our business and results of operations~~. As a result of the COVID- 19 pandemic, many employees have transitioned to a remote or hybrid work environment, which has increased risks associated with our information technology systems and networks. These increased risks include cyber- attacks, computer viruses, disruptions, or shutdowns that could result in a failure to protect our information technology systems and data integrity. ~~The further spread~~ **Another global pandemic or new variants** of COVID- 19, and the requirements to take action to help limit the spread of ~~the~~ illness, ~~may~~ **could** impact our ability to carry out our business as usual. For example, the COVID- 19 pandemic ~~may divert~~ **diverted** healthcare resources away from the conduct of clinical trials and ~~interrupt~~ **interrupted** the operations of the FDA ~~and comparable foreign regulatory agencies~~, which ~~could delay~~ **delayed** product approval timelines, **including** ~~as it did~~ for Omnipod 5. Our financial condition or results of operations may be adversely affected by international business risks. In addition to the United States, we sell **our products** ~~the Omnipod System~~ in Europe, Canada, the Middle East and Australia. Our international operations are subject to risks that are inherent in conducting business under foreign laws, regulations and customs. International sales made up **24** ~~over 25~~ % of our revenues in ~~2022~~ **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** ~~Omnipod Systems~~ are manufactured ~~at~~ **by a** third- party contract manufacturer ~~facility~~ in China. Our efforts to introduce or expand our current or future products in international markets may not be successful, in which case we may have expended significant resources without realizing the expected benefit. Ultimately, the investment required for expansion into international markets could exceed the results of operations generated from this expansion. In addition to the risks discussed elsewhere in this Item 1A, other risks associated with doing business internationally, include: • political instability and actual or anticipated military or political conflicts; • trade protection measures, such as tariff increases, and import and export licensing and control requirements; • negative consequences from changes in or interpretations of tax laws; • difficulty in establishing, staffing, and managing international operations; • difficulties associated with foreign legal systems, including increased costs associated with enforcing contractual obligations in foreign jurisdictions; • adapting to the differing laws and regulations, business and clinical practices, and consumer preferences in international markets; • difficulties in managing international relationships, including any relationships that we establish with foreign partners, distributors, or sales or marketing agents; and • difficulty in collecting accounts receivable and longer collection periods. ~~In addition, in January 2020, the U. K. withdrew from the European Union, commonly referred to as " Brexit ". While the UK and the European Union entered into a Trade and Cooperation Agreement, a number of areas are still unsettled, and it is possible that there could be greater restrictions on imports and exports and on the movement of people between the U. K. and European Union countries as well as increased regulatory complexities.~~ Failure to comply with the U. S. Foreign Corrupt Practices Act and similar worldwide anti- bribery laws could materially adversely affect our business and result in civil and / or criminal sanctions. The FCPA, the U. K. Bribery Act, and similar anti- bribery laws enacted in other jurisdictions generally prohibit companies and their intermediaries from making improper payments to foreign officials for the purpose of obtaining or retaining business. Because of the predominance of government- sponsored healthcare systems around the world, most of our customer relationships outside of the United States are with governmental entities and are therefore subject to such anti- bribery laws. Because we do business in the U. K., the U. K. Bribery Act also extends to our interaction with public and private sector entities and persons outside the U. K., including in the United States. Our policies mandate compliance with these anti- bribery laws. We operate in parts of the world that have experienced governmental corruption to some degree, and in certain circumstances strict compliance with anti- bribery laws may conflict with local customs and practices. Despite our training and compliance programs, our internal control policies and procedures may not always protect us from reckless or criminal acts committed by our employees or agents. Violations of anti- bribery laws, or allegations of such violations, could disrupt our business and have a material adverse effect on our results of operations, financial condition, and cash flows. Risks Related to Supply Chain, Operations, and Drug Delivery Our ~~Omnipod System~~ inventory is produced and maintained in a limited number of locations. ~~Our~~ **While we expect to begin production at our newly constructed** manufacturing ~~of the Omnipod System is conducted~~ **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 ~~U. S. Omnipod System~~ inventory **in the United States** is held at a single location in Massachusetts and our ~~European Omnipod System~~ inventory **in Europe** is maintained by a third- party logistics entity primarily ~~in~~ **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 ~~product~~ **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 ~~Omnipod Systems~~ **our products** in the United States, a third- party contract manufacturer in China **manufactures** ~~performs assembly~~ and supplies a significant portion of ~~all finished Omnipod Systems~~ **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** ~~Omnipod System~~ for delivery of a specific drug other than insulin. Substantially all of our commercialized Drug Delivery revenue consists of sales of a customized version of our product for use in Amgen' s Neulasta Onpro kit under an agreement that expires in December ~~2023~~ **2028** . The marketing and sales initiatives driving this product line differ markedly from those on which we rely for our sales of Omnipod ~~Systems~~ **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** ~~Omnipod System~~ ; • our achievement of satisfactory development and pricing terms with the pharmaceutical companies that sell such drugs; • our development of appropriate modifications to our Omnipod ~~System~~ technology to address the needs and parameters required for the respective drug- delivery opportunities; • manufacturing issues relating to the modified **Pod** ~~Omnipod System~~ ; • long lead- times associated with the development, regulatory approvals, and ramp up applicable to the use of modified **Pods** ~~Omnipod Systems~~ for the delivery of such drugs; • relatively small number of modified **Pods** ~~Omnipod Systems~~ needed to address each drug- delivery opportunity; • uncertainties regarding the market acceptance of such drugs and the modified **Pod** ~~Omnipod System~~ as an appropriate delivery device; • uncertainties relating to the success of the pharmaceutical companies in marketing and selling such drugs as well as the modified **Pods** ~~Omnipod Systems~~ as the appropriate delivery devices; • intense competition in the drug- delivery industry, including from competitors which have substantially greater resources; • ~~demand for non- insulin drugs, including the impact of generics and biosimilars; •~~ maintaining appropriate gross margins; and • regulatory requirements and reimbursement rates associated with such drugs. If we are unsuccessful in overcoming one or more of these challenges, or if our agreement with Amgen is terminated or not renewed, our financial results could be **negatively** ~~materially and adversely~~ impacted. Risks Related to Government Regulation and Litigation We are subject to extensive government regulation, which could restrict the sales and marketing of our products and could cause us to incur significant costs. Our medical device products and operations are subject to extensive regulation by the FDA and various other federal, state, local, and foreign government authorities. Government regulation of medical devices is meant to assure their safety and effectiveness, and includes regulation of, among other things: • design, development and manufacturing; • testing, labeling, and content and language of instructions for use and storage; • clinical trials; • regulatory clearances and approvals, including premarket clearance and approval; • product safety; • advertising and promotion; • marketing, sales, and distribution; • conformity assessment procedures; • product traceability and record keeping procedures; • product complaints, complaint reporting, recalls and field safety corrective actions; • post- market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; • post- market studies; and • product import and export. Before a new medical device, or a significant modification of a medical device, including a new use of or claim for an existing product, can be marketed in the United States, it must first receive **regulatory** ~~either 510 (k)~~ clearance ~~or PMA from the FDA~~ , unless an exemption applies. **Obtaining such regulatory** ~~While we have received 510 (k)~~ clearance ~~for our Omnipod Insulin Management System as well as modified versions of this device, including Omnipod DASH and Omnipod 5, we may be required to obtain a new 510 (k) clearance or PMA for significant further post- market modifications. Obtaining 510 (k) clearance or PMA~~ can be expensive and lengthy **. Delays in obtaining or inability** ~~, and we may not be able~~ to obtain ~~them in a timely fashion or at all. Delays in obtaining~~ future clearances could adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn could harm our revenue and future profitability. We also are subject to numerous post- marketing regulatory requirements, which include quality system regulations related to the manufacture of our devices, labeling regulations, and medical device reporting regulations. The last of these regulations requires us to report to the FDA if our devices cause or contribute to a death or serious

injury, or malfunction in a way that would likely cause or contribute to a death or serious injury if the malfunction recurred. If we fail to comply with present or future regulatory requirements that are applicable to us, we may be subject to enforcement action by the FDA, which may include any of the following sanctions: • untitled letters, warning letters, fines, injunctions, consent decrees, and civil penalties; • customer notification, or orders for repair, replacement, or refunds; • voluntary or mandatory recall or seizure of our current or future products; • administrative detention by the FDA of medical devices believed to be adulterated or misbranded; • operating restrictions, suspension or shutdown of production; • refusing our requests for **regulatory** ~~510 (k)~~ clearance ~~or PMA~~ of new products, new intended uses or modifications to ~~the~~ **our** Omnipod ~~System~~ **products** ; • rescinding ~~510 (k)~~ **, suspending or withdrawing** clearance ~~or suspending or withdrawing PMAs~~ that ~~have~~ **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) ~~approval~~ **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. ~~As part of this effort, the FDA is reviewing the adverse event reporting and recall processes for insulin pumps.~~ Any change in the laws or regulations that govern the clearance and approval processes relating to our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market, and distribute existing products. **We** ~~The Omnipod System is~~ also ~~sold~~ **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 ~~2~~ are required to comply with the FDA’ s QSR, which is a complex regulatory framework that covers the procedures and documentation of the design, testing, production, control, quality assurance, sterilization, labeling, packaging, storage, shipping, and servicing of our devices. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through periodic, sometimes unannounced, inspections by the FDA. We cannot assure you that our facilities or our contract manufacturers’ facilities ~~would~~ **will** pass any future quality system inspection. If our or our contract manufacturers’ facilities fails a quality system inspection ~~, the manufacturing or distribution of our~~ **or** ~~devices~~ **otherwise fails to adhere to QSR requirements, this** could **delay production of** ~~be interrupted, and~~ our ~~operations disrupted.~~ **products and lead to business disruption;** ~~Failure~~ **failure** to take adequate and timely corrective action in response to an adverse quality system inspection **or QSR violation** could ~~force a suspension or shutdown of~~ **result in business disruption; failure to take adequate and timely corrective action in response to an adverse quality system inspection** ~~our~~ **or** ~~labeling operations or the manufacturing operations of our contract manufacturer, or a recall of our devices. If we, or our contract manufacturer, fail to adhere to~~ QSR **violation** ~~requirements, this~~ could **result in** ~~delay production of our products and lead to~~ fines, difficulties in obtaining regulatory clearances, recalls, enforcement actions, including injunctive relief or consent decrees, or other consequences, which could have a material adverse effect on our financial condition or results of operations. Malfunction of our products could lead to recalls or safety alerts **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 ~~, such as our voluntary MDCs issued in October and November 2022,~~ or involuntary, may require the dedication of our time and capital, could distract management from operating our business and potentially harm our reputation and financial results. ~~In the event of a recall, we may also be subject to liability claims, be required to bear other costs, or take other actions that may have a negative impact on our future sales and our ability to generate profits. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA.~~ We may initiate voluntary recalls involving our products in the future that we determine do not require notification to the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls **and** ~~. In addition, the FDA~~ 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 ~~were found to be noncompliant with state DME licensure rules, we could lose our licensure in that state, which could prohibit us from selling our current or future products directly to consumers in that state. Several states require that DME providers be licensed in order to sell products to customers in that state. Certain of these states require, among other things, that DME providers maintain an in- state location. Although we believe we are in compliance with all applicable state regulations regarding licensure requirements, if we were found to be noncompliant, we could lose our licensure in that state, which could prohibit us from selling our current or future products directly to consumers in that state. If we~~ fail to comply with Medicare, Medicaid, fraud and abuse, and other healthcare regulations, we could be subject to substantial penalties and / or be excluded from participation in government programs. Our relationships with customers and third- party payors are subject to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain our sales, marketing, and other promotional activities by limiting the kinds of financial arrangements, including sales programs and certain customer and product support programs, we may have with hospitals, physicians, customers, or other potential purchasers of medical devices. These laws include, among others, the federal healthcare Anti- Kickback Statute, the federal civil False Claims Act, other federal healthcare false statement and fraud statutes, the Open Payments program, the Civil Monetary Penalties Law, and analogous fraud and abuse and transparency laws in most states, as described in " Item 1 — Business — Government Regulation **.** " ~~.~~ We conduct various marketing and product training activities that involve making payments to healthcare providers and entities. While we believe and make every effort to ensure that our business arrangements with third parties and other activities and programs comply with all applicable laws, these laws are complex and our activities may be found not to be compliant with one of these laws, which may result in significant civil, criminal, and / or administrative penalties, fines, damages, and exclusion from participation in federal healthcare programs. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to respond to, and thus could have a material adverse effect on our business, financial condition, and results of operations. Our compliance with Medicare and Medicaid regulations may be reviewed by federal or state agencies, including the OIG, CMS, and the Department of Justice, or may be subject to whistleblower lawsuits under federal and state false claims laws. To ensure compliance with Medicare, Medicaid, and other regulations, government agencies conduct periodic audits of us to ensure compliance with various supplier standards and billing requirements. Risks Related to Privacy and Security We are subject to complex and evolving laws and regulations regarding privacy and data protection, many of which are subject to change and uncertain interpretation, which could result in claims, changes to our business practices, monetary penalties, increased cost of operations, or declines in user growth or engagement, or otherwise harm our business. We are subject to a variety of laws and regulations relating to privacy and data protection, data security, data retention and deletion, personal information, electronic contracts, and other communications. The introduction of new products or expansion of our activities in certain jurisdictions may subject us to additional laws and regulations. For example, data privacy laws at the federal and state levels protect the confidentiality of certain health information and restrict the use and disclosure of that protected information. In particular, the U. S. privacy rules under HIPAA protect medical records and other personal health information by limiting their use and disclosure, giving individuals the right to access, amend, and seek accounting of their own health information, and limiting most use and disclosures of health information to the minimum amount reasonably necessary to accomplish the intended purpose. **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 ~~2023~~ **2024** . These consumer rights include the right to know what personal information is collected, the right to know whether the data is sold or disclosed and to whom, the right to request a company to delete the personal information collected, the right to opt- out of the sale of personal information, and the right to non- discrimination in terms of price or service when a consumer exercises a privacy right. ~~Colorado and Virginia~~ **The California laws** have ~~enacted~~ **served as a model for many subsequently adopted laws in other states. In 2023,** similar privacy laws **became** ~~that will also take effect~~ **effective** in ~~2023~~ **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 data. If we fail to comply with these regulations, we could be subject to civil sanctions, including fines and penalties for noncompliance. In addition, foreign data protection, privacy, and other laws and regulations can be more restrictive than those in the United States. Data localization laws in some countries generally mandate that certain types of data collected in a particular country be stored and / or processed within that country. We could be subject to audits in Europe and around the world, particularly in the areas of consumer and data protection, as we continue to grow and expand our operations. Legislators and regulators may make legal and regulatory changes, or interpret and apply existing laws, in ways that make our products less useful to users, require us to incur substantial costs, expose us to unanticipated civil or criminal liability, or cause us to change our business practices. These changes or increased costs could negatively impact our business and results of operations in material ways. For example, the GDPR imposes requirements in the European Economic Area relating to, among other things, consent to process personal data of individuals, the information provided to individuals regarding the processing of their personal data, the security and

confidentiality of personal data, notifications in the event of data breaches, and use of third- party processors. If we fail to comply with these standards, we could be subject to criminal penalties and civil sanctions, including significant fines and penalties. The increased scope of regulation around the world may require expanded compliance programs and resources. As our efforts to gain insights from data increase for the operation of our products and services and for the improvement of business processes, including sales and marketing, our exposure to increasingly complex privacy regulation may impede our ability to use data in this way. We rely on the proper function, availability, and security of our product and information technology systems and a successful cyber- attack or other breach or disruption of our product or these systems could have a material adverse effect on our business and results of operations. We rely on information technology systems to process, transmit, and store electronic information in our day- to- day operations. The nature of our business involves the receipt and storage of personal and financial information regarding our customers, including sensitive medical information. We use our information technology systems to manage or support a variety of business processes and activities, including sales, shipping, billing, customer service, procurement, supply chain, manufacturing, and accounts payable. In addition, we use enterprise information technology systems to record, process, and summarize transactions and other financial information and results of operations for internal reporting purposes and to comply with financial reporting, legal, and tax regulatory requirements. Many of our information systems are cloud- hosted and managed by third- party vendors, some of which may have access to confidential business, employee, healthcare professional, and / or customer information. Our information technology systems may be susceptible to damage, disruptions, or shutdowns due to computer viruses, attacks by computer hackers, failures during the process of upgrading or replacing software, databases or components thereof, power outages, hardware failures, telecommunication failures, user errors, or catastrophic events. Any failure by us to maintain or protect our information technology systems and data integrity, including from cyber- attacks, intrusions, disruptions, or shutdowns, could result in the unauthorized access to customer data and personally identifiable information, theft of intellectual property or other misappropriation of assets or the loss of key data and information, or otherwise compromise our confidential or proprietary information and disrupt our operations. Additionally, the FDA has warned that insulin pumps may have cybersecurity vulnerabilities and could be manipulated by hackers, causing danger to people with diabetes. After extensive testing and research in conjunction with an independent third- party firm, a potential security vulnerability in ~~the~~ **Classic** Omnipod was identified. ~~(This vulnerability does not exist in Omnipod DASH or Omnipod 5.)~~ Successful exploitation of this vulnerability may allow an attacker to gain access to the Pod to intercept, modify, or interfere with the wireless radio frequency communications to or from the PDM. This may allow attackers to read sensitive data, change pump settings, or control insulin delivery. Insulet is aware of a specific group of people with diabetes who have been able to duplicate the Pod communication protocol using a smartphone and a bridge, which in turn allows the Pod to be controlled using an unauthorized device. This practice is commonly referred to as Do- It- Yourself (DIY) and is not the intended use **with** ~~for the~~ Omnipod ~~System~~ **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. ~~We recently experienced a data security incident impacting a subset of our customers in which the impacted customer' s IP address, and whether the customer was a Omnipod DASH user and has a PDM, were inadvertently shared with website performance and marketing partners of Insulet through website " cookies " and other trackers. These trackers have since been disabled, and no financial information, social security numbers, email addresses, or passwords were exposed. All affected customers and relevant authorities were notified, and we did not view this as a material event.~~ Any future significant compromise or breach of our data security, whether external or internal, or misuse of customer, third- party payor, employee, supplier, or Company data, could result in significant costs, lost sales, fines, lawsuits, and damage to our reputation. In addition, as the regulatory environment related to information security, data collection and use, and privacy becomes increasingly rigorous, with new and constantly changing requirements applicable to our business, compliance with those requirements could also result in additional costs. Risks Related to Our Debt We may not be able to generate sufficient cash flow from operations to service our debt, which is substantial. As of December 31, ~~2022~~ **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 ~~offset taxable income~~ **reduce taxes payable** when a corporation has undergone significant changes in its stock ownership or equity structure. **The** ~~Our ability to use net operating losses may be limited by prior changes in our ownership and may be further limited by the~~ issuance of common stock in connection with the conversion of our Convertible Senior Notes, or ~~by~~ the consummation of other **equity** transactions **could limit** ~~. As a result,~~ our ability to ~~use~~ **utilize** net operating loss **and tax credit** carryforwards to offset **future** U. S. federal **and state taxes payable** ~~taxable income may become subject to limitations~~ . General Risks Our success depends on our ability to attract, motivate, and retain key personnel. Our success depends on our ability to retain our employees and to attract and retain additional qualified personnel in the future. We face intense competition for employees, particularly in light of recent labor shortages and as people are increasingly able to work remotely. We face challenges in maintaining employee well- being, recognizing that the additional financial, family, and health burdens that many employees may be experiencing ~~due to~~ **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 ~~the~~ Omnipod ~~System~~ **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 ~~. Additionally, in December 2022 and February 2023, we acquired intangible assets from Automated Glucose Control LLC (" AGC ") and Bigfoot, which provided us important intellectual property~~ . We may not complete transactions in a timely manner, on a cost- effective basis, or at all, and we may not realize the expected benefits of any acquisition or investment. Even if we are successful in making an acquisition, the products and technologies that we acquire may not be successful or may require significantly greater resources and investments than we originally anticipated. We could also experience negative effects on our results of operations and financial condition from acquisition- related charges, amortization of intangible assets, and asset impairment charges if the acquisitions are not as successful as we originally anticipate. Acquisitions also present risks, uncertainties, and disruptions associated with the integration process, including difficulties in the integration of the operations of any acquired company, integration of acquired technology with our products, and the potential loss of key employees, customers, distributors, or suppliers of the acquired businesses. In addition, integration of an acquired business may require management resources that otherwise would be available for development of our existing business. If an acquired business fails to operate as anticipated or cannot be successfully integrated into our existing business, our stock price, business, financial condition, and results of operations could be materially and adversely affected. Furthermore, we may have to incur debt or issue equity to pay for any future acquisitions or investments, the issuance of which could be dilutive to our existing stockholders. We may need to raise additional funds in the future, and these funds may not be available on acceptable terms or at all. ~~Our capital requirements will depend on many factors, including: • revenue generated by sales of our current products and any other future products that we may develop; • costs associated with capital expenditures, including adding additional manufacturing capacity; • costs associated with any expansion, including expanding our sales and marketing efforts globally; • expenses we incur in manufacturing and selling our products; • costs of developing new products or technologies and enhancements to our products; • costs of complying with regulatory requirements, including obtaining and maintaining FDA approval or clearance of our current or future products; • costs associated with litigation; and • the number and timing of any acquisitions or other strategic transactions.~~ We may in the future seek additional funds from public and private stock or debt offerings, borrowings under credit lines, or other sources, and we may need to raise additional debt or equity financing to repay our outstanding Senior Convertible Notes or other debt obligations. If we issue equity or debt securities to raise additional funds, our existing stockholders may experience dilution, and the new equity or debt securities may have rights,

preferences, and privileges senior to those of our existing stockholders. In addition, if we raise additional funds through collaboration, licensing, or other similar arrangements, it may be necessary to relinquish valuable rights to our potential future products or proprietary technologies or grant licenses on terms that are not favorable to us. Our ability to raise additional capital may be adversely impacted by current economic conditions, including inflation and worldwide political unrest, and we may not be able to raise any necessary capital on acceptable terms, or at all. If we are unable to raise additional capital due to these or other factors, we may need to further manage our operational expenses, including potentially curtailing planned product development activities. In addition, we may not be able to execute our business plan, take advantage of future opportunities, or respond to competitive pressures or unanticipated customer requirements. If any of these events occur, it could adversely affect our business, financial condition, and results of operations. The price of our common stock may be volatile. The market price of our common stock is affected by a number of factors, including factors related to our operating performance as a high- growth company and the operating performance of our competitors. At times, the fluctuations in the market price of our common stock have been unrelated or disproportionate to our operating performance. In particular, the U. S. equity markets have at times experienced significant price and volume fluctuations that have affected the market prices of equity securities of many medical device and technology companies. **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. 27**