

Risk Factors Comparison 2025-02-18 to 2024-02-22 Form: 10-K

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This Form 10-K contains forward-looking information based on our current expectations. Because our business is subject to many risks and our actual results may differ materially from any forward-looking statements made by or on behalf of us, this section includes a discussion of important factors that could affect our business, operating results, financial condition and the trading price of our common stock. You should carefully consider these risk factors, together with all of the other information included in this Form 10-K as well as our other publicly available filings with the SEC. If any of the following risks actually occurs, our business, financial condition, results of operations and future prospects could be materially and adversely harmed.

Business Risks ~~We the foregoing or unexpected expenses, it could materially adversely affect our business, results of operations, financial condition or cash flows.~~ Our existing products may be rendered obsolete and we may be unable to effectively introduce and market new products or may fail to keep pace with advances in technology. The medical device market is ~~highly competitive and is~~ characterized by rapidly advancing technology. ~~Product designs change often to adjust to shifting market preferences and other factors, and therefore product life cycles are relatively short.~~ Our success and growth depends, in part, on our ability to anticipate technological advancements and competitive innovations and introduce new products to adapt to these advancements and innovations. ~~To~~ Any delays in our product launches may significantly impede our ability to enter or compete in ~~a~~ **the marketplace, we have made, and we must continue to make, substantial investments in** ~~have made~~ a limited operating history in certain markets and may not be able to sustain or grow our profitability or generate positive cash flows from operations in the future. We were founded in 2004 and did not generate any revenue until 2007. Moreover, while we have successfully developed, obtained regulatory clearance or approval for, and introduced a number of ~~we must continue to make, substantial investments in new products~~ **product in development, whether internally through research and development** ~~our~~ **or externally through licensing** target markets, in certain markets we have a limited operating history upon which investors can evaluate our ~~or acquisitions~~ business and prospects, and this limited operating history may not be indicative of our future results. We incurred operating losses in 2021. We can give no assurance that we will be ~~successful~~ profitable or cash flow positive in ~~identifying~~ the future. Our sales, **developing** general and administrative expenses have increased, and we expect that they will continue to increase, to support our ~~or past acquiring,~~ and anticipated future growth **marketing new products or enhancing our existing products**. We have also expended significant amounts on research and development to develop our products, and we expect to continue to do so. We also expend significant amounts on maintaining inventory levels of raw materials, components and finished products to meet anticipated customer demand. In addition, our coil products are sold on a consignment basis, which requires us to expend significant amounts on inventory that is placed at many ~~may experience~~ **delays** customer locations. Our ability to sustain our growth and profitability and generate positive operating cash flow in the future may be influenced by many factors, including: • our ability to achieve and maintain market acceptance of our products; • unanticipated problems and additional costs relating to the development and testing of new products; • our ability to introduce, manufacture at scale, build new inventory and commercialize new products; • our ability to produce sufficient quantities of our products to meet demand; • the impact of competition; • the timing and impact of market, reimbursement and regulatory developments; • our ability to expand into new markets; • pricing pressure from competitors; • the availability and adequacy of third-party reimbursement for procedures in which our products are used; and • our ability to obtain and maintain adequate intellectual property protection for our products and technologies. If we encounter difficulties with ~~any phase of a~~ **the foregoing** or unexpected expenses, it..... continue to make, substantial investments in new product **launch, including during research and** development, **clinical trials** whether internally through research and development or externally through licensing or acquisitions. We can give no assurance that we will be successful in identifying, **regulatory review** developing or acquiring, **manufacturing** and marketing new products or enhancing our existing products. In addition, we can give no assurance that new products or alternative treatment techniques developed by competitors will not render our current or future products obsolete or inferior, technologically or economically. **Our competition may respond more quickly to new or emerging technologies or a changing clinical landscape, undertake more extensive marketing campaigns, have greater financial, marketing and other resources than us or be more successful in attracting potential customers and strategic partners**.

The success of any new products that we develop or acquire depends on achieving and maintaining market acceptance. Market acceptance for our current and new products could be affected by a number of factors, including: • our ability to market and distribute our products effectively; • the availability, perceived efficacy and pricing of alternative products from our competitors; • the development of new products or alternative treatments by others that render our products and technologies obsolete; • the price, quality, effectiveness and reliability of our products; • our customer service and reputation; • our ability to convince specialist physicians and other healthcare providers to use our products on their patients; and • the timing of market entry of new products or alternative treatments. For example, treatment protocols for ischemic stroke patients vary according to the particular hospital, often resulting in significant delays and gaps in patients being assessed for and receiving interventional treatment. We believe that the stroke care system in the United States has not been historically geared towards interventional treatment of stroke due to the absence of clinical evidence that interventional techniques were effective. Specialist physician societies and we and our competitors are making efforts to alter the existing stroke care pathway, but we anticipate that these efforts will take years to be fully successful. The success of these efforts may depend on whether we and our competitors can effectively use substantial clinical data- demonstrating that intervention yields superior clinical results relative to cases where intervention is not used- to convince specialist physicians to use interventional techniques to treat ischemic stroke patients. Even if these efforts are

successful, it may be years before existing systems and care pathways are changed. Our inability to maintain or grow the market acceptance of our existing products, or to develop and market new products, could result in write-offs of our inventory and otherwise have a material and adverse effect on our business, results of operations, financial condition or cash flows. ~~Delays in product introductions could adversely affect our business, results of operations, financial condition or cash flows. The medical device market is highly competitive and designs change often to adjust to shifting market preferences and other factors. Therefore, product life cycles are relatively short. As a result, any delays in our product launches may significantly impede our ability to enter or compete in a given market and may reduce the sales that we are able to generate from these products. We may experience delays in any phase of a product launch, including during research and development, clinical trials, regulatory review, manufacturing and marketing. In addition, our competition may respond more quickly to new or emerging technologies or a changing clinical landscape, undertake more extensive marketing campaigns, have greater financial, marketing and other resources than us or be more successful in attracting potential customers and strategic partners. Given these factors, we cannot assure you that we will be able to continue or increase our level of success. If we are unable to introduce new and innovative products, or if there are delays in product introductions, our business, results of operations, financial condition or cash flows could be materially adversely affected.~~ We face significant competition, and if we are unable to compete effectively, we may not be able to achieve or maintain significant market penetration or improve our results of operations. The medical device industry is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. We compete with a number of manufacturers and distributors of neuro and vascular devices. Our most notable competitors are Boston Scientific, Inari **Medical**, Medtronic, Stryker, Terumo and several private companies. Most of these competitors are large, well-capitalized companies with longer operating histories and greater resources than us. We also compete with a number of smaller medical device companies that have a single product or a limited range of products. Our competitors may be able to spend more on product acquisition, development, marketing, sales and other product initiatives, or be more focused in their spending and activities, than we can. Some of our competitors have:

- significantly greater name recognition;
- broader or deeper relations with healthcare professionals, customers, group purchasing organizations and third-party payors;
- more established distribution networks;
- additional lines of products and the ability to offer rebates or bundle products to offer greater discounts or other incentives to gain a competitive advantage;
- greater experience in conducting research and development, manufacturing, clinical trials, marketing and obtaining regulatory clearance or approval for products; and
- greater financial and human resources for product development, sales and marketing and patent litigation.

We compete primarily on the basis that our products are able to treat patients with neuro and vascular diseases and disorders and other health conditions safely and effectively, with improved outcomes and procedural cost savings. Our continued success depends on our ability to:

- develop innovative, proprietary products that can cost-effectively address significant clinical needs;
- continue to innovate and develop scientifically advanced technology;
- obtain and maintain regulatory clearances or approvals;
- demonstrate efficacy in Penumbra-sponsored and third-party clinical trials and studies;
- apply technology across product lines and markets;
- attract and retain skilled research and development and sales personnel; and
- cost-effectively manufacture and successfully market and sell products.

We cannot assure you that we will be able to compete effectively on the basis of these factors. Additionally, our competitors with greater financial resources could acquire or develop new technologies or products that effectively compete with our existing or future products. If we are unable to effectively compete, it would materially adversely affect our business, results of operations, financial condition and cash flows. We may not be able to achieve or maintain satisfactory pricing and margins for our products. Manufacturers of medical devices have a history of price competition, and we can give no assurance that we will be able to achieve satisfactory prices for our products or maintain prices at the levels we have historically achieved. If we are unable to achieve or maintain our prices, or if our costs increase and we are unable to offset such increase with an increase in our prices, our margins could erode and we may be unable to achieve or maintain profitable operations in the future. Events beyond our control, such as **the COVID-19 pandemic, pandemics, war or geopolitical instability**, can impact global supply chains, resulting in an increase in the cost of certain raw materials and components used in our products. While we have taken steps to reduce our manufacturing costs and to increase efficiencies, there can be no assurance that such measures will be successful or will reduce our costs commensurate with the increase in the cost of raw materials and components. If we are unable to increase our pricing or reduce our manufacturing costs in response to increases in the cost of raw materials and components used in our products, our business, results of operations, financial condition and cash flows may be materially adversely affected. Our future growth depends, in part, on our ability to further penetrate our current customer base and increase the frequency of use of our products by our customers as well as expand our user base to include additional specialist physicians and other healthcare providers in both our existing and future target end markets. Currently, the primary users of our products are specialist physicians, including interventional neuroradiologists, neurosurgeons, interventional neurologists, interventional radiologists, interventional cardiologists and vascular surgeons. Our future growth will require us to continue to make our current specialist physician and other healthcare provider customers aware of the benefits of our products to generate increased demand and frequency of use, and thus increase sales to such customers. Our future growth will also depend on our ability to expand our customer base, which will require us to convince specialist physicians and other healthcare providers in our existing and future target end markets that are not current customers of our products' efficacy, to educate them in the proper use of our products and to sell our products to their affiliated hospitals or other organizations. Convincing such specialist physicians and other healthcare providers to use new products and to dedicate the time and energy necessary for adequate education in the use of our products is challenging, especially in new markets where treatments or therapies using our products are not established. Although we are attempting to increase the number of patients treated with our products through our established relationships and focused sales efforts, we cannot provide assurance that our efforts will increase the use of our products by our existing customers. In addition, expanding our customer base in existing and new target end markets may require, among other things, additional clinical evidence supporting patient benefits, training in a

manner to which we are not accustomed, or other resources that we do not readily have available or are not cost effective for us to provide. If we are unable to increase the frequency of use of our products by our existing customers and expand our customer base to include additional specialist physicians and other healthcare providers in both our existing and future target end markets, our sales growth will be limited, which could materially adversely affect our business, results of operations, financial condition or cash flows. We may not have the resources to successfully market and sell our products, which would adversely affect our business and results of operations. The marketing and sales of our products requires us to invest in training and education and employ a salesforce that is large enough to interact with the specialist physicians and other healthcare providers who use our products. Entering new markets also requires a significant amount of time and expense in order to identify and establish relationships with key opinion leaders among the specialist physicians and other healthcare providers who may use our products in those markets. We may not have adequate resources to market and sell our products successfully against larger competitors. If we cannot market and sell our products successfully, our business, results of operations, financial condition and cash flows could be materially adversely affected. Third- party reimbursement may not be available or adequate for the procedures or sessions for which our products are used, and may be subject to change. Our ability to commercialize new products successfully in both the United States and international markets depends in part on the availability of, and hospitals' and other customers' ability to obtain, adequate levels of third- party reimbursement for the procedures or sessions in which our products are used. In the United States, the cost of medical care is funded, in substantial part, by government insurance programs, such as Medicare and Medicaid, and private and corporate health insurance plans. Third- party payors may deny reimbursement if they determine that a device used in a procedure has not received appropriate FDA or other governmental regulatory clearances or approvals, is not used in accordance with cost- effective treatment methods as determined by the payor, or is experimental, unnecessary or inappropriate. Our ability to commercialize our products successfully will depend, in large part, on the extent to which adequate reimbursement levels for the cost of their use are obtained from government authorities, private health insurers and other organizations, such as health maintenance organizations. Further, healthcare in the United States and international markets is also being affected by economic pressure to contain reimbursement levels and costs, and various healthcare reform proposals have emerged and may continue to emerge at the U. S. state and federal level. Changing reimbursement models and the impact of healthcare reform laws, either domestically or internationally, could materially adversely affect our business, results of operations, financial condition or cash flows. We have generated a significant portion of our revenue and revenue growth from a limited number of product families, and our revenue and business prospects would be adversely affected if sales of any of these product families were to decline. We have generated most of our revenue and revenue growth from a limited number of product families. If any one or more of these product families were adversely affected because of regulatory, third- party reimbursement or intellectual property issues or any other reason, or if one of our competitors introduced one or more products that specialist physicians or other healthcare providers believe are superior to our products, our revenue from one of these product families could decline. A significant decline in our sales of any of these product families could also negatively impact our financial condition and our ability to conduct product development activities, and therefore negatively impact our business prospects. If specialist physicians or other healthcare providers do not recommend and endorse, or use, our products or if our relationships with specialist physicians or other healthcare providers deteriorate, our products may not be accepted or maintain acceptance in the marketplace, which would adversely affect our business and results of operations. Our products are sold primarily to hospitals for use by specialist physicians and other healthcare providers practicing at their facilities. In order for us to sell our products, specialist physicians and other healthcare providers must recommend and endorse them for the hospital to purchase them, and must use them in treating their patients to generate follow- on sales. We may not obtain the necessary recommendations or endorsements for new products from specialist physicians and other healthcare providers, our products may not receive approval from the relevant hospital' s value analysis committee, or we may not be able to maintain the current or future level of acceptance and usage of our products. Acceptance of our products depends on educating the medical community as to the distinctive characteristics, perceived benefits, safety, clinical efficacy and cost- effectiveness of our products compared to products of our competitors or treatments that do not use our products, and on training specialist physicians and other healthcare providers in the proper application and use of our products. We invest in significant training and education of our sales representatives, specialist physicians and other healthcare providers to achieve market acceptance of our products, with no assurance of success. If we are not successful in obtaining and maintaining the recommendations or endorsements of specialist physicians and other healthcare providers for our products, if specialist physicians and other healthcare providers prefer our competitors' products or other alternative treatments that do not use our products, if our products do not receive approval from relevant hospitals' value analysis committees, or if our products otherwise do not gain or maintain market acceptance, our business could be adversely affected. In addition, the research, development, marketing and sales of our products are dependent, in part, upon our working relationships with specialist physicians and other healthcare providers. We rely on them to provide us with knowledge and feedback regarding our products and the marketing of our products. If we are unable to develop or maintain strong relationships with specialist physicians and other healthcare providers and receive their advice and input, the development and marketing of our products could suffer, which could materially adversely affect our business, results of operations, financial condition or cash flows. Our dependence on key suppliers puts us at risk of interruptions in the availability of our products, which could reduce our revenue and adversely affect our results of operations. We require the timely delivery of sufficient amounts of components and materials to manufacture our products. For reasons of quality assurance, cost effectiveness or availability, we typically procure certain raw materials and components from a single or limited number of suppliers. We generally acquire such raw materials and components through purchase orders placed in the ordinary course of business, and as a result we may not have a significant inventory of these materials and components and generally do not have any guaranteed or contractual supply arrangements with many of these suppliers. Our reliance on these suppliers subjects us to risks that could harm our business, including, but not limited to, difficulty locating and qualifying alternative suppliers. For example, FDA and

regulators outside of the United States may require additional testing of any raw materials or components from new suppliers prior to our use of these materials or components. In the case of a device with clearance under Section 510 (k) of the FD & C Act, referred to as a 510 (k), we may be required to submit a new 510 (k) if a change in a raw material or component supplier results in a change in a material or component supplied that is not within the 510 (k) cleared device specifications. If we need to establish additional or replacement suppliers for some of these materials or components, our access to the materials or components might be delayed while we qualify such suppliers and obtain any necessary FDA approvals or clearances. Our suppliers may also be subject to regulatory inspection and scrutiny. Any adverse regulatory finding or action against those suppliers could impact their ability to supply us with raw materials and components for our products. We may also face delays, yield issues and quality control problems if we are required to locate and secure new sources of materials or components. Our dependence on third- party suppliers involves several other risks, including limited control over pricing, availability, quality and delivery schedules. Suppliers of raw materials and components may decide, or be required, for reasons beyond our control, to cease supplying raw materials and components to us or to raise their prices. Shortages of raw materials, quality control problems, or production capacity constraints or delays by our suppliers could negatively affect our ability to meet our production requirements and result in increased prices for affected materials or components. Any material shortage, constraint or delay may result in delays in shipments of our products, which could materially adversely affect our results of operations. Finally, some of our products are sterilized prior to use at a third- party sterilizer in the United States using ethylene oxide. The U. S. Environmental Protection Agency has proposed regulations aimed at reducing hazardous air pollutants, including emissions of ethylene oxide, and any future regulatory action that requires sterilization facilities to modify their sterilization processes to limit the use of ethylene oxide could impact the supply of sterilization services as well as the cost for such services. In addition, certain sterilization facilities in the United States have undergone temporary closures mandated by state agencies in recent years due to concerns over the impact of emissions of ethylene oxide from such facilities, and any future closures could lead to increased demand for sterilization services at the facilities we currently use to sterilize our products, which could prevent us from being able to sterilize our products at a pace sufficient to meet product demand and / or result in an increase in the cost of sterilization services. While we continue to work to improve our capacity and flexibility in connection with the sterilization of our products, any regulations that limit the use of ethylene oxide at, or any temporary or permanent closures of, sterilization facilities, including the facilities we currently use, could, due to the limited number of sterilization facilities and the time required to approve and license, and gain regulatory approval for us to use, a sterilization facility, impact our ability to obtain sterilization services on a timely basis **or at commercially reasonable costs**, which could materially adversely affect our results of operations. We cannot be certain that we will be able to manufacture our products in high volumes at commercially reasonable costs. We currently ~~maintain our primary manufacturing operations at our facilities in Alameda and Roseville, California. We currently produce substantially all of our products at these~~ **our manufacturing facilities in Alameda and Roseville, California**, and we can give no assurance that these facilities will be adequate for our future needs. We may need to expend significant capital resources and further increase the size of our manufacturing capabilities as we grow our business. We could, however, encounter problems related to: • capacity constraints; • production yields; • quality control; • equipment availability; and • shortages of qualified personnel. Our continuous product innovation may limit our ability to identify and implement manufacturing efficiencies. Failure to do so may reduce our ability to manufacture our products at commercially reasonable costs. If we are unable to manufacture our products in high volumes at commercially reasonable costs, it could materially affect our ability to ~~adequately increase production of our products and~~ fulfill customer orders on a timely basis, which could have a material adverse effect on our business, results of operations, financial condition or cash flows. We are required to maintain high levels of inventory, which consume a significant amount of our working capital and could lead to permanent write- downs or write- offs of our inventory. We maintain a significant inventory of raw materials, components and finished goods, which subjects us to a number of risks and challenges. Our hospital customers typically maintain only small quantities of our products at their facilities, so as products are used, they order replacements that typically require prompt delivery. As a result, we must maintain sufficient levels of finished goods to permit rapid shipment of products following receipt of a customer order. In turn, we must also maintain a sufficient supply of raw materials and components inventory to permit rapid manufacturing and re- stocking of finished goods. Furthermore, our coil inventory is supplied to hospital customers on a consignment basis, which means that it is classified as part of our inventory for financial reporting purposes but is maintained at the hospital location until it is used. We have built, and will continue to build, a significant inventory of coils in order to support the introduction of and to provide adequate consignment stock for our new and existing coil products. Maintaining a significant inventory of raw materials, components and finished goods, including coils, consumes a significant amount of our working capital. This working capital could be used for other purposes, such as research and development or sales and marketing activities. As we grow our business, we may need substantial additional capital to fund higher levels of inventory, which may materially adversely affect our liquidity or result in dilution to our stockholders if we sell additional equity securities or leverage if we raise debt capital to finance our working capital requirements. Maintaining a significant inventory of raw materials, components and finished goods, including coils, also subjects us to the risk of inventory excess and obsolescence, which may lead to a permanent write- down or write- off of our inventory. While in inventory, our components and finished goods may become obsolete, and we may over- estimate the amount of inventory needed, which may lead to excessive inventory. In these circumstances we would write- down or write- off our inventory and may be required to expend additional resources or be constrained in the amount of end product that we can produce. **For example, during the three months ended June 30, 2024, we recorded a \$ 33. 4 million write- down of Immersive Healthcare inventory in connection with our strategic decision to explore alternative avenues for our Immersive Healthcare business**. Furthermore, our products have a limited shelf life due to sterilization requirements, and part or all of a given product or component may expire, resulting in a decrease in value and potentially a permanent write- down of our inventory. In addition, maintaining a significant inventory of raw materials,

components and finished goods at our facilities requires us to invest resources to safeguard such inventory and presents risk of misappropriation. In the event that a substantial portion of our inventory becomes excess or obsolete, or is otherwise damaged, misappropriated or destroyed, it could materially adversely affect our results of operations. Defects or failures or alleged defects or failures associated with our products could lead to recalls, safety alerts, or product- related or securities litigation, as well as significant costs and negative publicity. Manufacturing flaws, component failures, design defects, off- label uses or inadequate disclosure of product- related information could result in an unsafe condition or the injury or death of a patient. These problems could lead to a recall of, or issuance of a safety alert relating to, our products and result in significant costs, negative publicity and adverse competitive pressure. While we have had product recalls, they have all been voluntary. The circumstances giving rise to recalls are, however, unpredictable, and any recalls of existing or future products could materially adversely affect our business, results of operations, financial condition or cash flows. The medical device industry has historically been subject to extensive litigation over product liability claims. There are high rates of mortality and other complications associated with some of the medical conditions suffered by the patients whom specialist physicians use our devices to treat, and we may be subject to product liability claims if our products cause, or merely appear to have caused, an injury or death. In addition, an injury or death that is caused by the activities of our suppliers, such as those that provide us with components and raw materials, or by an aspect of a treatment used in combination with our products, such as a complementary drug or anesthesia, may be the basis for a claim against us by patients, hospitals, healthcare providers or others purchasing or using our products, even if our products were not the actual cause of such injury or death. An adverse outcome involving one of our products could result in reduced market acceptance and demand for all of our products, and could harm our reputation and our ability to market our products in the future. In some circumstances, adverse events arising from or associated with the design, manufacture or marketing of our products could result in the suspension or delay of regulatory reviews of our premarket notifications or applications for marketing. Any of the foregoing problems could disrupt our business and have a material adverse effect on our business, results of operation, financial condition or cash flows. Although we carry product liability insurance in the United States and in other countries in which we conduct business, including for clinical trials and product marketing, we can give no assurance that such coverage will be available or adequate to satisfy any claims. Product liability insurance is expensive, subject to significant deductibles and exclusions, and may not be available on acceptable terms, if at all. If we are unable to obtain or maintain insurance at an acceptable cost or on acceptable terms with adequate coverage or otherwise protect against potential product liability claims, we could be exposed to significant liabilities. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could materially adversely affect our business, financial condition and results of operations. Defending a product liability suit, regardless of its merit or eventual outcome, could be costly, could divert management' s attention from our business and might result in adverse publicity, which could result in reduced acceptance of our products in the market, product recalls or market withdrawals. In addition, the occurrence of an adverse event relating to our products, a product recall or a product liability claim against us may cause our stock price to decline, which could result in securities class action litigation claims against us. We were involved in one such lawsuit in 2021, which was voluntarily dismissed without prejudice in March 2021, and we may be the target of this type of litigation in the future. Any such litigation could result in substantial costs and a diversion of our management' s attention and resources. Our products are continually the subject of clinical trials conducted by us, our competitors, or other third parties, the results of which may be unfavorable, or perceived as unfavorable, which could materially adversely affect our business, financial condition and results of operations. As a part of the regulatory process of obtaining marketing clearance or approval for new products and new indications for existing products, as well as to provide specialist physicians and other healthcare providers with ongoing information regarding the efficacy of our products, we conduct and participate in numerous clinical trials with a variety of study designs, patient populations and trial endpoints. Our competitors and third parties also conduct clinical trials of our products without our participation. Unfavorable or inconsistent clinical data from existing or future clinical trials conducted by us, our competitors or third parties, or the market' s or regulators' perception of clinical data, may reduce adoption of our products, which could materially adversely affect our business, results of operations, financial condition or cash flows. Negative publicity regarding our products or marketing tactics by competitors or other third parties could reduce demand for our products, which would adversely affect sales and our financial performance. We may experience, from time to time, negative exposure in clinical publications or in marketing campaigns of our competitors. Such publications or campaigns may present negative individual physician experience regarding the safety or effectiveness of our products or may suggest our competitors' products are superior to ours, based on studies or clinical trials conducted or funded by competitors or that involved competitive products. Our reputation and competitive position may also be harmed by other publicly available information suggesting that our products are not safe. For example, we file adverse event reports under Medical Device Reporting (“MDR”) obligations with the FDA that are publicly available on the FDA' s website. We are required to file MDRs—**Medical Device Reports** if our products may have caused or contributed to a serious injury or death or malfunctioned in a way that could likely cause or contribute to a serious injury or death if it were to recur. ~~Our approach has been to file MDRs even in cases where reporting might not otherwise be required out of an abundance of caution.~~ Any such negative publicity could harm our reputation and future sales. ~~We face risks related to our investment in our immersive healthcare platform, including our inexperience with virtual reality and full body tracking technology, and we may be unsuccessful in developing and commercializing products using virtual reality and full body tracking technology. Since 2017, we have invested significant financial resources to develop and commercialize immersive healthcare products, including an acquisition paid in the form of shares of Penumbra common stock and options to purchase Penumbra common stock. Our company is experienced in and has a strong history of bringing technology to healthcare markets. While we are familiar with the healthcare markets that we plan to target initially, we do not have extensive experience with virtual reality technology and are relying on new hires and consultants with expertise in the field. Apart from funds we have invested to date, we continue to invest substantial additional funds for research and development, to establish manufacturing~~

operations, to hire dedicated sales and marketing personnel and to commercialize immersive healthcare products. We can give no assurance that we will be successful in developing and commercializing products using virtual reality and full body tracking technology. We have not yet determined the most appropriate business model to bring this technology to the healthcare field, and accordingly, our ability to successfully commercialize healthcare applications using virtual reality and full body tracking technology may be influenced by many factors, including: • our ability to install, set up and service new customers; • our ability to achieve and maintain market acceptance and expand into new markets; • our possible reliance on a limited number of suppliers for key components of the products we develop; • maintaining an appropriate program for compliance with regulations related to the privacy and security of individually-identifiable patient information, including but not limited to HIPAA; • the impact of competition, including with respect to the hardware and software underlying our immersive healthcare platform; • the timing and impact of market, reimbursement and regulatory developments, including our ability to obtain any required regulatory approvals or clearances both inside and outside the United States; and If we are unsuccessful in developing and commercializing immersive healthcare products, our business, financial conditions and results of operations could be materially and adversely affected. Our corporate culture has contributed to our success, and if we cannot maintain this culture as we grow, we could lose the innovative approach, creativity, and teamwork fostered by our culture, and our business may be harmed. We believe that a critical contributor to our success has been our corporate culture, which we believe fosters innovation, teamwork, and a focus on execution, as well as facilitates critical knowledge transfer and knowledge sharing. As we grow, we may find it difficult to maintain these important aspects of our corporate culture, which could limit our ability to innovate and operate effectively. Any failure to preserve our culture could also negatively affect our ability to retain and recruit personnel or execute on our business strategy. To successfully market and sell our products internationally, we must address a number of unique challenges applicable to international markets. For the years ended December 31, **2024**, **2023**, **and** **2022** **and** **2021**, we derived **28.24**, **5 %**, **28.5 %** **and** **30.2 %** **and** **29.4 %**, respectively, of our revenue from international sales. To accommodate our international sales, we have invested significant financial and management resources to develop an international infrastructure that will meet the needs of our customers. We anticipate that a significant portion of our revenue will continue to be derived from sales of our products in foreign markets **and that the percentage of our overall revenue that is derived from these markets may increase in the future**. This revenue and related operations will continue to be subject to the risks and challenges associated with international operations, including: • reliance on distributors; • varying coverage and reimbursement policies, processes and procedures ; • **pricing impacts due to national and regional tenders, including value-based procurement practices and government-imposed payback provisions** ; • difficulties in staffing and managing international operations from which sales are conducted; • difficulties in penetrating markets in which our competitors' products or alternative procedures that do not use our products are more established; • reduced protection for intellectual property rights in some countries; • export licensing requirements or restrictions, trade regulations and foreign tax laws; • fluctuating foreign currency exchange rates; • foreign certification, regulatory requirements and legal requirements; • lengthy payment cycles and difficulty in collecting accounts receivable; • customs clearance and shipping delays; • reliance on third-party logistics providers who warehouse and distribute finished products to our international customers; • pricing pressure in international markets; • political and economic instability; • preference for locally produced products; • higher incidence of corruption or unethical business practices; and • events resulting in negative impacts to, or uncertainty regarding, global trade, such as the reversal or renegotiation of international trade agreements and partnerships or the imposition of tariffs. If we are unable to successfully address these challenges, we may not be able to grow our international sales and our results of operations may suffer as a result. For example, certain unique macroeconomic and geopolitical factors, including those as a result of the **COVID-19 pandemic**, the Russian invasion of Ukraine or conditions in the Middle East as a result of the Israel- Hamas conflict, may cause instability and volatility in the global financial markets and disruptions within the healthcare industry that may negatively impact our business. In addition, the United States federal government has imposed **and / or threatened** tariffs on goods imported from China, **Mexico, Canada** and certain other countries, which has resulted in retaliatory tariffs **imposed and / or threatened** by China and other countries. Additional tariffs imposed by the United States on a broader range of imports, or further retaliatory trade measures taken by China or other countries in response, could result in an increase in supply chain costs or other pricing pressures that we may not be able to offset or may otherwise adversely impact our business and results of operations. Over the long term, we intend to grow our business internationally, **and to do so**, we will need to spend substantial sums to expand or develop direct sales capabilities in existing and new geographic areas, generate additional sales through existing distributors or attract additional distributors, or enter into other arrangements with third parties in international markets to commercialize our products in such markets. In December 2020, we agreed to license the technology for certain of our products to our existing distribution partner in China to permit our partner to manufacture and commercialize such products in China, in exchange for fixed payments upon the transfer of the **distinct** licensed technology and upon the provision of related regulatory support, as well as, **in certain cases**, royalty payments on downstream sales of the licensed products, which we expanded to include additional products in February 2022 **and**, September 2023 **and March 2024**. We can provide no assurance that this arrangement, which is novel for us, will be successful, or that we will benefit commercially from licensing our technology to a third party in exchange for fixed payments as opposed to selling our products through a distributor. In addition, transferring a portion of our technology to a partner based in China carries risks relating to the intellectual property being transferred. Historically, China has not protected intellectual property rights to the same extent as the United States, and infringement of intellectual property rights continues to pose a serious risk in doing business in China. Monitoring and preventing unauthorized use is difficult, and the measures we may take to protect our intellectual property rights may not be adequate to prevent misappropriation. As a result of our international operations, we are required to comply with tax requirements in multiple jurisdictions, the scope and impact of which may be unclear. Moreover, tax authorities in jurisdictions in which we do business could disagree with tax positions that we take, including, for example, our inter-company pricing policies, or could assert that we owe more taxes than we currently

pay due to the level and nature of our activities in such jurisdictions. We rely on our distributors to market and sell our products in certain international markets. We have established a direct sales capability in the United States, most of Europe, Canada and Australia, which we have complemented with distributors in certain other international markets. Sales to distributors represented **13.2%**, **16.7%**, **and 18.7%** ~~and 16.6%~~ of our revenue in **2024**, **2023**, **and 2022** ~~and 2021~~, respectively. Our success outside of the United States, most of Europe, Canada and Australia depends largely upon marketing arrangements with distributors, in particular their sales expertise and their relationships with specialist physicians and affiliated hospitals in their geographic areas. Distributors may terminate their relationship with us, sell competitive products or devote insufficient sales efforts or other resources to our products. We do not control our distributors, and they may not be successful in implementing our marketing plans. In addition, many of our distributors initially obtain and maintain foreign regulatory approval for the sale of our products in their respective countries, and their efforts in obtaining and maintaining regulatory approval may not be as robust as we desire or expect. As our business grows, we may seek to expand or otherwise modify our arrangements with our existing distributors and / or retain the services of additional distributors. For example, in December 2020, we entered into an agreement to license the technology for certain of our products to our existing distribution partner in China to permit our partner to manufacture and commercialize such products in China, in exchange for fixed payments upon the transfer of **distinct** the licensed technology and upon the provision of related regulatory support, as well as **, in certain cases,** royalty payments on downstream sales of the licensed products, which we expanded to include additional products in February 2022 ~~and~~, September 2023 **and March 2024**. However, there can be no assurances that this arrangement, which is novel for us, or other similar arrangements that we may enter into in the future, will be successful. Our failure to maintain our relationships with our existing distributors or our partner in China, or our failure to recruit and retain additional skilled distributors in existing or new international markets, could have an adverse effect on our operations. If current or future distributors or our partner in China do not perform adequately, or if we lose a significant distributor or our partner in China, we may not be able to maintain existing levels of international revenue or realize expected long term international revenue growth. We have in the past experienced turnover with some of our distributors that has adversely affected sales in the countries in which those distributors operate. Similar occurrences could happen in the future. Most of our customer relationships outside of the United States are with governmental entities, and we could be materially adversely affected by violations of the U. S. Foreign Corrupt Practices Act and similar anti- bribery laws in non- U. S. jurisdictions. The FCPA, the United Kingdom Bribery Act, the Chinese Anti- Unfair Competition Law, and similar anti- bribery laws in other non- U. S. jurisdictions generally prohibit companies and their intermediaries from making improper payments to foreign officials for the purpose of obtaining or retaining business. Because of the predominance of government- sponsored healthcare systems around the world, most of our customer relationships outside of the United States are with governmental entities, and physicians practicing in those systems are considered “ government officials. ” Therefore, our sales to these entities are subject to such anti- bribery laws. Our policies mandate compliance with these anti- bribery laws. We operate in many parts of the world that have experienced governmental corruption, and we have operations in certain countries, including working with a distributor in Russia and a local partner in China, where strict compliance with anti- bribery laws may be at variance with local customs and practices. Despite our training and compliance programs, our internal control policies and procedures may not always protect us from reckless or criminal acts committed by our employees, distributors or agents. Violations of the FCPA or other anti- bribery laws, or allegations of such violations, could disrupt our business and materially adversely affect our business, results of operations, financial condition or cash flows. Foreign currency exchange rates may adversely affect our results. We are exposed to the effects of changes in foreign currency exchange rates, and we have not historically hedged our foreign currency exposure. Approximately **28.2%**, **28.5%**, **and 30.2%**, ~~and 29.4%~~ of our revenue for the years ended December 31, **2024**, **2023**, **and 2022** ~~and 2021~~, respectively, were derived from sales in non- U. S. markets, and we expect sales in non- U. S. markets to continue to represent a significant portion of our revenue. For direct sales in our international markets, we are paid by our customers in their local currency, which is primarily euros. For sales to distributors in our international markets, we are paid principally in either U. S. dollars or euros, with some sales being denominated in other currencies. Therefore, when the U. S. dollar strengthens relative to the euro or other local currency, our U. S. dollar reported revenue from non- U. S. dollar denominated sales will decrease, or we will need to increase our non- U. S. dollar denominated prices, which may not be commercially practical. Conversely, when the U. S. dollar weakens relative to the euro or other local currency, our U. S. dollar reported expenses from non- U. S. dollar denominated operating costs will increase. Changes in the relative values of currencies occur regularly and, in some instances, could materially adversely affect our business, results of operations, financial condition or cash flows. For example, during 2022 the U. S. dollar strengthened relative to many local currencies in the non- U. S. markets where we do business, which adversely affected our U. S. dollar reported revenue. We have experienced rapid growth in recent periods, and if we fail to manage our growth effectively, our business and results of operations may suffer. We have significantly expanded our overall business, research and development, customer base, product portfolio, employee headcount and operations in recent periods. We have also established new operations in other countries. Our expansion has placed, and our expected future growth will continue to place, a significant strain on our managerial, operational, product development, sales and marketing, administrative, financial and other resources. We plan to continue to increase our salesforce. Our experience has been that it takes at least six months, and often longer, before new sales personnel generate enough sales to cover their costs, resulting in increased costs without offsetting revenue during periods in which we are increasing the size of our salesforce. More systems, facilities, processes and management employees are needed to allow us to continue to grow successfully. We are expanding and renovating our existing facilities around the world but particularly in Alameda, California, driven by our need to expand the space available for our product development and test capacities, as well as our need for additional information technology and office space. The expansion and renovation of our facilities entail risks that could cause disruption in the operations of our business. Such risks include potential interruption in data flow; unforeseen construction, scheduling, engineering, environmental, or geological problems; and unanticipated cost

increases. To meet anticipated demand for our products, we will also have to continue to buy additional equipment and hire additional research and development and manufacturing employees, including quality control personnel and other personnel involved in the production process. This expansion could result in operating difficulties including, but not limited to, difficulties in hiring the appropriate number of research and development and manufacturing employees, training and managing an increasing number of employees, delays in production and shipments, manufacturing inefficiencies and employees not working at capacity. In addition, at certain times we may need to rely on third party consultants, which may cost more than employees and may create operating inefficiencies and difficulties. If we do not adapt to meet these evolving challenges and if we are unable to manage our growth successfully, it could have a material and adverse effect on our business, results of operations, financial condition or cash flows. We depend on key personnel to operate our business and develop our products, and if we are unable to retain, attract and integrate qualified personnel, our ability to develop and successfully grow our business could be harmed. We believe that our future success is highly dependent on the contributions of our executive officers, particularly Adam Elsesser, our chief executive officer and president, as well as our ability to attract and retain highly skilled and experienced sales and marketing, technical and other personnel in the United States and in international markets. Each of these persons' efforts will be critical to us as we continue to develop our products and business. If we were to lose one or more of our key employees, including to competitors, we may experience difficulties in competing effectively, developing our products and implementing our business strategies. Our research and development and sales and marketing programs depend on our ability to attract and retain highly skilled technicians, engineers and salespeople. In general, we may not be able to attract or retain qualified employees in the future due to the intense competition for qualified personnel among life science businesses, particularly in the San Francisco Bay Area, where our corporate headquarters, research and development and primary manufacturing facility is located. In addition to the competition for personnel, the San Francisco Bay Area in particular is characterized by a high cost of living. Although we historically have not had any material difficulty attracting qualified experienced personnel to our company, we could in the future have such difficulties and may be required to expend significant financial resources in our employee recruitment and retention efforts. If we are not able to identify, recruit and retain highly qualified personnel, we may experience constraints that will adversely affect our ability to support our research, development, manufacturing and sales programs, and ultimately our ability to compete. If we are unable to identify, recruit and retain qualified salespeople, there could be a delay or decline in the adoption of our products. If key personnel were to leave Penumbra, either to join our competitors or otherwise, we may not be able to attract and retain equally qualified personnel to replace them, which could harm our ability to develop and successfully grow our business. We depend on information technology systems to operate our business, and issues with maintaining, upgrading or implementing these systems, could have a material adverse effect on our business. We rely on the efficient and uninterrupted operation of information technology systems to process, transmit and store electronic information in our day-to-day operations. All information technology systems are vulnerable to damage or interruption from a variety of sources. Our business has grown in size and complexity; this has placed, and will continue to place, significant demands on our information technology systems. To effectively manage this growth, our information systems and applications require an ongoing commitment of significant resources to maintain, protect, enhance and upgrade existing systems and develop and implement new systems to keep pace with changing technology and our business needs. In 2023, we completed implementation of a new enterprise resource planning ("ERP") software system implementation which replaced certain existing business, operational, and financial processes and systems. This ERP implementation project will continue to require investment of capital and human resources, the re-engineering of business processes, and the attention of many employees who would otherwise be focused on other areas of our business. This system change entails certain risks, including difficulties with changes in business processes that could disrupt our operations, such as our ability to track orders and timely ship products, manage our supply chain and aggregate financial and operational data. In addition, the implementation of the new system may not achieve the anticipated benefits and may divert management's attention from other operational activities, negatively affect employee morale, or have other unintended consequences. Delays in integration or disruptions to our business from implementation of new or upgraded systems could have a material adverse impact on our financial condition and operating results. Additionally, if we are not able to accurately forecast expenses and capitalized costs related to system upgrades and changes, this may have an adverse impact on our financial condition and operating results. If we fail to maintain or are unable to assert that our internal control over financial reporting is effective under the new ERP system, we could adversely affect our ability to accurately report our financial condition, operating results or cash flows. If we have a material weakness in our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be adversely affected, and we could become subject to investigations by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities, which could require additional financial and management resources. If the information we rely upon to run our businesses were to be found to be inaccurate or unreliable, if we fail to maintain or protect our information technology systems and data integrity effectively, if we fail to develop and implement new or upgraded systems to meet our business needs in a timely manner, or if we fail to anticipate, plan for or manage significant disruptions to these systems, our competitive position could be harmed, we could have operational disruptions, we could lose existing customers, have difficulty preventing, detecting, and controlling fraud, have disputes with customers, specialist physicians and other **healthcare** ~~care~~ providers, have regulatory sanctions or penalties imposed or other legal problems, incur increased operating and administrative expenses, lose revenues as a result of a data privacy breach or theft of intellectual property or suffer other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition or cash flows. Cost-containment efforts of our customers, purchasing groups and governmental organizations could have a material adverse effect on our sales and ability to achieve or maintain profitability. In an effort to reduce costs, many hospitals within the United States are members of Group Purchasing Organizations ("GPOs") and Integrated Delivery Networks ("IDNs"). GPOs and IDNs negotiate pricing arrangements with medical device companies and distributors and offer

the negotiated prices to affiliated hospitals and other members. GPOs and IDNs typically award contracts on a category-by-category basis through a competitive bidding process. Bids are generally solicited from multiple providers with the intention of driving down pricing or reducing the number of vendors. Due to the highly competitive nature of the GPO and IDN contracting processes, we may not be able to obtain or maintain contract positions with major GPOs and IDNs. Furthermore, the increasing leverage of organized buying groups may reduce market prices for our products, thereby reducing our profitability. While having a contract with a GPO or IDN for a given product category can facilitate sales to members of that GPO or IDN, such contract positions can offer no assurance that any level of sales will be achieved, as sales are typically made pursuant to purchase orders. Even when a provider is the sole contracted supplier of a GPO or IDN for a certain product category, members of the GPO or IDN **are** generally ~~are~~ free to purchase a certain percentage of such products from other suppliers. Furthermore, GPO and IDN contracts typically are terminable without cause by the GPO or IDN upon 60 to 90 days' notice. Accordingly, although we have multiple contracts with many major GPOs and IDNs, the members of such groups may choose to purchase from our competitors due to the price or quality offered by such competitors, which could result in a decline in our sales and profitability. If we are unable to educate specialist physicians or other healthcare providers in the proper use of our products, which may be more complex than competitive products or alternative treatments that do not use our products, our business may be materially adversely affected and we may experience a high risk of product liability. The successful use of our products depends, in part, on our ability to educate specialist physicians or other healthcare providers in the proper use of our products, which may be more complex than competitive products or alternative treatments that do not use our products. We educate specialist physicians or other healthcare providers on the proper techniques in using our products to achieve the intended outcome. However, our products may be more complicated to operate than competitive products or alternative treatments that do not use our products. In the event that specialist physicians or other healthcare providers perceive that our products are complex relative to alternative products or established treatments that do not use our products, we may have difficulty gaining or increasing adoption of our products. Further, we may be unable to provide adequate education on the use of our products to specialist physicians or other healthcare providers, and some specialist physicians or other healthcare providers may not be willing to invest the time required to become properly educated on the use of our products. If we are unable to educate specialist physicians or other healthcare providers to properly use our products, this may lead to inadequate demand for our products and materially adversely affect our business, results of operations, financial condition or cash flows. In addition, if we do not adequately educate specialist physicians or other healthcare providers on the use of our products, and our products are used incorrectly during procedures, we may be subject to claims against us by such specialist physicians or other healthcare providers, their hospitals or their patients. Our business, including our reputation, may consequently be adversely affected by any litigation that may occur based on error in the use of our products, and such litigation could also materially adversely affect our results of operations, financial condition or cash flows.

Regulatory Risks We are subject to stringent domestic and foreign medical device regulations, which may impede the approval or clearance process for our products, hinder our development activities and manufacturing processes and, in some cases, result in the recall or seizure of previously approved or cleared products. Our products, development activities and manufacturing processes are subject to extensive and rigorous regulation by FDA and by comparable regulatory authorities in foreign countries and by other regulatory agencies and governing bodies. Manufacturers of medical devices must comply with certain regulations that cover the composition, labeling, testing, clinical study, manufacturing, packaging and distribution of medical devices. In addition, most medical devices (Class II & III) must receive FDA clearance or approval before they can be commercially marketed in the United States. FDA may require testing and surveillance programs to monitor the effects of cleared or approved products that have been commercialized and can prevent or limit further marketing of a product based on the results of these post-marketing programs. Furthermore, most major markets for medical devices outside the United States require clearance, approval or compliance with certain standards and requirements before a medical device can be commercially marketed. The process of obtaining marketing approval or clearance from the FDA and foreign regulatory authorities for new products could take a significant period of time, require the expenditure of substantial resources, involve rigorous pre-clinical and clinical testing, require changes to our products and result in limitations on the indicated uses of our products. We cannot provide assurance that we will receive the required approval or clearance from FDA and foreign regulatory authorities for future products on a timely basis. Results from pre-clinical studies and early clinical trials may not allow us to predict results in later-stage testing. We cannot be certain that our future clinical trials will demonstrate the safety and effectiveness of any of our future products or will result in clearance or approval to market any of these products. In addition, our development activities could be harmed or delayed by a shutdown of the U. S. government, including FDA. The failure to receive approval or clearance for significant new products on a timely basis could have a material adverse effect on our business, results of operation, financial condition or cash flows. FDA and other foreign regulatory authorities worldwide also conduct periodic inspections of our facilities to determine compliance with FDA's QSR requirements, **EU MDR regulations requirements** and all comparable foreign regulations. Product approvals or clearances by FDA can be withdrawn, and new product approvals or clearances by FDA and foreign regulatory bodies can be delayed, due to failure to comply with regulatory requirements or the occurrence of unforeseen problems following initial approval or clearance of a product. In addition, state or federal legislation or regulations may impact key manufacturing processes, such as sterilization, which could require expensive and time-consuming changes to our manufacturing processes as well as the need for additional regulatory clearances or approvals. Failure to comply with regulatory requirements or the discovery of previously unknown problems with a product or manufacturer could result in fines, delays or suspensions of regulatory approvals or clearances, seizures or recalls of products (with the attendant expenses and adverse competitive impact), the banning of a particular device, an order to replace or refund the cost of any device previously manufactured or distributed, operating restrictions and criminal prosecution, as well as decreased sales as a result of negative publicity and product liability claims, all of which could have a material adverse effect on our business, results of operation, financial condition or cash flows. If we modify our FDA cleared products, we may need to

seek and obtain new clearances, which, if not granted, would prevent us from selling our modified products or require us to redesign our products. A component of our strategy is to continue to modify and upgrade our medical devices that have been cleared by FDA. FDA requires device manufacturers to make a determination of whether a modification requires a clearance; however, FDA can review a manufacturer's decision not to submit for additional clearances. Any modifications to an FDA cleared device that would significantly affect its safety or effectiveness or that would constitute a major change in its intended use may require a new 510 (k) clearance or ~~possibly~~ **potentially another pathway, such as** a PMA. We may not be able to obtain additional 510 (k) clearances or PMAs for new products or for modifications to, or additional indications for, our existing products in a timely manner, or at all. There can be no assurance that FDA will agree with our decisions not to seek clearances for particular device modifications. Delays in obtaining future clearances would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our revenue and future profitability. We have made minor modifications to our medical devices in the past and may make additional minor modifications in the future that we believe do not or will not require additional clearances and are well documented within our design control procedure. If FDA requires new clearances or approvals for any modifications, and we fail to obtain such approvals or clearances or fail to secure approvals or clearances in a timely manner, we may be required to recall and to stop the manufacturing and marketing of the modified device until we obtain FDA approval or clearance, and we may be subject to significant regulatory fines or penalties, all of which could harm our results of operations and require us to redesign our products. We may not receive necessary foreign regulatory approvals or clearances or otherwise comply with foreign regulations. For the years ended December 31, **2024, 2023, and 2022** ~~and 2021~~, sales outside the United States accounted for approximately **28.24**, **5**, **28.5**%, **and** **30.2**%, ~~and 29.4~~%, respectively, of our total sales, and we expect sales in non- U. S. markets to continue to represent a significant portion of our revenue. Foreign regulatory bodies have established varying regulations. Specifically, the European Union has promulgated rules that require that medical device products receive the right to affix the CE mark, an international symbol of adherence to quality assurance standards and compliance with applicable European medical device directives. Although we have received CE markings for all of the medical devices we currently sell in the European Union, we can give no assurance that we will be able to obtain European Union approval for any of our future products. Our inability or failure, or the inability or failure of our international distributors, to comply with varying foreign regulations or the imposition of new regulations could restrict or, in certain countries, result in the prohibition of the sale of our products, and thereby adversely affect our business, financial condition and results of operations. Our global regulatory environment is becoming increasingly stringent and unpredictable, which could increase the time, cost and complexity of obtaining regulatory approvals for our products, as well as the clinical and regulatory costs of supporting those approvals. Many countries that did not have regulatory requirements for medical devices have established such requirements in recent years and other countries have expanded existing regulations. Certain regulators are exhibiting less flexibility by requiring, for example, the collection of local preclinical and / or clinical data prior to approval. While harmonization of global regulations has been pursued, requirements continue to differ significantly among countries. We expect the global regulatory environment to continue to evolve, which could impact our ability to obtain future approvals for our products and increase the cost and time to obtain such approvals. By way of example, the European Union regulatory bodies have instituted EU MDR, which changed many aspects of the existing regulatory framework, such as clinical data requirements, and introduced new ones, such as Unique Device Identification. EU MDR imposes increased compliance obligations for many parts of our business in order to access the EU market. The notified bodies that oversee compliance with EU MDR face uncertainties as EU MDR is enforced, creating risks in several areas, including the CE Marking process, data transparency and application review timetables. We may not be able to meet regulatory quality requirements applicable to our manufacturing process. We are required to register with FDA as a device manufacturer and as a result, we are subject to periodic inspection by FDA for compliance with FDA's QSR requirements, which requires manufacturers of medical devices to adhere to certain requirements, including testing, quality control and documentation procedures. In addition, the **U. S. federal MDR-Medical Device Reporting** regulations require us to provide information to FDA whenever there is evidence that reasonably suggests that a device may have caused or contributed to a death or serious injury, or has malfunctioned, and if the malfunction were to recur, it would be likely to cause or contribute to a death or serious injury. Compliance with applicable regulatory requirements is subject to continual review and is rigorously monitored through periodic inspections by FDA. In the European Community, we are required to maintain certain ISO certifications in order to sell products and we undergo periodic inspections by notified bodies to obtain and maintain these certifications. **We received certification to** ~~On March 1, 2016, the ISO issued a new Quality Management System standard for medical device manufacturers, ISO 13485: 2016 . We received certification to ISO 13485: 2016 in 2018 and successfully completed our most recent surveillance~~ **recertification** ~~audit in 2023-2024~~. Compliance with this standard is subject to continual review and is monitored through periodic inspections by our notified body. Some foreign countries, most notably Japan and Brazil, have similar requirements or may require inspections of our manufacturing facilities before approving a product for sale in their country. We participate in the Medical Device Single Audit Program ("MDSAP") which allows for certification and review of compliance to standards and regulations required in the United States, Canada, Brazil, Australia, and Japan. We received our first MDSAP certification in 2018 and successfully completed our most recent **surveillance-recertification** ~~audit in 2023-2024~~. Some of our suppliers are subject to the same or similar scrutiny. If we or our suppliers fail to adhere to QSR, ISO or other regulatory requirements, this could delay production of our products and lead to fines, difficulties in obtaining regulatory clearances or approvals, recalls or other consequences, which could in turn have a material adverse effect on our business, results of operation, financial condition or cash flows. Notices of inspectional observations or deficiencies from FDA or other regulatory bodies could require us to undertake corrective and preventive actions or other actions in order to address FDA's or other regulatory body's concerns, which could be expensive and time- consuming to complete and could impose additional burdens and expenses. We are subject to periodic inspections by FDA and other regulatory bodies related to regulatory requirements that apply to medical devices designed and manufactured, and clinical trials

sponsored, by us. If we receive a notice of inspectional observations or deficiencies from FDA following an inspection, we may be required to undertake corrective and preventive actions or other actions in order to address FDA's concerns, which could be expensive and time-consuming to complete and could impose additional burdens and expenses. We have previously received and could in the future receive notices of inspectional observations or deficiencies from FDA. Failure to adequately address FDA's concerns could expose us to enforcement and administrative actions. We are subject to federal, state and foreign healthcare laws and regulations that could result in significant liability, require us to change our business practices and restrict our operations in the future. We are subject to various federal, state and foreign healthcare fraud and abuse laws and regulations, which could significantly impact our business. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it;
- federal civil and criminal false claims laws and civil monetary penalty laws, including civil whistleblower or qui tam actions, that 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 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;
- HIPAA, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. A person or entity does not need to have actual knowledge of these statutes or specific intent to violate them;
- HIPAA, as amended by HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their business associates that perform services for them that involve individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization, including mandatory contractual terms as well as directly applicable privacy and security standards and requirements;
- the federal physician sunshine requirements under the Affordable Care Act, which require certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to CMS information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), teaching hospitals, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives, and ownership and investment interests held by physicians and their immediate family members; and
- state and foreign law equivalents of each of the above federal laws, such as foreign and state anti-kickback, anti-benefit and false claims laws, as well as state and foreign laws and regulations governing interactions with healthcare professionals and requiring disclosure of payments and interactions with healthcare professionals and state and foreign laws governing the privacy and security of health information in certain circumstances. The scope and enforcement of each of these laws is uncertain and subject to rapid change, which may make it challenging to maintain compliance with such laws. In addition, federal and state enforcement bodies continue to closely scrutinize interactions between healthcare companies and healthcare providers, which may lead to an increased number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time- and resource-consuming and can divert management's attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have 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. 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 now or in the future, we may be subject to penalties, including civil and criminal penalties, damages, fines, disgorgement, exclusion from governmental health-care programs, and the curtailment or restructuring of our operations, any of which could have a material adverse effect on our business, results of operation, financial condition or cash flows. If we are found to have improperly promoted our products for off-label uses, we may become subject to significant fines and other liability. FDA and other regulatory agencies strictly regulate the promotional claims that may be made about medical devices. For example, devices cleared under section 510(k) cannot be marketed for any intended use that is outside of FDA's substantial equivalence determination for such devices. Physicians nevertheless may use our products ~~on in their~~ **the patients practice of medicine** in a manner that is inconsistent with the intended use cleared by FDA. If we are found to have promoted such "off-label" uses, we may become subject to significant government fines and other related liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

Risks Related to Our Intellectual Property We rely on a variety of intellectual property rights, and if we are unable to maintain or protect our intellectual property, our business and results of operations will be harmed. Our commercial success will depend, in part, on our ability to obtain and maintain intellectual property protection for our products and related technologies both in the United States and elsewhere, successfully defend our intellectual property rights against third-party challenges and successfully enforce our intellectual property rights to prevent third-party infringement. While we rely primarily upon a combination of patents, trademarks and trade secret protection, as well as nondisclosure, confidentiality and other contractual agreements to protect the intellectual property related to our brands, products and other proprietary technologies, protection derived from patents is relatively limited. The process of obtaining patent protection is expensive and time-consuming, and we may not be able to prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may choose not to seek patent protection for certain innovations or products and may choose not to pursue patent protection in certain jurisdictions, and under the laws of certain jurisdictions,

patents or other intellectual property rights may be unavailable or limited in scope and, in any event, any patent protection we obtain may be limited. As a result, some of our products are not, and in the future may not be, protected by patents. We generally apply for patents in those countries where we intend to make, have made, use or sell products and where we assess the risk of infringement to justify the cost of seeking patent protection. However, we do not seek protection in all countries where we sell products and we may not accurately predict all the countries where patent protection would ultimately be desirable. If we fail to timely file a patent application in any such country or major market, we may be precluded from doing so at a later date. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories in which we have patent protection that may not be sufficient to terminate infringing activities. Furthermore, we cannot guarantee that any patents will be issued from any pending or future owned or licensed patent applications, or if any current or future patents will provide us with any meaningful protection or competitive advantage. Even if issued, existing or future patents may be challenged, including with respect to ownership, narrowed, invalidated, held unenforceable or circumvented, any of which could limit our ability to prevent competitors and other third parties from developing and marketing similar products or limit the length of terms of patent protection we may have for our products and technologies. Other companies may also design around technologies we have patented, licensed or developed. In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our products or practicing our own patented technology. The patent positions of medical device companies can be highly uncertain and involve complex legal, scientific and factual questions for which important legal principles remain unresolved. The standards that the U. S. Patent and Trademark Office (“USPTO”) and its foreign counterparts use to grant patents are not always applied predictably or uniformly. Changes in either the patent laws, implementing regulations or the interpretation of patent laws may diminish the value of our rights. The legal systems of certain countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. Because patent applications in the United States, Europe and many other jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in scientific literature lag behind actual discoveries, we cannot be certain that we were the first to make the inventions claimed in our issued patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in our patents or applications. We can give no assurance that all of the potentially relevant art relating to our patents and patent applications has been found; overlooked prior art could be used by a third party to challenge the validity, enforceability and scope of our patents or prevent a patent from issuing from a pending patent application. As a result, we may not be able to obtain or maintain protection for certain inventions. Therefore, the validity, enforceability and scope of our patents in the United States, Europe and in other countries cannot be predicted with certainty and, as a result, any patents that we own or license may not provide sufficient protection against our competitors. Third parties may challenge any existing patent or future patent we own or license through adversarial proceedings in the issuing offices or in court proceedings, including as a response to any assertion of our patents against them. In any of these proceedings, a court or agency with jurisdiction may find our patents invalid and / or unenforceable, or even if valid and enforceable, insufficient to provide protection against competing products and services sufficient to achieve our business objectives. We may be subject to a third- party pre- issuance submission of prior art to the USPTO, or reexamination by the USPTO if a third party asserts a substantial question of patentability against any claim of a U. S. patent we own or license. The adoption of the Leahy-Smith America Invents Act (“Leahy- Smith Act”) in September 2011 established additional opportunities for third parties to invalidate U. S. patent claims, including inter partes review and post- grant review proceedings. Outside of the United States, patents we own or license may become subject to patent opposition or similar proceedings, which may result in loss of scope of some claims or the entire patent. In addition, such proceedings are very complex and expensive, and may divert our management’s attention from our core business. If any of our patents are challenged, invalidated, circumvented by third parties or otherwise limited or expire prior to the commercialization of our product candidates, and if we do not own or have exclusive rights to other enforceable patents protecting our products or other technologies, competitors and other third parties could market products and use processes that are substantially similar to, or superior to, ours and our business would suffer. The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep a competitive advantage. For example: • others may be able to develop products that are similar to, or better than, ours in a way that is not covered by the claims of our patents; • we might not have been the first to make the inventions covered by our patents or pending patent applications; • we might not have been the first to file patent applications for these inventions; • any patents that we obtain may not provide us with any competitive advantages or may ultimately be found invalid or unenforceable; or • we may not develop additional proprietary technologies that are patentable. We may file lawsuits or initiate other proceedings to protect or enforce our patents or other intellectual property rights, which could be expensive, time consuming and unsuccessful. Competitors may infringe our issued patents or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time- consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent’s claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly, which could adversely affect our competitive business position, business prospects and financial condition. Our commercial success depends significantly on our ability to operate without infringing upon the intellectual property rights of third parties. The medical device industry is subject to rapid technological change and substantial litigation regarding patent and other intellectual property rights. Our competitors in both the United States and abroad, many of which have substantially

greater resources and have made substantial investments in patent portfolios and 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, use and sell our products. Numerous third- party patents exist in the fields relating to our products, and it is difficult for industry participants, including us, to identify all third- party patent rights relevant to our products and technologies. Moreover, because some patent applications are maintained as confidential for a certain period of time, we cannot be certain that third parties have not filed patent applications that cover our products and technologies. Patents could be issued to third parties that we may ultimately be found to infringe. Third parties may also have or obtain valid and enforceable patents or proprietary rights that could block us from developing product candidates using our technology. Our failure to obtain or maintain a license to any technology that we require may materially harm our business, financial condition and results of operations. Furthermore, we would be exposed to a threat of litigation. From time to time, we may be party to, or threatened with, litigation or other proceedings with third parties, including non- practicing entities, who allege that our products, components of our products and / or proprietary technologies infringe, misappropriate or otherwise violate their intellectual property rights. The types of situations in which we may become a party to such litigation or proceedings include: • we or our collaborators may initiate litigation or other proceedings against third parties seeking to invalidate the patents held by those third parties or to obtain a judgment that our products or processes do not infringe those third parties' patents; • we or our collaborators may participate at substantial cost in International Trade Commission proceedings to abate importation of products that would compete unfairly with our products; • if our competitors file patent applications that claim technology also claimed by us or our licensors, we or our licensors may be required to participate in interference, derivation or opposition proceedings to determine the priority of invention, which could jeopardize our patent rights and potentially provide a third party with a dominant patent position; • if third parties initiate litigation claiming that our processes or products infringe their patent or other intellectual property rights, we and our collaborators will need to defend against such proceedings; • if third parties initiate litigation or other proceedings seeking to invalidate patents owned by or licensed to us or to obtain a declaratory judgment that their product or technology does not infringe our patents or patents licensed to us, we will need to defend against such proceedings; • we may be subject to ownership disputes relating to intellectual property, including disputes arising from conflicting obligations of consultants or others who are involved in developing our products; and • if a license to necessary technology is terminated, the licensor may initiate litigation claiming that our processes or products infringe or misappropriate their patent or other intellectual property rights and / or that we breached our obligations under the license agreement, and we and our collaborators would need to defend against such proceedings. These lawsuits and proceedings, regardless of merit, are time- consuming and expensive to initiate, maintain, defend or settle, and could divert the time and attention of managerial and technical personnel, which could materially adversely affect our business. Any such claim could also force us to do one or more of the following: • incur substantial monetary liability for infringement or other violations of intellectual property rights, which we may have to pay if a court decides that the product or technology at issue infringes or violates the third party' s rights, and if the court finds that the infringement was willful, we could be ordered to pay treble damages and the third party' s attorneys' fees; • pay substantial damages to our customers or end users to discontinue use or replace infringing technology with non- infringing technology; • stop manufacturing, selling, using, exporting or licensing the product or technology incorporating the allegedly infringing technology or stop incorporating the allegedly infringing technology into such product or technology; • obtain from the owner of the infringed intellectual property right a license, which may require us to pay substantial upfront fees or royalties to sell or use the relevant technology and which may not be available on commercially reasonable terms, or at all; • redesign our products and technology so they do not infringe or violate the third party' s intellectual property rights, which may not be possible or may require substantial monetary expenditures and time; • enter into cross- licenses with our competitors, which could weaken our overall intellectual property position; • lose the opportunity to license our technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property against others; • find alternative suppliers for non- infringing products and technologies, which could be costly and create significant delay; or • relinquish rights associated with one or more of our patent claims, if our claims are held invalid or otherwise unenforceable. Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity, adversely impact prospective customers, cause product shipment delays, or prohibit us from manufacturing, marketing or otherwise commercializing our products and technology. Any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operation, financial condition or cash flows. In addition, we may indemnify our customers and distributors against claims relating to the infringement of intellectual property rights of third parties related to our products. Third parties may assert infringement claims against our customers or distributors. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers or distributors, regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of our customers, suppliers or distributors, or may be required to obtain licenses for the products they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. The occurrence of any of these events may have a material adverse effect on our business, results of operation, financial condition or cash flows. Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our existing and future products. Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our

issued patents. For example, the Leahy- Smith Act included a number of significant changes to U. S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, and may also affect patent litigation. The USPTO developed new regulations and procedures to govern administration of the Leahy- Smith Act, including switching the U. S. patent system from a “ first- to- invent ” system to a “ first- to- file ” system. Under a “ first- to- file ” system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The Leahy- Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, results of operation, financial condition or cash flows. In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and applications. Furthermore, the U. S. Supreme Court and the U. S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U. S. and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future. Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. The USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions. In addition, periodic maintenance fees on our owned and in- licensed patents are due to be paid to governmental patent agencies over the lifetime of the patents. Future maintenance fees will also need to be paid on other patents that may be issued to us. We have systems in place to remind us to pay these fees, and we employ outside firms to remind us or our licensor to pay annuity fees due to patent agencies on our patents and pending patent applications. In certain cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, 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. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business, results of operation, financial condition or cash flows. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. We own 43-45 trademarks, related to our company name, logo, products and technology, that are registered with the USPTO as well as 214-225 trademarks registered outside of the United States as of December 31, 2023-2024 . Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks or names. We may not be able to protect our rights in these trademarks and trade names, which we need in order to build name recognition with potential customers in our markets of interest. There is no guarantee we will be able to secure registration for any of our pending trademark applications with the USPTO or comparable foreign authorities. In addition, third parties have registered trademarks similar or identical to our trademarks, and may in the future file for registration of such trademarks. If they succeed in registering or developing common law rights in such trademarks, and if we are not successful in challenging such third- party rights, we may not be able to use these trademarks to market our products in those countries where such third parties have registered such trademarks or obtained such common law rights. In any case, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. In addition, we may be involved in litigation or other proceedings to protect our trademark rights associated with our company name or the names used with our products. Any objections we receive from the USPTO, foreign trademark authorities or third parties relating to our pending applications could require us to incur significant expense in defending the objections or establishing alternative names. Names used with our products may be claimed to infringe names held by others or to be ineligible for proprietary protection. If we have to change the name of our company or any product, we may experience a loss in goodwill associated with our brand name, customer confusion or a loss of sales. If we are unable to protect the confidentiality of our trade secrets and other proprietary information, our business and competitive position may be harmed. In addition to patent protection, we also rely on confidential proprietary information, including trade secrets and know- how, to develop and maintain our competitive position. We seek to protect our confidential proprietary information, in part, by entering into confidentiality agreements with our employees, consultants, collaborators, strategic partners and others upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual’ s relationship with us be kept confidential. Our agreements with employees and our personnel policies also provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. Thus, despite such agreements, such inventions may become assigned to third parties. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants or contractors use technology or know- how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions. To the extent that an individual who is not obligated to assign rights in intellectual property to us is rightfully an inventor of intellectual property, we may need to obtain an assignment or a license to that intellectual property from that individual, or a third party or from that individual’ s assignee. Such assignment or license may not be available on commercially

reasonable terms or at all. Adequate remedies may not exist in the event of unauthorized use or disclosure of our proprietary information. The disclosure of our trade secrets would impair our competitive position and may materially harm our business, financial condition and results of operations. Costly and time consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to maintain trade secret protection could adversely affect our competitive business position. In addition, others may independently discover or develop our trade secrets and proprietary information, and the existence of our own trade secrets affords no protection against such independent discovery. We may also employ individuals who were previously or concurrently employed at research institutions and / or other medical device companies, including our competitors or potential competitors. We may be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, or that patents and applications we have filed to protect inventions of these employees, even those related to one or more of our products, are rightfully owned by their former or concurrent employer. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Risks Related to Our Finances and Capital Requirements We may require additional financing in the future and may not be able to obtain such financing on favorable terms, if at all, which could force us to delay, reduce or eliminate our research and development activities or otherwise harm our business. Since our initial public offering in September 2015, we have financed our business primarily through our operations and sales of our equity securities. We are unable to predict the extent of any future operating cash flows or whether we will be able to ~~achieve~~ maintain or grow our profitability in the future. If we require additional financing to continue or expand our operations, for research and development, for acquisitions or for other purposes, we may determine to engage in equity or debt financings or incur other indebtedness. We may not be able to timely secure additional debt or equity financing on favorable terms, or at all. If we raise additional funds through the issuance of equity or convertible debt or other equity-linked securities, our existing stockholders could suffer significant dilution. Any debt financing obtained by us in the future could involve restrictive covenants relating to our capital raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions. If needed funds are not available in adequate amounts or on acceptable terms from additional financing sources, our business will be materially adversely affected. By engaging in acquisitions and other business development arrangements, we will incur a variety of costs and may potentially face numerous risks that could adversely affect our business and operations. We have in the past, and expect in the future, to seek to acquire additional businesses, assets, technologies or products to enhance our business if appropriate opportunities become available. In connection with any acquisitions, we could issue additional equity securities or convertible debt or equity-linked securities, which would dilute our stockholders, **and could** cause us to incur substantial debt to fund the acquisitions, ~~or~~ assume significant liabilities. For example, in October 2021 and September 2023, ~~we~~ completed acquisitions that were paid in the form of shares of our common stock and / or options to purchase our common stock. Acquisitions involve numerous risks, including problems integrating the purchased operations, technologies or products, unanticipated costs and other liabilities, diversion of management's attention from our core businesses, adverse effects on existing business relationships with current and / or prospective customers and / or suppliers, risks associated with entering markets in which we have no or limited prior experience and potential loss of key employees. Acquisitions may also require us to record goodwill and non-amortizable intangible assets that will be subject to impairment testing on a regular basis and potential periodic impairment charges, incur amortization expenses related to certain intangible assets, **and or** incur write-offs and restructuring and other related expenses, any of which could harm our results of operations and financial condition. **For example, in 2024 we incurred \$ 115.3 million in impairment and other charges in connection with a decision to wind down and exit our Immersive Healthcare business.** If we fail in our integration efforts with respect to any of our acquisitions and are unable to efficiently operate as a combined organization, our business and financial condition may be adversely affected. Fluctuations in our effective tax rate and changes to tax laws may adversely affect us. As an international company, we are subject to taxation in numerous countries, states and other jurisdictions. Our effective tax rate is derived from a combination of statutory tax rates in the various jurisdictions in which we operate. In preparing our financial statements, our effective tax rate is based on estimates of the amount of tax that will become payable in each of these jurisdictions. Our effective tax rate may, however, differ from estimates due to numerous factors, including a change in the mix of our profitability from country to country and changes in tax laws. The fluctuations in our effective tax rate could have an adverse effect on our business, financial condition and results of operations and cash flows. Our excess tax benefits and deficiencies are required to be recorded in the income statement when stock awards vest or are settled and as discrete items on the tax rate in the period in which they occur. The amount of excess tax benefits and deficiencies can fluctuate from period to period based on the price of our stock, the volume of share-based grants settled or vested, and the fair value assigned to equity awards under U. S. GAAP. For interim reporting purposes, we are required to exclude the excess tax benefits and deficiencies from the annual estimated tax rate and not to forecast the potential impact to our rate. As a result, we could experience an effective tax rate significantly different from previous periods or from our expectations. In addition, changes in tax law or ~~declines~~ in our underlying profitability may negatively or positively impact our financial outlook of operations, which could lead to a corresponding charge or benefit to income taxes attributable to adjustments to the valuation allowance recorded against our deferred tax assets ("DTAs") on our consolidated balance sheets. The tax charge or benefit resulting from such change in valuation allowance could result in fluctuations in our effective tax rate and have a material negative impact on our financial condition and results of operations.

Risks Relating to Securities Markets and Investment in Our Common Stock The price of our common stock may be volatile, and you could lose all or part of your investment. The trading price of our common stock has been and is likely to continue to be volatile. From January 1, 2023-2024 through December 31, 2023-2024, our closing stock price as reported on The New York Stock Exchange ("NYSE") has ranged from ~~181~~ **\$ 163.44-64** to ~~344~~ **\$ 273.06-15**. Stock markets have experienced extreme volatility that has often been unrelated to the operating performance of particular companies.

These broad market fluctuations may adversely affect the trading price of our common stock. In addition, limited trading volume of our stock may contribute to its future volatility. Price declines in our common stock could result from general market and economic conditions, some of which are beyond our control, and a variety of other factors, including any of the risk factors described in this Form 10-K or those that we have not anticipated. These broad market and industry factors may harm the market price of our common stock, regardless of our operating performance, and could cause you to lose all or part of your investment in our common stock since you might be unable to sell your shares at or above the price you paid for such shares. Factors that could cause fluctuations in the market price of our common stock include the following: • price and volume fluctuations in the overall stock market from time to time; • volatility in the market prices and trading volumes of medical device company stocks; • changes in operating performance and stock market valuations of other medical device companies generally, or those in our industry in particular; • sales of shares of our common stock by us or our stockholders; • failure of securities analysts to maintain coverage of us, changes in financial estimates by securities analysts who follow our company, or our failure to meet these estimates or the expectations of investors; • the financial projections we may provide to the public, any changes in those projections or our failure to meet those projections; • announcements by us or our competitors of new products or services; • the public's reaction to our press releases, other public announcements and filings with the SEC; • rumors and market speculation involving us or other companies in our industry; • actual or anticipated changes in our results of operations or fluctuations in our results of operations; • actual or anticipated developments in our business, our competitors' businesses or the competitive landscape generally; • litigation involving us, our industry or both, or investigations by regulators into our operations or those of our competitors; • developments or disputes concerning our intellectual property or other proprietary rights; • announced or completed acquisitions of businesses or technologies by us or our competitors; • new laws or regulations or new interpretations of existing laws or regulations applicable to our business; • changes in accounting standards, policies, guidelines, interpretations or principles; • any significant change in our management; and • general economic conditions and slow or negative growth of our markets. In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instituted against these companies. We were involved in one such lawsuit in 2021, which was ~~voluntary~~ **voluntarily** dismissed without prejudice ~~in March 2021~~, and we may be the target of this type of litigation in the future. This litigation could result in substantial costs and a diversion of our management's attention and resources. If our executive officers, directors and largest stockholders choose to act together, they may be able to significantly influence our management and operations, acting in their own best interests and not necessarily those of other stockholders. As of December 31, ~~2023~~ **2024**, our executive officers, directors and holders of 5% or more of our outstanding stock and their affiliates beneficially owned approximately ~~54.39~~ **54.39** ~~1.4~~ **1.4** % of our voting stock in the aggregate. These stockholders, acting together, would be able to significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with the interests of other stockholders, and they may act in a manner that advances their best interests and not necessarily those of other stockholders. This concentration of ownership may have the effect of delaying, preventing or deterring a change in control of our company, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company and might ultimately affect the market price of our common stock. A sale of a substantial number of shares of our common stock in the public market could cause the market price of our common stock to drop significantly, even if our business is doing well. Sales of a substantial number of shares of our common stock could occur at any time. These sales, or the perception in the market that the holders of a large number of shares of our common stock intend to sell shares, could reduce the market price of our common stock. As of December 31, ~~2023~~ **2024**, our directors, executive officers and holders of 5% or more of our outstanding stock beneficially owned approximately ~~54.39~~ **54.39** ~~1.4~~ **1.4** % of our outstanding stock in the aggregate. If one or more of them were to sell a substantial portion of the shares they hold, it could cause our stock price to decline. We have also registered the offer and sale of all shares of common stock that we may issue under our equity compensation plans. As of December 31, ~~2023~~ **2024**, approximately 7, ~~700~~ **400**, 000 shares of common stock that are either subject to outstanding options or other equity awards or reserved for future issuance under our equity incentive plans have been registered on Form S-8 registration statements and may be freely sold in the public market upon issuance, except for shares held by affiliates who have certain restrictions on their ability to sell. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline. Techniques employed by short sellers have in the past and may in the future drive down the market price of our common stock. Short selling is the practice of selling securities that the seller does not own but rather has borrowed from a third-party with the intention of buying identical securities back at a later date to return to the lender. The short seller hopes to profit from a decline in the value of the securities between the sale of the borrowed securities and the purchase of the replacement shares, as the short seller expects to pay less in that purchase than it received in the sale. As it is in the short seller's best interests for the price of the stock to decline, many short sellers publish, or arrange for the publication of, negative opinions regarding the relevant issuer and its business prospects in order to create negative market momentum and generate profits for themselves after selling a stock short. These short attacks have led to selling of shares in the market. We have been in the past, and may be in the future, subject to such attacks by short sellers. If we are the subject of unfavorable allegations, we may have to expend a significant amount of resources to investigate such allegations and / or defend ourselves. While we would strongly defend against any such short seller attacks, we may be constrained in the manner in which we can proceed against the relevant short seller by applicable state law or issues of commercial confidentiality. Such a situation could be costly and time-consuming, and could be distracting for our management team. Our restated certificate of incorporation, our second amended and restated bylaws and Delaware law contain provisions that could discourage another company from acquiring us and may prevent attempts by our stockholders to replace or remove our current management. Provisions of Delaware law (where we are incorporated), our restated certificate of incorporation and our second amended and restated bylaws may discourage, delay or

prevent a merger or acquisition that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace or remove our board of directors. These provisions include: • authorizing the issuance of “ blank check ” preferred stock without any need for action by stockholders; • requiring supermajority stockholder voting to effect certain amendments to our restated certificate of incorporation and second amended and restated bylaws; • eliminating the ability of stockholders to call and bring business before special meetings of stockholders; • prohibiting stockholder action by written consent; • establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings; • dividing our board of directors into three classes so that only one third of our directors will be up for election in any given year; and • providing that our directors may be removed by our stockholders only for cause. In addition, we are subject to Section 203 of the Delaware General Corporation Law, which may have an anti- takeover effect with respect to transactions not approved in advance by our board of directors, including discouraging takeover attempts that could have resulted in a premium over the market price for shares of our common stock. These provisions apply even if a takeover offer may be considered beneficial by some stockholders and could delay or prevent an acquisition that our board of directors determines is not in our and our stockholders’ best interests and could also affect the price that some investors are willing to pay for our common stock. Our second amended and restated bylaws designate the state courts located within the state of Delaware (or if no state court located within Delaware has jurisdiction, the federal district court for the District of Delaware) as the exclusive forum for certain disputes between us and our stockholders, which could limit our stockholders’ ability to access a favorable judicial forum for disputes with us or our directors, officers or employees. Our second amended and restated bylaws designate the state courts located within the state of Delaware (or if no state court located within Delaware has jurisdiction, the federal district court for the District of Delaware), in all cases subject to the court’ s having personal jurisdiction over the indispensable parties named as defendants, as the exclusive forum for any derivative action or proceeding brought on our behalf ; any action asserting a claim of a breach of fiduciary duty ; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our restated certificate of incorporation or our second amended and restated bylaws ; or any action asserting a claim against us that is governed by the internal affairs doctrine. This forum selection provision will not apply to any causes of action arising under the Securities Act of 1933, as amended (the “ Securities Act ”), or the Securities Exchange Act of 1934, as amended (the “ Exchange Act ”) or, in each case, the rules and regulations thereunder, or for any other claim for which the U. S. federal courts have exclusive jurisdiction. The choice of forum provision 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 such lawsuits against us and our directors, officers and other employees. In addition, if a court were to find the choice of forum provision contained in our second amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business and financial condition. We do not anticipate paying cash dividends, and accordingly, stockholders must rely on stock appreciation for any return on their investment. We do not anticipate paying cash dividends in the future. As a result, only appreciation of the price of our common stock, which may never occur, would provide a return to stockholders. Investors seeking cash dividends should not invest in our common stock. An additional valuation allowance against our deferred tax assets could require a charge to earnings, which could result in a negative impact on our results of operations. Primarily as a result of net operating losses, stock- based compensation, various accruals and reserves, and tax credits, we maintain foreign and domestic DTAs. DTAs reflect an expected benefit to be realized in the future that may be used to reduce the amount of tax that we would otherwise be required to pay in future periods. DTAs are reduced by a valuation allowance when it is more likely than not that the future realization of all or some of the DTAs will not be achieved. Valuation allowances related to DTAs can be affected by changes to tax laws, statutory tax rates, future taxable income levels and input from our tax advisors or regulatory authorities. At this time, we consider it more likely than not that we will have sufficient taxable income in the future that will allow us to realize the benefits of the domestic DTAs we maintain as of December 31, 2023-2024, exclusive of our California tax credit DTAs. However, it is possible that some of our foreign or domestic DTAs could ultimately expire unused, or future DTAs could be created, due to vesting or settlement of stock awards or other book to tax differences, for which we will not have sufficient taxable income in the future to fully utilize. In such case, a valuation allowance to reduce our DTAs may be required, which would materially increase our tax expense in the period the valuation allowance is recorded and could have a material adverse impact on our financial condition and results of operations . **We cannot guarantee we will make any additional repurchases of our common stock under our share repurchase program or otherwise. On August 5, 2024, our Board of Directors approved a share repurchase authorization in the amount of up to \$ 200. 0 million, allowing us to repurchase our common stock from time to time at such prices as we deem appropriate through open market purchases, block transactions, privately negotiated transactions, including accelerated share repurchase transactions, or otherwise. The repurchase authorization expires on July 31, 2025. Under this authorization, we entered into an accelerated share repurchase agreement (“ ASR ”) with JPMorgan Chase Bank, National Association to repurchase \$ 100. 0 million of our common stock during the three months ended September 30, 2024. During the three months ended September 30, 2024, we repurchased an aggregate of 517, 763 shares under the ASR at an aggregate cost of \$ 100. 4 million, including legal and financial advisor fees of \$ 0. 4 million associated with the repurchase. As of December 31, 2024, we had remaining authority to purchase \$ 100. 0 million of its common stock under the share repurchase authorization. Refer to Note “ 12. Share Repurchase Program ” to our consolidated financial statements in Part II, Item 8 of this Form 10- K for more information. The timing and amount of any future repurchases, if any, will be subject to liquidity, stock price, market and economic conditions, compliance with applicable legal requirements such as Delaware surplus and solvency tests, and other relevant factors. Any failure to repurchase stock after we have announced our intention to do so may**

negatively impact our reputation and investor confidence in us and may negatively impact our stock price. In addition, the existence of our share repurchase program could cause our stock price to be higher than it otherwise would be and could potentially reduce the market liquidity for our stock. Although this share repurchase program is intended to enhance long- term stockholder value, there is no assurance it will do so because the market price of our common stock may decline below the levels at which we repurchased shares of common stock and short- term stock price fluctuations could reduce the effectiveness of the program.

General Risk Factors It is difficult to forecast future performance, which may cause our financial results to fluctuate unpredictably. A number of factors over which we have limited or no control may contribute to fluctuations in our financial results, such as:

- variations in revenue due to the unavailability of specialist physicians who use our products during certain times of the year, such as those periods when there are major conferences on conditions they treat or those periods when high volume users of our products take time off of work;
- positive or negative media coverage of our products or the procedures or products of our competitors or our industry;
- publication of clinical trial results or studies by us or our competitors;
- changes in our sales process due to industry changes, such as changes in the stroke care pathway;
- delays in receipt of anticipated purchase orders;
- delays in customers receiving products;
- performance of our independent distributors;
- our ability to obtain further regulatory clearances or approvals;
- the timing of product development and clinical trial activities, including the pace of enrollment;
- delays in, or failure of, product and component deliveries by our suppliers;
- changes in reimbursement policies or levels;
- the number of procedures performed in any given period using our products, which can sometimes vary significantly between periods;
- customer response to the introduction of new products or alternative treatments, and the degree to which we are effective in transitioning customers to our products; and
- fluctuations in foreign currency.

In the event our actual revenue and results of operations do not meet our or others' forecasts for a particular period, the market price of our common stock may decline substantially.

Natural disasters and other events beyond our control could harm our business. Natural disasters or other catastrophic events, such as earthquakes, flooding, wildfires, power shortages, pandemics, terrorism, political unrest, telecommunications failure, vandalism, cyber- attacks, geopolitical instability, war, drought, sea level rise and other events beyond our control may cause damage or disruption to our operations, the operations of our suppliers and service providers, international commerce and the global economy, and could seriously harm our revenue and financial condition and increase our costs and expenses. For example, impacts from the COVID-19 pandemic and measures taken in response thereto, such as constraints in the capacities of hospitals and other healthcare providers to perform non-COVID related procedures, changes to our on-site operations, delays in product development efforts and related clinical trials and regulatory clearances and approvals, and disruptions to global supply chains and labor markets, resulting in cost inflation and raw material supply constraints, adversely affected our business is subject to the risk of nonpayment by our customers. We sell our products through various payment arrangements, and may experience losses due to a customer's failure to make payments according to the contractual terms. Our customers may fail to make payment for a variety of reasons, and we may not be able to predict whether a customer will make payment in a timely manner, or at all. Although we have systems in place to monitor and mitigate risks associated with customer nonpayment, there can be no assurance that similar such systems will be effective in reducing or eliminating the credit risk relating to the sale of our products. If the losses we experience as a result of customer nonpayment in the future exceed our expectations, such losses could have a material adverse effect on our financial condition or results of operations. Natural disasters and other events beyond our control could harm our business. Natural disasters or other future catastrophic events, such as earthquakes, flooding, wildfires, power shortages, pandemics, terrorism, political unrest, telecommunications failure, vandalism, cyber- attacks, geopolitical instability, war, drought, sea level rise and other events beyond our control, may cause damage or disruption to our operations, the operations of our suppliers and service providers, international commerce and the global economy, and could seriously harm our revenue and financial condition and increase our costs and expenses. In addition, For example, the geographic location of our Alameda, California headquarters and Alameda and Roseville, California production facilities, as well as the facilities of certain of our key suppliers and service providers, subject them to earthquake and wildfire risks. Should one or more of our facilities be significantly damaged or destroyed by natural or man- made disasters, such as earthquakes, fires or other events, our existing inventory of raw materials, components and finished goods may be damaged or destroyed and it could take months to relocate or rebuild, during which time our employees may seek other positions, our research, development and manufacturing would cease or be delayed and our products may be unavailable. Moreover, in the event we are required to obtain additional production capacity due to one or more of our facilities being damaged or destroyed, because of the time required to approve and license a manufacturing facility under FDA and non- U. S. regulatory requirements, we may not be able to resume production on a timely basis even if we are able to obtain replacement production capacity. While we maintain property and business interruption insurance, such insurance has limits and would only cover the cost of rebuilding and relocating and lost profits, but not losses we may suffer due to our products being replaced by competitors' products. The inability to perform our research, development and certain of our manufacturing activities, combined with our limited inventory of raw materials and components and manufactured products, may cause specialist physicians or other healthcare providers to discontinue using our products or harm our reputation, and we may be unable to reestablish relationships with those specialist physicians or other healthcare providers in the future. Furthermore, other parties in our supply chain are similarly vulnerable to natural disasters or other sudden, unforeseen, and severe adverse events. A natural disaster or other catastrophic event in any of our major markets could have a material adverse impact on our business, financial condition, results of operations, or cash flows. Failure to protect our information technology infrastructure against cyber- based attacks, network security breaches, service interruptions, or data corruption could significantly disrupt our operations and adversely affect our business and operating results. We rely on information technology, telephone networks and systems, including the internet **technology, networks and systems managed by third parties**, to process and transmit

sensitive electronic information and to manage or support a variety of business processes and activities, including sales, billing, marketing, procurement and supply chain, manufacturing, and distribution. We use enterprise information technology systems, **including systems managed by third parties**, to record, process, and summarize financial information and results of operations for internal reporting purposes and to comply with regulatory, financial reporting, legal, and tax requirements. Our information technology systems, **and those systems we use that are managed by third parties**, are vulnerable to a **cyberattack** ~~cyber-attack~~, malicious intrusion, breakdown, destruction, loss of data privacy or other significant disruption. Any such successful attacks could result in the theft of intellectual property or other misappropriation of assets, data breach, or otherwise compromise our confidential or proprietary information and disrupt our operations. **Cyberattacks** ~~Cyber-attacks~~ are becoming more sophisticated and frequent, and our systems ~~could~~, **as well as those of third parties that we utilize, have been in the past, and may be in the future**, the target of malware and other **cyberattacks** ~~cyber-attacks~~. We have invested in our systems and the protection of our data to reduce the risk of an intrusion or interruption, and we monitor our systems on an ongoing basis for any current or potential threats. However, we can give no assurances that these measures and efforts will prevent interruptions ~~or~~, **breakdowns or intrusions, or that we will not be impacted by interruptions, breakdowns or intrusions of third-party systems that we utilize**. If we are unable to detect or prevent a security breach, **cyberattack** ~~or cyber-attack~~ or other disruption from occurring, **or if we are impacted by a security breach, cyberattack or other disruption suffered by a third party whose systems we utilize**, then we could incur losses or damage to our data, or **be subject to** inappropriate disclosure of our confidential information or that of others; and we could sustain damage to our reputation and customer and employee relationships, suffer disruptions to our business and incur increased operating costs including costs to mitigate any damage caused and protect against future damage, and be exposed to additional regulatory scrutiny or penalties and to civil litigation and possible financial liability, any of which could have a material adverse effect on our business, financial condition, results of operations or cash flows. In addition, our information technology, **as well as technology systems of third parties that we utilize**, may be susceptible to damage, disruptions or shutdowns due to power outages, user errors, implementation of new operational systems or software or upgrades to existing systems and software, or catastrophes or other unforeseen events. Such events could result in the disruption of business processes, network degradation and system downtime, along with the potential that a third party will exploit our critical assets such as intellectual property, proprietary business information and data related to our customers, suppliers and business partners. To the extent that such disruptions occur, our customers and partners may lose confidence in our ~~solutions~~ **company** and we may lose business or brand reputation, resulting in a material and adverse effect on our business, financial condition, results of operations or cash flows. Our operations are subject to environmental, health and safety, and data privacy laws and regulations, compliance with which may be costly. Our business is subject to federal, state, and local laws and regulations relating to the protection of the environment, worker health and safety and the use, management, storage, and disposal of hazardous substances and wastes. Failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions. In addition, environmental laws and regulations could require us to pay for environmental remediation and response costs, or subject us to third-party claims for personal injury, natural resource or property damage, relating to environmental contamination. Liability may be imposed whether or not we knew of, or were responsible for, such environmental contamination. The cost of defending against environmental claims, of compliance with environmental, health and safety regulatory requirements or of remediating contamination could materially adversely affect our business, results of operations, financial condition or cash flows. Additionally, we are subject to laws and regulations with respect to the collection, use, disclosure, transfer and storage of personal data that we may collect from our employees, customers, third parties that we do business with, or patients or in conjunction with clinical trials, or that we may receive in connection with the use of our ~~products, including our immersive healthcare~~ products. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues that may affect our business. Several privacy laws have recently been adopted in domestic and foreign jurisdictions where we do business that include enhanced data protection requirements as well as substantial fines for breaches of personal data. We have modified and will continue to modify our practices in order to comply with these and other requirements, which requires us to incur costs and expenses, and we may face difficulties in complying with all privacy and data protection legal requirements that apply to us now or in the future, as well as financial penalties and liabilities if we are unable to do so. We incur significant costs and devote substantial management time as a result of operating as a public company. As a public company, we **are subject to** ~~incur significant legal, accounting and other~~ **the reporting requirements of** ~~expenses as we devote resources to comply with~~ the Exchange Act, the Sarbanes- Oxley Act of 2002 (“ Sarbanes- Oxley Act ”), and the Dodd- Frank Wall Street Reform and Consumer Protection Act (“ Dodd- Frank Act ”), as well as rules and regulations subsequently implemented by the SEC and the NYSE, **including the establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices**. We expect that **compliance** ~~Compliance~~ with these requirements ~~will increase our~~ **causes us to incur** legal and financial compliance costs and ~~will make~~ **makes** some activities more time consuming and costly. For example, the Dodd- Frank Act imposes disclosure requirements regarding the use in components of our products of “ conflict minerals ” mined from the Democratic Republic of Congo and adjoining countries, which requires us to devote resources to comply with such disclosure requirements, including due diligence to determine the source of any conflict minerals used in our products, and could affect the pricing, sourcing and availability of minerals used in the manufacture of components we use in our products. We plan to continue to invest resources to comply with the evolving laws, regulations and standards applicable to public companies, and this investment may result in increased general and administrative expenses and a diversion of management’ s time and attention from revenue- generating activities to compliance activities. Operating as a public company and being subject to these rules and regulations makes it more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. As a result, it may be difficult for us to attract and retain qualified members of our board of directors or

executive officers. The costs associated with operating as a public company may decrease our net income or increase any future net loss and may cause us to reduce costs in other areas of our business or increase the prices of our products to offset the effect of such costs. Additionally, if these requirements divert our management's attention from other business concerns, they could have a material adverse effect on our business, results of operation, financial condition or cash flows. If we fail to maintain an effective system of disclosure controls and **procedures and** internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable regulations could be impaired. ~~As a public company, we are subject to the reporting requirements of the Exchange Act, Sarbanes-Oxley Act, and the listing standards of the NYSE. We expect that the requirements of these rules and regulations will continue to increase our legal, accounting and financial compliance costs, make some activities more difficult, time consuming and costly, and place significant strain on our personnel, systems and resources.~~ The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are continuing to develop and refine our disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we will file with the SEC is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that information required to be disclosed in reports under the Exchange Act is accumulated and communicated to our principal executive and financial officers. We are also continuing to improve our internal control over financial reporting. In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal control over financial reporting, we have expended, and anticipate that we will continue to expend, significant resources, including accounting-related costs and significant management oversight. Our current controls and any new controls that we develop may become inadequate because of changes in our business. Further, weaknesses in our disclosure controls **and procedures** or our internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective **disclosure** controls **and procedures**, or any difficulties encountered in their implementation or improvement, could ~~harm our operating results or~~ cause us to fail to meet our reporting obligations and may result in financial statements that may not accurately reflect the results of our business and operations. ~~Any~~ **In addition, any** failure to implement and maintain effective internal control over financial reporting ~~also~~ could adversely affect the results of management evaluations and independent registered public accounting firm audits of our internal control over financial reporting **and related opinions** that we include in our periodic reports that are filed with the SEC. Ineffective disclosure controls and procedures and internal control over financial reporting could also cause investors to lose confidence in our reported financial and other information, which would likely have a negative effect on the trading price of our common stock. ~~In addition, if we are unable to continue to meet these requirements, we may not be able to remain listed on the NYSE. As a public company, we are required to provide an annual management report on the effectiveness of our internal control over financial reporting and our independent registered public accounting firm is required to audit the effectiveness of our internal control over financial reporting. If we identify material weaknesses in our internal controls over financial reporting, if we are unable to assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal controls over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be adversely affected, and we could become subject to investigations by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities, which could require additional financial and management resources. Any failure to maintain effective disclosure controls and procedures and internal control over financial reporting could have a material and adverse effect on our business and results of operations, and cause a decline in the price of our common stock. If securities or industry analysts publish inaccurate or unfavorable research about our business or cease publishing research, our stock price and trading volume could decline. The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.~~ **49-47**