

Risk Factors Comparison 2025-02-26 to 2024-02-21 Form: 10-K

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

An investment in our common stock, or in securities convertible into or exchangeable for our common stock, involves a high degree of risk. You should carefully consider the risks described below, together with all of the other information included in this Annual Report, as well as in our other filings with the SEC, in evaluating our business. If any of the following risks actually occur, our business, financial condition, operating results and future prospects could be materially and adversely affected. In that case, the trading price of our common stock may decline and you might lose all or part of your investment. The risks described below are not the only ones we face. Additional risks that we currently do not know about or that we currently believe to be immaterial may also impair our business, financial condition, operating results, liquidity, and future prospects. Certain statements below are forward- looking statements. For additional information, see “ Cautionary Note Regarding Forward-Looking Statements ” at the beginning of this Annual Report and Part II, Item 7, Management’ s Discussion and Analysis of Financial Condition and Results of Operations of this Annual Report. Risks Related to Our Business and Our Industry We have incurred significant operating losses since inception and cannot assure you that we will achieve sustained profitability. Since our inception in January 2006, we have incurred a significant net loss. As of December 31, ~~2023~~ **2024**, we had an accumulated deficit of \$ ~~951.1~~ **8.0** million ~~million~~ **billion**. To date, we have funded our operations primarily through cash collected from product sales, private and public offerings of our equity securities, and debt ~~financing~~ **financings**. We have devoted substantially all of our resources to the design, development and commercialization of our products, the scaling of our manufacturing and business operations, and the research and development of our current products and products under development. Since the first quarter of 2013, we have been able to manufacture and sell our insulin pump products at a cost and in volumes sufficient to allow us to achieve a positive overall gross margin. ~~For the years ended December 31, 2023 and 2022, our gross profits were \$ 367.7 million and \$ 413.0 million, respectively.~~ Although we have achieved a positive overall gross margin during the years ended December 31, **2024**, 2023 and 2022, we had net losses from operations **in those years** of \$ 222.6 million and \$ 94.6 million, ~~respectively~~, and we may continue to incur **net losses from operations** in the future. To implement our business strategy and achieve consistent profitability, we need to, among other things, increase sales of our products and the gross profit associated with those sales, maintain an appropriate customer service, training and support infrastructure, fund ongoing research and development (R & D) activities, create additional efficiencies in our manufacturing processes while adding to our capacity, and obtain regulatory clearance, certification or approval to commercialize our products currently under development both in the United States and the ~~24 more than 25~~ countries outside the United States in which our insulin pumps are available. We expect our expenses will continue to increase as we pursue these objectives and make investments in our business. Additional increases in our expenses without commensurate increases in sales could significantly increase our operating losses. The extent of our future operating losses and the timing of our profitability are highly uncertain in light of a number of factors, including the timing of the launch of new products and product features by us and our competitors, market acceptance of our products and competing products by people with insulin- dependent diabetes, their caregivers and healthcare providers, the timing of regulatory clearance, certification, or approval of our products and the products of our competitors, the actual efficiencies gained in our manufacturing processes, and general economic conditions. Any additional operating losses will have an adverse effect on our stockholders’ equity, and we cannot assure you that we will be able to **achieve and** sustain profitability. We currently rely on sales of insulin pump products to generate a significant portion of our revenue, and any factors that negatively impact sales of these products may adversely affect our business, financial condition and operating results. We generate nearly all of our revenue from the sale of ~~our t- slim X2~~ insulin pumps and the related insulin cartridges and infusion sets. ~~In addition, we including our~~ recently launched ~~our~~ Tandem Mobi insulin pump. Sales of these products may be negatively impacted by many factors, including: • market acceptance of the insulin pumps and related products manufactured and sold by our key competitors, including Insulet, Medtronic, ~~and~~ Ypsomed **and Beta Bionics**; • the potential that breakthroughs for the monitoring, treatment or prevention of diabetes may render our insulin pumps obsolete or less desirable **or reduce the size of our potential market**; • adverse regulatory or legal actions relating to our products, or similar products or technologies of our competitors; • failure of our Tandem Device Updater to accurately and timely provide customers with remote access to new product features and functionality as anticipated, or our failure to obtain regulatory clearance, certification, or approval for any such updates; • changes in reimbursement rates or policies relating to insulin pumps or similar products or technologies by third- party payors; • competitive pricing and attrition rates of consumers who cease using our products; • our inability to enter into contracts with third- party payors on a timely basis and on acceptable terms; • problems arising from the expansion of our manufacturing capabilities and commercial operations, or destruction, loss, or temporary shutdown of our manufacturing facilities; • concerns regarding the perceived safety, reliability or cybersecurity of any of our products, or any component thereof, particularly in connection with the launch of additional mobile app features and functionality and other software products; and • claims that any of our products, or any component thereof, infringes on patent rights or other intellectual property rights of third parties. In addition, sales of any of our current or future insulin pump products with **continuous glucose monitoring (CGM)** integration are subject to the continuation of our applicable agreements with Dexcom, Abbott, or other third parties which, under some circumstances, may be subject to termination, with or without cause, on relatively short notice. Sales of our current or future products may also be negatively impacted in the event of any regulatory or legal actions relating to CGM products that are compatible with our pumps, or in the event of any disruption to the availability of the applicable CGM- related supplies, such as sensors or transmitters, in a given market in which our products are sold. Sales of our products may also be adversely impacted

if the CGM products that are compatible with our pumps are not viewed as superior to competing CGM products in markets where our products are sold, or if the price of these products is not competitive with similar products available in the market. Because we currently rely on sales of our ~~t: slim X2 insulin pump pumps~~, and expect to rely on sales of our ~~Tandem Mobi insulin pump~~, and related products to generate a significant majority of our revenue, any factors that negatively impact sales of these products (or negatively impact the products or components integrated with these products) could adversely affect our business, financial condition and operating results. Furthermore, any disruption in our supply chain could negatively impact our ability to manufacture or otherwise supply sufficient product quantities to meet current customer demand, or any unexpected increase in demand, which could also have the effect of magnifying the negative impact of any of the factors described above - ~~Uncertainty in current global economic and political conditions could adversely affect our ability to predict product demand and impact our financial results. Our operations and performance depend in part on worldwide economic and political conditions. Many of the jurisdictions in which our products are sold have experienced and could continue to experience unfavorable general economic conditions, such as a recession or economic slowdown, which could negatively affect the affordability of, and consumer demand for, our products. Under difficult economic conditions, consumers may seek to modify spending priorities and reduce discretionary spending by delaying purchases of our products, which could reduce our profitability and could negatively affect our overall financial performance. Other financial uncertainties in our major markets and unstable political conditions in certain markets, including civil unrest and governmental changes, could undermine global consumer confidence and reduce consumers' purchasing power, thereby reducing demand for our products. We cannot predict the reoccurrence of any economic slowdown or the strength or sustainability of the economic recovery, worldwide, in the United States, or in our industry. These and other economic factors could have a material adverse effect on our business, financial condition, and results of operations.~~ Our ability to maintain and grow our revenue depends in part on retaining a high percentage of our customer base. A key to maintaining and growing our revenue is the retention of a high percentage of our customers due to the potentially significant revenue generated from ongoing purchases of single- use infusion sets, insulin cartridges and other supplies. In addition, our pumps are designed and tested to remain effective for at least four years and a customer may consider purchasing another product from us when the time comes to replace the pump. We have developed retention programs, ~~including our Tandem Choice Program~~, aimed at our customers, their caregivers and healthcare providers, which include discounts, training specific to our products, ongoing support by our sales and clinical employees, and technical support and customer service. Demand for our products from our existing customers could decline or could fail to increase as anticipated or projected as a result of a number of factors, including the introduction of competing products, breakthroughs for the monitoring, treatment or prevention of diabetes, changes in reimbursement rates or policies, manufacturing problems, perceived safety or reliability issues with our products or components or the products of our competitors, the failure to secure regulatory clearance, certification, or approvals for products or product features in a timely manner or at all, product development or commercialization delays, the impacts and disruption from health epidemics or pandemics, international conflicts, or for other reasons. The failure to retain a high percentage of our customers and increase sales to these customers consistent with our forecasts would have a material adverse effect on our business, financial condition and operating results. ~~We operate in a very competitive industry..... could be materially and adversely affected.~~ Failure to secure or retain adequate coverage or reimbursement for our current ~~products and our potential~~ future products by third- party payors could adversely affect our business, financial condition and operating results. A substantial portion of the purchase price of an insulin pump is typically paid for by third- party payors, including private insurance companies, preferred provider organizations and other managed care providers. Future sales of our current and future products will be limited unless our customers can rely on third- party payors to pay for all or part of the associated purchase cost. Access to adequate coverage and reimbursement for our current and future products by third- party payors is essential to the acceptance of our products by customers. As guidelines in setting their coverage and reimbursement policies, many third- party payors in the United States use coverage decisions and payment amounts determined by the Centers for Medicare and Medicaid Services (CMS), which administers the U. S. Medicare program. Medicare periodically reviews its reimbursement practices for diabetes- related products, and there is uncertainty as to the future Medicare **coverage structure and** reimbursement rate for our products. It is also possible that CMS may continue to review and modify the current coverage and reimbursement of diabetes- related products in connection with anticipated changes to the regulatory approval process for insulin pumps and related products, software applications and services. In addition, third- party payors that do not follow the CMS guidelines may adopt different coverage and reimbursement policies for our current and future products. Further, it is possible that some third- party payors will not offer any coverage for our current or future products. For instance, it is possible that third- party payors may adopt policies in the future that designate one or more of our competitors as their preferred, in- network durable medical equipment provider of insulin pumps and that such policies would discourage or prohibit the payors' members from purchasing our products, which would adversely impact our ability to sell our products. ~~We~~ **are pursuing a multi- channel managed care strategy and have begun offering certain products through the pharmacy channel. However, the commercial opportunity in the pharmacy channel will be limited unless a substantial portion of the sales price for these products is covered 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. Medicare Part D plan sponsors may provide coverage for certain products under the Medicare Part D prescription drug program, which requires negotiating with third- party payors to provide these products through the pharmacy channel in the United States. If our efforts to enter into additional contracts with intermediaries and third- party payors are not successful, our ability to offer Mobi or any future products through the pharmacy channel will be limited.** ~~We~~ currently have contracts establishing reimbursement for our insulin pump products with a number of national and regional third- party payors in the United States. While we may enter into additional contracts both in the United States and the ~~more than 25~~ countries outside the United States in which our insulin

pumps are available through third- party payors, and add coverage for future products under our current agreements, we cannot guarantee that we will succeed in doing so or that the reimbursement contracts that we are able to negotiate will enable us to sell our products on a profitable basis **or in certain channels, including the pharmacy channel**. In particular, we have limited experience securing reimbursement in international markets ~~other than Canada, as that process is managed by local distributors~~. Government involvement in funding healthcare may limit access to or reimbursement for ~~our the Company's~~ products. In addition, existing contracts with third- party payors generally include numerous quality and compliance related requirements, including audit rights, and can be modified or terminated by the third- party payor without cause and with little or no notice to us. Our compliance with the administrative procedures or requirements may result in increased costs for us and delays in processing approvals by those third- party payors for customers to obtain coverage for our products, and any payor audits of our compliance obligations may result in requests for refunds or other costs. Failure to secure or retain adequate coverage or reimbursement for our current and future products by third- party payors, or delays in processing approvals by those payors, could result in the loss of sales, which could have a material adverse effect on our business, financial condition and operating results. Further, the healthcare industry in the United States is increasingly focused on cost containment as government and private insurers seek to control healthcare costs by imposing lower payment rates and negotiating reduced contract rates with third- party payors. If third- party payors deny coverage or reduce their current levels of payment, or if our production costs increase faster than increases in reimbursement levels, we may be unable to sell our products on a profitable basis. We ~~We~~ operate in a very competitive industry and if we fail to compete successfully against our existing or ~~potential future~~ competitors, or if the competitive environment harms our business partners, our financial condition and operating results may be negatively affected. The medical device industry is intensely competitive, subject to rapid change and highly sensitive to the introduction of new products, treatment techniques or technologies, as well as other activities of industry participants. To continue to compete effectively, we must continue to create, invest in or acquire advanced technology, incorporate this technology into our proprietary products, obtain regulatory clearance, certification, or approvals in a timely manner, and manufacture and successfully market our products. Given these factors, we cannot guarantee that we will be able to compete effectively or continue our level of success. Our primary competitors are major medical device companies, primarily Insulet, Medtronic, ~~and Ypsomed~~ **and Beta Bionics**. There are also a number of other companies developing and marketing their own insulin delivery systems and / or related software applications, including insulin pumps and Bluetooth- enabled insulin pens to support MDI therapy. Our primary competitors ~~may~~ enjoy several competitive advantages over us, including: • greater financial and human resources for sales and marketing, product development, customer service and clinical resources; • greater ability to respond to competitive pressures, regulatory uncertainty, or challenges within the financial markets; • established relationships with healthcare providers, third- party payors and regulatory agencies; • established reputation and name recognition among healthcare providers and other key opinion leaders in the medical industry generally and the diabetes industry in particular; • larger and more established distribution networks; • greater ability to cross- sell products or provide incentives to healthcare providers to use their products; and • more experience in conducting R & D, manufacturing, clinical trials, and obtaining regulatory approval or clearance. In addition, the competitive environment in which we operate has resulted and may continue to result in competitive pressures on our manufacturers, suppliers, distributors, collaboration partners and other business constituents. For example, we have entered into development agreements with Dexcom, which provide us **with** non- exclusive licenses to integrate various generations of Dexcom CGM technology with our insulin pump products. Abbott also offers glucose sensors which compete with Dexcom CGMs. ~~We~~ **Further, we have also** entered into ~~an agreement~~ **agreements** with Abbott to develop and commercialize integrated diabetes solutions using Abbott's glucose ~~sensor sensors~~. There can be no assurance that our collaborations with Dexcom and Abbott will be successful or that we will not experience delays, business disputes, or other unanticipated challenges. Competitive pressures within our industry could negatively impact the financial condition of our business partners and impact their ability to fulfill contractual obligations to us, which could negatively impact our product sales, result in delays in obtaining regulatory clearances, certifications, or approvals for new products, harm our reputation, and result in harm to our financial condition and operating results. For these and other reasons, we may not be able to compete successfully against our current or potential future competitors, which could have a material adverse impact on our financial condition and operating results. Competing products, therapeutic techniques or other technological developments and breakthroughs for the monitoring, treatment or prevention of diabetes may render our products obsolete or less desirable **or reduce the size of our potential market**. Our ability to grow our business and achieve our strategic objectives will depend, among other things, on our ability to develop and commercialize products for the treatment of diabetes that offer distinct features and functionality, are easy- to- use, provide superior treatment outcomes, receive adequate coverage and reimbursement from third- party payors, and are otherwise more appealing than available alternatives. Our primary competitors, as well as a number of other companies and medical researchers are pursuing new delivery devices, delivery technologies, therapeutic techniques, sensing technologies, treatment techniques, procedures, drugs and other therapies for the monitoring, treatment and prevention 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, ~~and could result in cause consumers to delay~~ **delayed the purchase purchases of our or products a decline in market share. For example, in 2023 and 2024, ongoing adoption of the GLP- 1 class of drugs in diabetes and news surrounding the expansion of use of GLP- 1 drugs in obesity likely had a negative impact on the insulin therapy market**. Because the insulin- dependent diabetes market is large and growing, we anticipate companies will continue to dedicate significant resources to developing competing products and technologies. The introduction by competitors of products that are or claim to be superior to our products may create market confusion that may make it difficult to differentiate the benefits of our products over competing products. In addition, some of our competitors employ

aggressive pricing strategies, including the use of discounts, rebates, low-cost product upgrades or other financial incentives that could adversely affect sales of our products. If a competitor develops a product that competes with or is perceived to be superior to our products, or if competitors continue to utilize strategies that place downward pressure on pricing within our industry, our sales may decline, our operating margins could be reduced and we may fail to meet our financial projections, which would materially and adversely affect our business, financial condition and operating results. Moreover, we have designed our hardware products to resemble modern consumer electronic devices to address certain **embarrassment-wearability** and functionality concerns consumers have raised with respect to traditional pumps. Similarly, our newer mobile software applications are being designed to incorporate features and functions that are common to other consumer-oriented applications. These consumer industries are themselves highly competitive, and characterized by continuous new product introductions, rapid developments in technology, and subjective and changing consumer preferences. If, in the future, consumers cease to view our products as contemporary or convenient as compared to then-existing consumer technology, our products may become less desirable. **We**

~~The failure of our insulin pumps and related products to achieve and maintain market acceptance could result in us achieving sales below our expectations, which would cause our business, financial condition and operating results to be materially and adversely affected. Our current business and growth strategy is highly dependent on our~~ may face unexpected challenges in marketing and selling our products, and training new customers on the use of our products, which could harm our ability to achieve our sales forecasts. We have limited experience marketing and selling our newer products as well as training new customers on their use, particularly in markets outside of United States. In addition, the vast majority of our existing customers are individuals with type 1 diabetes, and we have limited experience marketing and selling our products to customers with type 2 diabetes. Our financial condition and operating results are and will continue to be highly dependent on our ability to adequately promote, market and sell our insulin pump and related products, and the ability of our diabetes educators to train new customers on the use of our products. If our sales and marketing representatives or diabetes educators are restricted in their ability to interact with healthcare professionals and customers, our sales could decrease or may not increase at levels that are in line with our forecasts. **Our** If we are unable to maintain our existing sales, **and** marketing **efforts**, clinical and customer service infrastructure, we may fail to increase our sales to meet our forecasts. A key element of our business strategy involves ~~our sales, marketing, clinical and customer service personnel driving adoption of our products. We have significantly increased the number of sales, marketing, clinical and customer service personnel employed by us since we began commercial sales. However, we have faced considerable challenges in growing and managing these resources, including with respect to recruiting, training and assimilation of sales territories and new clinical training staff. We expect to continue to face significant challenges as we seek to further increase the number of our sales, clinical and customer service personnel to optimize the coverage of our existing sales territories, as well as expand the number and scope of our existing sales territories. These challenges may be even greater in connection with our commercial expansion outside of the United States, where we have limited experience. Unexpected turnover among our sales, marketing, clinical and customer service personnel, or unanticipated challenges in recruiting additional personnel, would have a negative impact on our ability to achieve our sales projections. Further, if a sales, marketing or clinical representative was to depart and be retained by one of our competitors, we may fail to prevent him or her from helping competitors solicit business from our existing customers, which could adversely affect our sales. Similarly, if we are largely not able to recruit and retain a network of diabetes educators and customer service personnel, we may not be able to successfully train and service new customers, which could delay new sales and harm our reputation. These risks may be greater in the event of general labor shortages in the United States. If we are unable to retain our personnel in line with our strategic plans, we may not be able to effectively commercialize our existing products or products under development, or enhance the strength of our brand, either of which could result in the failure of our sales to increase in line with our projections or cause sales to decline. Our sales and marketing efforts are dependent on independent distributors who are free to market products that compete with our products. If we are unable to maintain or expand our network of independent distributors, our sales may be negatively affected. We believe a majority of our sales within the United States will continue to be to independent distributors for the foreseeable future, and it is possible that the percentage of our sales to independent distributors could increase, particularly in light of our reliance on independent distributors outside of the United States.~~ For example, our dependence upon independent distributors in the United States could increase if third-party payors decide to contract with independent distributors directly in lieu of contracting with us to supply our products to their members directly. Our dependence upon independent distributors could also increase if customers prefer to purchase all of their diabetes supplies through a single source, instead of purchasing pump-related products through us and other diabetes supplies through other suppliers. If we are unable to maintain or expand our network of independent distributors, our sales may be negatively affected. None of our independent distributors in the United States have been required to sell our products exclusively and each of them may freely sell the products of our competitors. As a result, our independent distributors may not devote a sufficient level of resources and the support required to generate awareness of our products and grow or maintain product sales at the levels we expect, which may negatively affect our sales. For the year ended December 31, 2023, two independent distributors each accounted for more than 10% of our worldwide sales. If any of our key independent distributors were to cease to distribute our products or reduce their promotion of our products as compared to the products of our competitors, our sales could be adversely affected. In that case, we may need to seek alternative independent distributors or increase our reliance on our other independent distributors or our direct sales representatives, which may not prevent our sales from being adversely affected. Additionally, to the extent we enter into additional arrangements with independent distributors to perform sales, marketing or distribution services, the terms of the arrangements could result in our product margins being lower than if we directly marketed and sold our products. If the third parties on which we increasingly rely to assist us with our current and anticipated pre-clinical development or clinical trials do not perform as expected, we may not be able to obtain regulatory clearance, certification, or approval or commercialize our products. As our clinical infrastructure expands, we expect to increasingly rely on third parties, such as contract research

organizations, medical institutions, clinical investigators and contract laboratories to conduct some of our current and anticipated pre-clinical investigations and clinical trials. If we are not able to reach mutually acceptable agreements with these third parties on a timely basis, these third parties do not successfully carry out their commitments or regulatory obligations or meet expected deadlines, or the quality or accuracy of the data they obtain is compromised due to the failure to adhere to agreed-upon 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 clearance, certification, or approval for, or successfully commercialize, our products on a timely basis, if at all, and our business, operating results and prospects may be adversely affected. We are dependent on clinical investigators and clinical sites to enroll participants in our current and anticipated clinical trials and human factors studies, and the failure to successfully complete those trials and studies could prevent us from obtaining regulatory clearances, certifications, or approvals for or commercializing our products. As part of our product development efforts, we expect to increasingly rely on clinical investigators and clinical sites to enroll participants in our clinical trials or users in our human factors testing and other third parties to manage such trials and testing and to perform related data collection and analysis. However, we may not be able to control the amount and timing of resources that clinical sites may devote to our clinical trials or other studies. If these clinical investigators and clinical sites fail to enroll a sufficient number of patients, fail to ensure compliance by patients with clinical protocols, or fail to comply with regulatory requirements, we may be unable to successfully complete our clinical trials or other studies, which could prevent us from obtaining regulatory clearances, certifications, or approvals for our products and commercializing our products, which would have an adverse impact on our business. If important assumptions about the potential market for our products are inaccurate, or if we have failed to understand what people with insulin-dependent diabetes are seeking in an insulin pump, our business and operating results may be adversely affected. Our business strategy was developed based on a number of important assumptions about the diabetes industry in general, and the insulin-dependent diabetes market in particular, any one or more of which may prove to be inaccurate or may change over time. For example, we believe that the benefits of insulin pump therapy as compared to other common insulin treatment alternatives will continue to drive growth in the market for insulin pump therapy. In addition, ~~we believe~~ **World Health Organization data indicates that** the incidence of diabetes in the United States and worldwide is increasing. Further, ~~our view is that~~ diabetes management can vary greatly from person to person, creating multiple market segments based on clinical needs and personal preferences. However, each of these assumptions may prove to be inaccurate and limited sources exist to compare treatment alternatives and obtain reliable market data. The actual incidence of diabetes, and the actual demand for our products or competing products, could differ materially from our projections ~~if our assumptions are incorrect~~. In addition, our strategy of focusing exclusively on the insulin-dependent diabetes market may limit our ability to increase sales or achieve profitability. Another key element of our business strategy is using market research to understand what people with diabetes are seeking to improve in their diabetes therapy management. This strategy underlies our entire product design, marketing and customer support approach and is the basis on which we developed our current products and are pursuing the development of new products. However, our market research is based on interviews, focus groups and online surveys involving people with insulin-dependent diabetes, their caregivers and healthcare providers, which represent only a small percentage of the overall insulin-dependent diabetes market. As a result, the responses we receive may not be reflective of the broader market and may not provide us **with** accurate insight into the desires of people with insulin-dependent diabetes. In addition, understanding the meaning and significance of such market research responses necessarily requires that analysis be conducted and conclusions be drawn. We may not be able to perform an analysis that yields meaningful results, or the conclusions we draw from the analysis could be misleading or incorrect. Moreover, even if our market research has allowed us to better understand the features and functionality consumers are seeking in an insulin pump to improve management of their diabetes therapy, there can be no assurance that consumers will actually purchase our products or that our competitors will not develop products with similar features. **Any concerns regarding the safety** ~~We expect to face complexities frequently encountered by companies in competitive and~~ **efficacy of** rapidly evolving markets, which may make it difficult to evaluate our **products could limit** business and forecast our future sales and **cause unforeseen negative effects** operating results. We operate in a competitive and rapidly evolving market. Important industry changes, such as FDA approval and the launch of new products by our competitors, as well as changes specific to our business, such as the timing of our launch of new products currently in development, increasing reliance on digital health products and connected devices, and our potential expansion of commercial sales in international markets, combine to make it more difficult for us to predict our future sales and operating results, as well as our expected timeframe to achieve profitability. In assessing our business prospects, you should consider **and financial results. Studies to evaluate** these ~~the safety~~ factors as well as the various risks and difficulties frequently encountered by companies in competitive and rapidly evolving markets, particularly those companies that manufacture and sell medical devices. These risks include our ~~or effectiveness~~ ability to: • implement and execute our business strategy; • manage and improve the productivity of our **latest** sales, marketing, clinical and customer service infrastructure to grow sales of our existing and proposed products **in a controlled setting are only available over the past few years. As a result**, and enhance our ability to provide service and support to our customers; • achieve and maintain market acceptance of our products and increase awareness of our brand among people with insulin-dependent diabetes, their caregivers and healthcare providers; • **comply may not be familiar** with familiar with our studies and may be slower to adopt or recommend our products. Further, even with data from controlled studies third-party payors may not be willing to provide coverage or reimbursement for our products. We remain subject to regulatory and product liability risks, and these and other factors could slow the adoption of our products and result in our sales being lower than anticipated. In addition, future studies or clinical experience may indicate that treatment with our products is not superior to treatment with competing products. Such results could slow the adoption of our products and significantly reduce our sales, which could prevent us from achieving our forecasted sales targets or achieving or sustaining profitability. If the results of clinical studies or other experience, such as our monitoring or investigation of customer

complaints, indicate that our products may cause or create an unacceptable risk of unexpected or serious complications or other unforeseen negative effects, we could be required to inform our customers of these risks or complications or, in more serious circumstances, we could be subject to mandatory product recalls, suspension or withdrawal of clearance, certification, or approval from regulatory authorities or Notified Bodies, product recalls or seizure, operating restrictions, interruption of production, fines, civil penalties and criminal prosecution which could result in significant legal liability, harm to our reputation, **and a decline in broad range of regulatory requirements within a highly regulated industry**; • enhance our manufacturing capabilities, increase production of products- **product sales. Any alleged illness** efficiently while maintaining quality standards, and adapt our- **or injury** manufacturing facilities to the production of new products; • respond effectively to competitive pressures and developments; • enhance our existing products and develop proposed products; • manage cybersecurity and other technological risks associated with **any of our products** our- **or** expanding portfolio of digital health products- **product** ; **recalls may negatively impact our financial results** and align these products to **business prospects depending on a number of factors** dynamic threat landscape; • obtain and maintain regulatory clearance, certification **including the scope and seriousness of the problem** , **degree of publicity, reaction of** or our approval to **enhance customers and healthcare professionals, competitive response, and consumer perceptions generally**. Even if such an **allegation our- or product liability claim lacks merit, cannot be substantiated, is unsuccessful or is not fully pursued, the negative publicity surrounding any assertion that our products have caused or carry a risk of causing illness, injury or death could adversely affect our reputation with customers, healthcare professionals, third- party payors, and** existing products and **potential collaborators** commercialize proposed products; • perform clinical trials and other studies with respect to our existing products and proposed products; and • attract, retain and **could adversely affect** motivate qualified personnel in various areas of our business. As a result of these or **our** other risks, we may not be able to execute key components of our business strategy, and our business, financial condition and operating results **and cause a decline in our stock price.** **Furthermore, general concerns regarding the perceived safety or reliability of any of our products, or any component thereof,** may **suffer have a similar adverse effect on us** . Our ability to achieve profitability will depend, in part, on our ability to reduce the per- unit cost of our products while also increasing production volume. We believe our ability to reduce the per- unit cost of our insulin pumps and related products will have a significant impact on our ability to achieve profitability. Our cost of sales includes raw materials and component parts, labor costs, product training expenses, freight, reserves for expected warranty costs, royalties, scrap and charges for excess and obsolete inventories. It also includes manufacturing overhead costs, including expenses relating to quality assurance, manufacturing engineering, material procurement and inventory control, facilities, equipment, information technology and operations supervision and management. Our warranty reserve requires a significant amount of judgment and is primarily estimated based on historical experience. Recently released versions of our pump may not incur warranty costs in a manner similar to previously released pumps and the launch of our mobile app also may result in unanticipated changes in historical trends. If we are unable to increase our production volumes while sustaining or reducing our overall cost of sales, including through arrangements such as volume purchase discounts, negotiation of pricing and cost reductions with our suppliers, more efficient training programs for customers, improved warranty performance or fluctuations in warranty estimates, it will be difficult to reduce our per- unit costs and our ability to achieve profitability will be constrained. In addition, the per- unit cost of our products is significantly impacted by our overall production volumes, and any factors that prevent our products from achieving market acceptance, cause our production volumes to decline, alter our product mix, result in our sales growing at a slower rate than we expect, or result in the closure of our manufacturing facilities, would significantly impact our expected per- unit costs, which would adversely impact our gross margins. Further, we may not achieve **the** anticipated improvements in manufacturing efficiency as we undertake actions to expand our manufacturing capacity. We are also subject to other general market and economic conditions that may increase our expenses, including unpredictable variability in commodity prices, wage increases and inflation. If we are unable to effectively manage our overall costs while increasing our production volumes and lowering our per- unit costs, we may not be able to achieve or sustain profitability, which would have an adverse impact on our business, financial condition and operating results. Manufacturing risks may adversely affect our ability to manufacture products, which could negatively impact our sales and operating margins. Our business strategy depends on our ability to manufacture our current and proposed products in sufficient quantities and on a timely basis to meet consumer demand, while adhering to product quality standards, complying with regulatory requirements and managing manufacturing costs. We are subject to numerous risks related to our manufacturing capabilities, including: • quality or reliability defects in product components that we source from third- party suppliers; • our inability to secure product components in a timely manner due to shipping delays at ports of entry or exit, the impact of natural disasters, global conflicts, health pandemics or other issues, in sufficient quantities and on commercially reasonable terms; • difficulty identifying and qualifying alternative suppliers for components in a timely manner; • implementing and maintaining acceptable quality systems while experiencing rapid growth; • our failure to increase production of products to meet demand; • our inability to modify production lines and expand manufacturing facilities to enable us to efficiently produce future products or implement changes in current products in response to consumer demand or regulatory requirements; • our inability to manufacture multiple products simultaneously while utilizing common manufacturing equipment; • government- mandated or voluntary closures of, or operational limitations impacting, our manufacturing facilities; and • potential damage to or destruction of our manufacturing equipment or manufacturing facilities. As demand for our products increases, and as the number of our commercial products expands, we will have to invest additional resources to purchase components, hire and train employees, and enhance our manufacturing processes and quality systems. We may also increase our utilization of third parties to perform contracted manufacturing services for us, and we may need to acquire additional custom designed equipment to support the expansion of our manufacturing capacity. In addition, although we expect some of our products under development to share product features and components with our current products, manufacturing of these products may require modification of our production lines,

hiring of specialized employees, identification of new suppliers for specific components, qualifying and implementing additional equipment and procedures, obtaining new regulatory clearances, certifications, or approvals, or developing new manufacturing technologies. Ultimately, it may not be possible for us to manufacture these products at a cost or in quantities sufficient to make these products commercially viable. ~~We continue to monitor factors that could negatively impact our supply chain, such as shortages of semiconductors and copper that are needed to manufacture our insulin pumps and accessories and custom components for our insulin pumps and cartridges where we rely on a limited number of qualified suppliers. If we continue to experience these or similar manufacturing challenges, or if these challenges worsen in the future, it could have a negative impact on product sales and harm our reputation.~~ If we and our suppliers fail to increase our production capacity to meet consumer demand while also maintaining product quality standards, obtaining and maintaining regulatory clearances, certifications, or approvals, and efficiently managing costs, our sales and operating margins could be negatively impacted, which would have an adverse impact on our financial condition and operating results. We depend on a limited number of third-party suppliers for certain components and products, and the loss of any of these suppliers, their inability to provide us with an adequate supply of components or products, or our inability to adequately forecast customer demand, could harm our business. We currently rely, and expect to continue to rely, on third- party suppliers to supply components of our current products and our potential future products, including our single- use insulin cartridges. For example, we rely on plastic injection molding companies to provide plastic molded components, electronic manufacturing suppliers to provide electronic assemblies, and machining companies to provide machined mechanical components. We also purchase all of our infusion sets and pump accessories from third- party suppliers. For our business strategy to be successful, our suppliers must be able to provide us with components and products in sufficient quantities, in compliance with regulatory requirements and quality control standards, in accordance with agreed- upon specifications, at acceptable costs and on a timely basis. Although we have long- term supply agreements with many of our suppliers, these agreements do not include long- term capacity commitments. Under most of our supply agreements, we make purchases on a purchase order basis and have no obligation to buy any given quantity of components or products until we place written orders, and our suppliers have no obligation to manufacture for us or sell to us any given quantity of components or products until they accept an order. In addition, our suppliers may encounter problems that limit their ability to manufacture components or products for us, including financial difficulties, damage to their manufacturing equipment or facilities, inability to obtain raw materials or other components, or problems with their own suppliers. If we fail to obtain sufficient quantities of high- quality components to meet demand on a timely basis, we could lose customer orders, our reputation may be harmed, and our business could suffer. We generally use a small number of suppliers for our components and products, some of which are located outside the United States, including in China, Mexico and Costa Rica. Depending on a limited number of suppliers exposes us to risks, including limited control over costs, including tariffs, availability, quality and delivery schedules. Moreover, in some cases we do not have long- standing relationships with our manufacturers and may not be able to convince suppliers to continue to make components available to us unless there is demand for such components from their other customers. As a result, there is a risk that certain components could be discontinued and no longer available to us at acceptable prices, or at all. We have in the past been, and we may in the future be, required to make significant “ last time ” purchases of component inventories that are being discontinued by the manufacturer to ensure supply continuity. If any one or more of our suppliers cease to provide us with sufficient quantities of components in a timely manner or on terms acceptable to us, we would have to seek alternative sources of supply. We **consistently evaluate** ~~are actively pursuing~~ alternative suppliers of several existing components and qualifying new alternatives to existing select components, but there is no assurance that we will be able to identify alternative sources that meet our requirements and at comparable prices, or at all. Because of factors such as the proprietary nature of our products, our quality control standards and applicable regulatory requirements, we cannot quickly engage additional or replacement suppliers for some of our critical components. Failure of any of our suppliers to deliver products at the level our business requires could harm our reputation and limit our ability to meet our sales projections, which could have a material adverse effect on our business, financial condition and operating results. We place orders with our suppliers using our forecasts of customer demand, which are based on a number of assumptions and estimates, in advance of purchase commitments from our customers. As a result, we incur inventory and manufacturing costs in advance of anticipated sales, which sales ultimately may not materialize or may be lower than expected. If we overestimate customer demand, we may experience higher inventory carrying costs and increased excess or obsolete inventory, which would negatively impact our results of operations. By the same token, if we underestimate future demand, we may be unable to meet future production requirements, **or** our inventory of critical materials may be below our targeted stocking levels. We expect it will be particularly difficult to accurately forecast demand during the global pandemic and even for some time while travel and social- distancing restrictions are lifted. We may also have difficulty obtaining components from other suppliers that are acceptable to the FDA or other **comparable foreign** regulatory authorities, or Notified Bodies, and the failure of our suppliers to comply with regulatory requirements could expose us to regulatory action including warning letters, product recalls, termination or interruption of distribution, operating restrictions, product seizures, delays in obtaining approval or clearance of future products, suspension or withdrawal of approvals, clearances, or certification, fines, civil penalties, or criminal prosecution. Such a failure by our suppliers could also require us to cease using the components, seek alternative components or technologies, and modify our products to incorporate alternative components or technologies, which could necessitate additional regulatory clearances, certifications, or approvals. Any disruption of this nature, or any increased expenses associated with any such disruption, could negatively impact our ability to manufacture our products on a timely basis, in sufficient quantities, or at all, which could harm our commercialization efforts and have a material adverse impact on our operating results. Any disruption at one of our facilities could adversely affect our business and operating results. Although we operate in multiple locations, most of our current operations are still conducted in San Diego, California, including our final pump assembly, some manufacturing processes, and the majority of our research and development, management and administrative functions. In addition, the majority of our

inventories of component supplies and finished goods is stored at two facilities in San Diego. We take precautions to safeguard our facilities and data infrastructure, including by acquiring insurance, employing back-up generators, adopting health and safety protocols, implementing cybersecurity protections, and utilizing off-site storage of computer data. However, vandalism, terrorism, unplanned power outages, cyberattacks or a natural disaster, such as an earthquake, fire or flood, or other catastrophic event, could damage or destroy our manufacturing equipment or our inventories of component supplies and finished goods, cause substantial delays in our operations, result in the loss of key information, result in reduced sales, and cause us to incur additional expenses. Our insurance coverage may not be sufficient to provide coverage with respect to the damages incurred in any particular case, and our insurance carrier may deny coverage with respect to all or a portion of our claims. Regardless of the level of insurance coverage or other precautions taken, damage to our facilities may have a material adverse effect on our business, financial condition and operating results. We may not experience the anticipated operating efficiencies of our manufacturing and warehousing operations. We continue to scale our business operations and add manufacturing requirements for products currently under development. We have outsourced the majority of our t: slim cartridge manufacturing demand to an experienced third-party contract manufacturer ~~We may consider~~ **and consistently evaluating the** outsourcing **of** other aspects of our operations ~~in the future~~. If we fail to achieve the operating efficiencies that we anticipate, our manufacturing and operating costs may be greater than expected, which would have a material adverse impact on our operating results. In addition, we or our third-party contract manufacturers may encounter problems during manufacturing for a variety of reasons, including failure to follow specific protocols and procedures, failure to comply with applicable regulations, equipment malfunction, component part supply constraints and environmental factors, any of which could delay or impede our ability to meet customer demand and have a material adverse impact on our business, financial condition and operating results. Further, because of the custom nature of our cartridge manufacturing process and product components, and the highly regulated nature of our products overall, in the event of any problems with a contract manufacturer, we may not be able to quickly establish additional or alternative arrangements. We expect that the management and support of our facilities, increasing reliance on third-party contract manufacturers and the increase of our manufacturing volumes will place significant burdens on our management team, particularly in areas relating to operations, quality, regulatory, facilities and information technology. We may not be able to effectively manage our ongoing manufacturing operations and we may not achieve the operating efficiencies that we anticipate, either from our own facilities or from our use of contract manufacturing. Further, additional increases in demand for our products may require that we further expand our business operations, which may require that we obtain additional facilities, make additional investments in capital equipment or increase our utilization of third-party contract manufacturing. **Any concerns regarding the safety and efficacy..... a similar adverse effect on us.** We may enter into collaborations, licensing arrangements, joint ventures, strategic alliances or partnerships with third parties that may not result in the development of commercially viable products or the generation of significant future revenues. In the ordinary course of our business, we may enter into collaborations, licensing arrangements, joint ventures, strategic alliances or partnerships to develop proposed products or technologies, pursue new markets, or protect our intellectual property assets. We may also elect to amend or modify similar agreements that we already have in place. Proposing, negotiating and implementing collaborations, licensing arrangements, joint ventures, strategic alliances or partnerships may be a lengthy and complex process, and may subject us to business risks. For example, other companies, including those with substantially greater financial, marketing, sales, technology or other business resources, may compete with us for these opportunities, or may be the counterparty in any such arrangements. We may not be able to identify or complete any such collaboration in a timely manner, on a cost-effective basis, on acceptable terms or at all. In addition, we may not realize the anticipated benefits of any such collaborations that we do identify and complete. In particular, these collaborations may not result in the development of products or technologies that achieve commercial success or result in positive financial results ~~or~~ may otherwise fail to have the intended impact on our business. Additionally, we may not be in a position to exercise sole decision-making authority regarding a collaboration, licensing or other similar arrangement, which could create the potential risk of creating impasses on decisions. Further, our collaborators and business partners may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals. It is possible that conflicts may arise with our collaborators and other business partners, such as conflicts concerning the achievement of performance milestones, or the interpretation of significant terms under any agreement, such as those related to financial obligations, termination rights or the ownership or control or other licenses of intellectual property rights. If any conflicts arise with our current or future collaborators, they may act in their self-interest, which may be adverse to our best interest, and they may breach their obligations to us. In addition, we have limited control over the amount and timing of resources that our current collaborators, such as Dexcom and Abbott, or any future collaborators devote to our arrangement with them or our future products. Disputes between us and our current, future or potential collaborators may result in litigation or arbitration which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements are contractual in nature and may be terminated or dissolved under the terms of the applicable agreements and, in such event, we may not continue to have rights to the products relating to such transaction or arrangement or may need to purchase such rights at a premium. For example, we have entered into multiple development and commercialization agreements with Dexcom, which provide us non-exclusive licenses to integrate various currently available and future generations of Dexcom's CGM technology with our insulin pump products. Under certain circumstances, these agreements may be terminated by either party without cause or on short notice. Our current agreements with Dexcom do not grant us rights to integrate future generations of Dexcom CGM technology, beyond G7 CGM devices, with any of our current or future products. Termination of any of our agreements with Dexcom would require us to redesign certain current products and products under development, and attempt to integrate an alternative CGM system into our insulin pump systems, which would require significant development and regulatory activities that could result in an interruption or substantial delay in the availability of the product to our customers. The termination of our existing commercial agreements with Dexcom would disrupt our ability to commercialize our existing products and our

development of future products, which could have a material adverse impact on our financial condition and results of operations, negatively impact our ability to compete and cause our stock price to decline. **Modifications to our business strategy or restructuring of our operations could lead to higher costs or otherwise impact the profitability of our business or the value of our assets. As changes occur in our business environment, we have adjusted, and may continue to adjust, our business strategies.** We may also decide depend on the knowledge and skills of our senior management and other key employees, and if we are unable to **further restructure** retain and motivate them or our operations recruit additional qualified personnel, our **specific** business may suffer **functions, or assets**. We have **However, any new structure and strategies may not deliver the expected** benefited **benefits** substantially from the leadership and performance of our senior management, **such as supporting** well as certain key employees. For..... be able to retain our personnel or **our growth objectives** attract new, qualified personnel. In addition, adoption of new work models and requirements about when or how often employees work on site or remotely may present new challenges. As certain jobs and employers increasingly operate remotely, competition for **or enhancing shareholder value** talent may change in ways that cannot be fully predicted at this time. Moreover, we may need to increase employee wages, equity incentives, and benefits to attract and retain our personnel, which would increase our expenses. It may be difficult to continue to incentivize employees with meaningful equity incentives while limiting the use of the share reserve under our current long-term incentive plans. The loss of the services of certain members of our senior management or key employees could prevent **prove less effective than** or our previous approach. Additionally delay the implementation and completion of our strategic objectives, **external factors, including evolving technology, shifting consumer behaviors, acceptance of** or our products divert management's attention to seeking qualified replacements, and **macroeconomic changes**, any general labor shortages could also negatively impact our ability to expand and scale functions that are needed to support the ongoing development of our products and the future growth of our business. Each member of senior management, as well as the vast majority of our employees may terminate employment without notice and without cause or good reason. The members of our senior management are not subject to non-competition agreements. Accordingly, the adverse effect resulting from the loss of certain members of senior management could be compounded by our inability to prevent them **the value** from competing with us. We may seek to grow our business through acquisitions of products or **our assets**, technologies, or investments in businesses, and the failure to successfully manage these **These changes** acquisitions or investments, or the failure to integrate them with our **or events** existing business, could have a material adverse effect on our business, financial condition and operating results. From time to time, we may **lead** consider opportunities to acquire or invest in other companies, products or technologies that may enhance our product platform or technology, expand the breadth of our markets or customer base, or otherwise advance our business strategies. Potential and completed acquisitions and investments involve numerous risks, including: • problems assimilating, maintaining or operating the acquired products or technologies; • issues maintaining uniform standards, procedures, controls and policies; • unanticipated costs, liabilities, impairment charges or write-offs associated with acquisitions **adjusting** or our investments; • diversion of management's attention from our existing business **strategy**; • risks associated with entering new markets in which we have limited or no experience; and • increased legal and accounting costs relating to the acquisitions or to comply with regulatory requirements or other compliance matters. We do not know if we will be able to identify future acquisitions or investments we deem suitable, whether we will be able to successfully complete any such acquisitions or investments on favorable terms or at all, or whether we will be able to successfully integrate any acquired products or technologies into our business. Our potential **potentially necessitate writing down asset values** inability to integrate any acquired products or technologies effectively may adversely affect our business, operating results and financial condition.

Risks Related to Our International Operations Commercializing our products outside of the United States may result in a variety of risks associated with international operations that could materially adversely affect our business. Our sales in the approximately **25-24** countries in which our products are offered outside the United States, which accounted for approximately **26-28** % of our total sales during **2023-2024**, are accompanied by certain financial and other risks related to international business markets, including: • local product preferences and differing regulatory requirements for product clearances, certifications, or approvals; • differing U. S. and foreign medical device import and export rules; • more restrictive privacy and security laws relating to personal information of end- users and employees, including GDPR and other E. U. Member State national legislation; • reduced protection for our intellectual property rights in certain countries outside the **U.-S.-United States compared to the protection than that** exists in the **United States U.-S.-**; • unexpected changes in tariffs, trade barriers and regulatory requirements; • economic weakness, including inflation and workforce instability, and political instability in foreign economies and markets; • compliance with tax, employment, immigration and labor laws, such as the Foreign Corrupt Practices Act and comparable foreign legislation; • difficulties associated with foreign legal systems, including increased costs associated with enforcing contractual obligations in foreign jurisdictions; • political instability and actual or anticipated military or political conflicts; • difficulties in managing international relationships, including any relationships that we establish with foreign partners, distributors, or sales or marketing agents; • foreign taxes, including withholding **of and** payroll taxes; • different reimbursement systems; and • foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country. In addition, entry into international markets may require significant financial resources, impose additional demands on our manufacturing, quality, regulatory, customer support and other general and administrative personnel, and could divert management's attention from managing our core business. We have limited experience with regulatory environments and market practices internationally, and we may not be able to penetrate or successfully operate in new markets. If we are unable to expand internationally, **effectively transition to direct sales in certain European countries**, manage the complexity of our global operations successfully or if we incur unanticipated expenses, we may not achieve the expected benefits of this expansion and our financial condition and results of operations could be materially and adversely impacted. Failure to obtain any required regulatory authorization, clearance or certification in foreign jurisdictions will prevent us from marketing our products in international markets. We sell our products in **certain**

approximately 25 countries outside the United States and may seek to begin commercial sales of our products in additional geographies in the future. As we continue to expand our operations outside of the United States and launch new products, we are increasingly subject to additional regulatory and legal requirements in the international markets. These additional legal and regulatory requirements may result in our incurring significant costs and expenditures. We have limited experience complying with applicable laws and regulations in international markets generally, and in particular when we enter new markets, and if we are not able to comply with any such requirements, our international expansion and business could be significantly harmed. 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.

Because Risks Related to Our Indebtedness We have incurred a significant amount of indebtedness, and the agreements governing such indebtedness subject us to required debt service payments, as well as financial and operational covenants, any of which may restrict our financial flexibility and affect our ability to operate our business. From time to time, we have financed our liquidity needs under various credit arrangements and we may borrow additional funds in the future. For example, in May 2020, we completed the offering of \$ 287. 5 million aggregate principal amount of 1. 50 % Convertible Senior Notes due 2025 (the 2025 Notes), which are governed by the terms of an indenture (the 2025 indenture). In March 2024, we completed the offering of \$ 316. 3 million aggregate principal amount of 1. 50 % Convertible Senior Notes due 2029 (the 2029 Notes and, together with the 2025 Notes, the Notes), which are governed by the terms of an indenture (the 2029 indenture and, together with the 2025 Notes, the indentures). In March 2024, we used the proceeds from the offering of the 2029 Notes to repurchase approximately \$ 246. 7 million aggregate principal amount of the 2025 Notes in privately negotiated transactions with holders of the 2025 Notes and as of December 31, 2024, we had approximately \$ 40. 8 million aggregate principal amount of the 2025 Notes outstanding. The Notes are our senior unsecured obligations, and interest on the Notes is payable global our sales and profits may fluctuate or decline in cash semi- annually at a response to changes in foreign currency exchange rates- rate of 1 or other international risks. 50 Activities outside the United States accounted for approximately 26% of per year. Our failure to comply with certain obligations under the Notes, our- or total sales during 2023. Foreign currency fluctuations inability to make required debt service payments, could result in volatility of our revenue. In addition, we are exposed to transaction risk because we incur some of our sales and- an expenses in currencies event of default under other-- the relevant indenture than the U. A default S. dollar. Our most significant currency exposures are to the Canadian dollar, if the Euro and Swiss franc, and the exchange rates between these currencies and the U. S. dollar may fluctuate substantially. We do not cured actively hedge our- or waived exposure to currency rate fluctuations. The strengthening of the U. S. dollar would likely negatively impact our results. We price some of our products in U. S. dollars, and thus changes in exchange rates can make our products more expensive in some offshore markets and reduce our sales. Inflation could result in acceleration of also make our products more expensive and increase the indebtedness, credit risks to which we are exposed. Future foreign currency fluctuations could favorably or unfavorably impact and increase the volatility of our revenue, profitability, and stock price. These and other risks may have a material adverse effect on our business, financial condition and liquidity. Further, if our indebtedness is accelerated, we cannot be certain that cash will be available to pay the indebtedness and we may not have the ability to refinance the indebtedness on terms satisfactory to us or at all. In addition, our current or future level of indebtedness could affect our business, operations and strategy in several important ways, including the following: • we may be required to dedicate a portion of our current liquidity or cash flow from operations to interest payments, limiting the availability of cash for other purposes; • covenants contained in future agreements governing indebtedness may limit our ability to borrow additional funds, refinance indebtedness or make certain investments; • debt covenants may affect our flexibility in planning for, and reacting to, changes in the economy and our industry; • a high level of indebtedness may increase our vulnerability to adverse economic and competitive conditions; and • a high level of indebtedness may limit our ability to obtain additional financing in the future or negatively impact the terms on which additional financing may be obtained. Servicing the Notes will require a significant amount of cash, and we may not have sufficient cash flow from our business to repay the Notes. Our ability to make scheduled payments of the principal and interest on the Notes, or to refinance the Notes depends on our future business operations and liquidity, which are subject, to numerous risks and uncertainties, including, market acceptance of our products, regulatory clearance, certification, or approval for our products, and the competitive environment in which we operate. Our business may not generate or sustain a level of cash flow from operations sufficient to service the Notes and any future indebtedness we may incur. If we are unable to generate sufficient cash flow, we may be required to adopt one or more alternatives, such as reducing or delaying capital expenditures, selling or licensing assets, refinancing indebtedness, or obtaining additional equity capital. Our ability to successfully engage in these activities will depend on a number of factors, including the value of our assets, our operating results and financial condition, the value of regulations are more stringent than current legal be correlated to an increase in

the market price and volatility of our ~~common stock~~ or regulatory requirements common stock. In addition, upon a default by an option counterparty, we may ~~experience increased compliance burdens and costs~~ suffer more dilution than we currently anticipate with respect to ~~meet the regulatory obligations as well as adverse impacts on raw material sourcing, manufacturing operations and the distribution of our products~~ common stock. Risks Related to Our Future Financings and Financial Results We may need or otherwise determine to raise additional funds in the future and if we are unable to raise additional funds when necessary or desirable, we may not be able to achieve our strategic objectives. As of December 31, ~~2024~~ 2023, we had \$ ~~438~~ 467 . ~~3~~ 9 million in cash, cash equivalents and short-term investments. Our management expects the continued growth of our business, including the expansion of our customer service infrastructure to support our growing base of customers, our plans to continue expanding commercial operations ~~may~~ incur or other financial commitments we may make in connection with current and potential new acquisitions, investments, business or commercial collaborations, development agreements or licensing arrangements; and • general and administrative expenses. As a result of these and other factors we may in the future seek capital from public or private offerings of our equity or debt securities, or from other sources. If we issue equity or debt securities to raise additional funds, our existing stockholders may experience dilution, we may incur significant financing or debt service costs, 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 collaborations, licensing, joint ventures, strategic alliances, partnership arrangements 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. If we are unable to raise additional capital when necessary, we may not be able to maintain our existing sales, marketing, clinical and customer service infrastructure, enhance our current products or develop new products, take advantage of future opportunities, respond to competitive pressures, changes in supplier relationships, or unanticipated changes in customer demand. Any of these events could adversely affect our ability to achieve our strategic objectives, which ~~could~~ as a whole. Our operating results, and the variability of these operating results, will be affected by numerous factors, including: • our ability to commercialize and sell our current and future products and our ability to increase sales and gross profit from our products, including insulin pumps and the related insulin cartridges and infusion sets; • the number and mix of our products sold in each quarter; • acceptance of our products by people with insulin-dependent diabetes, their caregivers, healthcare providers and third-party payors; • the pricing of our products and competing products, including the use of discounts, rebates or other financial incentives by us or our competitors; • the effect of third-party coverage and reimbursement policies; • our ability to maintain our existing infrastructure; • the amount of, and the timing of the payment for, insurance deductibles required to be paid by our customers and potential customers under their existing insurance plans; • interruption in the manufacturing or distribution of our products, including as a result of our anticipated initiation of direct sales in select European countries beginning in 2026; • our ability to simultaneously manufacture multiple products that meet quality, reliability and regulatory requirements; • seasonality and other factors affecting the timing of purchases of our products; • timing of new product offerings, acquisitions, licenses or other significant events by us or our competitors; • results of clinical research and trials on our existing and future products; • the ability of our suppliers to timely provide us with an adequate supply of components that meet our requirements for product quality and reliability; • regulatory clearances, certifications, or approvals, or adverse regulatory or legal actions, affecting our products or those of our competitors; and • the timing of revenue and expense recognition associated with our product sales pursuant to applicable accounting standards. In addition, we expect our operating expenses will continue to increase as we expand our business, which may exacerbate the quarterly fluctuations in our operating results. If our quarterly or annual operating results fall below the expectation of investors or securities analysts, the price of our common stock could decline substantially. Further, any quarterly or annual fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially, and these price fluctuations could result in further pressure on our stock price. We believe quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance. **Risks Related to Privacy and Security We may be subject to stringent and evolving U.S.** Risks Related to Macroeconomic Conditions and External Factors Uncertainty in current global economic and political conditions could adversely affect our ability to predict product demand and impact our financial results and makes it more likely that our actual results could differ materially from expectations. Our operations and performance depend in part on worldwide economic and political conditions. Many of the jurisdictions in which our products are sold have experienced and could continue to experience unfavorable general economic conditions, such as a recession or economic slowdown, including as a result of political instability and military hostilities in certain geographies, concerns over the potential downgrade of ~~United States~~ U.S. sovereign debt and continued sovereign debt, monetary and financial uncertainties in Europe and other geographies, and domestic and global inflationary trends, any of which could negatively affect the affordability of, and consumer demand for, our products. Under difficult economic conditions, consumers may seek to modify spending priorities and reduce discretionary spending by delaying purchases of our products, which could reduce our profitability and could negatively affect our overall financial performance. Other financial uncertainties in our major markets and unstable political conditions in certain markets, including civil unrest and governmental changes, could undermine global consumer confidence and reduce consumers' purchasing power, thereby reducing demand for our products. We cannot predict the reoccurrence of any economic slowdown or the strength or sustainability of the economic recovery, worldwide, in the United States, or in our industry. These and other economic factors could have a material adverse effect on our business, financial condition, and results of operations. In October 2023 **Changes in U. S. trade policy**, Hamas initiated ~~including the imposition of tariffs~~ an and attack against Israel, provoking a state of war and the ~~resulting~~ risk of a larger regional conflict. While we cannot predict the broader consequences, these conflicts and retaliatory and counter-retaliatory actions could materially adversely affect ~~global~~ our business, financial condition, and operating results. Based on the complex relationships between the United States and certain foreign countries, there is inherent risk that political, diplomatic and national security influences might lead to trade, ~~disputes and impacts and / or disruptions to our operations.~~ There is ~~currency~~

currently significant uncertainty about the future relationship between the United States, Mexico, Canada and China including potential exchange-- changes with respect to trade policies, rates treaties, inflation tariffs, taxes regional economies, and other limitations on cross- border operations. We import various components, subcomponents and finished products from both Mexico and China and any changes in tariffs, trade barriers, and other regulatory requirements could have and- an the global economy adverse effect on our business, financial condition and operating results, the extent of which cannot be predicted with certainty at this time in turn may disrupt sales through our local distributor in Israel. Public health threats, epidemics, or pandemics could have a material adverse effect on our operations, the operations of our business partners, and the global economy as a whole. Public health threats and other highly communicable diseases and outbreaks could adversely impact our operations, the operations of our customers, suppliers, distributors and other business partners, as well as the healthcare system in general. For example, certain development activities, such as human factors studies associated with our product development efforts and activities supporting the manufacturing scale- up for new products and the recruitment of participants in ongoing clinical studies, may be modified or delayed due to impacts of public health threats, which could our development timelines and regulatory strategies. These delays could have a negative impact on our product commercialization efforts and the future demand for our products. In addition to the foregoing impacts, disruptions from outbreaks or epidemics, could result in delays in or the suspension of our manufacturing operations, research and product development activities, regulatory work streams, clinical development programs and other important commercial functions. In particular, if we or our third- party manufacturers are required to delay or suspend our manufacturing operations, we may encounter severe product shortages, which would adversely affect our results of operations and harm our reputation. We are also dependent upon our third- party suppliers for many of our product components and for our manufacturing- related equipment, and the incidence of disease could have a material adverse impact on the operations of our suppliers, which could prevent them from timely delivering products to us or supporting our requirements for manufacturing- related equipment. The full extent of the impact of potential future public health threats on our business and operations is subject to change and will continue to depend on a number of factors, including the scope and duration of the pandemic and any resulting changes to general economic conditions in the countries in which we operate and sell our products. **Because** Climate change or our other extreme weather conditions and related regulations may have a long- term impact on our business. Climate- related events, including the increasing frequency of extreme weather events and their impact on the U. S., Mexico, Canada, and other major regions' critical infrastructure along with potential related regulations, have the potential to disrupt our business, our third- party suppliers, and/ or the business of our customers. For example, our third- party contract manufacturers are located in regions subject to natural disasters, including earthquakes, hurricanes, floods, fires and other catastrophic events. We strive to partner with organizations that mitigate their business risks associated with climate change. However, we recognize that inherent risks related to climate change, other extreme weather conditions and related regulations exist wherever global business is **global** conducted. While these dangers currently have a low- assessed risk of disrupting our normal business operations, they pose a potential long- term impact on our business. Although it is difficult to predict and adequately prepare to meet the challenges to our business posed by climate change, if new laws or our regulations are more stringent than current legal....., our plans to continue expanding commercial sales of and profits may fluctuate our- or products- decline in response to changes in foreign currency exchange rates or other international risks. Activities outside of the United States, the growth accounted for approximately 28 % of our manufacturing and warehousing operations, and the increase total sales during 2024. Foreign currency fluctuations could result in volatility of our revenue facility footprint to accommodate additional headcount and R- & D activities, will continue to increase our expenses. In addition, the amount we are exposed to transaction risk because we incur some of our future product sales is difficult to predict and actual expenses in currencies other than the U. S. dollar. Our most significant currency exposures are to the Canadian dollar, the Euro and Swiss franc, and the exchange rates between these currencies and the U. S. dollar may fluctuate substantially. We do not actively hedge our exposure to currency rate fluctuations. The strengthening of the U. S. dollar would likely negatively impact our results. We price some of our products in U. S. dollars, and thus changes in exchange rates can make our products more expensive in some offshore markets and reduce our sales may not be in line with our forecasts. Accordingly, **Inflation** could also make our products more expensive and increase the credit risks to which we are exposed. future Future capital requirements will depend on many factors, including: • foreign currency fluctuations could favorably or unfavorably impact and increase the volatility of our revenue generated by sales of our products, profitability, as well as the gross profits and gross margin we realize from such sales; • the costs associated with maintaining and expanding an and stock price. These appropriate sales, marketing, clinical and customer service infrastructure; • expenses associated with developing and commercializing our proposed products or technologies, including capital expenditures we make to maintain or enhance our manufacturing operations and distribution capabilities; • the cost of obtaining and maintaining regulatory clearance, certification, or approval for our products and our manufacturing facilities, and of ongoing compliance with other risks legal and regulatory requirements; • expenses we incur in connection with current or future litigation or governmental investigations; • expenses we may incur or other financial commitments we may..... achieve our strategic objectives, which could have a material adverse effect on our business, financial condition and operating results of. Our operating operations results may fluctuate significantly from quarter to quarter. There has been and may continue to be meaningful variability in our operating results from quarter to quarter, as well as within each quarter, especially around the time of anticipated new product launches or regulatory clearances, certifications, or approvals by us or our competitors, and as a whole. The effects of inflation could adversely affect our business. Inflation has the potential to negatively impact our liquidity, business, financial condition, and results of operations by increasing our overall cost structure. The presence of inflation in the economy has led to, and may continue to lead to, higher interest rates, increased capital costs, supply shortages, and rising labor, component, manufacturing, and shipping costs, along with weaker exchange rates and other similar effects. As a result of, we have experienced, and may continue to

experience, higher costs. While we may implement measures to mitigate inflation's impact, if these commercial launch of measures prove ineffective, our products in geographies outside business, financial condition, results of operations, and liquidity could be significantly harmed. Even if these measures are successful, there may be a delay between the implementation of these actions and their effect on our operations, compared to when the inflationary costs are incurred.

Risks Related to Privacy and Security We may be subject to stringent and evolving United States. Our operating results, and the..... stringent and evolving U. S. and foreign laws, regulations, and rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences. In the ordinary course of business, we process personal data. Our data processing activities may subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal data privacy and security policies, and contractual requirements. **A** There are a number of U. S. laws in the United States governing govern the privacy and security of personal data, including data breach notification laws, data privacy laws, consumer protection laws (e. g., Section 5 of the Federal Trade Commission Act), and other similar laws at the federal and state levels (e. g., wiretapping laws). For example, the United States U. S.-Health Insurance Portability and Accountability Act of 1996 ("HIPAA") as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), imposes specific requirements relating to the privacy of protected health information. As another example, the Controlling the Assault of Non-Solicited Pornography and Marketing Act of 2003 ("CAN-SPAM") and the Telephone Consumer Protection Act of 1991 ("TCPA") impose specific requirements on communications with customers. **Numerous** For example, the TCPA imposes various consumer consent requirements and other restrictions on certain telemarketing activity and other communications with consumers by phone, fax or text message. TCPA violations can result in significant financial penalties, including penalties or criminal fines imposed by the Federal Communications Commission or fines of up to 1,500 U. S. Dollars per violation imposed through private litigation or by state authorities. In recent years, numerous U. S. states — including California, Virginia, Colorado, Connecticut, and Utah — have enacted comprehensive data privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. These state laws also allow for statutory fines for noncompliance. For example, under as per the California Consumer Privacy Act of 2018 (CCPA), as amended by the California Privacy Rights Act of 2020 (CPRA) (collectively, "CCPA"), noncompliance may carry fines of up to \$7,500 U. S. Dollars per intentional violation; the CCPA also allows private litigants affected by certain data breaches to recover significant statutory damages. While these laws generally exempt some data processed in the context of clinical trials and data governed by HIPAA, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us, the third parties upon whom we rely, and our customers. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. Outside the United States, an increasing number of laws, regulations, and industry standards govern data privacy and security. For example, the European Union's General Data Protection Regulation ("EU GDPR"), the United Kingdom's General Data Protection Regulation ("UK GDPR") (collectively, "GDPR"), and Canada's Personal Information Protection and Electronic Documents Act ("PIPEDA") or the applicable provincial alternatives, impose strict requirements for processing personal data. For example, under the GDPR, companies may face temporary or definitive bans on personal data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR / 17.5 million Pounds Sterling under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. In Canada, PIPEDA and various related provincial laws, as well as Canada's Anti-Spam Legislation ("CASL"), may apply to our operations. Additionally, regulators are increasingly scrutinizing companies that process children's data. Numerous laws, regulations, and legally binding codes, such as the Children's Online Privacy Protection Act ("COPPA"), California's Age Appropriate Design Code (effective in July 2024), the CCPA, and other U. S. state comprehensive data privacy laws, the GDPR govern, and the UK Age Appropriate Design Code, impose various obligations on companies that process processing of children data, including requiring certain consents to process such data and extending certain rights to children and their parents with respect to that personal data. Some of these obligations have wide-ranging applications, including for services that do not intentionally target child users (defined in some circumstances as a user under the age of 18 years old). These laws may be, or in some cases have already been, subject to legal challenges and changing interpretations, which may further complicate our efforts to comply with these laws. Our employees and personnel may use Artificial Intelligence ("AI") technologies (including generative AI) to perform their work. The use and disclosure of personal data in AI technologies is subject to various data privacy laws and other data privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use AI, it could make our business less efficient and result in competitive disadvantages. The development and use of AI/Machine Learning ("ML") technologies present various data privacy risks that may impact our business. AI/ML are subject to data privacy laws, as well as increasing regulation and scrutiny. Several jurisdictions around the globe, including the European Union and certain U. S. states, have proposed or enacted, or are considering, laws governing the development and use of AI/ML. For example, European regulators have proposed a stringent AI regulation, and we expect other jurisdictions will adopt similar laws. Additionally, certain data privacy laws extend rights to consumers (such as the right to delete certain personal data) and regulate automated decision-making, which may prove to be incompatible with our desired

uses of AI/ML. These obligations may make it harder for us to conduct our business using AI/ML, require us to change our business practices and/or retrain our AI/ML, prevent or limit our use of AI/ML, or lead to regulatory fines or penalties. For example, the FTC has required other companies to turn over (or disgorge) valuable insights or trainings generated through the use of AI/ML where they allege the company has violated data privacy and consumer protection laws. If we cannot use AI/ML or that use is restricted, our business may be less efficient, or we may be at a competitive disadvantage. We may be subject to new laws governing the privacy of consumer health data. For example, Washington's My Health My Data Act ("MHMD") broadly defines consumer health data, places restrictions on processing such data (including imposing stringent requirements for consent), provides consumers certain rights with respect to their health data, and creates a private right of action to allow individuals to sue for violations of the law. Other states are considering and may adopt similar laws. Additionally, under various privacy laws and other obligations, we may be required to obtain certain consents to process personal data. For example, some of our data processing practices may be challenged under wiretapping laws, if we obtain consumer information from third parties through various methods, including chatbot and session replay providers, or via third-party marketing pixels. These practices may be subject to increased challenges by class action plaintiffs. Our inability or failure to obtain consent for these practices could result in adverse consequences, including class action litigation and mass arbitration demands. In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring certain data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA) and the UK have significantly restricted the transfer of personal data to the United States and other countries whose data privacy laws it deems inadequate. Other jurisdictions may adopt **or have already adopted** similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement/Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant organizations based in the United States who self-certify and participate in the Framework), these mechanisms are subject to legal challenges. If these legal challenges change or invalidate these transfer mechanisms, there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful mechanism for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered **Additionally, under various privacy laws and other obligations, we may be required to obtain** certain companies **consents** to **process** suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer obligations. Additionally, in May 2023, the Irish Data Protection Commission determined that a major social media company's use of the standard contractual clauses to transfer personal data **. For example, some of our data processing practices may be challenged under wiretapping laws, if we obtain consumer information from Europe third parties through various methods. These practices may be subject to increased challenges by class action plaintiffs. Our inability or failure to obtain consent for the these United States was insufficient practices could result in adverse consequences, including class action litigation and mass arbitration demands** levied a 1.2 billion Euro fine against the company and prohibited the company from transferring EU personal data to the United States. In addition to data privacy laws, we are contractually subject to industry standards adopted by industry groups. For example, we are subject to the Payment Card Industry Data Security Standard ("PCI DSS"). The PCI DSS requires companies to adopt certain measures to ensure the security of cardholder information, including using and maintaining firewalls, adopting proper password protections for certain devices and software, and restricting data access. Noncompliance with PCI DSS can result in penalties ranging from 5,000 to 100,000 U.S. Dollars per month by credit card companies, litigation, damage to our reputation, and revenue losses. We are also bound by other contractual obligations related to data privacy, including those imposed by our payors and business partners, including obligations to comply with applicable data privacy laws. Our failure to comply with our contractual obligations may result in a loss of revenue, loss of existing and future business opportunities, and payment of financial damages to the other parties involved. We publish privacy policies, marketing materials and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy **and security**. **If Regulators in the United States are increasingly scrutinizing these statements, and if** these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, **misleading**, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences. Obligations related to data privacy are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources, which may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties **with whom we work** that process personal data on our behalf. In addition, these obligations may require us to change our business model. We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy obligations. Moreover, despite our efforts, our employees and personnel or third parties **on-with** whom we **rely-work**, may fail to comply with such obligations, which could negatively impact our business operations. In addition, a shift in consumers' data privacy expectations or other social, economic or political developments could impact the regulatory enforcement of these obligations, which could increase the cost of and complicate our

compliance with applicable obligations. If we or the third parties ~~on~~ **with** whom we ~~rely~~ **work** fail, or are perceived to have failed to address or comply with applicable data privacy obligations, we could face significant consequences, including but not limited to: government enforcement actions (e. g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class- action claims) and mass arbitration demands; additional reporting requirements and / or oversight; bans on processing of personal data; orders to destroy or not use personal data; and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing data privacy- related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis; if viable, these claims carry the potential for monumental statutory damages, depending on the volume of personal data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations. If our information technology systems or those ~~of~~ **third parties upon which with whom** we ~~rely~~ **work**, our data, or our software are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; harm to our reputation; loss of revenue or profits; loss of customers or sales; and other adverse consequences. In the ordinary course of business, the efficient operation of our business depends on our information technology and communication systems, as well as those of ~~our suppliers, contract manufacturers, distributors and other third-party business partners. We and the~~ **third parties upon which with whom** we ~~rely~~ **work**. ~~We and the~~ **third parties with whom we work** process, use, generate, disclose, make accessible, protect, secure, dispose of, share, and transmit confidential, personal, or other sensitive data, including health information, proprietary sales and marketing data, accounting and financial information, manufacturing and quality records, inventory management data, product development tasks, research and development data, customer service and technical support information. ~~Cyberattacks~~ **Cyberattacks** These systems and the underlying data are vulnerable to damage or interruption from a number of causes, including earthquakes, fires, floods and other natural disasters, terrorist attacks, attacks by computer viruses or hackers, malware, ransomware or other destructive software, ~~eyber-~~ **attacks**, social- engineering attacks (including phishing and deep fakes, which may be increasingly more difficult to identify as fake), malicious code, denial- of- service attacks, credential harvesting, supply chain attacks, power losses, and computer system, data network failures, and other similar threats. ~~Cyber- attacks~~, malicious internet- based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties ~~upon which with whom~~ **we rely work**. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer “ hackers, ” threat actors, “ hacktivists, ” organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation- state- supported actors. Some actors now engage and are expected to continue to engage in ~~cyberattacks~~ **cyber- attacks**, including without limitation nation- state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we ~~and the third parties upon which with whom~~ **we rely work** may be vulnerable to a heightened risk of these attacks, including retaliatory ~~cyberattacks~~ **eyber- attacks**, that could significantly disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services. Our systems, those of the third parties ~~upon which with whom~~ **we rely work**, and the underlying data are vulnerable to damage or interruption from a ~~number~~ **variety** of causes ~~threats~~, including ~~without limitation~~ earthquakes, fires, floods ~~and~~, other natural disasters, terrorist attacks. ~~We and the third parties upon which we rely are also subject to a variety of evolving threats, including but not limited to~~, social- engineering attacks (including phishing and deep fakes, which may be increasingly more difficult to identify as fake), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial- of- service attacks, credential stuffing, supply chain attacks, personnel misconduct or error, ransomware attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by AI, and other similar threats. Notably, severe ransomware attacks are becoming increasingly prevalent ~~and can lead to significant interruptions in our operations, impact our ability to provide our products or services, loss of sensitive data and income, reputational harm, and diversion of funds~~. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. In addition, our insulin pumps and other products rely on software and hardware, some of which is developed by third ~~-party service providers~~ **parties with whom we work**, that could contain vulnerabilities. We take steps ~~designed~~ **designed** to detect, ~~mitigate~~ **mitigate** and remediate vulnerabilities in our information systems (such as our hardware and / or software, including that of third parties ~~upon which with whom~~ **we rely work**) ~~and products~~, but we may not be able to detect, mitigate, and remediate such vulnerabilities, ~~including on a timely basis or at all, including because the threats and techniques used to exploit the vulnerability change frequently and are often sophisticated in nature~~. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Our risks may increase significantly due to the use of mobile and cloud- based applications in our medical devices. For example, while ~~use of~~ **use of** our Tandem Device Updater ~~is designed to give~~ **is designed to give** us the ability to quickly recover from certain risks and / or vulnerabilities, the use of mobile applications enables third parties to store their information on mobile devices that we do not control. ~~The Tandem Device Updater may also not operate as intended if the software being transmitted contains errors, vulnerabilities or viruses. Vulnerabilities in our products and information systems could be exploited and result in a security incident. In addition to vulnerabilities, the reliance of our insulin pumps and other products on software and hardware exposes us and our customers to risks that may impact the performance of our products. For example, in March 2024, we issued a recall of our Apple iOS t:~~

connect mobile app in the United States relating to an issue that could cause rapid depletion of a user's t: slim X2 insulin pump battery (the March 2024 Recall). On August 20, 2024, we released an updated version of the impacted app to correct the issue described in the March 2024 recall. Any of the previously identified or similar threats and risks could **in the future, as they have in the past,** cause a security incident or other interruption that could result in the unauthorized, unlawful or accidental disclosure, access, acquisition, modification, destruction, loss, alteration, or encryption of our sensitive information or our information technology systems or those of the third parties **upon whom we rely work**. A security incident or other interruption could disrupt our ability (and that of third parties **upon whom we rely work**) to provide our **platform/** products **and** services. Furthermore, many of the third parties **upon whom we rely work** are subject to similar risks. We rely on third parties and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, and other functions and systems. Our ability to monitor **information security practices of** these third parties **information security practices is** limited, and these third parties may not have adequate information security measures in place. If the third parties **upon whom we rely work** experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if these third parties fail to satisfy their privacy- or security- related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such an award. In addition, supply chain attacks have increased in frequency and severity, and we cannot guarantee that **infrastructure belonging to these** third parties **infrastructure** in our supply chain **or, our- or the third-party partners'** supply chains **of third parties with whom we work** have not been compromised. Moreover, remote work has **become more common and has** increased risks to our information technology systems and data **, as more of our employees use network connections, computers and devices outside our premises or network, including working at home, while in transit, and in public locations.** Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program. We may expend significant resources or modify our business activities to try to protect against security incidents. **Whether or not our security measures and those of the third parties upon whom we rely are ultimately successful, our expenditures on those measures could have an adverse impact on our financial condition and results of operations, and divert management's attention from pursuing our strategic objectives.** Certain data privacy and security obligations may require us to implement and maintain reasonable or specific security measures or industry standards to protect our information technology systems and sensitive information. Applicable data privacy and security obligations may require us **, or we may voluntarily choose,** to notify relevant stakeholders **, including affected individuals, customers, regulators, and investors,** of security incidents **, or to take other actions**. Such disclosures **are and related actions can be** costly, and the disclosure or the failure to comply with **such applicable** requirements could lead to adverse consequences. If we (or a third party **upon whom we work rely**) experience a security incident (such as the phishing attack we experienced in 2020 **), or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example e. g. , investigations, fines, penalties, audits, and inspections); additional reporting requirements and / or oversight; restrictions on processing sensitive information (including personal data ,); litigation (including class claims) and mass arbitration demands; indemnification obligations; negative publicity; reputational harm; loss of investor, partner or customer confidence in the effectiveness of our cybersecurity measures;** monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data **), financial loss; and other similar harms. Security incidents and attendant consequences may cause customers to stop using or our products,** prevent customers **from to stop** using our products, deter new customers from using our products, and negatively impact our ability to grow and operate our business **. Whether a cybersecurity incident is reportable to our investors may not be straightforward, may take considerable time to determine, and may be subject to change as the investigation of the incident progresses, including changes that may significantly alter any initial disclosure that we provide. Moreover, experiencing a material cybersecurity incident and any mandatory disclosures could lead to negative publicity, loss of investor, partner or customer confidence in the effectiveness of our cybersecurity measures, diversion of management's attention, governmental investigations, lawsuits, and the expenditure of significant capital and other resources.** Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims. In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. The failure of our or our service providers' third parties' information technology systems or our pumps' software or other mobile or cloud applications to perform as we anticipate, or our failure to effectively identify, investigate and mitigate potential threats through ongoing maintenance and enhancement of software applications, information technology systems and privacy policies and controls, could disrupt our entire operation or adversely affect our software products or ability to provide our products and services. For example, we market our Tandem Device Updater as having the unique capability to deploy software updates to our pumps, which allows customers remote access to new and enhanced features. The failure of our Tandem Device Updater to provide software updates as we anticipate, including as a result of our inability to secure and maintain necessary regulatory approvals, the inability of our pumps to properly receive software updates, or errors, vulnerabilities or viruses embedded within the software being transmitted, or the

failure of our customers to properly use the system to complete the update, could result in decreased sales, increased warranty costs, and harm to our reputation, any of which could have a material adverse effect on our business, financial condition and operating results. Our sensitive information could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, or vendors' (or other third parties upon with whom we work rely) use of generative artificial intelligence ("AI") or machine learning ("ML") technologies (collectively, "AI / ML" technologies). Any sensitive information (including confidential, competitive, proprietary, or personal data), that we input into a third-party generative AI platform could be leaked or disclosed to others, including if sensitive information is used to train the third parties' AI model. Additionally, **Cyberattacks aimed at our devices, where AI / ML technologies ingest products, services, or related systems, with the intent to alter or misuse them in ways that are inconsistent with our FDA clearances and approvals, could pose risks to users. Medical devices are increasingly connected to the internet, personal data and makes connections using such data, those technologies technology may reveal devices, hospital networks, and other personal medical devices to enhance healthcare features, improve treatment capabilities or for sensitive information generated healthcare providers, and help patients manage their conditions. However, these same advancements can also heighten cybersecurity risks, including the potential for unauthorized access and misuse** by the model. Moreover, AI models may create flawed, incomplete, or inaccurate outputs, some of which may appear correct. This may happen if the inputs that the model relied on were inaccurate, incomplete or flawed (including if a bad actor "poisons" the AI with bad inputs or logic), or if the logic of the AI is flawed (a so-called "hallucination"). We may use AI / ML outputs to make certain decisions. Due to these potential inaccuracies or flaws, the model could be biased and could lead us to make decisions that could bias certain individuals (or classes of individuals), and adversely impact their **third parties** rights, employment, and ability to obtain certain pricing, products, services, or benefits. If such AI-based outputs are deemed to be biased, we could face adverse consequences, including exposure to reputational and competitive harm, customer loss, and legal liability. We experienced a breach of our information technology systems in January 2020. On January 17, 2020, we learned that an unauthorized person gained access to a few employees' email accounts through a cyber-attack commonly known as "phishing." As a result, we have been defending a lawsuit entitled Joseph Deluna et al. v. Tandem Diabetes **cyberattacks that infiltrate, disrupt, or compromise our devices, products, services, or related systems could affect the quality- of- Care care, Inc patients receive or compromise the confidentiality of patient information. Additionally, which any alteration or misuse of these devices, products, or services in was ways filed in the Superior that are inconsistent with Court-- our FDA clearances and approvals could create risks** of the State of California in the County of San Bernardino. On November 28, 2022, the court granted our motion for **users and expose** summary adjudication on the plaintiffs' allegations that we violated the Confidentiality of Medical Information Act. On February 8, 2023, the plaintiffs asked the court to dismiss their **the** remaining two claims with prejudice, which terminated the case at the Superior Court. On March 7, 2023, the plaintiffs filed a notice of appeal of the Court's order granting the Company **company to potential liabilities**'s motion for summary adjudication. On August 15, 2023, the parties reached a settlement and on August 21, 2023, the Court issued an order dismissing the appeal. The risks posed by any future similar matters include civil monetary damages, attorney fees and costs, other legal penalties, reputational damage, loss of **goodwill, and competitive harm**. Risks Related to Legal and Intellectual Property Our ability to comprehensively protect our intellectual property and proprietary technology is uncertain. We rely primarily on patent, trademark and trade secret laws, as well as confidentiality and non-disclosure agreements, to protect our proprietary technologies. However, such methods may not be adequate to protect us or permit us to gain or maintain a competitive advantage. We have applied for patent protection relating to certain existing and proposed products and processes. If we fail to file a patent application timely in any jurisdiction, it could result in us forfeiting certain patent rights in that jurisdiction. Further, we cannot assure you that any of our patent applications will be granted in a timely manner or at all. The rights granted to us under our patents, and the rights we are seeking to have granted in our pending patent applications, may not provide us with any commercial advantage. In addition, those rights could be opposed, contested or circumvented by our competitors, or be declared invalid or unenforceable in judicial or administrative proceedings. The failure of our patents to adequately protect our technology might make it easier for our competitors to offer the same or similar products or technologies. Due to differences between foreign and U. S. patent laws, our patented intellectual property rights may not receive the same degree of protection in foreign countries as they would in the United States. Even if patents are granted outside of the United States, effective enforcement in those countries may not be available. We rely on our trademarks and trade names to distinguish our products from the products of our competitors, and have registered or applied to register many of these trademarks. We cannot assure you that our current or future trademark applications will be approved in a timely manner or at all. From time to time, third parties oppose our trademark applications, or otherwise challenge our use of trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote additional resources to marketing new brands. Further, we cannot assure you that competitors will not infringe upon our trademarks, or that we will have adequate resources to enforce our trademarks. We have entered into confidentiality agreements and intellectual property assignment agreements with our officers, employees, temporary employees and consultants regarding our intellectual property and proprietary technology. We also enter into confidentiality agreements with potential collaborators and other counterparties, and the terms of our collaboration agreements typically contain provisions governing the ownership and control of intellectual property. In the event of unauthorized use or disclosure or other breaches of those agreements, we may not be provided with meaningful protection for our trade secrets or other proprietary information. To protect our proprietary rights, we may in the future need to assert claims of infringement against third parties, which may be difficult, expensive and time consuming. The outcome of litigation to enforce our intellectual property rights in patents, copyrights, trade secrets or trademarks is subject to rapid change and constant evolution and, consequently, intellectual property protection in our industry can be uncertain. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially

valuable. In the event of an adverse judgment, a court could hold that some or all of our asserted intellectual property rights are not infringed, or are invalid or unenforceable, and could award attorneys' fees. The occurrence of any of these events may have a material adverse effect on our business, financial condition and operating results. Patent litigation in the medical device industry is common, and we may be subject to litigation that could cause us to incur substantial costs and divert the attention of management from our business. Our success will depend in part on not infringing the patents or violating the other proprietary rights of third parties. While we review third party patents in advance of product launches to try to identify and avoid any infringement concerns, the large number of patents, the rapid rate of new patent issuances, and the complexity of the technology involved mean that there can be no assurance that all potentially relevant patents are identified or that our products do not infringe existing patents or patents that may be granted in the future. As such, there is a risk that third parties may assert patent infringement claims against us. Despite our efforts to avoid infringement and to resolve any claims that may arise, litigation may be necessary to defend against these claims, which could result in substantial costs and diversion of resources and may have a material adverse effect on our business, financial condition, and results of operations. Our competitors in both the United States and markets outside of United States may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make and sell our current products or products under development. From time to time, we may receive communications from third parties alleging our infringement of their intellectual property rights or offering a license to their intellectual property relating to products that we are currently developing could require us to do one or more of the following: • stop selling current products, developing new products or using technology that allegedly infringes **on** third- party intellectual property; • try to obtain a license to intellectual property from the third parties, which may not be available on reasonable terms or at all; • try to re- design our products around third- party intellectual property; • incur significant royalty payments and legal expenses; or • pay substantial damages to the party whose intellectual property rights we are allegedly infringing. For example, ~~in~~ **November 2023**, at the Unified Patent Court (~~the~~ **“UPC”**), **Paris Central Division (UPC Paris)** , we filed a revocation action and an action for a declaration of non- infringement of EP Patent No. 2 196 231 B1 (the ~~“~~ **‘ 231 patent** ~~”~~) against Roche Diabetes Care GmbH. While Roche contends that Tandem’ s t: slim X2 pump infringes the ~~‘ 231 patent~~ **practice infringe** the ~~‘ 231 patent~~ **‘ 231 patent**. Furthermore, we contend that the claims of the ~~‘ 231 patent~~ **are invalid over the prior art and should be revoked** . **In January February 2024** , **Roche filed an infringement action against Tandem and its distributor in Germany at the UPC, Hamburg Local Division (UPC Hamburg) contending that Tandem’ s t: slim X2 pump, and the offering, marketing, using, importing, possessing, and supplying of such devices infringes certain claims of the ‘ 231 patent. Roche seeks, among other things, damages and other monetary relief, costs and expenses of the legal proceedings, and an order to cease and desist the allegedly infringing activities. At the UPC Hamburg, Tandem has asserted that the t: slim X2 pump does not infringe the claims of the ‘ 231 patent and Tandem’ s distributor has asserted that the t: slim X2 pump does not infringe the claims of the ‘ 231 patent and that the claims of the ‘ 231 patent are invalid and should be revoked. On November 6, 2024, the UPC Paris held a hearing on Tandem’ s action to revoke the claims of the ‘ 231 patent. On December 18, 2024, the UPC Paris upheld the patent. The hearing in Hamburg on invalidity and non- infringement is scheduled for June 12, 2025. In December 2023** , F. Hoffman- La Roche AG and Roche Diabetes Care GmbH (collectively, ~~“~~ **Roche** ~~”~~), filed an infringement action at the UPC **, Dusseldorf Division (UPC Dusseldorf)** against ~~multiple defendants including~~ **Tandem Diabetes Care, Inc. and Tandem Diabetes Care Europe B. V. and Tandem’ s distributors in Germany, France, the Netherlands and Denmark** . Roche alleges our t: slim X2 insulin pump, and the offering, marketing, using, importing, possessing, and supplying of such devices ~~infringe~~ **infringe** EP Patent No. 1 970 677 B1 (the ~~“~~ **‘ 677 patent** ~~”~~) . **While Roche contends that Tandem’ s t: slim X2 pump infringes the ‘ 677 patent, we contend that our t: slim X2 pump does not infringe the ‘ 677 patent. Furthermore, we contend that the claims of the ‘ 677 patent are invalid over the prior art and should be revoked** . Roche seeks, among other things, damages and other monetary relief, costs and expenses of the legal proceedings, and an order to cease and desist the allegedly infringing activities . **On April 9, 2025, the UPC Dusseldorf will hold a hearing on Roche’ s action asserting infringement of the ‘ 677 patent, Tandem and its distributors’ counterclaims that the t: slim X2 pump does not infringe the ‘ 677 patent, and Tandem and its distributors’ actions to revoke the claims of the ‘ 677 patent** . As the UPC is a new court system that came into effect in 2023, enforcement and litigation under the UPC is new and we cannot accurately predict the outcome of such proceedings. If any of our ~~products are dosing devices is~~ **products are** found to infringe Roche’ s patents and Roche’ s patents are also found to be valid, we could be required to redesign our technology or obtain a license from Roche to continue importing, marketing and selling our dosing devices in certain countries in Europe. However, we may not be successful in the redesign of our technology or able to obtain any such license on commercially reasonable terms or at all. We also could be forced, including by court order, to cease importing, marketing and selling certain of our products in certain countries in Europe that are found to be infringing until the patents expire. Even if we were ultimately to prevail, litigation with Roche could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business. We cannot reasonably estimate the final outcome, including any potential liability or any range of potential future charges associated with litigation. We do not maintain insurance to cover the expense or any liability that may arise from an intellectual property dispute. Any litigation or claim against us may cause us to incur substantial costs, divert the attention of management from our business and harm our reputation. Further, as we launch new products, increase our sales and expand the geographic regions in which we commercialize our products we believe the likelihood of our involvement in intellectual property disputes will increase. We may be subject to damages resulting from claims that we, or our employees, have wrongfully used or disclosed trade secrets or other proprietary information of our competitors. Many of our employees were previously employed at other medical device companies, including those that are our competitors or could become our competitors. We may be subject to claims that we, or our employees, have used or disclosed trade secrets or other proprietary information. In addition, we may be subject to allegations that we caused an employee to breach the terms of his or

her non-competition or non-solicitation agreement. Even if we successfully defend against these claims, any resulting litigation could cause us to incur substantial costs, divert the attention of management from our business and harm our reputation. If our defense of those allegations fails, in addition to paying monetary damages, we may lose valuable intellectual property rights or key personnel. A loss of key personnel or intellectual property rights could limit our ability to commercialize products, which could have an adverse effect on our business. We may incur product liability losses, and insurance coverage may be inadequate or unavailable to cover these losses. Our business exposes us to potential product liability claims that are inherent in the medical device industry. We are subject to product liability lawsuits alleging that component failures, manufacturing defects, design defects, or inadequate disclosure of product-related risks or information resulted in an unsafe condition, injury or death to customers. The risk of product liability claims may be even greater after we launch new products with new features or enter new markets where we have no prior experience selling our products. In addition, the misuse of our products or the failure of customers to adhere to operating guidelines could cause significant harm to customers, which could result in product liability claims. Product liability lawsuits and claims, safety alerts or product recalls could cause us to incur substantial costs, divert the attention of management from our business, harm our reputation and adversely affect our ability to attract and retain customers. Although we maintain third-party product liability insurance coverage, it is possible that claims against us may exceed the coverage limits of our insurance policies. Even if any product liability loss is covered by an insurance policy, these policies have substantial deductibles. In addition, we expect the cost of our product liability insurance will increase as our sales increase. Product liability claims in excess of applicable insurance coverage could have a material adverse effect on our business, financial condition and operating results. In addition, any product liability claim brought against us, with or without merit, could result in further increases of our product liability insurance premiums and make it more difficult to obtain insurance coverage in the future.

Adhering to regulations concerning public company corporate governance and reporting requirements may place a strain on our resources and distract management from other priorities. Numerous laws and regulations, particularly those enacted under the Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, new SEC rules, and Nasdaq Stock Market listing requirements, impose obligations on public companies like ours. These have expanded the scope, complexity, and cost of corporate governance, reporting, and disclosure practices. Complying with these laws, including new disclosure requirements, has required and will continue to require substantial management time and oversight, as well as significant accounting and legal expenses. Additionally, changes to accounting rules or standards, such as a potential mandate for U. S. companies to prepare financial statements using International Financial Reporting Standards, could negatively impact our financial results and business, potentially leading to higher accounting fees. These laws and regulations, often vague in their details, are subject to interpretation, and their application may evolve as new guidance emerges from regulatory bodies. This uncertainty could lead to higher costs due to ongoing updates in governance and disclosure practices. We plan to continue investing resources to comply with these evolving laws and regulations, which may increase general and administrative expenses and divert management's attention from revenue-generating activities to compliance efforts. If our compliance efforts differ from regulatory expectations due to ambiguities in the laws, authorities may initiate legal action, which could negatively impact our business.

Risks Related to Our Regulatory Environment Our products and operations are subject to extensive governmental regulation, and failure to comply with applicable requirements could cause our business to suffer. The medical device industry is regulated extensively by governmental authorities, principally the FDA and corresponding state regulatory agencies in the United States, foreign regulatory authorities, and Notified Bodies in the EU. The regulations are very complex and are subject to rapid change and varying interpretations. Regulatory restrictions or changes could limit our ability to carry on or expand our operations or result in higher than anticipated costs or lower than anticipated sales. The FDA and other **United States U. S.** governmental agencies and **comparable** foreign regulatory authorities **and Notified Bodies** regulate numerous elements of our business, including:

- product design and development;
- pre-clinical and clinical testing and trials;
- product safety;
- establishment registration and product listing;
- labeling, packaging and storage;
- marketing, manufacturing, sales and distribution;
- import and export;
- pre-market clearance, certification, or approval;
- servicing and post-market surveillance;
- advertising and promotion; and
- recalls and field safety corrective actions.

Before we can market or sell a new regulated product or a significant modification to an existing product in the United States, we must obtain either clearance under Section 510 (k) of the Food, Drug and Cosmetic Act (510 (k)) or approval of a pre-market approval (PMA) application from the FDA, unless an exemption from pre-market review applies. The process of obtaining regulatory clearances, certification, or approvals to market a medical device can be costly and time-consuming, which may be exacerbated if the FDA or other **comparable** regulatory authorities or Notified Bodies in the EU changes their clearance, certification, and approval policies, and we may not be able to obtain these clearances, certification for our proposed products or approvals on a timely basis or at all, including as a result of:

- our inability to demonstrate that our products are safe and effective for their intended users;
- the data from our pre-clinical studies or clinical trials may be insufficient to support clearance, certification, or approval; or
- the failure of the manufacturing process or facilities we use to meet applicable requirements.

Any delay in, or failure to receive or maintain, clearance, certification, or approval for our products under development could prevent us from generating revenue from these products or achieving profitability. Further, regulatory enforcement or inquiries, or other increased scrutiny on us, could dissuade some customers from using our products and adversely affect our reputation and the perceived safety and efficacy of our products. Since our inception we have been audited or inspected by various regulatory authorities and Notified Bodies on numerous occasions. We also regularly respond to routine inquiries from regulatory authorities and Notified Bodies. In some instances, these audits, inspections and inquiries result in findings that require us to take corrective actions, which could include changes to our internal policies, procedures or operations, revisions to our product labeling, issuances of customer notifications or the initiation of product recalls, any of which could result in product liability claims and lawsuits. Our failure to appropriately respond to these findings and take corrective action, or to comply with applicable regulations for any other reason, could

jeopardize our ability to sell our products and result in enforcement actions such as fines, civil or criminal penalties, injunctions, warning letters, product recalls, operating restrictions, interruption of production, delays in the introduction of products into the market, refusal of the FDA or other **comparable foreign** regulatory authorities or Notified Bodies to grant future clearances, certification, or approvals, and the suspension or withdrawal of existing clearances, certifications, or approvals by the FDA, other **comparable foreign** regulatory authorities or Notified Bodies. Any of these sanctions could result in higher than anticipated costs, lower than anticipated sales, and diversion of management time and resources, any of which could have a material adverse effect on our reputation, business, financial condition and operating results. New products or modifications to our existing products may require new 510 (k) clearances, PMAs or certifications, or may require us to cease marketing or recall the modified products until clearances, certifications or approvals are obtained. Any modification to a 510 (k)- cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design, or manufacture, requires a new 510 (k) clearance or, possibly, a PMA. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary for changes that we have made to our products. If the FDA disagrees with our determination and requires us to submit new 510 (k) notifications or PMAs for modifications to our previously cleared or approved products, for which we concluded that new clearances or approvals were not necessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties. Further, the FDA's ongoing review of and potential changes to the 510 (k) program may make it more difficult for us to modify our previously cleared products, either by imposing stricter requirements on when a new 510 (k) for a modification to a previously cleared product must be submitted, or by applying more onerous review criteria to such submissions. For those medical devices sold in the EU and for which we have obtained a CE Certificate of Conformity by a Notified Body, we must notify ~~our~~ **the Notified Body if that carried out the conformity assessment of the medical devices we market or sell in the EEA of any planned** significant changes ~~are made~~ to the products or if there are substantial changes to our quality assurance systems affecting those products. **The Notified Body will then assess the changes and determine whether additional audits or actions are required prior to their implementation**. Obtaining variation of existing CE Certificates of Conformity or a new CE Certificate of Conformity can be a time- consuming process, and delays in obtaining required future clearances, certifications or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. **Moreover, any substantial changes that take place in the coming years may impact the continuing validity of our CE Certificates of Conformity that were issued on the basis of the Medical Device Directive**. A recall or suspension of our products, or the discovery of serious safety issues with our products, could have a significant negative impact on us. The FDA and equivalent foreign regulatory authorities have the authority to require the recall or suspension, either temporarily or permanently, of commercialized products in the event of material deficiencies or defects in quality systems, product design or manufacture or in the event that a product poses an unacceptable risk to health. Regulatory authorities have broad discretion to require the recall or suspension of a product or to require that manufacturers alert customers of safety risks, and may do so even in circumstances where we do not believe our product poses an unacceptable risk to health. In addition, manufacturers may, under their own initiative, recall a product or suspend sales if any material deficiency in a product is found or alert customers of unanticipated safety risks. A government-mandated or voluntary recall or suspension by us, one of our distributors or any of our other third- party suppliers could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls, suspensions or other notices relating to any products that we distribute would divert managerial and financial resources, and have an adverse effect on our reputation, financial condition and operating results. Further, under the FDA's Medical Device Reporting regulations and equivalent regulations and requirements in other geographies, we are required to maintain appropriate quality systems and report incidents in which our product may have caused or contributed to serious injury or death in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to serious injury or death. Repeated product malfunctions may result in a voluntary or involuntary product recall or suspension of product sales, which could divert managerial and financial resources, impair our ability to manufacture our products in a cost- effective and timely manner and have an adverse effect on our reputation, financial condition and operating results. We have initiated product recalls in the past, and our risk of future product recalls may increase as we launch new products or offer new software updates for existing products. ~~Any adverse event involving any products that we distribute could result in future voluntary corrective actions, such as recalls or customer notifications, or regulatory authority action, which could include inspection, mandatory recall or other enforcement action. For example, the Australian Therapeutic Goods Administration (TGA) temporarily suspended our pump product sales in Australia starting November 24, 2020, however sales of pump- related supplies were allowed to continue. Effective April 1, 2021, following discussions with the TGA, the temporary suspension was lifted for our t: slim X2 with Basal- IQ technology, subject to certain post- market surveillance obligations and other conditions. We discontinued sales of earlier generation products in Australia and we started offering our Control- IQ technology in Australia. There can be no assurance that the TGA will not reimpose the suspension of our pump product sales or impose other regulatory restrictions in the future. In addition, other regulatory authorities may take similar actions against us, and any regulatory challenges we encounter could have a negative impact on our product sales and harm our reputation. Any corrective actions we take in response to this action or future matters with the TGA or other regulatory authorities, whether voluntary or involuntary, will require the dedication of our time and capital, may distract management from operating our business, may harm our reputation and financial results or could result in additional regulatory scrutiny in other geographies.~~ In addition, we may be required to conduct costly post- market testing and surveillance to monitor the safety or effectiveness of our products in the EU. We must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including

unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension, variation or withdrawal of CE Certificates of Conformity, product seizures, injunctions or the imposition of civil or criminal penalties that would adversely affect our business, operating results and prospects. **In addition, we have in the past relied on our distributors for assistance with market surveillance in Europe and we may face additional challenges in responding to a voluntary or mandatory recall, requirement to repair or similar corrective action during and after our planned transition to direct sales in select European countries beginning in 2026.** Our failure to comply with **United States U.S.**-federal and state fraud and abuse laws, including anti-kickback laws and other **United States U.S.**-federal and state anti-referral laws, or comparable foreign legislation, could have a material, adverse impact on our business. The **United States U.S.** has numerous federal and state laws pertaining to healthcare fraud and abuse. Violations of these laws are punishable by criminal and civil sanctions, including, imprisonment, significant monetary penalties and exclusion from participation in federal funded programs such as Medicare and Medicaid. Healthcare fraud and abuse regulations are complex and evolving. Minor irregularities can potentially give rise to claims. The laws that may affect our ability to operate include: • the federal and state Anti-Kickback Statutes, which prohibit, among other things, persons from knowingly and willfully soliciting, receiving, offering, paying or providing remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and state Medicaid programs; • federal and state false claims laws which prohibit, among other things, persons from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to Medicare, state Medicaid programs, or other third-party payors; • federal and state physician self-referral laws, such as the Stark Law, which prohibit a physician from referring Medicare or Medicaid patients to an entity providing “designated health services,” including a company that furnishes durable medical equipment, with which the physician or their immediate family member has a financial relationship unless that financial relationship meets an exception under the applicable law; • federal and state laws, such as the Civil Monetary Penalties Law, that prohibit an individual or entity from offering or transferring remuneration to any person eligible for benefits under a federal or state health care program which such individual or entity knows or should know are likely to influence such eligible individual’s choice of provider, practitioner or supplier of any item or service for which payment may be made under federal health care programs such as Medicare and state Medicaid programs; • federal criminal laws enacted as part of HIPAA that prohibit, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; • federal and state disclosure laws, such as the Physician Payments Sunshine Act, which require certain manufacturers, including medical device manufacturers, to submit annual data pertaining to payments or other transfers of value to covered recipients, including physicians and certain other healthcare providers, and teaching hospitals, **as well as information regarding ownership and investment interests held by physicians and their immediate family members**; • federal and state laws governing the use, disclosure and security of personal information, including protected health information, such as HIPAA and the **HITECH Health Information Technology for Economic and Clinical Health**; and • foreign and **United States U.S.**-state law equivalents of each of the above federal laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers. Outside the United States, interactions between medical device companies and healthcare professionals are also governed by strict laws, such as national anti-bribery laws of European countries, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians’ codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment. Our relationships with healthcare providers and other third parties are subject to scrutiny under these laws. **Violations of any of these laws and other applicable healthcare fraud and abuse laws may be punishable by criminal and civil sanctions, including significant fines and civil monetary penalties, the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid), disgorgement and corporate integrity agreements, which impose, among other things, rigorous operational and monitoring requirements on companies.** Any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, financial condition and operating results. Federal government agencies continue to issue proposed and final rules implementing additional process, controls and guidelines for compliance under these laws with which we will be required to comply. We cannot predict the impact of any changes in these laws and whether they might be retroactive. Further, the **United States U.S.**-Department of Justice (DOJ) in conjunction with other federal agencies, has increased its scrutiny of interactions between healthcare companies and healthcare providers. Adjusting to new regulatory guidelines and responding to investigations can be time and resource-consuming and can divert management’s attention from our core business. Additionally, if we settle an investigation, we may be forced to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. All of the foregoing could increase our costs or otherwise have an adverse effect on our business. The scope and enforcement of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Our current or future activities could be subject to challenge under these laws. Any of these challenges could have a material adverse effect on our reputation, business, financial condition and operating results. ~~We may be liable if we engage in the promotion of the off-label use of our products. Our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition against the promotion of the off-label use of our products or the pre-promotion of unapproved products. Healthcare providers may use our products off-label, as the FDA does not restrict or regulate a physician’s choice of treatment within the practice of medicine. However, if the FDA or other foreign regulatory authorities determine that our promotional materials or training constitutes promotion of an off-label use or the pre-promotion of an unapproved product,~~

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 fines and 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 unapproved use, which could result in significant fines or penalties. Although our policy is to refrain from statements that could be considered off-label promotion of our products or pre-promotion of an unapproved product, the FDA or another regulatory authority could disagree and conclude that we have engaged in improper promotional activities. In addition, the off-label use of our products may increase the risk of product liability claims, which are expensive to defend and could result in substantial damage awards against us and harm our reputation. The advertising and promotion of medical devices in the EU is subject to the national law of individual EU Member States implementing Directive 93/42 on medical devices, or MDD, Directive 90/385/EEC on active implantable medical devices, or AIMD, and applying Regulation 2017/745 on medical devices, or MDR, Directive 2006/114/EC concerning misleading and comparative advertising, and Directive 2005/29/EC on unfair commercial practices, as well as other national legislation of individual EU Member States governing the advertising and promotion of medical devices. EU Member States' national legislation may also restrict or impose limitations on our ability to advertise our products directly to the general public. In addition, voluntary EU and national industry Codes of Conduct provide guidelines on the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals. Legislative or regulatory healthcare reforms, or other regulatory reforms, may result in downward pressure on the price of and decrease reimbursement for our products, and uncertainty regarding the healthcare regulatory environment could have a material adverse effect on our business. The sales of our products depend in part on the availability of coverage and reimbursement from third-party payors such as government health administration authorities, private health insurers, health maintenance organizations and other healthcare-related organizations. Both the federal and state governments in the United States continue to propose and pass new legislation and regulations designed to, among other things, expand healthcare coverage to more individuals, contain or reduce the cost of healthcare, and improve the quality of healthcare outcomes. For example, the **Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the Affordable Care Act)** has substantially changed the way healthcare is financed by both governmental and private insurers and encourages improvements in the quality of healthcare items and services. In the future, additional changes could be made to governmental healthcare programs that could significantly impact the success of our products. This legislation and regulation may result in decreased reimbursement for medical devices, which may create additional pressure to reduce the prices charged for medical devices. Reduced reimbursement rates could significantly decrease our revenue, which in turn would place significant downward pressure on our gross margins and impede our ability to become profitable. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (the "IRA 2022") into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA **the Affordable Care Act** marketplaces through plan year 2025. The IRA 2022 also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. We cannot predict which, if any, additional healthcare reform proposals will be adopted, when they may be adopted or what impact they may have on the existing regulatory environment, or our ability to operate our business. Any of these factors could have a material adverse effect on our operating results and financial condition. In the EU **(and in Northern Ireland)**, the MDR became applicable on May 26, 2021, repealing and replacing both the MDD and Directive 90/385/EEC on active implantable medical devices. The MDR establishes transitional provisions. However, the changes to the regulatory system implemented in the EU by the MDR include stricter requirements for clinical evidence and pre-market assessment of safety and performance, new classifications to indicate risk levels, requirements for third party testing by Notified Bodies, tightened and streamlined quality management system assessment procedures and additional requirements for the quality management system, additional requirements for traceability of products and transparency as well as a refined responsibility of economic operators. We are also required to provide clinical data in the form of a clinical evaluation report. Fulfillment of the obligations imposed by the MDR may cause us to incur substantial costs. We may be unable to fulfil these obligations, or our Notified Body may consider that we have not adequately demonstrated compliance with our related obligations to merit a CE Certificate of Conformity on the basis of the MDR. Moreover, in the EU, some EU Member States may, after a medical device is CE marked, require the completion of additional studies that compare the cost-effectiveness of a particular medical device candidate to currently available therapies. This Health Technology Assessment, or HTA process, which is currently governed by the national laws of the individual EU Member States, is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medical device in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medical device will often influence the pricing and reimbursement status granted to these products by the competent authorities of individual EU Member States. In December 2021, Regulation No 2021/2282 on HTA, amending Directive 2011/24/EU, was adopted in the EU. This Regulation, which entered into force in January 2022 and **will apply has applied** as of January 2025, is intended to boost cooperation among EU Member States in assessing health technologies, **including new medical devices**, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. **The Regulation will permit EU Member States to use common HTA tools, methodologies, and procedures across the EU to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement.** If the conclusions of these assessments are negative, or compare our products unfavorably with competing products, this may impact our pricing and reimbursement status. If we are unable to obtain or maintain favorable pricing and reimbursement status in EU Member States for our medical devices or medical devices that we may successfully develop and for which we may obtain

certification, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected. In addition, the exit of the UK from the EU, commonly referred to as “Brexit” could lead to **further** regulatory divergence between the EU and the UK. On May 26, 2021, the MDR became applicable in the EU. However, the MDR is not applicable in the UK **Great Britain (i. e. England, Wales and Scotland), but does apply in Northern Ireland**. In the UK **Great Britain**, medical devices are governed by the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) which, for the time being, retains a regulatory framework similar to the framework set out by the MDD. The **government plans UK’s regulator, the Medicines & Healthcare products Regulatory Agency, or MHRA, has published a road- map** to introduce new **regulations** legislation governing medical devices with an aim for core aspects of the future regime for medical devices to apply from July 1, 2025. **The first of the regulations, which** New legislation has been proposed and is also anticipated for adoption in late 2023 to bring into force **strengthened-- strengthen** post- market surveillance requirements ahead of the wider future **is scheduled to come into force on June 17, 2025. Further updated regulatory regulations** regime. These post- market surveillance requirements are expected **scheduled to follow in apply from mid-2024 2025 and 2026**. Should the UK or Great Britain further diverge from the EU from a regulatory perspective, tariffs could be put into place in the future. We could therefore, both now and in the future, face significant additional expenses to operate our business, which could significantly and materially harm or delay our ability to generate revenue or achieve profitability of our business. Any further changes in international trade, tariff and import / export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non- tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the EU and the UK. Governments outside the United States tend to impose strict price controls, reimbursement approval and rebate policies, which may adversely affect our ability to generate revenue. In some countries, particularly EU countries and EFTA member states, the pricing, reimbursement and rebates of health products is subject to governmental control, and in such countries, there can be considerable pressure by governments and other stakeholders on prices, as well as reimbursement and rebates. If reimbursement of our products is unavailable or limited in scope or amount or if pricing or rebates are set at unsatisfactory levels in any such country, our prospects for generating revenue outside of the United States, if any, could be adversely affected and our business could be harmed. **Our advertising and promotion may include claims about our product in comparison to competing products, which could expose us to heightened regulatory scrutiny, enforcement risks, and the potential for litigation. The FDA applies a heightened level of scrutiny to comparative claims in advertising and promotion, ensuring that promotional labeling is truthful and not misleading. There may be differing interpretations of whether certain communications align with a product’s FDA- required labeling, and the FDA assesses these communications on a case- by- case basis. Additionally, making comparative claims may raise concerns among our competitors. If a company claims in its advertising that its product is superior to a competitor’s or that the competitor’s product is inferior, it could face the risk of a lawsuit from the competitor under federal and state false advertising, unfair trade practices, or potentially state libel laws. Such lawsuits could seek injunctive relief to stop further advertising, a court order for corrective advertising, and compensatory or punitive damages, where allowed by law. Direct- to- consumer marketing and social media initiatives may subject us to increased regulatory scrutiny. Our efforts to promote our products through direct- to- consumer marketing and social media initiatives may lead to increased scrutiny of how we communicate risk information, benefits, or claims, under the oversight of the FDA, FTC, HHS- OCR, or other regulatory bodies. Risks Related to Environmental, Social and Governance Matters Environmental, social, and governance (ESG) regulations, initiatives, directives, policies, and requirements could expose us to various risks. Some regulators, customers, investors, employees, and other stakeholders are focused on ESG issues and related disclosures. These evolving regulations and shifting stakeholder expectations have led, and may continue to lead, to higher general and administrative costs, as well as increased management time and attention spent on compliance. For instance, collecting, measuring, and reporting ESG- related data is becoming more complex due to changing reporting standards, including from international regulatory bodies. In 2023, California passed three separate climate bills addressing greenhouse gas emissions data, climate- related financial risks, and emissions- related claims and carbon offsets. These ESG requirements and initiatives are subject to change, can be unpredictable, and may be challenging and costly for us to meet due to the complexity of our supply chain and the outsourced manufacturing of certain components. If we fail to comply or are unable to ensure our suppliers’ compliance with these policies, customers may stop purchasing from us or pursue legal action, potentially damaging our reputation, revenue, and financial performance. Our business could be adversely affected by changing expectations and challenges associated with implementing ESG initiatives, establishing ESG- related goals, gathering ESG data, and disclosing ESG- related information. We may disclose certain ESG- related initiatives and goals in our SEC filings or other public communications. However, implementing these initiatives and goals could be challenging and costly, with the technologies required potentially being inefficient or slow to develop. Additionally, we may face criticism regarding the accuracy, adequacy, or completeness of our disclosures. Statements about our ESG initiatives, goals, and progress may rely on evolving measurement standards, developing internal controls and processes, and assumptions that could change over time. Furthermore, we may be criticized for the scope or nature of these initiatives or goals, or for any revisions made to them. If our ESG data, processes, or reporting are incomplete or inaccurate, or if we fail to make timely progress toward our ESG goals, our reputation, business, financial performance, and growth may suffer. Climate change or other extreme weather conditions and related regulations may have a long- term impact on our business. Climate- related events, including the increasing frequency of extreme weather events and their impact on the United States, Mexico, Canada, and other major regions’ critical infrastructure along with potential related regulations, have the potential to disrupt our business, our third- party suppliers, and / or the business of our customers. For example, our third- party contract manufacturers are located in August 2023 regions subject to natural disasters, including**

earthquakes, hurricanes, floods, wild fires and other catastrophic events. We strive to partner with organizations that mitigate their business risks associated with climate change. However, we recognize that inherent risks related to climate change, other extreme weather conditions and related regulations exist wherever global business is conducted. While these dangers currently have a low rebate agreement with the French Comité économique des produits de santé (CEPS) for sales of our t: slim X2 with Control IQ pump in France went into effect, assessed risk of disrupting our normal business operations, they pose a potential long- term impact on our business. The rebate agreement with CEPS provides Although it is difficult to predict and adequately prepare to meet the challenges to our business posed by climate change, if new laws or regulations specified reimbursements and requires specified rebates be paid, and we are more stringent than currently -- current in legal or regulatory requirements, we may experience increased compliance burdens and costs to meet the process of determining the regulatory obligations as well as adverse impact impacts on raw material sourcing and allocation of such reimbursements and rebates under the agreement. While we currently cannot estimate the amount of such reimbursements and rebates that will be allocable to us, manufacturing operations and the distribution of we may ultimately determine that we need to pay all or our products, a portion of the Other rebates. Any such rebates that we are required to pay could adversely affect our ability to generate revenue from sales of t: slim X2 with Control IQ in France.

General Risks The price of our common stock may continue to fluctuate significantly. The trading price of our common stock has been and will continue to be volatile in response to a variety of factors, including the following:

- actual or anticipated fluctuations in our financial and operating results from period to period;
- market acceptance of our current products and products under development, and the recognition of our brand;
- introduction of proposed products, technologies or treatment techniques by us or our competitors;
- announcements of significant contracts, acquisitions, divestitures or partnerships by us, our competitors or our collaboration partners;
- regulatory clearance, certification, or approval of our products or the products of our competitors or collaboration partners, or the failure to obtain such clearances, certifications, or approvals on the projected timeline or at all;
- the announcement of a product recall, suspension or other safety notice associated with our products or the products of our competitors, or other similar regulatory enforcement actions;
- financial and operating results relative to the expectations of securities analysts and other market participants and the issuance of securities analysts' reports or recommendations;
- threatened or actual litigation, regulatory proceedings, or government investigations; and
- general political or economic conditions.

In addition, the trading price of our common stock may fluctuate substantially due to other factors, including the numerous risks and uncertainties described in this section. Fluctuations in our stock price may negatively affect the liquidity of our common stock, which could further impact our stock price. Further, our common stock may be susceptible to significant price and volume fluctuations as a result of stock market dynamics, which may impact our common stock without regard to our financial condition or operating performance. Given the competitiveness of the life sciences and medical device industry, the prices at which our common stock trades may fluctuate more significantly than might otherwise be typical, even with other market conditions, including general volatility, held constant. This volatility could negatively impact our ability to raise additional capital or utilize equity as consideration in any acquisition transactions we may pursue, and could make it more difficult for existing stockholders to sell their shares of the common stock at a price they consider acceptable or at all.

well as certain key employees. For example, key members of our management have experience successfully scaling an early- stage medical device company to achieve profitability. Our success will depend on our ability to motivate and retain our current management and key employees, and to attract, motivate and retain qualified personnel in the future. In our industry, it is common to attract, motivate and retain executive talent and other employees with compensation packages that include a significant equity component. We have issued, and may continue to issue, additional equity incentives that we believe will enhance our ability to retain our current key employees and attract the necessary additional executive talent. Competition for senior management and key employees in our industry is intense and over the past year we have also experienced general labor shortages in various areas of our business. We cannot guarantee that we will be able to retain our personnel or Anti- takeover provisions in our organizational documents and Delaware law may delay or prevent a change of control, which could reduce our stock price and prevent our stockholders from removing our current board of directors. Our amended and restated certificate of incorporation and bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions:

- authorize the issuance of preferred stock with powers, preferences and rights that may be senior to our common stock, which can be created and issued by the board of directors without prior stockholder approval;
- provide for a staggered board of directors whereby the board is currently divided into three classes, although our board and stockholders have approved the phased declassification of the board of directors such that the board structure will be completely declassified by our 2024 annual meeting of stockholders;
- provide for the removal of a director only with cause and then by the affirmative vote of the holders of a majority of the outstanding shares;
- prohibit stockholders from calling special stockholder meetings;
- prohibit stockholders from acting by written consent without holding a meeting of stockholders;
- require the vote of at least two- thirds of the outstanding shares to approve certain amendments to the certificate of incorporation or and bylaws; and
- require advance written notice of stockholder proposals and director nominations.

We are also subject to the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15 % or more of our outstanding voting stock. These and other provisions in our amended and restated certificate of incorporation, bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by our then- current board of directors, including a merger, tender offer or proxy contest involving our company. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline. We may seek to grow our business through acquisitions of products or technologies, or investments in businesses, and the failure to successfully manage these acquisitions or investments, or the failure to integrate them with our existing business, could have a material adverse effect on our business, financial condition and operating results. From time to

time, we may consider opportunities to acquire or invest in other companies, products or technologies that may enhance our product platform or technology, expand the breadth of our markets or customer base, or otherwise advance our business strategies. Potential and completed acquisitions and investments involve numerous risks, including: • problems assimilating, maintaining or operating the acquired products or technologies; • issues maintaining uniform standards, procedures, controls and policies; • unanticipated costs, liabilities, impairment charges or write-offs associated with acquisitions or investments; • diversion of management's attention from our existing business; • risks associated with entering new markets in which we have limited or no experience; and • increased legal and accounting costs relating to the acquisitions or to comply with regulatory requirements or other compliance matters. We do not know if we will be able to identify future acquisitions or investments we deem suitable, whether we will be able to successfully complete any such acquisitions or investments on favorable terms or at all, or whether we will be able to successfully integrate any acquired products or technologies into our business. Our potential inability to integrate any acquired products or technologies effectively may adversely affect our business, operating results and financial condition. Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited. Under current law, federal net operating losses (NOLs) incurred in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal NOLs ~~NOL carryforwards in a taxable year~~ is limited to 80 % of taxable income ~~in such year~~. ~~It is uncertain if and to what extent various states will conform to federal tax laws.~~ As of December 31, ~~2023~~ **2024**, we had accumulated federal and state NOL carryforwards of approximately \$ ~~168.96.5 million, and \$ 248.0 million, and \$ 262.4 million, respectively.~~ Of the total federal NOL carryforwards, approximately \$ ~~78.13.42 million~~ were generated after January 1, 2018, and therefore do not expire under current law but can only be utilized to offset 80 % of future taxable income. The remaining federal NOL carryforwards of \$ ~~89.83.62 million~~ will begin to expire in 2033, and state tax loss carryforwards continue to expire. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50 % change in its equity ownership value over a three-year period, the corporation's ability to use its pre-change NOL and research credit carryforwards may be subject to substantial limitations, which could cause U. S. federal income taxes to be paid earlier than would be paid if such limitations were not in effect and could cause NOL carryforwards to expire unused. **Similar rules may apply under state tax laws. In addition, there may be other limitations under state law on our ability to utilize NOL carryforwards, including temporary suspensions or other limitations on the use of NOL carryforwards to offset taxable income.** We believe we experienced at least one ownership change that significantly reduced our ability to utilize our pre- 2018 NOL and research credit carryforwards before they expire. Additionally, future ownership changes under Section 382 may also limit our ability to fully utilize any remaining tax benefits. Uncertainties in the interpretation and application of existing, new and proposed tax laws and regulations could materially affect our tax obligations and effective tax rate. The tax regimes to which we are subject or under which we operate are unsettled and may be subject to significant change. The issuance of additional guidance related to existing or future tax laws, or changes to tax laws or regulations proposed or implemented by the current or a future **United States U. S.** presidential administration, Congress, or taxing authorities in other jurisdictions, including jurisdictions outside of the United States, **or by bodies such as the European Commission or the Organization for Economic Co- operation and Development (OECD),** could materially affect our tax obligations **(including the costs of compliance)** and effective tax rate. To the extent that such changes have a negative impact on us, including as a result of related uncertainty, these changes may adversely impact our business, financial condition, results of operations, and cash flows. The amount of taxes we pay in different jurisdictions depends on the application of the tax laws of various jurisdictions, including the United States, to our international business activities, tax rates, new or revised tax laws, or interpretations of tax laws and policies, and our ability to operate our business in a manner consistent with our corporate structure and intercompany arrangements. The taxing authorities of the jurisdictions in which we operate may challenge our methodologies for pricing intercompany transactions pursuant to our intercompany arrangements or disagree with our determinations as to the income and expenses attributable to specific jurisdictions. If such a challenge or disagreement were to occur, and our position was not sustained, we could be required to pay additional taxes, interest, and penalties, which could result in one- time tax charges, higher effective tax rates, reduced cash flows, and lower overall profitability of our operations. Our financial statements could fail to reflect adequate reserves to cover such a contingency. Similarly, a taxing authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a "permanent establishment" under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions. Effective January 1, 2022, the Tax Cuts and Jobs Act of 2017 eliminated the option to deduct research and development expenses for tax purposes in the year incurred and requires taxpayers to capitalize and subsequently amortize such expenses over five years for research activities conducted in the United States and over 15 years for research activities conducted outside the United States. Although there have been legislative proposals to repeal or defer the capitalization requirement to later years, there can be no assurance that the provision will be repealed or otherwise modified. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation. Our tax obligations and effective tax rate in the jurisdictions in which we conduct business could increase, including as a result of the base erosion and profit shifting (BEPS) project ~~that is being led by the Organization for Economic Co- operation and Development (OECD),~~ and other initiatives led by the OECD or the European Commission. ~~For example~~ **In particular**, the OECD is leading work on proposals, commonly referred to as "BEPS 2.0", which, if ~~and~~ **an** to the extent implemented, would make important changes to the international ~~iteration of the project~~ tax system. These proposals are based on two "pillars," involving the reallocation of taxing rights in respect of certain multinational enterprises above a fixed profit margin to the jurisdictions in which they carry on business (subject to certain revenue threshold rules which we do not currently meet but may meet in the future) (~~referred to as~~ "Pillar One") and

imposing a minimum effective corporate tax rate on certain multinational enterprises (referred to as “Pillar Two”). A number of countries in which we conduct business, including through our subsidiaries, such as the Netherlands and Switzerland, have enacted with effect from January 1, 2024, or are in the process of enacting, core elements of the Pillar Two rules. Based on our current understanding of the minimum revenue thresholds contained in the Pillar Two proposal rules, we expect that we are likely to fall within the their scope of its rules in the short- to- medium term. The OECD has issued administrative guidance providing, subject to the application of any relevant transition and/or safe harbor rules in relation to the implementation of the Pillar Two proposal. We are monitoring developments and evaluating the potential impacts of these new rules, including on our effective tax rates and associated compliance costs, and considering our eligibility to qualify for these any relevant transition or safe harbor rules. If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud, which could harm our business and result in a decline in the trading price of our common stock. Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement adequate controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations, or to prevent the circumvention of our controls or fraud. For example, Mr. Sheridan, our principal executive officer, and Ms. Vosseller, our principal financial and accounting officer, are involved in a personal relationship and share a primary residence. While our board of directors is informed of the relationship and appropriate actions have been taken to ensure compliance with SEC rules and Company policies and procedures, the existence of this relationship could create additional risk, or the perception of additional risk, that our controls and procedures may not be effective. In addition, any testing by us conducted in connection with Section 404 (a) of the Sarbanes- Oxley Act, or any testing conducted by our independent registered public accounting firm in connection with Section 404 (b) of the Sarbanes- Oxley Act may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses, may require prospective or retroactive changes to our consolidated financial statements, or may identify other areas for further attention or improvement. Any failure to implement appropriate internal controls could also cause investors to lose confidence in our reported financial information, which could harm our business and result in a decline in the trading price of our common stock.

Risks Related to Our Indebtedness

We have incurred a significant amount of indebtedness, and the agreements governing such indebtedness subject us to required debt service payments, as well as financial and operational covenants, any of which may restrict our financial flexibility and affect our ability to operate our business. From time to time, we have financed our liquidity needs under various credit arrangements and we may borrow additional funds in the future. For example, in May 2020, we completed the offering of \$ 287.5 million principal amount of 1.50 % Convertible Senior Notes due 2025 (the Notes), which are governed by the terms of an indenture. The Notes are our senior unsecured obligations. The Notes contain certain debt service requirements. Pursuant to the Notes, interest is payable in cash semi-annually at a rate of 1.50 % per year. Our failure to comply with certain obligations under the Notes, or inability to make required debt service payments, could result in an event of default. A default, if not cured or waived, could result in acceleration of the indebtedness, which could have a material adverse effect on our business, financial condition and liquidity. Further, if our indebtedness is accelerated, we cannot be certain that cash will be available to pay the indebtedness and we may not have the ability to refinance the indebtedness on terms satisfactory to us or at all. In addition, our current or future level of indebtedness could affect our business, operations and strategy in several important ways, including the following: • we may be required to dedicate a portion of our current liquidity or cash flow from operations to interest payments, limiting the availability of cash for other purposes; • covenants contained in future agreements governing indebtedness may limit our ability to borrow additional funds, refinance indebtedness or make certain investments; • debt covenants may affect our flexibility in planning for, and reacting to, changes in the economy and our industry; • a high level of indebtedness may increase our vulnerability to adverse economic and competitive conditions; and • a high level of indebtedness may limit our ability to obtain additional financing in the future or negatively impact the terms on which additional financing may be obtained. Servicing the Notes will require a significant amount of cash, and we may not have sufficient cash flow from our business to repay the Notes. Our ability to make scheduled payments of the principal and interest on the Notes, or to refinance the Notes depends on our future business operations and liquidity, which are subject, to numerous risks and uncertainties, including, market acceptance of our products, regulatory clearance, certification, or approval for our products, and the competitive environment in which we operate. Our business may not generate or sustain a level of cash flow from operations sufficient to service the Notes and any future indebtedness we may incur. If we are unable to generate sufficient cash flow, we may be required to adopt one or more alternatives, such as reducing or delaying capital expenditures, selling or licensing assets, refinancing indebtedness, or obtaining additional equity capital. Our ability to successfully engage in these activities will depend on a number of factors, including the value of our assets, our operating results and financial condition, the value of our common stock, and the status of the capital markets at such time. We may not be able to engage in any of these activities on commercially reasonable terms or at all, which could result in a default under the Notes, or our future indebtedness. In addition, we may from time to time seek to retire or purchase our outstanding debt, including the Notes, through cash purchases and/or exchanges for equity securities, in open market purchases, privately negotiated transactions or otherwise. Such repurchases or exchanges, if any, will depend on prevailing market conditions, our liquidity requirements, contractual restrictions, and other factors. The amounts involved in any such transactions, individually or in the aggregate, may be material. Further, any such purchases or exchanges may result in us acquiring and retiring a substantial amount of such indebtedness, which could impact the trading liquidity of such indebtedness. An event of default occurred under the indenture governing the Notes. On or about October 24, 2023, we were notified that additional interest had been accruing on the Notes since May 2021 pursuant to the terms of the indenture, as a result of our failure to timely remove the restrictive legends on the Notes and switch the Notes to an unrestricted CUSIP. This additional interest accrued at a rate of 0.50 % per annum on the outstanding principal amount of the Notes. The failure to pay these overdue amounts when required constituted an event of default under the indenture. We paid all

overdue amounts related to this matter in November 2023. Early repayment of the Notes due to an event of default would likely significantly impact our liquidity and financial condition, which could have a material adverse effect on our business. We may not have sufficient cash or be able to obtain financing to repurchase the Notes upon a fundamental change, or to settle conversions of the Notes. Holders of the Notes have the right to require us to repurchase their Notes upon the occurrence of a fundamental change (as defined in the indenture governing the Notes) at a repurchase price equal to 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest, if any. In addition, upon conversion of the Notes, unless we elect to deliver solely shares of our common stock to settle such conversion, we will be required to settle all or a portion of our conversion obligation through the payment of cash, which could adversely affect our liquidity. However, we may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of the Notes or settle conversions of the Notes. In addition, our ability to repurchase the Notes or to pay cash upon conversions of the Notes may be limited by agreements governing our future indebtedness. Our failure to repurchase Notes at a time when the repurchase is required by the indenture, or to pay any cash payable on future conversions of the Notes as required by the indenture, would constitute an event of default under the indenture. A default under the indenture, or the fundamental change itself, could also lead to a default under agreements governing our existing or future indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and repurchase the notes or make cash payments upon conversions thereof. Conversion of the Notes will, to the extent we deliver shares upon conversion of such Notes, dilute the ownership interest of existing stockholders and may otherwise have a negative impact on the trading price of our common stock. The conversion of some or all of the Notes will dilute the ownership interests of existing stockholders to the extent we deliver shares upon conversion of any of the Notes. Any sales in the public market of the common stock issued upon the conversion of the Notes could adversely affect prevailing market prices of our common stock. In addition, the perception that some or all of the Notes may be converted into shares of our common stock in the future could have a negative impact on the trading price of our common stock. Certain provisions in the indenture governing the Notes may delay or prevent an otherwise beneficial takeover attempt. Certain provisions in the indenture governing the Notes may make it more difficult or expensive for a third party to acquire us. For example, the terms of the Notes require us to offer to repurchase the Notes in the event of a fundamental change and, in certain circumstances, to increase the conversion rate for a holder that converts its Notes in connection with a make-whole fundamental change (as defined in the indenture governing the Notes). A takeover of the Company may trigger the requirement that we offer to repurchase the Notes and / or increase the conversion rate of the Notes for a holder that elects to convert its Notes, which could make it more costly for a potential acquirer to engage in such takeover. These and other provisions set forth in the indenture may have the effect of delaying or preventing a takeover of the Company that would otherwise be beneficial to investors. The Capped Call Transactions may affect the value of the Notes and our common stock. In connection with the issuance of the Notes, we entered into capped call transactions (the Capped Call Transactions) with the option counterparties. The Capped Call Transactions are expected generally to reduce the potential dilution to our common stock upon any conversion of the Notes and / or offset any cash payments we are required to make in excess of the principal amount of converted Notes, as the case may be, with such reduction and / or offset subject to a cap. The option counterparties or their respective affiliates may modify their hedge positions by entering into or unwinding various derivatives with respect to our common stock and / or purchasing or selling our common stock or other securities of ours in secondary market transactions before the maturity of the Notes. This activity could also cause or avoid an increase or a decrease in the market price of our common stock or the Notes, which could affect a Note holder's ability to convert the Notes. The potential effect, if any, of any of these transactions and activities on the market price of our common stock or the Notes will depend in part on market conditions and cannot be ascertained at this time, but any of these activities could adversely affect the value of our common stock and the value of the Notes and, under certain circumstances, the ability of the Note holders to convert the Notes. We are subject to counterparty risk with respect to the Capped Call Transactions. The option counterparties are financial institutions, and we will be subject to the risk that any or all of them may default under the Capped Call Transactions. If an option counterparty becomes subject to insolvency proceedings, we will become an unsecured creditor in those proceedings with a claim equal to our exposure at that time under the Capped Call Transaction with such option counterparty. Our exposure will depend on many factors but, in general, an increase in our exposure will be correlated to an increase in the market price and volatility of our common stock. In addition, upon a default by an option counterparty, we may suffer more dilution than we currently anticipate with respect to our common stock.