Risk Factors Comparison 2024-03-01 to 2023-03-16 Form: 10-K

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Our business is subject to numerous risks. You should carefully consider the following risks and all other information contained in this Annual Report, as well as general economic and business risks, together with any other documents we file with the SEC. If any of the following events actually occur or risks actually materialize, it could have a material adverse effect on our business, operating results and financial condition and cause the trading price of our common stock to decline. Summary of Risks Affecting Our ~~Business~~ **BusinessOur** ~~Our~~ business is subject to numerous risks. The following summary highlights some of the risks you should consider with respect to our business and prospects. This summary is not complete, and the risks summarized below are not the only risks we face. You should review and consider carefully the risks and uncertainties described in the " Risk Factors " section of this Annual Report on Form 10- K, which includes a more complete discussion of the risks summarized below as well as a discussion of other risks related to our business and an investment in our common stock, as well as our other public filings with the Securities and Exchange Commission, or SEC. Any of the following risks could have a material adverse effect on our business, financial condition, results of operations and prospects and cause the trading price of our common stock to decline: ● We have incurred significant operating losses since inception and cannot assure you that we will ever achieve or sustain profitability. Our results of operations may fluctuate significantly from quarter to quarter or year to year. ● We expect that a substantial majority of our future revenue will result from our Commercialization Agreement with Ascensia. If Ascensia fails to perform satisfactorily under this agreement, including among other things if they are delayed or unsuccessful in growing the adoption of our product, our commercialization efforts and financial results would be directly and adversely affected . ● Our actual operating results may..... business, financial condition and operating results . ● The markets in which we participate are highly competitive, and our primary competitors, as well as a number of other companies, medical researcher and existing medical device companies, are pursuing new delivery devices, delivery technologies, sensing technologies, procedures, drugs and other therapies for the monitoring, treatment and prevention of diabetes. Any technological breakthroughs in diabetes monitoring, treatment or prevention could reduce the potential market for Eversense or render Eversense less competitive or obsolete, which would significantly reduce our potential sales. ● We have limited operating history as a commercial- stage company and may face difficulties encountered by companies early in their commercialization in competitive and rapidly evolving markets. ● Our **actual operating** results may differ significantly from any guidance provided.If our actual results of operations fall below the expectations of investors or securities analysts,the price of our common stock could decline significantly.● Medical device development involves a lengthy and expensive process,with an uncertain outcome.We may incur additional costs or experience delays in completing,or ultimately be unable to complete,ongoing development for lifecycle management of our products.● Our products and operations are subject to extensive governmental regulation,and failure to comply with applicable requirements could cause our business to suffer.In particular,the FDA and other foreign regulatory clearance,certification,or approval processes are expensive,time- consuming and uncertain,and the failure to maintain required regulatory clearances,certifications and approvals could prevent us from commercializing Eversense and future versions of Eversense.● The ~~COVID- 19 pandemic has,and may continue to materially affect our operations,including at our headquarters in Maryland and at our clinical trial sites,as well as the business and operations of our manufacturers,distributors or other third parties with whom we conduct business.We are unable to predict the extent to which the pandemic and related restrictions will continue to impact our business,operations,financial performance and the achievement of our strategic objectives.● The~~ ongoing military action by Russia in Ukraine **and Israel in Gaza** could have negative impact on the global economy which could materially adversely affect our business,operations,operating results and financial condition.There is uncertainty regarding the ultimate impact the conflict,including any escalation or further expansion of the conflict' s current scope,will have on our customers,the global economy,supply chains,logistics,fuel prices,raw material pricing and our business.● Surging natural gas and electricity costs in Europe poses a threat to our contract manufacturers ability to maintain operations in Europe which can adversely affect or business supply chain.If the energy crisis or other supply chain challenges impact our ability to obtain raw materials on a timely basis or without significant increases in costs,our financial results and business operations may be adversely affected.● Failure to secure or retain coverage or adequate reimbursement for Eversense or future versions of Eversense systems,including the related **insertion and removal procedures,by third- party payors could adversely affect our business,financial condition and operating results.● We have partnerships with companies such as NPG to establish broad inserter networks and as the number of insertions increase so does our reliance on these companies.If NPG or other partners fail to perform satisfactorily under these agreements our commercialization efforts and financial results would be directly and adversely affected.28 ● Our** stock price has been highly volatile and may continue to be highly volatile. The stock market in general and the market for innovative, emerging medtech and biotechnology companies in particular, has experienced volatility that has often been unrelated to the operating performance of particular companies. We cannot predict the action of market participants and, therefore, can offer no assurances that the market for our common stock will be stable or appreciate over time. ● Our operating results are subject to significant fluctuations. ● We contract with third parties for the manufacture of Eversense. Risks associated with the manufacturing of our products, loss of key suppliers or disruption to their facilities could reduce our gross margins and negatively affect our operating results. ● We operate in a regulated industry and our business, operations and the business and operations of our third- party manufacturers are subject to various foreign, U. S. federal, state and local laws and regulations, including those promulgated by the FDA and equivalent foreign regulatory ~~agencies~~ **authorities** , among others. Failure to comply with applicable laws and

regulations should harm our business and we may incur significant expenditures related to compliance efforts. ● **Failure or perceived failure to comply with existing or future laws, regulations, contracts, self- regulatory schemes, standards, and other obligations related to data privacy and security (including security incidents) could harm our business. Compliance or the actual or perceived failure to comply with such obligations could increase the costs to our products, limit their use or adoption, and otherwise negatively affect our operating results and business. ●** Holders of ~~convertible notes~~ **debt instruments** may exert substantial influence over us and may exercise their control in a manner adverse to the interests of our common stockholders. ~~27~~ Risks Relating to our Business and our Industry We have incurred significant operating losses since inception and cannot assure you that we will ever achieve or sustain profitability. Since our inception, we have incurred significant net losses ~~from operations~~ and expect to incur additional losses in the near future. ~~Our positive~~ **We incurred total net (loss)** income ~~in~~ **of ($ 60. 4) million and $ 142. 1 million for** the ~~current year~~ **years** ~~is~~ **ended December 31, 2023, and 2022, respectively. Positive net income during 2022 was** substantially the result of fair value gains due to embedded derivatives in our convertible notes. **As** ~~We incurred total net income (loss) of $ 142. 1 million, ($ 302. 5) million, and ($ 175. 2) million for the years ended~~ December 31, ~~2022~~ **2023** ~~, 2021 and 2020, respectively. As of December 31, 2022~~, we had an accumulated deficit of $ ~~808~~ **869** . ~~9~~ **3** million. To date, we have financed our operations primarily through sales of our equity securities and debt financings. We have devoted substantially all of our resources to the research and development of our products, including conducting clinical trials, and the commercial launch of Eversense ~~90- day and Eversense E3~~ in the United States ~~and Eversense 90- day~~ , **select** ~~Eversense XL and Eversense E3 in EEA~~ markets **in Europe** , the Middle East, and Africa (EMEA). To implement our business strategy we need to, among other things, gain regulatory approval or certification in other regions where we intend to sell our products, expand our commercial launch in the United States and Europe, and develop future generations of Eversense. We have never been profitable **from** ~~in past years and positive net income in the current year is largely driven by changes in fair value of derivatives. Excluding changes to the fair value of our derivative and option~~ **operations and** ~~agreements, we~~ do not expect to be profitable for at least the next several years. We expect our expenses to increase significantly as we pursue these objectives. The extent of our future operating losses and the timing of profitability are highly uncertain, and we expect to continue incurring expenses and operating losses over the next several years. Any additional operating losses may have an adverse effect on our stockholders' equity, and we cannot assure you that we will ever be able to achieve profitability. Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our development efforts, obtain regulatory approvals or certificates, diversify our product offerings or continue our operations. Our Commercialization Agreement with Ascensia to market Eversense may not be successful. We have entered into a Commercialization Agreement with Ascensia, pursuant to which we have granted Ascensia the exclusive right to distribute Eversense worldwide, subject to initial exceptions based on our other current exclusive distribution agreements. Pursuant to this agreement, our future success will be dependent on Ascensia effectively marketing and selling Eversense. We expect that the substantial majority of our future revenue will come **29** pursuant to this agreement in future years **. Prior to our Commercialization Agreement with Ascensia, Ascensia had limited experience with marketing durable medical equipment and no experience marketing CGM systems. In order to strengthen commercial execution, Ascensia has recently established an independent dedicated business unit responsible for commercializing Eversense, which reports directly to Ascensia' s parent company, PHC Holdings Corporation (" PHC "), and Ascensia has engaged a new president of CGM to lead that business unit. However, there can be no assurance that these efforts will be successful** . If Ascensia fails to perform satisfactorily under this agreement, including among other things if they are delayed or unsuccessful in growing the adoption of our product, our commercialization efforts and financial results would be directly and adversely affected. The Commercialization Agreement is terminable by Ascensia under a number of circumstances, including if we undergo a change of control. The agreement is terminable by either party if the other party materially breaches its obligations under the agreement; provided, however, that if Ascensia is unable to achieve the specified minimum spending or revenue targets described above, then we will only have the right to covert Ascensia' s exclusive rights to nonexclusive rights, which may make it difficult for us to successfully engage with another commercial partner. The agreement is also terminable by either party if the other party undergoes bankruptcy, dissolution or winding up. We cannot guarantee this agreement with Ascensia will be successful, that it will continue, or that we will be able to achieve or maintain any particular volume of sales under the agreement or increase the volume of sales at a satisfactory pace or at all from this relationship in the future. ~~28~~ Our Commercialization Agreement with Ascensia and the terms of our debt may discourage a change of control of our company. The terms of our agreements with Ascensia and PHC may discourage a third party from acquiring, or attempting to acquire, control of our company, even if a change of control was considered favorable by some or all of our stockholders. For example, because of the exclusivity of the distribution arrangements with Ascensia and the minimum five- year term of that exclusivity (which may be extended under certain circumstances), prospective strategic acquirors may be unwilling to undertake an acquisition of our company ~~. In addition, under the terms of the PHC Notes, we may be required to make significant payments to redeem these notes upon a change of control~~ . We have limited operating history as a commercial- stage company and may face difficulties encountered by companies early in their commercialization in competitive and rapidly evolving markets. Our experience as a commercial- stage company upon which to evaluate our business, future sales expectations and operating results is limited. In assessing our business prospects, you should consider the various risks and difficulties frequently encountered by companies early in their commercialization in competitive and rapidly evolving markets, particularly companies that develop and sell medical devices. These risks include our ability to: ● obtain regulatory clearance, certification or approval to commercialize our products; ● perform clinical trials with respect to current Eversense or future versions of Eversense; ● implement and execute our business strategy; ● expand and improve the productivity of our sales and marketing infrastructure to grow sales of Eversense or future versions of Eversense; ● increase awareness of our brand and Eversense and build loyalty

among people with diabetes, their caregivers and healthcare providers; ● manage expanding operations; ● manage and secure effective sales of our product through our new collaboration with Ascensia, including its establishment of required commercial infrastructure in the U. S. and elsewhere, and its adapting to a new product category in which it has limited experience; ● expand the capabilities and capacities of our third- party manufacturers, including increasing production of current products efficiently and having our vendors adapt their manufacturing facilities to the production of new products; ● respond effectively to competitive pressures and developments; ● enhance Eversense and develop future versions of Eversense; and ● attract, retain and motivate qualified personnel in various areas of our business. **30** Due to our limited operating history as a commercial- stage company, we may not have the institutional knowledge or experience to be able to effectively address these and other risks that may face our business. In addition, we may not be able to develop insights into trends that could emerge and negatively affect our business and may fail to respond effectively to those trends. As a result of these or other risks, we may not be able to execute key components of our business strategy, and our business, financial condition and operating results may suffer. If we are unable to successfully expand our commercialization of Eversense in the United States and Europe through our Commercialization Agreement with Ascensia, our business will be harmed. We have limited commercialization experience in both the United States and Europe. We have invested substantially all of our efforts and financial resources to the development and commercialization of Eversense. Our ability to generate revenue from our products will depend heavily on successful commercialization of products in the United States and Europe, which is entirely dependent on our collaboration with Ascensia, and on continuing development of future generations of our Eversense system. The success of any products that we develop will depend on several factors, including: ● receipt of timely marketing approvals from applicable regulatory authorities or CE Certificates Conformity from Notified Bodies in the EEA; ~~29~~ ● our ability to procure and maintain suppliers and manufacturers of the components of Eversense and future versions of Eversense; ● market acceptance of Eversense by people with diabetes, the medical community and third- party payors; ● our ability to obtain and maintain coverage and adequate reimbursement for Eversense and the related insertion and removal procedures from third- party payors; ● our success in educating healthcare providers and people with diabetes about the benefits, administration and use of Eversense and future versions of Eversense; ● the prevalence and severity of adverse events experienced with Eversense and future versions of Eversense; ● the perceived advantages, cost, safety, convenience and accuracy of alternative diabetes management therapies; ● obtaining and maintaining patent, trademark and trade secret protection and regulatory exclusivity for Eversense and otherwise protecting our rights in our intellectual property portfolio; ● maintaining compliance with regulatory requirements, including current good manufacturing practices; and ● maintaining a continued acceptable accuracy, safety, duration and convenience profile of Eversense. Our revenue is dependent, in part, upon the size of the markets in the territories for which we have regulatory approval or certification, the accepted price for the product, the ability to obtain coverage and reimbursement, and whether we own the commercial rights for that territory. If the number of people with diabetes we target is not as significant as we estimate or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products. Our revenue is dependent on the success of Ascensia in commercializing our product and its future versions. Our product is a new product for Ascensia globally and they must continue to establish certain functions of their U. S. commercial organization to successfully market and sell our CGM system. Ascensia' s continued organizational development of its sales and marketing capabilities will be critical to successful commercialization of our Eversense systems. If Ascensia is unable to maintain effective sales, marketing and other functions that are required to support the product, it will have a materially negative impact on our net revenues from Eversense. Approval in the United States by the FDA or approval, or certification by a regulatory agency or Notified Body in another country does not guarantee approval, or certification by the regulatory authorities or Notified Bodies in other countries or jurisdictions or ensure approval, or certification for the same conditions of use. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Approval or certification processes vary among countries and can involve additional product testing and validation and additional administrative review periods. If we do not achieve one or more of these approvals, or certifications in a timely manner or at all, we could experience significant delays or an inability to fully commercialize Eversense and achieve profitability. **31** Both before and after a product is commercially released, we will have ongoing responsibilities under U. S. and EU regulations. We will also be subject to periodic inspections by the FDA, the Notified Bodies in the EEA and comparable foreign authorities to determine compliance with regulatory requirements, such as the ~~Quality System Regulation (" QSR ")~~, of the FDA, medical device reporting regulations, vigilance in reporting of adverse events and regulations regarding notification, corrections, and recalls. These inspections can result in observations or reports, warning letters or other similar notices or forms of enforcement action. If the FDA, or any comparable foreign regulatory authority concludes that we are not in compliance with applicable laws or regulations, or that any of our products are ineffective or pose an unreasonable health risk, such authority could ban these products, suspend, vary or cancel our marketing authorizations or CE Certificates of Conformity, impose" stop- sale" and" stop- import" orders, refuse to issue export certificates, detain or seize adulterated or misbranded products, order a recall, repair, replacement, correction or refund of such products, or require us to notify health providers and others that the products present unreasonable risks of substantial harm to the public health. Discovery of previously unknown problems with our product' s design or manufacture may result in restrictions on the use of Eversense, restrictions placed on us or our suppliers, or withdrawal or variation of an existing regulatory clearance or CE Certificate of Conformity for Eversense. The FDA, competent authorities of EEA countries and comparable foreign regulatory authorities may also impose operating restrictions, enjoin and restrain certain violations of applicable law pertaining to medical devices, assess civil or criminal penalties against our officers, employees or us, or recommend criminal prosecution of our company. Adverse regulatory action may restrict us from effectively marketing and selling our products. In addition, negative publicity and product liability ~~30~~ claims resulting from any adverse regulatory action could have a material adverse effect on our business, financial condition, and operating results. Foreign governmental regulations have become increasingly stringent and more extensive, and we may become subject to even more rigorous

regulation by foreign governmental authorities in the future. Penalties for a company' s noncompliance with foreign governmental regulation could be severe, including revocation or suspension of a company' s business license and civil or criminal sanctions. In some jurisdictions, such as Germany, any violation of a law related to medical devices is also considered to be a violation of unfair competition law. In such cases, governmental authorities, our competitors and business or consumer associations may then file lawsuits to prohibit us from commercializing Eversense in such jurisdictions. Our competitors may also sue us for damages. Any domestic or foreign governmental law or regulation imposed in the future may have a material adverse effect on our business, financial condition and operating results. We are dependent on one product, Eversense. Our success depends on our ability to continue to develop, commercialize and gain market acceptance for our products. Our current business strategy is highly dependent on the successful commercialization of Eversense by Ascensia and achieving and maintaining market acceptance. In order to sell Eversense to people with diabetes, we and Ascensia must educate them, their caregivers and healthcare providers that Eversense is an attractive alternative to competitive products for the monitoring of glucose levels, including SMBG, as well as other competitive CGM systems and alternatives to CGM methodologies. Market acceptance and adoption of Eversense depends on educating people with diabetes, as well as their caregivers and healthcare providers, as to the distinct features, ease- of- use, positive lifestyle impact, and other perceived benefits of Eversense as compared to competitive products. Achieving and maintaining market acceptance of Eversense could be negatively impacted by many factors, including: ● the failure of Eversense to achieve wide acceptance among people with diabetes, their caregivers, healthcare providers, third- party payors and key opinion leaders in the diabetes treatment community; ● lack of evidence supporting the accuracy, duration, safety, ease- of- use or other perceived benefits of Eversense over competitive products or other currently available diabetes management therapies; ● perceived risks associated with the use of Eversense or similar products or technologies generally; ● the introduction of competitive products and the rate of acceptance of those products as compared to Eversense; ● adverse results of clinical trials relating to Eversense or similar competitive products; ~~and~~ ● loss of regulatory approval or CE Certificates of Conformity for Eversense, adverse publicity or other adverse events including any product liability lawsuits; and ● any limitations in the ability of Ascensia to effectively communicate and promote product benefits. **32** In addition, Eversense may be perceived by people with diabetes, their caregivers or healthcare providers to be more complicated or less effective than traditional monitoring methodologies, including SMBG or CGM systems which require less calibration, and people may be unwilling to change their current regimens. Moreover, healthcare providers tend to be slow to change their medical treatment practices because of perceived liability risks arising from the use of new products and the uncertainty of third- party payor reimbursement. Accordingly, healthcare providers may not recommend Eversense unless and until there is sufficient evidence to convince them to alter the treatment methods they typically recommend, such as receiving recommendations from prominent healthcare providers or other key opinion leaders in the diabetes treatment community. If we are not successful in educating people with diabetes of the benefits of Eversense, or if we are unable to achieve the support of caregivers and healthcare providers or widespread market acceptance for Eversense, then our sales potential, strategic objectives and profitability could be negatively impacted, which would adversely affect our business, financial condition and operating results. ~~31 our business,financial condition and operating results.~~ We contract with third parties for the manufacture of Eversense.Risks associated with the manufacturing of our products could reduce our gross margins and negatively affect our operating results.We do not have any manufacturing facilities or direct manufacturing personnel.We currently rely,and expect to continue to rely,on third parties for the manufacture of Eversense for commercial sale and development of future CGM products.Our business strategy depends on our third- party manufacturers' ability to manufacture Eversense in sufficient quantities and on a timely basis so as to meet consumer demand,while adhering to product quality standards,complying with regulatory requirements and managing manufacturing costs.We are subject to numerous risks relating to our reliance on the manufacturing capabilities of our third- party manufacturers,including:● quality or reliability defects in Eversense;● inability to secure product components in a timely manner,in sufficient quantities or on commercially reasonable terms;● failure to increase production of Eversense to meet demand;● inability to modify production lines to enable us to efficiently produce future products or implement changes in current products in response to regulatory requirements;● difficulty identifying and qualifying alternative manufacturers in a timely manner;● inability to establish agreements with current or future third- party manufacturers or to do so on acceptable terms;or ● potential damage to or destruction of our manufacturers' equipment or facilities. ~~36~~ These risks are likely to be exacerbated by our limited experience with Eversense and its manufacturing process.As demand for our products increases,our third- party suppliers will need to invest additional resources to purchase components,hire and train employees,and enhance their manufacturing processes.If our manufacturers fail to increase production capacity efficiently,our sales may not increase in line with our expectations and our operating margins could fluctuate or decline.Further,we may be required to fund capital investments at our third- party suppliers to support increased production capacity.In addition,although we expect some of our future versions of Eversense to share product features and components with our current Eversense E3 product,manufacturing future versions of Eversense may require the modification of production lines,the identification of new manufacturers for specific components,or the development of new manufacturing technologies.It may not be possible for us to manufacture these products at a cost or in quantities sufficient to make these future versions of Eversense commercially viable.We depend on a limited number of third- party suppliers for the components of Eversense and the loss of any of these suppliers,or their inability to provide us with an adequate supply of materials,could harm our business.We rely on third- party suppliers to supply and manufacture the components of our Eversense system.For our business strategy to be successful,our suppliers must be able to provide us with components and Eversense systems 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.Future increases in sales of Eversense,whether **33** expected or unanticipated,could strain the ability of our suppliers to deliver an increasingly large supply of components and Eversense systems in a manner that meets these various requirements.We generally use a small number of suppliers of components for our products.Depending on a limited number of

suppliers exposes us to risks,including limited control over pricing,availability,quality and delivery schedules.Generally,we do not have long- term supply agreements with our suppliers,and,in many cases,we make our purchases on a purchase order basis.Under most of our supply and manufacturing agreements,we have no obligation to buy any given quantity of products,and our suppliers have no obligation to sell us or to manufacture for us any given quantity of components or products.As a result,our ability to purchase adequate quantities of components or our products may be limited,and we may not be able to convince suppliers to make components and products available to us.Additionally,our suppliers may encounter problems that limit their ability to supply components or manufacture products for us,including financial difficulties,damage to their manufacturing equipment or facilities,or product discontinuations.As a result,there is a risk that certain components could be discontinued and no longer available to us.We may be required to make significant" last time" purchases of component inventory that is being discontinued by the supplier to ensure supply continuity.If we fail to obtain sufficient quantities of high- quality components to meet demand for our products in a timely manner or on terms acceptable to us,we would have to seek alternative sources of supply.Because of factors such as the proprietary nature of our products,our quality control standards and regulatory requirements,we may not be able to quickly engage additional or replacement suppliers for some of our critical components.Failure of any of our suppliers to deliver components at the level our business requires could disrupt the manufacturing of our products and limit our ability to meet our sales commitments,which could harm our reputation and adversely affect our business.We may also have difficulty obtaining similar components from other suppliers that are acceptable to the FDA or other foreign regulatory ~~agencies~~ **authorities** ,and the failure of our suppliers to comply with strictly enforced regulatory requirements could expose us to regulatory action including warning letters,product recalls,and termination of distribution,product seizures or civil penalties.It 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 result in a requirement to seek additional regulatory approvals or certifications.Any disruption of this nature or increased expenses could harm our commercialization efforts and adversely affect our operating results.Our third- party suppliers operate primarily at facilities in a single location,and any disruption to these facilities could adversely affect our business and operating results.Each of our third- party suppliers operates at a facility in a single location and substantially all of our inventory of component supplies and finished goods is held at these locations.We,and our suppliers,take precautions to safeguard facilities,including acquiring insurance,employing back- up generators,adopting health and safety protocols and utilizing off-site storage of computer data.However,vandalism,terrorism or a natural or other disaster,such as an ~~37~~ earthquake,health epidemic,such as the coronavirus,fire or flood,could damage or destroy equipment or our inventory of component supplies or finished products,cause substantial delays in our operations,result in the loss of key information,or cause us to incur additional expenses.Our insurance may not cover our losses in any particular case.In addition,regardless of the level of insurance coverage,damage to our or our suppliers' facilities could **harm our business,financial condition and operating results.** If we do not enhance our product offerings through our research and development efforts, we may fail to effectively compete or become profitable. In order to capture and grow market share in the intensively managed diabetes market, we will need to enhance and broaden our product offerings in response to the evolving demands of people with diabetes and healthcare providers, as well as competitive pressures and technologies. These development needs include additional features, extended product life and other attributes we believe may be desired by patients. We may not be successful in developing, obtaining regulatory approval or certification for, or marketing future versions of Eversense. In addition, notwithstanding our market research efforts, our future products may not be accepted by people with diabetes, their caregivers, healthcare providers or third-party payors who reimburse people with diabetes for Eversense and healthcare providers for their services. The success of Eversense or future versions of Eversense will depend on numerous factors, including our ability, and the ability of our commercial partners, to: **34** ● identify the product features that people with diabetes, their caregivers and healthcare providers are seeking in a CGM system and successfully incorporate those features into our products; ● develop and introduce future generations of Eversense in a timely manner; ● offer products at a price that is competitive with other products then available; ● adequately protect our intellectual property and avoid infringing upon the intellectual property rights of third parties; ● demonstrate the accuracy and safety of Eversense or future versions of Eversense; ● obtain coverage and adequate reimbursement for Eversense or future versions of Eversense and the related insertion and removal procedures; and ● obtain the necessary regulatory approvals or certifications for Eversense and future versions of Eversense. However, if regulatory authorities or Notified Bodies were to disagree, this would adversely impact our ability to commercialize that product enhancement. If we fail to generate demand by developing products that incorporate features requested by people with diabetes, their caregivers or healthcare providers, or if we do not obtain regulatory clearance, certification or approval for future versions of Eversense in time to meet market demand, we may fail to generate sales sufficient to achieve or maintain profitability. We have in the past experienced, and we may in the future experience, delays in various phases of product development, approval, certification and commercial launch, including during research and development, regulatory submission and approval or certification, manufacturing, limited release testing, marketing and customer education efforts. Any delays in our anticipated product launches may significantly impede our ability to successfully compete in our markets. In particular, such delays could cause customers to delay or forego purchases of our products, or to purchase our competitors' products. Even if we are able to successfully develop future versions of Eversense when anticipated, these products may not produce sales in excess of the costs of development, and they may be quickly rendered obsolete by the changing preferences of people with diabetes or the introduction by our competitors of products embodying new technologies or features. Failure to secure or retain coverage or adequate reimbursement for Eversense or future versions of Eversense systems, including the related insertion and removal procedures, by third- party payors, and an inability of patients to be able to access the product, could adversely affect our business, financial condition and operating results. We plan to derive nearly all of our revenue from sales of Eversense in the United States and Europe and expect to do so for the next several years. Patients who receive treatment for their medical

conditions and their healthcare providers generally rely on third party payors to reimburse all or part of the costs associated with their medical treatment, including healthcare providers' services. As a result, access to coverage and adequate reimbursement for Eversense by third- party payors is essential to the acceptance of our products by people with diabetes. Similarly, healthcare providers may choose not to order a product unless third- party payors cover and reimburse a substantial portion of the product. Coverage determinations and reimbursement levels of both our products and the healthcare provider' s performance of the insertion and removal procedures are critical to the commercial success of our product, and if we or our commercial partners are not able to secure positive coverage determinations and reimbursement levels for our products or the insertion and removal procedures, our business would be materially adversely affected. ~~32~~ Within and outside the United States, reimbursement is obtained from a variety of sources, including government sponsored and private health insurance plans. These third- party payors determine whether to provide reimbursement for specific products and procedures. A third- party payor' s decision to provide coverage for our products does not imply that an adequate reimbursement rate will be obtained. Further, one third- party payor' s decision to cover our products does not assure that other payors will also provide coverage for the products or will provide coverage at an adequate reimbursement rate. In addition, there may be significant delays in obtaining a reimbursement determination, and coverage, if granted, may be more limited than the purposes for which the product is cleared or certified by the FDA, a Notified Body in the EEA or other foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers its associated costs, including research, development, manufacture, sale and distribution. For example, payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed, and may be incorporated into existing payments for other services. Net prices for products may be **35** reduced by mandatory discounts or rebates required by government healthcare programs or third- party payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices. Private insurance companies and other private, third- party payors set payor- specific reimbursement policies. The extent of coverage and the rate of reimbursement varies on a payor- by- payor basis. Most of the largest private third- party payors, in terms of the number of covered lives, have issued coverage policies for the category of CGM devices. These policies include varied coverage requirements regarding patient condition and characteristics. Many of these coverage policies reimburse for CGM systems under durable medical equipment benefits, which are restrictive in nature and require the healthcare provider or supplier to comply with extensive documentation and other requirements. In addition, those third- party payors that cover CGM products may and have included limitations as to the patient conditions and characteristics eligible for coverage and may adopt different coverage and reimbursement policies for our products, which could also diminish payments for Eversense. It is possible that some third- party payors will not offer any coverage for our products. Even if favorable coverage and reimbursement status is attained for Eversense, less favorable coverage policies and reimbursement rates may be implemented in the future. Eversense is an implantable medical device in the clinic setting and thus follows a different reimbursement path when compared to the current CGM class. Some payors will adopt a payment methodology that will bundle payment of device and procedure back to the implanting clinic. Other payors may choose to reimburse device and procedure separately. Without a Category 1 code to define the payment process, there will be some heterogeneity in this process. Given this heterogeneity, we will have to work closely with certified clinics to keep abreast of which process to follow and what to expect. This will be disruptive to some clinics and could delay product uptake until the process of payment becomes more homogenous and well defined for clinics to follow. Until a steady state is reached, delays in processing and clinic operating coordination could result in the loss of sales, which could negatively affect our business, financial condition and operating results. Third- party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs by imposing lower payment rates and negotiating reduced contract rates, among others. As such, we believe that future coverage and reimbursement may be subject to increased restrictions, such as additional preauthorization requirements, both in the United States and in international markets. Our dependence on the commercial success of our Eversense products makes us particularly susceptible to any cost containment or reduction efforts. If third- party coverage and reimbursement of products for which we may receive regulatory approval or certification is not available or adequate in either the United States or international markets, or if our production costs increase faster than increases in reimbursement levels, we or our commercial partners may be unable to sell Eversense or future versions of Eversense profitably and our business would be adversely impacted. Moreover, in the EU some countries may 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 ~~33~~ status granted to these products by the competent authorities of individual EU Member States. On January 31, 2018, the European Commission adopted a proposal for a regulation on health technologies assessment. The Regulation 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. In December 2021 the HTA Regulation was adopted and entered into force on January 11, 2022. It will apply from 2025. In ~~March 2019~~ **April 2022** , **as** ~~we launched~~ a ~~patient~~ **part of commercialization efforts, our partner Ascensia implemented the PASS program designed to enhance affordability and** access **to** ~~program, the~~ Eversense **for** ~~Bridge Program, to assist those~~ patients who do not have insurance coverage for Eversense, or whose insurance is denied or **is** insufficient. ~~Pursuant to this program, we provided financial assistance to eligible patients purchasing Eversense, which may have been substantial depending on a patient' s insurance coverage. We also assisted patients in their appeal of adverse coverage decisions made by insurance providers. In December 2020, we terminated the Eversense Bridge Program. We expect our partner Ascensia to~~

~~implement patient assistance programs and related programs as part of its commercialization efforts.~~ The ~~lack of a patient assistance program, or a~~ program' s design being ineffective, **or a lack of a patient assistance program** could adversely impact the sales of Eversense and, consequently our net revenues. In addition, we may not be able to recognize a substantial portion of the revenue related to Eversense insertions for the patients participating in these access programs. The amount of time required to obtain favorable coverage and reimbursement **36** decisions, including navigating the appeals process with third- party payors, is uncertain, and we may see increased product utilization without corresponding recognized revenue. Our operating results may be adversely impacted if we are unable to obtain successful appeals or favorable coverage decisions by insurance providers, or if there are not effective patient access programs in place. If important assumptions we have made about what people with intensively managed diabetes are seeking in a CGM system are inaccurate, 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 ~~intensively managed~~ diabetes market **for CGM** in particular, any one or more of which may prove to be inaccurate. For example, we believe that the benefits of CGM will continue to drive increased rates of market acceptance for products in this space. However, this trend is uncertain and limited sources exist to obtain reliable market data. Another key element of our business strategy is utilizing market research to understand how people with diabetes are seeking to improve their diabetes therapy management. This strategy underlies our entire product design, marketing and customer support approach and is the basis on which we developed Eversense. However, our market research is based on interviews, focus groups and online surveys involving people with ~~intensively managed~~ diabetes **on insulin** , their caregivers and healthcare providers that represent only a small percentage of the overall ~~intensively managed~~ diabetes market. As a result, the attributes we incorporated into the Eversense system may not be reflective of what is desired by the various constituents in the diabetes market. Consequently, our estimates of our future market share and penetration may not be accurate and our sales may be less than estimated. We operate in a very competitive industry and if we fail to compete successfully against our existing or potential competitors, many of whom have greater resources than we have, our sales and operating results may be negatively affected. The market for CGM systems is developing and competitive, subject to rapid change and significantly affected by new product introductions. We compete with well- capitalized companies, some of which are publicly traded, that manufacture CGM systems including Dexcom, Medtronic and Abbott. Each of these companies has received approval from the FDA to market their respective CGM system. Dexcom' s CGM system was the first CGM system to be approved by the FDA for marketing as a non- adjunctive device, and Abbott' s Freestyle Libre was also approved for non- adjunctive use. Both Dexcom (G6 and G7) and Abbott (Freestyle Libre) systems have factory calibration, and do not require user calibration. Dexcom has also received the first FDA iCGM indication allowing its Dexcom G6 and G7 to be interoperable with other diabetes tech devices such as insulin pumps. As the industry evolves, we anticipate encountering increasing competition from companies that integrate CGM with insulin pumps. Abbott also received an iCGM indication for their Freestyle Libre 2 **and 3** ~~product~~ **products** and we expect all other CGM companies to pursue an iCGM indication including Medtronic. ~~34~~ In addition to CGM providers, we also compete with providers of SMBG systems. Three companies currently account for a substantial share of the worldwide sales of SMBG systems: Roche Diabetes Care, a division of Roche Diagnostics; Abbott; and Ascensia Diabetes Care Holdings AG. There are also a number of academic and other institutions involved in various phases of our industry' s technology development. Many of these competitors enjoy several advantages over us, including: ● greater financial and human resources for sales and marketing, and product development; ● established relationships with healthcare providers and third- party payors; ● established reputation and name recognition among healthcare providers and other key opinion leaders in the diabetes industry; ● in some cases, an established base of long- time customers; ● products supported by long- term clinical data; ● larger and more established sales, marketing and distribution networks; **37** ● greater ability to cross- sell products or provide incentives to healthcare providers to use their products; and ● more experience in conducting research and development, manufacturing, clinical trials, and obtaining regulatory approval or clearance and certification. In addition, mergers and acquisitions in the diabetes industry may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or that may be necessary for, our programs. If we are unable to effectively compete with our competitors, we may fail to meet our strategic objectives, and our business, financial condition and operating results could be harmed. Competitive products or other technological innovations for the monitoring, treatment or prevention of diabetes may render our products less competitive or obsolete. Our ability to achieve our strategic objectives will depend, among other things, on our ability to develop and commercialize products for the monitoring and management of diabetes that offer distinct features, have a longer duration than available alternatives, are easy- to- use, receive adequate coverage and reimbursement from third- party payors, include essential safety features and are more appealing than available alternatives. Our primary competitors, as well as a number of other companies, medical researchers and existing medical device companies are pursuing new delivery devices, delivery technologies, sensing technologies, procedures, drugs and other therapies for the monitoring, treatment and prevention of diabetes. For example, the National Institutes of Health and other supporters of diabetes research are continually seeking ways to prevent, cure or improve treatment of diabetes, which if successful could render glucose monitoring devices, like Eversense, obsolete. Any technological breakthroughs in diabetes monitoring, treatment or prevention could reduce the potential market for Eversense or render Eversense less competitive or obsolete altogether, which would significantly reduce our potential sales. Because of the size of the diabetes market, we anticipate that companies will continue to dedicate significant resources to developing competitive products. The frequent 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 competitive products. In addition, the entry of multiple new products may lead some of our competitors to employ pricing strategies that

could adversely affect the pricing of our products. If a competitor develops a product that competes with or is perceived to be superior to Eversense, or if a competitor employs strategies that place downward pressure on pricing within our industry, our sales may decline significantly or may not increase in line with our expectations, either of which would harm our business, financial condition and operating results. ~~35~~ The size and future growth in the market for CGM systems and CGM- related products has not been established with precision and may be smaller than we estimate, possibly materially. If our estimates and projections overestimate the size of this market, our sales growth may be adversely affected. Our estimates of the size and future growth in the market for CGM systems and CGM- related products, including the number of people currently managing their diabetes with insulin who may benefit from and be amenable to using Eversense, is based on a number of internal and third-party studies, reports and estimates. In addition, our internal estimates are based in large part on current treatment patterns by healthcare providers using CGM systems and our belief that the incidence of diabetes in the United States and worldwide is increasing. While we believe these factors have historically provided and may continue to provide us with effective tools in estimating the total market for CGM systems and CGM related products and our products, these estimates may not be correct and the conditions supporting our estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. The actual incidence of diabetes, and the actual demand for our products or competitive products, could differ materially from our projections if our assumptions are incorrect. As a result, our estimates of the size and future growth in the market for our CGM systems may prove to be incorrect. If the actual number of people with diabetes who would benefit from Eversense **38** and the size and future growth in the market for Eversense is smaller than we have estimated, it may impair our projected sales growth and have an adverse impact on our business. Our ability to maintain and grow our revenue will depend on establishing a customer base and retaining a high percentage of our customer base. A key to maintaining and growing our revenue will be establishing a customer base and retaining a high percentage of our customers due to the potentially significant revenue generated from ongoing purchases of disposable sensors. Ascensia intends to continue developing customer loyalty programs to help with retention aimed at patients, their caregivers and healthcare providers, which include patient ambassadors, training specific to Eversense, ongoing support by sales and clinical employees and 24 / 7 technical support and customer service. If demand for our products fluctuates as a result of the introduction of competitive products, changes in reimbursement policies, manufacturing problems, perceived safety issues with our or our competitors' products, the failure to secure regulatory clearance or approvals, certifications or for other reasons, our ability to attract and retain customers could be harmed. The failure to retain a high percentage of our customers would negatively impact our business, financial condition and operating..... or our suppliers' facilities could harm our business, financial condition and operating results. Various factors outside our direct control may adversely affect manufacturing, sterilization and distribution of our products. The manufacture, sterilization and distribution of our products is challenging. Changes that our suppliers may make outside the purview of our direct control can have an impact on our processes, quality of our products and the successful delivery of products to our customers. Mistakes and mishandling are not uncommon and can affect supply and delivery. Some of these risks include: ● failure to complete sterilization on time or in compliance with the required regulatory standards; ● transportation and import and export risk, particularly given the international nature of our supply and distribution chains; ● delays in analytical results or failure of analytical techniques that we will depend on for quality control and release of products; ● natural disasters, labor disputes, financial distress, raw material availability, issues with facilities and equipment **(including through cyberattacks or other security incidents)** or other forms of disruption to business operations affecting our manufacturers or suppliers; and ● latent defects that may become apparent after products have been released and that may result in a recall of such products. If any of these risks were to materialize, our ability to provide our products to customers on a timely basis would be adversely impacted. Potential complications from Eversense or future versions of Eversense may not be revealed by our clinical experience. Based on our experience, complications from use of Eversense may include sensor errors, sensor failures or skin irritation under the adhesive dressing of the transmitter. Inflammation or redness, swelling, minor infection, and minor bleeding at the sensor insertion site are also possible risks with an individual' s use of the device. However, if unanticipated side- effects result from the use of Eversense or future versions of Eversense, we could be subject to liability and our systems would not be widely adopted. Additionally, we have limited clinical experience with repeated use of our CGM system in the same patient or the same insertion site. We cannot assure you that long- term use would not result in unanticipated complications, even after the device is removed. **39** Undetected errors or defects in Eversense or future versions of Eversense could harm our reputation, decrease the market acceptance of Eversense or expose us to product liability claims. Eversense or future versions of Eversense may contain undetected errors or defects. Disruptions or other performance problems with Eversense or future versions of Eversense, including our sensors not lasting for the full approved or certified duration of use, may harm our reputation. If that occurs, we may incur significant costs, the attention of our key personnel could be diverted, or other significant customer relations problems may arise. We may also be subject to increased warranty and liability claims for damages related to errors or defects in Eversense or future versions of Eversense. A material liability claim or other occurrence that harms our reputation or decreases market acceptance of Eversense could harm our business and operating results. This risk exists even if a device is cleared, certified or approved for commercial sale and manufactured in facilities licensed and regulated by the FDA or an applicable foreign regulatory authority. Any side effects, manufacturing defects, misuse or abuse associated with Eversense or future versions of Eversense systems could result in patient injury or death. The medical device industry has historically been subject to extensive litigation over product liability claims, and we cannot offer any assurance that we will not face product liability lawsuits. ~~38~~ The sale and use of Eversense or future versions of Eversense could lead to the filing of product liability claims if someone were to allege that Eversense or one of our products contained a design or manufacturing defect. A product liability claim could result in substantial damages and be costly and time consuming to defend, either of which could materially harm our business or financial condition. Product liability claims may be brought against us by people with diabetes, healthcare providers or others selling or otherwise coming into contact with our products, among others. If we cannot successfully defend

ourselves against product liability claims, we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in: ● costs of litigation; ● distraction of management' s attention from our primary business; ● the inability to commercialize Eversense or future versions of Eversense; ● decreased demand for Eversense; ● damage to our business reputation; ● product recalls or withdrawals from the market; ● withdrawal of clinical trial participants; ● substantial monetary awards to patients or other claimants; or ● loss of revenue. While we currently maintain product liability insurance covering claims up to $ 10. 0 million per ~~incident~~ **occurrence** , we cannot assure you that such insurance would adequately protect our assets from the financial impact of defending a product liability claim. Any product liability claim brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing such insurance coverage in the future. ~~If there are significant disruptions in our information technology systems, our business, financial condition and operating results could be adversely affected. The efficient operation of our business depends on our information technology systems. We rely on our information technology systems to effectively manage patient requisitions and data, customer service cases and replacement obligations, marketing data, accounting and financial functions, inventory and order management, product quality records, research and development data, and technical support functions. Despite our security measures, our information technology systems are vulnerable to damage or interruption from earthquakes, fires, floods and other natural disasters, terrorist attacks, attacks by computer viruses or hackers, power losses, and computer system or data network failures. In addition, our data management application and a variety of our software systems, including the software in our smart transmitter, are hosted by third- party service providers whose security and information technology systems are subject to similar risks, which could be subject to computer viruses or hacker attacks or other failures. If our or our third- party service provider' s security systems are breached or fail, unauthorized persons may be able to obtain access to sensitive data. If we or our third- party service providers were to experience a breach compromising sensitive data, our brand and reputation could be adversely affected, and the use of our products could decrease. The failure of our or our service providers' information technology systems or our transmitter' s software to perform as we anticipate or our failure to effectively implement new information technology systems could disrupt our entire operation or adversely affect our products and could result in decreased sales, increased overhead costs, and product shortages, all of which could negatively affect our reputation, business, financial condition and operating results.~~ We may enter into collaborations, in- 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, in- licensing arrangements, joint ventures, strategic alliances, partnerships or other arrangements to develop products and to pursue new markets. Proposing, negotiating and implementing collaborations, in- licensing arrangements, joint ventures, strategic alliances or partnerships may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing, sales, technology or other business resources, may compete with us for these opportunities or arrangements. We may not identify, secure, or complete any such transactions or arrangements in a timely manner, on a ~~39~~ cost-effective basis, on acceptable terms or at all. We have limited institutional knowledge and experience with respect to these business development activities, and we may also not realize the anticipated benefits of any such transaction or arrangement. In particular, these collaborations may not result in the development of products that achieve commercial success or result in significant revenues and could be terminated prior to developing any products. **40** Additionally, we may not be in a position to exercise sole decision- making authority regarding the transaction or arrangement, which could create the potential risk of creating impasses on decisions, and our future collaborators 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, 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 or the ownership or control of intellectual property developed during the collaboration. If any conflicts arise with any 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. For example, one of our vendors who provides a component to the Eversense sensor has communicated to us its belief that one of its employees should be named as a co- inventor on a related patent application. We have communicated to the third party that its employee should not be named as a co- inventor and its employee has not been named as a co- inventor to date. In addition, we may have limited control over the amount and timing of resources that any future collaborators devote to our or their future products. Disputes between us and our collaborators may result in litigation or arbitration which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements will be contractual in nature and will generally be terminable 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. If we enter into in- bound intellectual property license agreements, we may not be able to fully protect the licensed intellectual property rights or maintain those licenses. Future licensors could retain the right to prosecute and defend the intellectual property rights licensed to us, in which case we would depend on the ability of our licensors to obtain, maintain and enforce intellectual property protection for the licensed intellectual property. These licensors may determine not to pursue litigation against other companies or may pursue such litigation less aggressively than we would. Further, entering into such license agreements could impose various diligence, commercialization, royalty or other obligations on us. Future licensors may allege that we have breached our license agreement with them, and accordingly seek to terminate our license, which could adversely affect our competitive business position and harm our business prospects. We may seek to grow our business through acquisitions of complementary products or technologies, and the failure to manage acquisitions, or the failure to integrate them with our existing business, could harm our business, financial condition and operating results. From time to time, we may consider opportunities to acquire other companies, products or technologies that may enhance our product platform or technology, expand the breadth of our markets or customer base, or advance our business strategies. Potential acquisitions involve numerous risks, including: ● problems assimilating the acquired products or technologies; ● issues

maintaining uniform standards, procedures, controls and policies; ● unanticipated costs associated with acquisitions; ● diversion of management' s attention from our existing business; ● risks associated with entering new markets in which we have limited or no experience; ● increased legal and accounting costs relating to the acquisitions or compliance with regulatory matters; and ● unanticipated or undisclosed liabilities of any target. We have no current commitments with respect to any acquisition. We do not know if we will be able to identify acquisitions we deem suitable, whether we will be able to successfully complete any such acquisitions on favorable terms or at all, or whether we will be able to successfully integrate any acquired products or technologies. Our potential inability to integrate any acquired products or technologies effectively may adversely affect our business, operating results and financial condition. ~~40~~ The ongoing military action by Russia in Ukraine **and by Hamas in Gaza** could have negative impact on the global economy which could materially adversely affect our business, operations, operating results and financial condition. On February 24, 2022, Russian forces launched significant military action against Ukraine, and sustained conflict and disruption in the region is possible. The impact to Ukraine as well as actions taken by other countries, **41** including new and stricter sanctions imposed by Canada, the United Kingdom, the European Union, the U. S. and other countries and companies and organizations against officials, individuals, regions, and industries in Russia and Ukraine, and actions taken by Russia in response to such sanctions, and each country' s potential response to such sanctions, tensions, and military actions could adversely affect the global economy and financial markets and thus could affect our business, operations, operating results and financial condition as well as the price of our common stock and our ability to raise additional capital when needed on acceptable terms. **Separately, in early October 2023, Hamas, a militant group in control of Gaza, and Israel began an armed conflict in Israel, the Gaza Strip, and surrounding areas, which threatens to spread to other Middle Eastern countries including Lebanon, Syria, and Iran. The Hamas- Israel military conflict is ongoing, and its length and outcome are highly unpredictable.** The extent and duration of the military action, sanctions and resulting market disruptions are impossible to predict, but could be substantial. While our suppliers may source certain raw materials from ~~Russia and Ukraine~~ **areas with ongoing military conflict** , to date we have not been notified that the supply of these materials has been significantly impacted by ~~the~~ **these** ~~conflict~~ **conflicts** . We continue to monitor ~~the situation~~ **potential disruptions** closely and are proactively assessing and evaluating alternative sources to bolster supply of these materials moving forward, in addition to working closely with our suppliers in any product re- qualification that may be required. Revenue relating to products manufactured from raw materials sourced from ~~this region~~ **regions with current ongoing international conflict** does not constitute a material portion of our business. Further, there is uncertainty regarding the ultimate impact ~~the~~ **these** ~~conflict~~ **conflicts** , including any escalation or further expansion of the conflict' s current scope, will have on our customers, the global economy, supply chains, logistics, fuel prices, raw material pricing and our business. Surging natural gas and electricity costs in Europe poses a threat to our contract manufacturers ability to maintain operations in Europe which can adversely affect or business supply chainEurope' s energy crisis driven by the impacts of Russia' s military action in Ukraine is quickly soaring and causing extreme disruption to the manufacturing industry across the continent. The reduced natural gas supply to Europe has resulted in higher gas costs which have been unsustainable for energy intensive companies that operate across Europe. Several manufacturers have shut down, suspended or reduced operations amidst the skyrocketing prices. Several of our suppliers operate in Europe and may be impacted by the energy crisis as the result of increased production costs. Across Europe, these energy constraints could result in nations or regions enacting emergency energy related policies, limiting energy availability for manufacturers. The impact of these developments cannot be predicted with certainty, however, any such production constraints could further exacerbate an already ailing supply chain and could have a material, adverse effect on our operations and our ability to source materials that are required to manufacture our products. We continue to monitor the situation closely and continue to have discussions with our suppliers to determine whether there may be any uncertainty with regards to our ability to source materials that are required to manufacture our products. If the energy crisis or other supply chain challenges impact our ability to obtain raw materials on a timely basis or without significant increases in costs, our financial results and business operations may be adversely affected. Our business could be adversely affected by economic downturns, inflation, increases in interest rates, natural disasters, public health crises such as ~~the COVID- 19 pandemic~~ **pandemics** , political crises, geopolitical events, such as the crisis in Ukraine, or other macroeconomic conditions, which have in the past and may in the future negatively impact our business and financial performance. The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including, among other things, severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, increases in inflation rates, higher interest rates and uncertainty about economic stability. **A** ~~For example, the COVID- 19 pandemic resulted in~~ widespread **public health crisis such as** ~~unemployment, economic slowdown and extreme volatility in the capital markets. While the potential economic impact brought by, and the duration of, COVID- 19 may be difficult to assess or predict,~~ a ~~widespread~~ pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could negatively affect our liquidity. In addition, a recession or market correction resulting from the ~~spread~~ **effects** of ~~COVID- 19~~ **public health crises** could materially affect our business and the value of our ~~41~~ common stock. **It may** ~~The COVID- 19 pandemic has had and could continue to~~ have **further** negative impacts, such as (a) a global or U. S. recession or other economic crisis; (b) credit and capital markets volatility (and access to these markets, including by our suppliers and customers); (c) manufacturing supply disruption due to ~~" stay at home orders "~~ travel restrictions or other government actions; (d) disruptions in raw material **42** supply, our manufacturing operations, or in our distribution and supply chain; and (e) our ability to conduct planned clinical trials and commercialization activities. The ultimate impact of ~~the COVID- 19 pandemic or~~ a ~~similar~~ **public** health ~~epidemic~~ **crisis** is highly uncertain ~~and subject to change. We will continue to monitor the COVID- 19 situation closely~~ . The Federal Reserve recently raised interest rates multiple times in response to concerns about inflation and it may raise them again. Higher interest rates, coupled with reduced government spending and volatility in financial markets may increase economic uncertainty and affect consumer spending. If the equity and credit markets deteriorate, including as a result of political

unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. Increased inflation rates can adversely affect us by increasing our costs, including labor and employee benefit costs. Risks Related to our Financial Results and Need for Financing We will need to generate significant sales to achieve profitable operations. We intend **to continue** to increase our operating expenses in connection with the commercialization of Eversense with our collaboration partner Ascensia, our ongoing research and development activities including the development of next generation products and the clinical trials for those products, and the commensurate development of our management and administrative functions. We will need to generate significant sales to achieve profitability, and we might not be able to do so. Even if we do generate significant sales, we might not be able to achieve, sustain or increase profitability on a quarterly or annual basis in the future. If our sales grow more slowly than we expect, or if our operating expenses exceed our expectations, our financial performance and operating results will be adversely affected. Our operating results may fluctuate from quarter to quarter or year to year. We have limited operating history as a commercial- stage company and we anticipate that there will be meaningful variability in our operating results among years and quarters, as well as within each year and quarter. Our operating results, and the variability of these operating results, will be affected by numerous factors, including: ● regulatory clearance, certification or approvals affecting our products or those of our competitors; ● Ascensia' s ability to increase sales of Eversense and to commercialize and sell our future products, and the number of our products sold in each quarter; ● Ascensia' s ability to establish and grow an effective sales and marketing infrastructure and third- party distribution network; ● acceptance of our products by people with diabetes, their caregivers, healthcare providers and third-party payors; ● the pricing of our products and competitive products, and the effect of third- party coverage and reimbursement policies; ● 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; ● seasonality and other factors affecting the timing of purchases of Eversense; ● timing of new product offerings, acquisitions, licenses or other significant events by us or our competitors; ● results of clinical research and trials on our products in development; ● the ability of our suppliers to timely provide us with an adequate supply of components and CGM systems that meet our requirements; ● changes in the fair value of embedded derivative instruments in the terms of some of our financings, which are subject to potentially wide fluctuations from period to period as a result of changes in our stock price; ~~and~~42 -- **and** ● the timing of revenue recognition associated with our product sales pursuant to applicable accounting standards. As a result of our lack of operating history as a commercial- stage company and Ascensia' s lack of experience selling CGM systems, and Eversense in particular, and due to the complexities of the industry and regulatory framework in which we operate, it will be difficult for us to forecast demand for our future products and to forecast our sales with any degree of certainty. For example, many of the products we will seek to develop and introduce in the future will require regulatory approval, certification or clearance and import licenses before we can sell such products and given that **43** the timing of such approvals, certification, clearances or licenses may be uncertain, it will be difficult for us to predict sales projections for these products with any degree of certainty before such approvals, certifications, clearances or licenses are obtained. In addition, we will be increasing our operating expenses as we expand our business. Accordingly, we may experience substantial variability in our operating results from year to year and quarter to quarter. If our quarterly or annual operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly or annual fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance. Covenants under the ~~PHC Note Purchase~~ **Loan and Security** Agreement ~~and the indentures related to the 2023 Notes~~ and the 2025 Notes may result in the acceleration of outstanding indebtedness and limit the manner in which we operate. **In September 2023, we entered into a loan agreement (the " Loan and Security Agreement ") with several institutions (collectively, the " Lenders") and Hercules Capital, Inc. (" Hercules "), as administrative agent.** The ~~PHC Note Purchase~~ **Loan and Security** Agreement contains customary terms and covenants, including financial covenants, such as operating within an approved budget and achieving minimum revenue and liquidity targets, and negative covenants, such as limitations on indebtedness, liens, mergers, asset transfers, certain investing activities and other matters customarily restricted in such agreements. Most of these restrictions are subject to certain minimum thresholds and exceptions. The ~~Note Purchase~~ **Loan and Security** Agreement also contains customary events of default, after which **borrowings under** the ~~PHC Notes~~ **Loan and Security Agreement will** be due and payable immediately, including defaults related to payment compliance, material inaccuracy of representations and warranties, covenant compliance, material adverse changes, bankruptcy and insolvency proceedings, cross defaults to certain other agreements, judgments against the Company, change of control or delisting events, termination of any guaranty, governmental approvals, and lien priority. In addition, the indentures related to ~~the 2023 Notes and~~ the 2025 Notes contain, and any future indebtedness we incur may contain, various negative covenants that restrict, among other things, our ability to: ● incur additional indebtedness, guarantee indebtedness or issue disqualified stock or, in the case of such subsidiaries, preferred stock; ● declare or pay dividends on, repurchase or make distributions in respect of, their capital stock or make other restricted payments; ● make investments or acquisitions; ● create liens; ● enter into agreements restricting certain subsidiaries' ability to pay dividends or make other intercompany transfers; ● consolidate, merge, sell or otherwise dispose of all or substantially all of our assets and the assets of our restricted subsidiaries; ● enter into transactions with affiliates; ● sell, transfer or otherwise convey certain assets; and ● prepay certain types of indebtedness. As a result, we are limited in the manner in which we conduct our business and we may be unable to engage in favorable business activities, repurchase shares of our common stock or finance future operations or capital needs. Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial debt. ~~43~~ Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations

in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial **44** condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations. Despite our current debt levels, subject to certain conditions and limitations, we may still incur substantially more debt or take other actions which would intensify the risks discussed above. Despite our current consolidated debt levels, subject to certain conditions and limitations in the indentures related to the ~~2023 Notes and the~~ 2025 Notes and ~~PHC Notes~~ **the Loan and Security Agreement**, we may be able to incur substantial additional debt in the future, some of which may be secured debt. We may not be subject to any restrictions on incurrence of additional indebtedness under the terms of any future indebtedness. If new debt is added to our current debt levels, the related risks that we and they now face could intensify. Prolonged negative economic conditions could adversely affect us, our customers and third- party suppliers, which could harm our financial condition. We are subject to the risks arising from adverse changes in general economic and market conditions. Uncertainty about future economic conditions could negatively impact our existing and potential customers, adversely affect the financial ability of health insurers to pay claims, adversely impact our expenses and ability to obtain financing of our operations, and cause delays or other problems with key suppliers. Healthcare spending in the United States and Europe has been, and is expected to continue to be, under significant pressure and there are many initiatives to reduce healthcare costs. As a result, we believe that some insurers are scrutinizing insurance claims more rigorously and delaying or denying coverage and reimbursement more often. Because the sale of Eversense will generally depend on the availability of third- party coverage and reimbursement, any delay or decline in coverage and reimbursement will adversely affect our sales. Our business may be exposed to foreign exchange risks. We incur some of our expenses and derive revenues from the Eversense system in currencies other than the U. S dollar. As a result, we are exposed to foreign currency exchange risk as our results of operations and cash flows are subject to fluctuations in foreign currency exchange rates. We currently do not engage in hedging transactions to protect against uncertainty in future exchange rates between particular foreign currencies and the U. S. dollar. Therefore, for example, an increase in the value of the U. S. dollar against the euro or the British pound could have a negative impact on our revenue and earnings growth as euro and British pound revenue and earnings, if any, are translated into U. S. dollars at a reduced value. We cannot predict the impact of foreign currency fluctuations, and foreign currency fluctuations in the future may adversely affect our financial condition, results of operations and cash flows. Risks Related to Development of our Products If we modify our approved product or CE marked, we may need to seek additional approvals or CE Certificates of Conformity, which, if not granted, would prevent us from selling our modified products. A component of our strategy is to continue to modify and upgrade our Eversense system, which requires approval or certification by the FDA and analogous regulatory bodies in other jurisdictions. We may not be able to obtain additional regulatory approvals or certifications for new products or for modifications to, or additional indications for, our existing products in a timely fashion, or at all. Delays in obtaining future approvals or certification, including ~~44~~ potential delays in obtaining approval of our currently pending applications, would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our revenue and potential future profitability. Any modifications to the Eversense that could significantly affect its safety or effectiveness, including significant design and manufacturing changes, or that would constitute a major change in its intended use, manufacture, design, components, or technology requires approval of a new PMA, or PMA supplement or similar modifications in other jurisdictions. However, certain changes to a PMA- approved device do not require submission and approval of a **45** new PMA or PMA supplement, or appropriate modifications in other jurisdictions, and may only require notice to FDA in a PMA Annual Report, or similar notifications in other jurisdictions. In the U. S., the FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any such decision. The FDA may not agree with our decisions regarding whether new approvals are necessary. Our products could be subject to recall if the FDA determines, for any reason, that our products are not safe or effective or that appropriate regulatory submissions were not made. Similar regulatory considerations apply outside the U. S. If new regulatory approvals or certifications are required, this could delay or preclude our ability to market the modified system. For those medical devices sold in the EEA, we must notify our Notified Body if significant changes are made to the products or if there are substantial changes to our quality assurance systems affecting those products. Obtaining variation of existing CE Certificates of Conformity or a new Certificate can be a time-consuming process, and delays in obtaining required future clearances 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. Medical device development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, ongoing development for lifecycle management of our products. While we have completed pivotal trials in Europe and the United States, we are and may need to conduct future clinical trials in order to develop new versions of our system or to comply with requirements for post- approval studies. ~~For example, we currently have a pivotal trial underway to support a future PMA supplement for a 365- day sensor.~~ Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. Further, the outcomes of our earlier clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, clinical data is often susceptible to varying interpretations and analyses, and many companies that have believed their products performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval or certification. If we are unable to successfully complete clinical trials of Eversense or other testing, if the results of these trials or tests are not favorable or if there are safety concerns, we may: ● not obtain marketing approval or certification for such modifications; ● be delayed in obtaining marketing approval or certification for such modifications; ● be subject to additional post- marketing testing requirements; or ● have Eversense removed from the market after obtaining marketing approval. Our development costs will

also increase if we experience delays in testing, marketing approvals, or certification. Significant clinical trial delays also could allow our competitors to bring innovative products to market before we do and impair our ability to successfully commercialize our products. ~~45~~ Risks Related to Employee Matters and Managing our Growth Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel. We are highly dependent on the management, research and development, clinical, financial and business development expertise of Tim Goodnow, our Chief Executive Officer, Rick Sullivan, our Chief Financial Officer, Mukul Jain, our Chief Operating Officer, and Ken Horton, our General Counsel and Corporate Development Advisor, as well as the other members of our scientific and clinical teams. Although we have employment agreements with our executive officers, each of them may terminate their employment with us at any time and will continue to be able to do so. We do not maintain" key person" insurance for any of our executives or employees. Recruiting and retaining qualified scientific and clinical personnel and, as we progress the development of our product pipeline toward scaling up for commercialization, manufacturing and sales and marketing personnel, will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the **46** achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize our products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous medical device companies for similar personnel, many of which have greater financial and other resources dedicated to attracting and retaining personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited. Although it will be subject to restrictions on trading, a portion of the equity of our management team will not contain other contractual transfer restrictions. This liquidity may represent material wealth to such individuals and impact retention and focus of existing key members of management. We expect to expand our development and regulatory capabilities and our marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations. As of December 31, ~~2022~~ **2023** , we had ~~128~~ **132 full- time** employees. As our commercialization progresses, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of research, product development, clinical sciences, regulatory affairs, supply chain, and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations. Additionally, we have and may undertake cost reduction plans, which may include reorganization of our workforce. These actions could disrupt the employee base, our ability to attract and retain qualified personnel, or cause other operational and administrative inefficiencies. ~~46~~ Our employees, independent contractors, consultants, manufacturers and distributors may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements. We are exposed to the risk that our employees, independent contractors, consultants, manufacturers and distributors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or disclosure of unauthorized activities to us that violates FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA, manufacturing standards, federal and state healthcare laws and regulations, and laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are **47** not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, including, without limitation, damages, fines, disgorgement of profits, individual imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, and the curtailment or restructuring of our operations. 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 design, manufacture, testing and sale of medical devices. We could become the subject of product liability lawsuits alleging that component failures, manufacturing flaws, design defects or inadequate disclosure of product- related risks or product- related information resulted in an unsafe condition, injury or death to customers. In addition, the misuse of our products or the failure of customers to adhere to operating guidelines could cause

significant harm to customers, including death, which could result in product liability claims. Product liability lawsuits and claims, safety alerts or product recalls, with or without merit, could cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business, harm our reputation and adversely affect our ability to attract and retain customers, any of which could harm our business, financial condition and operating results. 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 typically have substantial deductibles for which we are responsible. Product liability claims in excess of applicable insurance coverage would negatively impact our business, financial condition and operating results. In addition, any product liability claim brought against us, with or without merit, could result in an increase of our product liability insurance premiums. Insurance coverage varies in cost and can be difficult to obtain, and we cannot guarantee that we will be able to obtain insurance coverage in the future on terms acceptable to us or at all. Risks Related to our Intellectual Property Our ability to 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. As of December 31, ~~2022~~ **2023** , we held a total of approximately ~~500~~ **508** issued patents and pending patent applications that relate to our CGM system. Our intellectual property portfolio includes ~~96~~ **105** issued United States patents, ~~200~~ **204** patents issued in countries outside the United States, and ~~204~~ **199** pending patent applications worldwide. Our patents expire between ~~2023~~ **2024** and 2042, subject to any patent extensions that may be available for such patents. If patents are issued on our pending patent applications, the resulting patents are projected to expire on dates ranging from 2032 to ~~2042~~ **2043** , subject to any patent term extensions or adjustments that may be available ~~47~~ for such patents. We are also seeking patent protection for our proprietary technology in Europe, Japan, China, Canada, India, Australia and other countries and regions throughout the world. We have two pending U. S. trademark application and 5 pending foreign trademark applications, as well as 12 U. S. trademark registrations and 129 foreign trademark registrations. We have applied for patent protection relating to certain existing and proposed products and processes. Currently, several of our issued U. S. patents as well as various pending U. S. and foreign patent applications relate to the structure and operation of our CGM sensor and CGM systems, which are important to the functionality of our products. If we fail to timely file a patent application in any jurisdiction, we may be precluded from doing so at a later date. Furthermore, we cannot assure you that any of our patent applications will be approved 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 meaningful 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. Even if we are successful in receiving patent protection for certain products and processes, our competitors may be able to design around our patents or develop products that provide outcomes which are comparable to ours without infringing on our intellectual property rights. Due to differences between foreign and **48** 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 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. For example, we have two pending applications in the United States for the" Eversense" trademark. We cannot assure you that our trademark applications will be approved in a timely manner or at all. Third parties also may oppose our trademark applications, or otherwise challenge our use of the 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 also rely on trade secrets, know- how and technology, which are not protectable by patents, to maintain our competitive position. We try to protect this information by entering into confidentiality agreements and intellectual property assignment agreements with our officers, employees, temporary employees and consultants regarding our intellectual property and proprietary technology. In the event of unauthorized use or disclosure or other breaches of those agreements, we may not have an adequate remedy to compensate us for our trade secrets or other proprietary information. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our commercial partners, collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in the related or resulting know- how and inventions. If any of our trade secrets, know- how or other technologies not protected by a patent were to be disclosed to or independently developed by a competitor, our business, financial condition and results of operations could be materially adversely affected. If a competitor infringes upon one of our patents, trademarks or other intellectual property rights, enforcing those patents, trademarks and other rights may be difficult and time consuming. Patent law relating to the scope of claims in the industry in which we operate is subject to rapid change and constant evolution and, consequently, patent positions in our industry can be uncertain. Even if successful, litigation to defend our patents and trademarks against challenges or to enforce our intellectual property rights could be expensive and time consuming and could divert management' s attention from managing our business. Moreover, we may not have sufficient resources or desire to defend our patents or trademarks against challenges or to enforce our intellectual property rights. Litigation also puts our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing. Additionally, we may provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially material. The occurrence of any of these events may harm our business, financial condition and operating results. ~~48~~ Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-

compliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications will be due to be paid to the United States Patent and Trademark Office (“ USPTO ”) the European Patent Office (“ EPO ”), and other foreign patent agencies over the lifetime of our owned patents and applications. The USPTO, the EPO and various foreign governmental patent agencies require compliance with several procedural, documentary, fee payment, and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non- compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non- payment of fees and failure to properly legalize and submit formal documents. If we or our licensors or collaboration partners fail to maintain the patents and patent applications covering our proprietary technologies, our competitors might be able to enter the market earlier with similar products or technology, which would have an adverse effect on our business. **49** The medical device industry is characterized by patent litigation, and we could become subject to litigation that could be costly, result in the diversion of management' s time and efforts, stop our development and commercialization measures, harm our reputation or require us to pay damages. Our success will depend in part on not infringing the patents or violating the other proprietary rights of third parties. Significant litigation regarding patent rights exists in our industry. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in competing technologies, 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 products. The large number of patents, the rapid rate of new patent issuances, and the complexities of the technology involved increase the risk of patent litigation. The medical device industry in general, and the glucose testing sector of this industry in particular, are characterized by the existence of a large number of patents and frequent litigation based on assertions of patent infringement. We are aware of numerous patents issued to third parties that may relate to the technology used in our business, including the design and manufacture of CGM sensors and CGM systems, as well as methods for continuous glucose monitoring. Each of these patents contains multiple claims, any one of which may be independently asserted against us. The owners of these patents may assert that the manufacture, use, sale or offer for sale of our CGM sensors or CGM systems infringes one or more claims of their patents. Furthermore, there may be additional patents issued to third parties of which we are presently unaware that may relate to aspects of our technology that such third parties could assert against us and materially and adversely affect our business. In addition, because patent applications can take many years to issue, there may be patent applications that are currently pending and unknown to us, which may later result in issued patents that third parties could assert against us and harm our business. In preparation for commercializing our Eversense products, we are performing an analysis, the purpose of which is to review and assess publicly available information to determine whether third parties hold any valid patent rights that a well- informed court would more likely than not find that we would infringe by commercializing our products, understanding that there are risks and uncertainties associated with any litigation and no predictions or assurances can be made regarding the outcome of any such litigation. Although our review and analysis are not complete and subject to the express limitations in the preceding sentence, we are not aware of any such valid patent rights. Moreover, we have not previously performed an exhaustive review of this type, and we cannot be certain that it will not result in our locating patent rights relating to our products of which we were not previously aware. ~~49~~ In the future, we could receive communications from various industry participants alleging our infringement of their intellectual property rights. Any potential intellectual property litigation could force us to do one or more of the following: ● stop selling our products or using technology that contains the allegedly infringing intellectual property; ● incur significant legal expenses; ● pay substantial damages to the party whose intellectual property rights we are allegedly infringing; ● redesign those products that contain the allegedly infringing intellectual property; or ● attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms or at all, and if available, may be non- exclusive, thereby giving our competitors access to the same technology. Patent litigation can involve complex factual and legal questions, and its outcome is uncertain. Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business, stop our development and commercialization measures and harm our reputation. Further, as the number of participants in the diabetes market increases, the possibility of intellectual property infringement claims against us increases. **50** We may be subject to damages resulting from claims that we, or our employees, have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition or non- solicitation agreements with our competitors. Many of our employees were previously employed at other medical device companies, including those that are our direct competitors or could potentially be our direct competitors. In some cases, those employees joined our company recently. We may be subject to claims that we, or our employees, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of these former employers or competitors. In addition, we may in the future be subject to allegations that we caused an employee to breach the terms of his or her non-competition or non- solicitation agreement. Litigation may be necessary to defend against these claims. Even if we successfully defend against these claims, litigation could cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. If our defense to those claims fails, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. There can be no assurance that this type of litigation will not occur, and any future litigation or the threat thereof may adversely affect our ability to hire additional direct sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize Eversense or future versions of Eversense, which could have an adverse effect on our business, financial condition and operating results. We may be subject to claims challenging the inventorship of our patents and other intellectual property. We may be subject to claims that former employees, collaborators or other third parties have an interest in

our owned patent rights, trade secrets, or other intellectual property as an inventor or co- inventor. For example, inventorship disputes may arise from conflicting obligations of employees, consultants or others who are involved in developing our medical devices or other technologies. Litigation may be necessary to defend against these and other claims challenging inventorship or our patent rights, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our medical devices and other technologies. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. ~~50~~ We are subject to the patent laws of countries other than the United States, which may not offer the same level of patent protection and whose rules could seriously affect how we draft, file, prosecute and maintain patents, trademarks and patent and trademark applications. Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties (for example, the patent owner has failed to" work" the invention in that country, or the third party has patented improvements). In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the aggressive enforcement of patent and other intellectual property protection which makes it difficult to stop infringement. We cannot be certain that the patent or trademark offices of countries outside the United States will not implement new rules that increase costs for drafting, filing, prosecuting and maintaining patents, trademarks and patent and trademark applications or that any such new rules will not restrict our ability to file for patent protection. For example, we may elect not to seek patent protection in some jurisdictions in order to save costs. We may be forced to abandon specific patents due to a lack of financial resources. **51** Our intellectual property rights do not necessarily address all potential competitive threats or confer meaningful competitive benefits. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain any competitive advantage. The following examples are illustrative: ● others may be able to make devices that are the same as or similar to Eversense but that are not covered by the claims of the patents that we own; ● we or any collaborators might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own and, therefore, we may be unable to enforce them; ● we might not have been the first to file patent applications covering certain of our inventions; ● others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights; ● it is possible that our pending patent applications will not lead to issued patents; ● issued patents that we own may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges; ● our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; and ● we may not develop additional proprietary technologies that are patentable. Risks Related to our Legal and 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 the Notified Bodies in the EEA. 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. These governmental authorities enforce laws and regulations that are meant to assure product safety and effectiveness, including the regulation of, among other things: ● product design and development; ~~51~~ ● preclinical studies and clinical trials; ● product safety; ● establishment registration and product listing; ● labeling and storage; ● marketing, manufacturing, sales and distribution; ● pre- market clearance, certification or approval; ● servicing and post- market surveillance; ● advertising and promotion; and ● recalls and field safety corrective actions. The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated revenues. Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as fines, civil penalties, injunctions, warning letters, recalls of products, delays in the introduction of products into the market, refusal of the regulatory agency or other regulators or Notified Bodies to grant future clearances, CE Certificates of Conformity or approvals, and the suspension, variation or withdrawal of existing approvals or CE Certificates of Conformity by such regulatory bodies. For example, **52** in September 2019 we voluntarily initiated a recall of Eversense sensors that had not yet been implanted, due to premature loss of function due to inadequate hydration of the sensor' s glucose- sensing surface. This recall, as well as any of the above sanctions, could result in higher than anticipated costs or lower than anticipated sales and harm our reputation, business, financial condition and operating results. The FDA regulatory clearance process and regulatory processes in other countries are expensive, time- consuming and uncertain, and the failure to obtain and maintain required regulatory clearances, certification and approvals could prevent us from commercializing Eversense and future versions of Eversense. Products that are approved through a PMA application generally need FDA approval before they can be modified, and similar approval or certification processes are required in other jurisdictions where we may want to market our products. The process of obtaining regulatory approvals or certifications to market a medical device can be costly and time- consuming, and we may not be able to obtain these approvals or certifications on a timely basis, or at all for our products. If the FDA requires us to go through a more rigorous examination for future products or modifications to existing products than we had expected, our product introductions or modifications could be delayed or canceled, which could cause our sales to decline or to not increase in line with our

expectations. The FDA or comparable foreign regulatory authorities and Notified Bodies can delay, limit or deny approval or certification of a device for many reasons, including: ● we may not be able to demonstrate that our products are safe and effective for their intended users; ● the data from our clinical trials may be insufficient to support approval or certification; and ● the manufacturing process or facilities we use may not meet applicable requirements. In addition, the FDA or comparable foreign regulatory authorities may change approval or certification policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or certification of our product modifications under development. Any delay in, or failure to receive or maintain, approval or certifications for our products could prevent us from generating revenue from these products or achieving profitability. ~~52~~ If we or our third- party suppliers fail to comply with the FDA' s or other foreign regulatory authorities' good manufacturing practice regulations, this could impair our ability to market our products in a cost- effective and timely manner. We and our third- party suppliers are required to comply with the FDA' s QSR, which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products. The FDA audits compliance with the QSR through periodic announced and unannounced inspections of manufacturing and other facilities. The FDA may impose inspections or audits at any time. If we or our suppliers have significant non- compliance issues or if any corrective action plan that we or our suppliers propose in response to observed deficiencies is not sufficient, the FDA could take enforcement action against us. We are subject to equivalent limitations and penalties in foreign countries. Any of the foregoing actions could impair our reputation, business, financial condition and operating results. A recall of our products, or the discovery of serious safety issues with our products, could have a significant negative impact on us. The FDA has the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture or in the event that a product poses an unacceptable risk to health. Our third- party suppliers may, under their own initiative, recall a product if any material deficiency in a device is found. A government- mandated or voluntary recall by us or one of our third- party distributors could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. For **53** example, in September 2019 we voluntarily initiated a recall of Eversense sensors that had not yet been implanted, due to premature loss of function due to inadequate hydration of the sensor' s glucose- sensing surface. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our reputation, financial condition and operating results, which could impair our ability to produce our products in a cost- effective and timely manner. Further, under the FDA' s medical device reporting regulations, we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Repeated product malfunctions may result in a voluntary or involuntary product recall, 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. Any adverse event involving our products could result in future voluntary corrective actions, such as recalls or customer notifications, or regulatory agency action, which could include inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results. 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 EEA. 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 which would adversely affect our business, operating results and prospects. ~~53~~ We are subject to the U. K. Bribery Act, the U. S. Foreign Corrupt Practices Act and other anti- corruption and anti- money- laundering laws in foreign jurisdictions, as well as export control laws, customs laws, sanctions laws and other laws governing our future global operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses, which could adversely affect our business, results of operations and financial condition. Our current and future global operations will expose us to trade and economic sanctions and other restrictions imposed by the United States, the European Union and other governments and organizations. The U. S. Departments of Justice, Commerce, State and Treasury and other federal agencies and authorities have a broad range of civil and criminal penalties they may seek to impose against corporations and individuals for violations of economic sanctions laws, export control laws, the Foreign Corrupt Practices Act (" FCPA ") and other federal statutes and regulations, including those established by the Office of Foreign Assets Control (" OFAC "). In addition, the U. K. Bribery Act of 2010 (" Bribery Act ") prohibits both domestic and international bribery, as well as bribery across both private and public sectors. An organization that" fails to prevent bribery" by anyone associated with the organization can be charged under the Bribery Act unless the organization can establish the defense of having implemented" adequate procedures" to prevent bribery. Under these laws and regulations, as well as other anti- corruption laws, anti- money- laundering laws, export control laws, customs laws, sanctions laws and other laws governing our operations, various government agencies may require export licenses, may seek to impose modifications to business practices, including cessation of business activities in sanctioned countries or with sanctioned persons or entities and modifications to compliance programs, which may increase compliance costs, and may subject us to fines, penalties and other sanctions. A violation of these laws or regulations could adversely impact our business, results of operations and financial condition. We will implement and maintain policies and procedures designed to ensure compliance by us, and our directors, officers, employees, representatives, third- party distributors, consultants and agents with the FCPA, OFAC restrictions, the Bribery Act and other export control, anticorruption, anti-

money- laundering and anti- terrorism laws and regulations, including in foreign jurisdictions. We cannot assure you, however, that our policies and procedures will be 54 sufficient or that directors, officers, employees, representatives, third- party distributors, consultants and agents have not engaged and will not engage in conduct for which we may be held responsible, nor can we assure you that our business partners have not engaged and will not engage in conduct that could materially affect their ability to perform their contractual obligations to us or even result in our being held liable for such conduct. Violations of the FCPA, OFAC restrictions, the Bribery Act or other export control, anti- corruption, anti- money- laundering and anti- terrorism laws or regulations, including in foreign jurisdictions, may result in severe criminal or civil sanctions, and we may be subject to other liabilities, which could have a material adverse effect on our business, financial condition, cash flows and results of operations. We are subject to additional federal, state and foreign laws and regulations relating to our healthcare business; our failure to comply with those laws could have an adverse impact on our business. Although we will not provide healthcare services, submit claims for third- party payor reimbursement, or receive payments directly from government health insurance programs or other third- party payors for Eversense, we are subject to broadly applicable federal, state, and foreign healthcare laws, including health care fraud and abuse and health information privacy and security laws, which could adversely impact our business. Such healthcare laws potentially applicable to our operations include: ● the federal Anti- Kickback Statute, which will apply to our marketing practices, educational programs, pricing policies and relationships with healthcare providers, by prohibiting, among other things, soliciting, receiving, offering or providing remuneration intended to induce the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare or Medicaid programs. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it to have committed a violation; ● federal civil and criminal false claims laws and civil monetary penalty laws, including the False Claims Act, which is enforceable through civil whistleblower or qui tam actions, prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment or approval to the federal government that are false or fraudulent, knowingly making a false statement material to an obligation to ~~54~~ pay or transmit money or property to the federal government or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the federal government. The government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the false claims statutes; ● HIPAA, and its implementing regulations, which created federal criminal and civil statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; ● HIPAA, as amended by HITECH, and their implementing regulations, which also imposes obligations on " covered entities, " including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective " business associates " that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity and their subcontractors, regarding the privacy, security and transmission of such individually identifiable health information; ● federal" sunshine" requirements imposed by the PPACA, on device manufacturers regarding the annual reporting to CMS, of any" transfer of value" made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners, and teaching hospitals, and ownership and investment interests held by physicians **and their immediate family members** . Failure to timely submit required information may result in significant civil monetary penalties; ● federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; ● state law equivalents of each of the above federal laws, such as anti- kickback and false claims laws that may apply to items or services reimbursed by any third- party payor, including commercial insurers; state laws that require device companies to comply with the industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state 55 laws governing the privacy and security of certain health information, many of which differ from each other in significant ways and often are not preempted by HIPAA; ~~● the California Consumer Privacy Act (" CCPA ") that creates new individual privacy rights for consumers (which is broadly defined)~~ and ~~places increased privacy and security obligations on entities handling certain personal data;~~ ● equivalent foreign legislation and requirements including in relation to interactions between medical devices companies and healthcare professionals, 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~~ **imprisonmentThe** ~~; and ● foreign data privacy regulations, such as the GDPR, which impose strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting, and may be strieter than U. S. laws. The~~ risk of our being found in violation of these laws and regulations is increased by the fact that the scope and enforcement of these laws is uncertain, many of them have not been fully interpreted by the regulatory authorities or the courts, their provisions are open to a variety of interpretations, or they vary country by country. We are unable to predict what additional federal, state or foreign legislation or regulatory initiatives may be enacted in the future regarding our business or the healthcare industry in general, or what effect such legislation or regulations may have on us. Federal, state or foreign governments may (i) impose additional restrictions or adopt interpretations of existing laws that could have a material adverse effect on us or (ii) challenge our current or future activities under these laws. Any of these challenges could impact our reputation, business, financial condition and operating results. profits,imprisonment,exclusion from governmental health care programs,such as Medicare and Medicaid,and the curtailment or restructuring of our operations,any of which could adversely affect our ability to operate our business and our financial results.Any federal,state or foreign regulatory review to which we may become subject,regardless of the outcome,would be costly and time- consuming.For example,to enforce compliance with the federal laws,the U.S.Department of Justice has recently increased its scrutiny of interactions

between healthcare companies and healthcare providers,which has led to a number of investigations,prosecutions,convictions and settlements in the healthcare industry.Dealing with investigations can be **57** time and resource consuming and can divert management' s attention from our core business.Additionally,if we settle an investigation with law enforcement or other regulatory agencies,we may be forced to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement.Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business .~~-~~The collection and use of personal health data in the EEA and UK is governed by the **EU and UK** GDPR **(collectively, GDPR)** . The GDPR applies to the processing of personal data by any company established in the EEA or UK and to companies established outside the EEA to the extent they process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA or UK. Under the ~~EU~~ GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 ~~55~~ million Euros **under the EU GDPR / 17. 5 million pounds sterling under the UK GDPR,** or 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. The GDPR enhances data protection obligations for data controllers of personal data, including stringent requirements relating to the consent of data subjects, expanded disclosures about how personal data is used, requirements to conduct privacy impact assessments for " high risk " processing, limitations on retention of personal data, mandatory data breach notification and " privacy by design " requirements, and creates direct obligations on service providers acting as processors. The **Swiss Federal Act on Data Protection, or the FADP, also applies to the collection and processing of personal data, including health- related information, by companies located in Switzerland, or in certain circumstances, by companies located outside of Switzerland. The** GDPR also imposes strict rules on the transfer of personal data outside of the EEA and UK to countries that do not ensure an adequate level of protection, like the United States. In the ordinary course of business, we may transfer personal data from the EEA and UK or other jurisdictions to the United States or other countries. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK or other jurisdictions to the United States in compliance with law, such as the EEA ~~and~~ **standard contractual clauses, the** UK' s ~~standard contractual clauses~~ **International Data Transfer Agreement / Addendum, and the EU- U. S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U. S.- based organizations who self- certify compliance and participate in the Framework** , these mechanisms are subject to legal challenges, and 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 manner for us to transfer personal data from the EEA or 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 certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR' s cross- border data transfer limitations. **In addition to data privacy and security laws, we are contractually subject to industry standards adopted by industry groups and, we are, or may become subject to such obligations in the future.** We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. 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 publish privacy policies and other statements regarding data privacy and security. If these policies or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences. **Our employees and personnel use generative artificial intelligence (" AI ") technologies to perform their work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of 57 this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages. 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 providers. 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.** Obligations related to data privacy and security **(and consumers' expectations)** are quickly changing, becoming increasingly stringent, and creating ~~regulatory~~ 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 that process personal data on our behalf **. If we or our parties on which we rely fail to comply or are alleged to have failed to 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 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 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, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any associated claims, inquiries, or investigations or other government actions could lead to unfavorable outcomes that have a material impact on our business including through significant penalties or fines, monetary judgments or settlements including criminal and civil liability for us and our officers and directors, increased compliance costs, delays or impediments in the development of new products, inability to process personal data or to operate in certain jurisdictions; negative publicity, increased operating costs, diversion of management time and attention, or other remedies that harm our business, including orders that we modify or cease existing business practices. Moreover, governments and regulators in certain jurisdictions, including Europe, are increasingly seeking to regulate the use, transfer and other processing of non- personal information (for example, under the European Union' s Data Act). This means that, if and to the extent such regulations are relevant to our operations or those of our customers, certain of the above risks and considerations may apply equally to our processing of both personal and non- personal information. If our information technology systems or those third parties upon which we rely or our data, 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; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences . In the ordinary course of our business, we and the third parties upon which we rely, process proprietary, confidential, and sensitive data, including personal data (such as health- related data), intellectual property and trade secrets (collectively, sensitive information). 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 we rely. 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. We and the third parties upon which we rely are subject to a variety of evolving threats, including but not limited to social- engineering attacks (including through **deep fakes, which may be increasingly more difficult to identify as fake, and** phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial- of- service attacks **,** ~~(such as~~ credential **58** stuffing ~~)~~ **attacks** , credential harvesting, personnel misconduct or error, ransomware attacks, supply- chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures **, attacks enhanced or facilitated by AI** , and other similar threats. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, 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. ~~56~~ Because of ~~the remote~~ **our hybrid** work policies ~~, we implemented due to the COVID- 19 pandemic~~ , sensitive information that is normally protected ~~, including company confidential information,~~ may be less secure **as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations . Future or past business transactions (such as acquisitions or integrations) could expose us to additional** ~~Cybersecurity~~ **cybersecurity risks** and ~~data~~ **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** ~~threats continue to evolve and raise the risk of an incident~~ that ~~could affect~~ **were not found during due diligence of such acquired** ~~our~~ **or** ~~operations~~ **integrated entities, and it may be difficult to integrate companies into** ~~or~~ **our** ~~compromise our sensitive~~ information **technology environment and security program** ~~. We may also need to collect more extensive health- related information from our employees to manage our workforce~~ . We rely on third- **parties** ~~party service providers~~ and technologies to operate critical business systems to process sensitive information in a variety of contexts. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If ~~our~~ **the** third- ~~party service providers~~ **parties upon whom we rely on** experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third- party service providers 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 award **. In addition, supply- chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third- party partners' supply chains have not been compromised. While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and / or software, including that of third parties upon which we rely). We may not, however, detect and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident** . Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to provide our products and services. **We may expend significant resources or modify our business activities to try to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures or industry- standard or reasonable security measures to**

protect our information technology systems and sensitive information. Applicable data privacy and security obligations may require us to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. If we ~~or (our~~ **or** ~~parties on which~~ **a third party upon whom** we rely **)** ~~fail to comply or are alleged to have failed to comply with applicable data privacy and security regulations, or if we were to~~ experience a security incident ~~involving personal data~~ **or are perceived to have experienced a security incident** , we ~~could face significant~~ **may experience adverse** consequences, **such as** ~~including but not limited to;~~ government enforcement actions (**for example** ~~e. g.~~ , investigations, fines, penalties, audits, **and** inspections ~~,~~ **); additional reporting requirements** and ~~similar~~ **/ or oversight; restrictions on processing sensitive information (including personal data**); litigation (including class ~~- action~~ claims); **indemnification obligations** ~~additional reporting requirements and / or oversight~~ ; ~~bans on processing personal data; orders to destroy or not use personal data. Any associated claims, inquiries, or investigations or other government actions could lead to unfavorable outcomes that have a material impact on our business including through significant penalties or fines, monetary judgments or settlements including criminal and civil liability for us and our officers and directors, increased compliance costs, delays or impediments in the development of new products,~~ negative publicity ~~, increased operating costs,~~ **; reputational harm; monetary fund diversions;** diversion of management ~~time and~~ attention ~~,~~ **; interruptions in** ~~or~~ **our operations (including availability of data); financial loss; and** other ~~remedies~~ **similar harms. Security incidents and attendant consequences 59 may prevent or cause customers to stop using our products, deter new customers from using our prodcuts, and negatively impact our ability to grow and operate our business. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance** that ~~harm~~ **limitations of liability in our contracts are sufficient to protect us from liabilities, damages,** ~~our -~~ **or** ~~business, including orders~~ **claims related to our data privacy and security obligations. We cannot be sure** that ~~we modify or~~ **our** ~~cease existing business~~ **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** ~~February 2021, in compliance with the~~ security incident ~~notification obligations laid~~ **, third parties may gather, collect, or infer sensitive information** ~~out~~ **about** ~~in the GDPR~~ **us from public sources** , ~~we notified the Italian Data~~ **data brokers** ~~Protection Authority (" Garante ")~~ , **or** ~~of an unintended disclosure of certain user e- mail addresses to~~ other ~~users in Italy. Subsequent~~ **means that reveals competitively sensitive details about our organization and could be used** to ~~this notification~~ **undermine our competitive advantage or market position. Additionally** , **sensitive information of** ~~we were able to settle~~ the ~~matter~~ **Company or our customers could be leaked, disclosed, or revealed as a result of or in connection** with ~~the Garante. It is possible that the Garante may, in the future, follow up regarding our corrective measures and overall GDPR compliance. Further investigations of the Garante could cause an adverse reaction by users of our product, negative publicity, financial penalties or~~ **our employees'** ~~negative regulatory implications under the GDPR~~ , ~~any of which could have a material adverse effect on our business. Moreover, governments and regulators in certain jurisdictions, including Europe, are increasingly seeking to regulate the use, transfer and other processing of non- personal~~ **personnel** ~~information (for example, under the European Union~~ ' s ~~Data Act)~~ , ~~an area which has typically been the subject of very limited or no specific regulation. This means that, if and to the extent such regulations are relevant to our~~ - **or vendors'** ~~operations or those of our customers, certain of the above risks and considerations may apply equally to our processing of both personal and non- personal information. Our activities, including our research, sales and marketing, and patient reimbursement support activities, may be subject to scrutiny under these laws. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us~~ **use** ~~now or in the future, we may be subject to penalties, including significant civil, criminal, and administrative penalties, damages, fines, disgorgement~~ of **generative AI technologies** profits, imprisonment, exclusion from governmental..... have an adverse effect on our business . We may be liable if the FDA, competent authorities of the EEA countries, or another regulatory agency concludes that we have engaged in the off- label promotion of our products. Our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition of the promotion of the off- label use of our 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, competent authorities of the EEA countries, or other foreign regulatory authorities determine that our promotional materials or training constitute promotion of an off- label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or competent authorities of the EEA countries, 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 we intend to train our marketing and direct sales force to not promote our products for uses outside of their cleared uses and our policy will be to refrain from statements that could be considered off- label promotion of our products, the FDA competent authorities of the EEA countries, or another regulatory agency could disagree and conclude that we have engaged in off- label promotion. In addition, the off- label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could result in substantial damage awards against us and harm our reputation. International sales of medical devices are subject to foreign government regulations, which vary substantially from country to country. In order to market our products in other countries, we must obtain regulatory approvals or certifications and comply with extensive safety and quality regulations in other countries. The advertising and promotion of our products in the EEA is subject to EEA countries' national laws implementing the AIMD and applying the Medical Device Regulation, 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 EEA countries governing the advertising and promotion of medical devices. EEA countries' 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, which could negatively impact our business, operating results and financial condition. Off- label use of our product by patients could lead to product liability claims and regulatory action. Eversense is currently labeled as non- adjunctive; however once a day fingerstick calibrations are still required. We have no control over whether patients adhere to labeling instructions and confirm blood glucose levels to ensure calibration with Eversense. If a patient fails to do so and has an adverse reaction to self- medication, the patient might make a claim against us. While we do not believe that, as a general matter, such a claim would have merit, the possibility of an adverse result to the manufacturer cannot be dismissed, and in any event, we could incur significant defense costs. Also, if there should be widespread off- label use of our system by patients, and resulting adverse medical events, the **60** FDA, competent authorities of the EEA countries or other foreign regulatory bodies might require us, to implement additional measures to reduce off- label use, which could be costly or reduce adoption of Eversense. Legislative or regulatory healthcare reforms may make it more difficult and costly for us to obtain regulatory clearance, certification or approval of our products. Recent political, economic and regulatory influences are subjecting the healthcare industry to fundamental changes. 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 ~~58~~ 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 contain or reduce the cost of healthcare. This legislation and regulation may result in decreased reimbursement for medical devices, which may further exacerbate industry- wide pressure to reduce the prices charged for medical devices. This could harm our ability to market our products and generate sales. On a global level, the regulatory environment is increasingly stringent and unpredictable. Many countries have introduced or expanded their existing regulation of medical devices or are planning to expand their existing regulation in the future. Regulatory requirements continue to differ significantly among countries. We expect this global regulatory environment will continue to evolve, which could impact the cost, the time needed to approve, and ultimately, our ability to maintain existing approvals or certifications or obtain future approvals or certifications for our products. For example, in the EU, on May 26, 2021, the EU Medical Device Regulation entered into application repealing and replacing both Directive 93 / 42 / EEC concerning medical devices and Directive 90 / 385 / EEC concerning active implantable medical devices. We affixed the CE mark to the original 90- day Eversense CGM system in June 2016, which marked the first certification for the product to be sold within the European Economic Area (EEA). Subsequently, we affixed the CE mark to the extended life Eversense XL CGM system in September 2017 which was sold in select markets in Europe and the Middle East. The changes to the regulatory system implemented in the EU by the Medical Device Regulation 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 a refined responsibility of economic operators. We are also required to provide clinical data in the form of a clinical evaluation report. Fulfilment of the obligations imposed by the Medical Device Regulation 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 Medical Device Regulation. In addition, the exit of the UK from the EU, commonly referred to as " Brexit " could lead to regulatory divergence between the EU and the UK. On **May** 26 ~~May~~ **,** 2021, the MDR entered into application in the EU. However, the MDR is not applicable in the UK. In the UK, 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 UK Medicines and Healthcare products Regulatory Agency plans on introducing new legislation governing medical devices with an aim to bring the new regulations into force by July 2024. 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. Regulations of the FDA and other regulatory agencies, including third country authorities and Notified Bodies, in and outside the U. S. impose extensive compliance and monitoring obligations on our business. These agencies review our design and manufacturing practices, labeling, record keeping, manufacturers' required reports of adverse experiences and other information to identify potential problems with marketed medical devices. We are subject to unannounced device inspections by Notified Bodies, as well as other regulatory ~~agencies~~ **authorities** overseeing the implementation and adherence of applicable regulations. These inspections may include our suppliers' facilities. In addition, the competent **61** authorities of individual EEA countries have powers to suspend the marketing and use, or demand the recall, of unsafe or non- compliant devices. They also have the power to bring enforcement action against companies or individuals for breaches of the device rules. Non- compliance may also result in Notified Bodies revoking, suspending or varying any CE Certificate of Conformity that they have issued for a device or the manufacturer' s quality system. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of our products. Delays in receipt of or failure to ~~59~~ receive regulatory clearances or approvals for our products would harm our business, financial condition and operating results. While a goal of healthcare reform is to expand coverage to more individuals, it also involves increased government price controls, additional regulatory mandates and other measures designed to

constrain medical costs. For example, the PPACA was enacted in March 2010. The PPACA substantially changes the way healthcare is financed by both governmental and private insurers, encourages improvements in the quality of healthcare items and services and significantly impacts the medical device industries. Among other things, the PPACA: ● establishes a new Patient- Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research; and ● implements payment system reforms including value- based payment programs, increased funding for comparative effectiveness research, reduced hospital payments for avoidable readmissions and hospital acquired conditions, and pilot programs to evaluate alternative payment methodologies that promote care coordination (such as bundled physician and hospital payments). There have been executive, judicial and Congressional challenges to certain aspects of the PPACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the PPACA such as removing penalties, starting January 1, 2019, for not complying with the PPACA' s individual mandate to carry health insurance and delaying the implementation of certain PPACA- mandated fees. Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the PPACA- mandated medical device tax and " Cadillac " tax on high- cost employer- sponsored health coverage and, effective January 1, 2021, also eliminated the health insurer tax. On June 17, 2021, the U. S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the " individual mandate " was repealed by Congress. Further, on August 16, 2022, President Biden signed the IRA into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in PPACA marketplaces through plan year 2025. The IRA 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 creating a new manufacturer discount program. It is possible that the PPACA will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and the healthcare reform measures of the Biden administration will impact the PPACA and our business. In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, includes reductions to Medicare payments to providers of 2 % per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through ~~2031~~ **2032** unless additional Congressional action is taken ~~. Under current legislation, the actual reduction in Medicare payments will vary from 1 % in 2022 to up to 4 % in the final fiscal year of this sequester~~ . On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. At this time, we cannot predict which, if any, additional healthcare reform proposals will be adopted, when they may be adopted or what impact they, or the PPACA, may have on our business and operations, and any of these impacts may be adverse on our operating results and financial condition. **62** Risks Related to our Common Stock Because our stock price has and will likely continue to be highly volatile, the market price of our common stock may be lower or more volatile than expected. Our stock price has been highly volatile. The stock market in general and the market for innovative, emerging medtech and biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. From January 1, ~~2021~~ **2022** through ~~March 10~~ **February 23** , ~~2023~~ **2024** , the trading price of our common stock has been as low as $ 0. ~~85~~ **48** per share and as high as $ ~~5~~ **3** . ~~27~~ **71** per share. This extreme stock price volatility ~~60~~ has been accompanied by extremely high trading volume in our common stock in comparison to historical experience. During this period, the average daily trading volume of our common stock has been approximately ~~15~~ **5. 2** million shares and on ~~January 19~~ **February 11** , ~~2021~~ **2022** , our trading volume exceeded ~~409~~ **106. 3** million shares, whereas the average daily trading volume from January 1, ~~2022~~ **2023** to December 31, ~~2022~~ **2023** was ~~6~~ **4** . ~~5~~ **3** million shares. The extreme increase in trading volume and volatility has not necessarily correlated to the company' s announcement of material developments and often appears unrelated to changes in actual or expected operating performance. Purchases or sales of large quantities of our stock, including the establishment and / or closing of significant short positions in our stock could have an unusual or adverse effect on our market price. Market fluctuations may also cause short sellers to periodically enter the market in the belief that we will have poor results in the future. Abnormal trading activity, including activity that is considered market manipulation, can lead to irrational and / or temporary movements in the price of our common stock, which, in turn, may increase its risk and volatility. We cannot predict the actions of market participants and, therefore, can offer no assurances that the market for our common stock will be stable or appreciate over time. The market price of our common stock may also be influenced by many additional factors, including: ● analyst coverage, recommendations or changes in their estimates of our financial performance; ● future announcements about us or our competitors, including the results of technological innovations or new commercial products; ● announcement of operating results and other factors relating to the commercialization of our products; ● clinical trial and topline data results; ● depletion of our cash reserves; ● sale of equity securities or issuance of additional debt; ● announcement by us of significant strategic partnerships, capital commitments or acquisitions; ● changes in government regulations; ● impact of competitor successes; ● developments in our relationships with our collaboration partners; ● global market or financial developments ~~, whether due to the global COVID- 19 pandemic or otherwise~~ ; ● announcements relating to health care reform, legislation and reimbursement levels, including third- party payor coverage decisions; ● sales of substantial amounts of our stock by existing stockholders (including stock by insiders or 5 % stockholders); ● regulatory approvals, certifications, timelines or other actions; ● litigation; ● public concern as to the safety of our products or recalls; ● the make- up of our shareholder base; and ● the other factors described in this Risk Factors section. The issuance of additional stock in connection with financings, acquisitions, investments, our equity incentive plans, or otherwise will dilute our existing stockholders. Our certificate of incorporation authorizes us to issue up to 900, 000, 000 shares of common stock and up to 5, 000, 000 shares of preferred stock with such rights and preferences as may be determined by our board of directors. **63** Subject to compliance with applicable rules and regulations, we may issue our shares of common stock, including securities convertible into common stock, in connection with a financing, acquisition, investment, our equity incentive

plans or otherwise. This includes the issuance, from time to time, of non- statutory stock options exercisable for shares of our common stock and / or restricted stock units that may be settled in shares of our common stock pursuant to the Senseonics Holdings, Inc. 2023 Commercial Equity Plan. Any such issuance could result in substantial dilution to our existing stockholders and cause the trading price of our common stock to decline. ~~61~~ Holders of our Series B convertible preferred stock and our ~~convertible~~ **2025** notes may convert their ~~note~~ **securities** into common stock and, upon conversion, will dilute your percentage of ownership. ~~Our note~~ **The Series B convertible preferred stock and 2025 Notes are convertible into our common stock at the option of the** holders **thereof. Accordingly, any conversion of convertible preferred stock or 2025 Notes would dilute the ownership of our holders of common stock. The potential dilutive effect of the conversion of shares of convertible preferred stock or convertible notes may also adversely affect our ability to obtain additional financing on favorable terms or at all. Certain shareholders may** have the ability exert substantial influence over us in a manner adverse to your interests. ~~The Series B convertible preferred stock, PHC Notes, and 2025 Notes are convertible into our common stock at the option of the holder. Accordingly, any conversion of convertible preferred stock would dilute the ownership of our holders of common stock. The potential dilutive effect of the conversion of shares of convertible preferred stock or convertible notes may also adversely affect our ability to obtain additional financing on favorable terms or at all.~~ Subject to maintaining specified ownership thresholds, ~~the holders of the~~ PHC ~~Notes have a~~ **continues to hold the** right to designate **up to** two individuals to serve on our board of directors **as outlined in their Investor Rights Agreement** . As a result, ~~the holders of the~~ PHC ~~Notes are~~ **may be** able to **significantly** influence our decisions, including the election and removal of directors, any merger, consolidation, sale of all or substantially all of our assets, or other significant corporate transactions. ~~The holders of the~~ PHC ~~notes~~ may have interests different the interests of the **other** holders of our common stock. Our GAAP operating results could fluctuate substantially due to changes in fair value of the derivatives related to the embedded conversion option, interest make- whole provision and make- whole fundamental change provision features of the notes. Our **2025** ~~convertible senior subordinated notes~~ **Notes** contain certain embedded features that require bifurcation of the embedded conversion option along with the fundamental change make- whole provision ~~, interest make- whole provision,~~ and the cash settled fundamental make- whole shares provision, and recorded the fair value of these embedded features as a derivative liability in the Company' s consolidated balance sheets in accordance with Accounting Standards Codification (" ASC ") Topic 815, Derivatives and Hedging. ASC 815 requires companies to bifurcate certain embedded derivatives from their host instruments and account for them as free- standing derivative financial instruments according to certain criteria. The fair value of the derivative is remeasured to fair value at each balance sheet date, with a resulting non- cash gain or loss related to the change in the fair value of the derivative being charged to earnings (loss). We utilize a third- party valuation expert and the binomial option pricing method to determine the fair value of the derivative instruments at each reporting date using inputs based on recent trading prices (Level 2) and other observable inputs, including our common stock price, implied volatility, and interest rates, or unobservable inputs (Level 3) where there is an absence of recent trading prices. We cannot predict the effect that the accounting for the options and notes and the associated fluctuations in the fair value of the liability options and embedded features of the **2025** ~~notes~~ **Notes** will have on our future GAAP financial results, the trading of our common stock and the trading price of the **2025** ~~notes~~ **Notes** , which could be material. Continued extreme volatility in our stock price, as we have experienced recently, could exacerbate such effects. If our estimates relating to our critical accounting policies are based on assumptions or judgments that change or prove to be incorrect, our operating results could fall below expectations of financial analysts and investors, resulting in a decline in our stock price. The preparation of financial statements in conformity with U. S. GAAP requires our management to make estimates, assumptions and judgments that affect the amounts reported in the consolidated financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to **64** be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, revenue and expenses that are not readily apparent from other sources. Our operating results may be adversely affected if our assumptions change or if actual circumstances differ from those in our assumptions, which could cause our operating results to fall below the expectations of financial analysts and investors, resulting in a decline in our stock price. Significant assumptions and estimates used in preparing our consolidated financial statements include those related to revenue recognition and variable consideration, reserves for inventory ~~62~~ obsolescence and warranties, stock- based compensation, embedded features of our senior convertible notes and income taxes. We do not intend to pay cash dividends in the foreseeable future. We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. In addition, pursuant to our debt agreements, we are precluded from paying any cash dividends. Accordingly, you may have to sell some or all of your shares of our common stock in order to generate cash flow from your investment. You may not receive a gain on your investment when you sell shares and you may lose the entire amount of the investment. Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our common stock may be lower as a result. There are provisions in our certificate of incorporation and bylaws that may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change of control was considered favorable by some or all of our stockholders. For example, our board of directors has the authority to issue up to 5, 000, 000 shares of preferred stock. The board of directors can fix the price, rights, preferences, privileges, and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change of control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders. Our charter documents also contain other provisions that could have an anti- takeover effect, including: ● only one of our three classes of directors is elected each year; ● stockholders are not entitled to remove directors other than by a 66 2 / 3 % vote and

only for cause; ● stockholders are not permitted to take actions by written consent; ● stockholders are not permitted to call a special meeting of stockholders; and ● stockholders are required to give advance notice of their intention to nominate directors or submit proposals for consideration at stockholder meetings. In addition, we are subject to the anti- takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions by prohibiting Delaware corporations from engaging in specified business combinations with particular stockholders of those companies. These provisions could discourage potential acquisition proposals and could delay or prevent a change of control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock. Our amended and restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. **65** Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim for breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders; ~~63~~ (3) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; or (4) any action asserting a claim governed by the internal affairs doctrine. However, this exclusive forum provision would not apply to suits brought to enforce a duty or liability created by the Securities Act or the Exchange Act. Our amended and restated bylaws further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. We note that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. These exclusive forum provisions may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. There is uncertainty as to whether a court would enforce such provisions, and the enforceability of similar choice of forum provisions in other companies' charter documents has been challenged in legal proceedings. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. If a court were to find these types of provisions to be inapplicable or unenforceable, and if a court were to find the exclusive forum provision in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could materially adversely affect our business. If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired. We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, the Sarbanes- Oxley Act of 2002, the Dodd- Frank Wall Street Reform and Consumer Protection Act of 2010 and the rules and regulations of the NYSE American. The Sarbanes- Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting and perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting. This requires that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. During the evaluation and testing process of our internal controls, if we identify one or more material weaknesses in our internal control over financial reporting that exists at the reporting date, we will be unable to assert that our internal control over financial reporting is effective. We have no material weaknesses in our internal control over financial reporting at December 31, ~~2022~~ **2023** . While we have established certain procedures and controls over our financial reporting processes, we cannot assure you that these efforts will prevent future material weaknesses or restatements of our financial statements. For future reporting periods, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our controls are documented, designed or operating. We may not be able to remediate any future material weaknesses, or to complete our evaluation, testing and any required remediation in a timely fashion. Any failure to maintain effective internal control over financial reporting could severely inhibit our ability to accurately report our financial condition or results of operations. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could **66** decline, and we could be subject to sanctions or investigations by the NYSE American, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets. ~~64~~ If securities or industry analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline. The trading market for our common stock is influenced by the research and reports that securities or industry analysts publish about us or our business, our market and our competitors. Securities or industry analysts may elect not to initiate or continue to provide coverage of our common stock, and such lack of coverage may adversely affect the market price of our common stock. Even if we have securities or industry analyst coverage, we will not have any control over the analysts, or the content and opinions included in their reports. The price of our stock could decline if one or more securities or industry analysts downgrade our stock or issue other unfavorable commentary or research. If one or more securities or industry analysts ceases coverage of our

company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline. Our effective tax rate may fluctuate, and we may incur obligations in tax jurisdictions in excess of accrued amounts. We are subject to taxation for US Federal and numerous U. S. states. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various places that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of such jurisdictions. Nevertheless, our effective income tax rate may be different than experienced in the past due to numerous factors, including passage of the newly enacted federal **or state** income tax ~~law~~ **laws**, changes in the mix of our profitability from state to state, the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities, changes in accounting for income taxes and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations and may result in tax obligations in excess of amounts accrued in our financial statements. We may be unable to utilize our **tax attribute** ~~federal net operating loss~~ carryforwards to reduce our income taxes. At December 31, ~~2022~~ **2023**, we had federal and state net operating loss, or NOL, carryforwards of $ ~~621~~ **656**. ~~5~~ **9** million and had research and experimental credit carryforwards of $ ~~13~~ **15**. ~~1~~ **3** million. NOL carryforwards in the amount of $ ~~197~~ **196**. ~~5~~ **4** million will expire in varying amounts between ~~2023~~ **2024** and 2037 and tax credits of $ ~~13~~ **15**. ~~1~~ **3** million will expire in varying amounts between ~~2023~~ **2024** and 2043. These net operating loss carryforwards **and credits** could expire unused and be unavailable to offset future income tax liabilities. Under the Tax Cuts and Jobs Act of 2017 **(“ TCJA ”)**, as modified by the **Coronavirus Aid, Relief, and Economic Security (“** CARES **”)** Act, federal NOL carryforwards generated in tax years beginning after December 31, 2017 may be carried forward indefinitely, but **limited** ~~in the case of tax years beginning after 2020, may only be used~~ to offset 80 % of our taxable income annually ~~. Federal NOL carryforwards generated in taxable years beginning in 2018 will similarly carry forward indefinitely but will not be subject to such 80 % of annual taxable income limitation~~. In addition, under Section 382 / 383 of the Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, if a corporation undergoes an" ownership change," which generally occurs if the percentage of the corporation' s stock owned by 5 % stockholders increases by more than 50 % over a three- year period, the corporation' s ability to use its pre- change NOL carryforwards and other pre- change tax attributes to offset its post- change income may be limited. We have not determined if we have experienced Section 382 / 383 ownership changes ~~in the past~~ and if a portion of our NOL and tax credit carryforwards are subject to an annual limitation under Section 382 / 383. In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, ~~some of~~ which may be outside of our control. If we determine that an ownership change has occurred and our ability to use our historical NOL and tax credit carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations. Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition, or results of operations. New tax laws, statutes, rules, regulations, or ordinances could be enacted at any time. Further, existing tax laws, statutes, rules, regulations, or ordinances could be interpreted differently, changed, repealed, or modified at any time. **67** ~~Any such enactment, interpretation, change, repeal, or modification could adversely affect us, possibly with retroactive effect. For instance, the recently enacted IRA imposes, among other rules, a 15 % minimum tax on the book income of certain large corporations and a 1 % excise tax on certain corporate stock repurchases. The Tax Cuts and Jobs Act of 65~~