Risk Factors Comparison 2024-02-09 to 2023-02-10 Form: 10-K

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Investing in our common stock involves a high degree of risk. These risks include, but are not limited to, those described below, each of which may be relevant to an investment decision. You should carefully consider the risks described below, together with the other information included or incorporated by reference in this Annual Report on Form 10- K. The realization of any of the following risks could have a significant adverse effect on our reputation, business, financial condition, results of operations, growth, and our ability to accomplish our strategic objectives. In that event, the trading price of our common stock could decline. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our reputation, business, financial conditions, results of operations, growth, and our ability to accomplish our strategic objectives. Risks Related to Our Business We have incurred significant operating losses since inception, we **may** ~~expect to~~ incur operating losses in the future and we may not be able to achieve or sustain profitability. We have incurred net losses since our inception in 2007. For the years ended December 31, **2023,** 2022, **and** 2021 ~~, and 2020~~ , we had net losses of $ **21. 2 million, $** 44. 9 million, **and** $ 42. 0 million, ~~and $ 57. 2 million,~~ respectively. As of December 31, ~~2022~~ **2023** , we had an accumulated deficit of $ ~~324~~ **345** . ~~3~~ **4** million. To date, we have financed our operations primarily through sales of our Inspire system, private placements of our convertible preferred securities, amounts borrowed under our credit facility, the initial public offering of our common stock that closed in May 2018 (" IPO"), and the three follow- on offerings of our common stock that closed in December 2018, April 2020, and August 2022. We have devoted significant resources to research and development activities related to our Inspire system, including clinical and regulatory initiatives to obtain marketing approval, and sales and marketing activities. Since 2011, our revenue has been derived, and we expect it to continue to be derived, primarily from sales of our Inspire system. Because of its recent commercial introduction, in particular in ~~Singapore~~ **Hong Kong** , our Inspire system has limited product and brand recognition, particularly in new markets. In addition, demand for our Inspire system may decline or may not increase as quickly as we expect. Our ability to generate revenue from sales of our Inspire system, or from any products we may develop in the future, may not be sufficient to enable us to transition to profitability and generate positive cash flows. We expect that our operating expenses will continue to increase as we continue to build our commercial infrastructure, invest in research and development, and develop, enhance, and commercialize new products. As a result, we **may** ~~expect to~~ continue to incur operating losses for the foreseeable future and may never achieve profitability. Furthermore, even if we do achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis. If we do not achieve or sustain profitability, it will be more difficult for us to finance our business and accomplish our strategic objectives, either of which would have a material adverse effect on our business, financial condition, results of operations, and cause the market price of our common stock to decline. In addition, failure of our Inspire system to significantly penetrate existing or new markets would negatively affect our business, financial condition, and results of operations. Our revenue is primarily generated from sales of our Inspire system and we are, therefore, highly dependent on it for our success. We began selling our Inspire system in 2011 in certain European countries, in 2014 in the U. S., **and** in 2021 in **certain Asia Pacific regions** ~~Japan, and in 2022 in Singapore~~ . Sales of our Inspire system accounted for primarily all of our revenue for the years ended December 31, **2023,** 2022, **and** 2021 ~~, and 2020~~ . We expect that sales of our Inspire system will continue to account for the substantial majority of our revenue going forward. Our ability to execute our growth strategy and become profitable will therefore depend upon the adoption by patients, physicians, and sleep centers, among others, of our Inspire therapy to treat moderate to severe OSA in patients who are unable to use or get consistent benefit from CPAP. We cannot ensure that our Inspire therapy will achieve or maintain broad market acceptance among physicians and patients. Any failure of the Inspire system to satisfy physician or patient demand or to achieve meaningful market acceptance will harm our business and future prospects. If patients or physicians are not willing to change current practices to adopt our Inspire therapy to treat moderate to severe OSA, our Inspire therapy may fail to gain increased market acceptance, and our business will be adversely affected. Our primary strategy to grow our revenue is to drive an increase in the adoption of our Inspire therapy to treat patients with moderate to severe OSA who are unable to use or get consistent benefit from CPAP. While the number of physicians prescribing our Inspire therapy has increased, there is a significant group of physicians who have not yet adopted our Inspire therapy, and additional physicians may choose not to adopt our Inspire therapy for a number of reasons, including, for example: • lack of availability of adequate third- party payor coverage or reimbursement; • lack of experience with our products and with upper airway neurostimulation as a treatment alternative; • our inability to convince key opinion leaders to provide recommendations regarding our Inspire therapy, or to convince physicians, patients, and healthcare payors that our Inspire therapy is an attractive alternative to other treatment options; • perceived inadequacy of evidence supporting clinical benefits or cost- effectiveness of our Inspire therapy over existing alternatives **; • challenges in obtaining prior authorization** ; • a perception among some physicians of patients' inability to tolerate the surgical procedure required to implant our Inspire system; • liability risks generally associated with the use of new products and procedures; and • the training required to use new products. Physicians and other medical professionals commonly screen and treat patients with moderate to severe OSA and are likely to prescribe more conventional second- line treatment methods for patients who are unable to use or obtain consistent benefit from CPAP. We believe that educating physicians in appropriate disciplines and other medical professionals about the clinical merits and patient benefits of our Inspire therapy as a treatment for moderate to severe OSA is a key element of increasing the adoption of our Inspire therapy. If additional physicians or other medical professionals do not adopt, or existing physician customers cease prescribing our Inspire therapy for any reason, including those listed above, our ability to execute our growth strategy will be impaired, and our business may be adversely affected. In addition, patients

may not be able to adopt or may choose not to adopt our Inspire therapy if, among other potential reasons, their airway anatomy would not allow for effective treatment with Inspire therapy, they are reluctant to receive an implantable device as opposed to an alternative, non- implantable treatment, they are worried about potential adverse effects of our Inspire system, such as infection, discomfort from the stimulation or tongue soreness or weakness, or they are unable to obtain adequate third- party coverage or reimbursement. If we are unable to achieve and maintain adequate levels of coverage or reimbursement for our Inspire system, or any future products we may seek to commercialize, our commercial success may be severely hindered. We currently derive all of our revenue from sales of our Inspire system and expect this to continue for the foreseeable future. The primary customers for our products are hospitals and ASCs. Our customers typically bill various third- party payors to cover all or a portion of the costs and fees associated with the procedures in which our products are used and bill patients for any deductibles or co- payments. Because there is often no separate reimbursement for supplies used in surgical procedures, the additional cost associated with the use of our products can affect the profit margin of the hospital or surgery center where the procedure is performed. Some of our target customers may be unwilling to adopt our products in light of the additional associated cost. Further, any decline in the amount payors are willing to reimburse our customers could make it difficult for existing customers to continue using or to adopt our products and could create additional pricing pressure for us. If we are forced to lower the price we charge for our products, our gross margins will decrease, which could have a material adverse effect on our business, financial condition, and results of operations, and impair our ability to grow our business. Several third- party payors do not currently cover our products and the related procedures because they have determined that our products and the related procedures are experimental or investigational. When our products and the related procedures are covered, they are reimbursed primarily on a per- patient prior authorization basis for patients covered by commercial insurers, under Local Coverage Determinations for patients covered by Medicare, and under U. S. government contract for patients who are treated by the Veterans Health Administration. Customers who perform the procedure may be subject to reimbursement claim denials upon submission of the claim. Customers may also be subject to recovery of overpayments if a payor makes payment for the claim and subsequently determines that the payor' s coding, billing or coverage policies were not followed. Our customers typically must directly bill patients enrolled with these third- party payors for the costs and fees associated with the procedures in which our products are used. Third- party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, no uniform policy of coverage and reimbursement for procedures using our products exists among third- party payors. Therefore, coverage and reimbursement for procedures using our products can differ significantly from payor to payor. Payors continually review new and existing technologies for possible coverage and can, without notice, deny or reverse coverage for new or existing products and procedures. There can be no assurance that third- party payor policies will provide coverage for procedures in which our products are used. If we are not successful in reversing existing non- coverage policies, or if third- party payors that currently cover or reimburse our products and related procedures reverse or limit their coverage in the future, or if other third- party payors issue similar policies, this could have a material adverse effect on our business. Further, we believe that future coverage and reimbursement may be subject to increased restrictions, such as additional prior authorization requirements, both in the U. S. and in international markets. In Europe, reimbursement is entirely regulated at the member state level, varies significantly between member states, and member states are facing increased pressure to limit public healthcare spending. Third- party coverage and reimbursement for procedures using our products or any of our products in development for which we may receive regulatory approval or certification may not be available or adequate in either the U. S. or international markets, which could have an adverse effect on our business, financial condition and results of operations, and impair our ability to grow our business. We currently compete and will in the future continue to compete against other companies, some of which have longer operating histories, more established products or greater resources than we do, which may prevent us from achieving increased market penetration and improved operating results. The medical technology industry is highly competitive, subject to change and significantly affected by new product introductions and other activities of industry participants. Our competitors have historically dedicated and will continue to dedicate significant resources to promoting their products or developing new products or methods to treat moderate to severe OSA. We consider our primary competition to be other neurostimulation technologies designed to treat OSA. Though we are currently the only such technology approved for commercialization in the U. S. by the FDA, we currently compete outside the U. S. with LivaNova, which produces an open- loop neurostimulation device and is currently conducting clinical trials of its device in the U. S. We also compete outside the U. S. with Nyxoah, which markets a bilateral hypoglossal nerve stimulation device in certain countries outside the U. S., and is conducting its first pivotal trial as it seeks FDA approval in the U. S. We believe other emerging businesses are in the early stages of developing neurostimulation devices designed to treat OSA. In addition, we also compete, both within and outside of the U. S., with invasive surgical treatment options such as UPPP and MMA and, to a lesser extent, oral appliances, which are primarily used in the treatment of mild to moderate OSA. In addition, our Inspire therapy is approved for use as a second- line therapy in the treatment of moderate to severe OSA in patients who cannot use or obtain consistent benefit from CPAP. If one or more CPAP device manufacturers successfully develop a CPAP device that is more effective, better tolerated or otherwise results in better compliance by patients, or if improvements in other **first or** second- line therapies make them more effective, cost effective, easier to use or otherwise more attractive than our Inspire therapy, sales of our Inspire system could be significantly and adversely affected, which could have a material adverse effect on our business and financial condition and results of operations. In addition, if other companies are successful in developing neurostimulation devices that are approved for a broader range of indications than our Inspire system, we will be at a further competitive disadvantage, which could also affect our business, financial condition and results of operations **. During 2023, glucagon- like peptide 1 (" GLP- 1s"), a class of drug indicated for diabetes and obesity, continued to gain popularity as a weight- loss drug. Use of GLP- 1s, or similar treatments, for these clinical indications may directly or indirectly treat OSA. Additionally, GLP- 1s are currently being clinically evaluated as a potential**

treatment for OSA. Although we believe that there could be a benefit to our business as a result of GLP- 1s, there can be no assurance of such benefit. If GLP- 1s are successful in treating OSA in an indication for which Inspire therapy is approved, demand for our Inspire system could be reduced . Many of the companies against which we compete may have competitive advantages with respect to primary competitive factors in the OSA treatment market, including, for example: • greater company, product, and brand recognition; • superior product safety, reliability, and durability; • better quality and larger volume of clinical data; • more effective marketing to and education of patients, physicians, and sleep centers; • greater product ease of use and patient comfort; • more sales force experience and greater market access; • better product support and service; • more advanced technological innovation, product enhancements, and speed of innovation; • more effective pricing and revenue strategies; • lower procedure costs to patients; • more effective reimbursement teams and strategies; • dedicated practice development; and • more effective clinical training teams. Most of the other OSA treatments against which we compete have a greater penetration into the OSA treatment market. Oral appliances and other surgical treatments are better known to ENT physicians, sleep centers, and the other physicians on whom we rely for referrals. We also compete with other medical technology companies to recruit and retain qualified sales, training, and other personnel, including members of our in- house prior authorization team. In addition, though there are currently no pharmacologic therapies approved to treat OSA, we may in the future face competition from pharmaceutical companies that develop such therapies. We also expect to experience increased competition in the future as other companies develop and commercialize competing neurostimulation devices. Any of these companies may also have the competitive advantages described above. **We are involved, and may become involved in the future, in disputes and other legal or regulatory proceedings that, if adversely decided or settled, could materially and adversely affect our business, financial condition, and results of operations. We are, and may in the future become, party to litigation, regulatory proceedings or other disputes. In general, claims made by or against us in disputes and other legal or regulatory proceedings can be expensive and time- consuming to bring or defend against, requiring us to expend significant resources and divert the efforts and attention of our management and other personnel from our business operations. These potential claims may include but are not limited to personal injury and class action lawsuits, intellectual property claims and regulatory investigations relating to the advertising and promotional claims about our products and services and employee claims against us based on, among other things, discrimination, harassment or wrongful termination. Any one of these claims, even those without merit, may divert our financial and management resources that would otherwise be used to benefit the future performance of our operations. Any adverse determination against us in these proceedings, or even the allegations contained in the claims, regardless of whether they are ultimately found to be without merit, may also result in settlements, injunctions or damages that could have a material adverse effect on our business, financial condition and results of operations. Additionally, securities class action litigations are often brought against companies following periods of volatility in the overall market and in the market price of a company' s securities. On December 22, 2023, we and certain of our executive officers were named in a putative class action lawsuit. The complaint was filed on behalf of a potential group of similarly situated investors who purchased our common stock between May 3, 2023 and November 7, 2023. The complaint alleges that we and / or our executive officers made false and / or misleading statements regarding the effectiveness of our Acceleration Program, a program designed to facilitate customers' receiving prior authorizations from doctors with the goal of increasing demand for our Inspire therapy. This lawsuit and any future lawsuits to which we may become a party are subject to inherent uncertainties and could result in very substantial costs, divert our management' s attention and resources and materially harm our business, operating results and financial condition.** Our business, financial condition, results of operations and growth ~~has~~ **have** been and could in the future be significantly harmed by the effects of **public health crises, such as pandemics. The occurrence or reoccurrence of regional epidemics, a global pandemic or** ~~the~~ **other public health crises, such as** COVID- 19 ~~pandemic~~ **, may adversely affect** ~~or~~ **our** ~~other pandemics. The COVID- 19 pandemic has negatively impacted our business, results of~~ operations ~~and~~ **,** financial condition ~~by significantly decreasing and delaying the number of Inspire therapy procedures performed and patients screened for eligibility for Inspire therapy~~ , and **results of operations. The extent** ~~the COVID- 19 pandemic may continue~~ to ~~negatively~~ **which such health crises** impact our business **going forward** ~~, results of operations and financial condition. The number of Inspire therapy procedures performed, similar to other elective surgical procedures, decreased in 2020 and early 2021 compared to pre- pandemic levels as health care organizations in the U. S. and globally have prioritized the treatment of patients with COVID- 19. Resurgences of COVID- 19 in various U. S. and European regions, Japan, and Singapore have, and may in the future, negatively impact our procedure volumes. The COVID- 19 pandemic continues to rapidly evolve and its impact on our business~~ will depend on ~~several~~ factors ~~that are highly uncertain~~ **such as the duration** and ~~unpredictable. The COVID- 19 pandemic may adversely~~ **scope; governmental, business, and individuals' actions in response to such public health crises; and the** impact **on economic activity, including the possibility of recession** ~~our~~ **or** ~~procedure volumes. These measures and challenges may continue for the duration of the pandemic, which is uncertain, and may reduce our revenue and negatively impact our business, results of operations and~~ financial **market** ~~condition while the pandemic continues. Further, if there are additional or reinstated government mandated or recommended cancellations of elective surgical procedures, this could create in the future a substantial backlog of patients seeking appointments with physicians and surgeries to be performed at hospitals and ambulatory surgery centers, and as a result, patients seeking Inspire therapy procedures to be performed may have to navigate limited provider capacity which could have a significant adverse effect on our business, results of operations and financial condition. Other future pandemics may lead to similar impacts. Numerous foreign, state, and local jurisdictions have imposed, and others in the future may impose orders and restrictions to control the spread of COVID- 19. These disruptions have included, and future disruptions may also include, restrictions on our personnel and personnel of partners to travel and access customers for training and case support; inability~~ **instability** ~~of our suppliers to manufacture and test our Inspire therapy and its components and to deliver these on a timely basis, or at all; inventory shortages or obsolescence; delays in~~

~~approvals or certifications by regulatory authorities or notified bodies; delays in ongoing preclinical studies; delays in operations at insurance agencies, which may impact timelines for the issuance of insurance coverage policies; diversion of or limitations on employee resources that would otherwise be focused on the operations of our business, delays in growing or reductions in our sales team, and additional government requirements or other incremental mitigation efforts that may further impact our or our suppliers' capacity to manufacture our Inspire system. The extent to which the COVID- 19 pandemic or other future pandemics cause disruptions to our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity and spread of COVID- 19, future waves of infection, and the actions to contain COVID- 19 or treat its impact, among others~~ . The disruption to global financial markets or a recession or market correction resulting from **a public health crisis** ~~the COVID- 19 pandemic or other future pandemics~~ could materially affect our business. The occurrence of any such events may lead to reduced disposable income and access to health insurance which could adversely affect the number of Inspire systems sold. Our long- term growth depends on our ability to enhance our Inspire system, expand our indications, and develop and commercialize additional products. It is important to our business that we continue to enhance our Inspire system and develop and introduce new products. Developing products is expensive and time-consuming and could divert management' s attention away from our core business. The success of any new product offering or product enhancements to our Inspire system will depend on several factors, including our ability to: • properly identify and anticipate physician and patient needs; • develop and introduce new products and product enhancements in a timely manner; • avoid infringing upon the intellectual property rights of third- parties; • demonstrate, if required, the safety and efficacy of new products with data from preclinical studies and clinical studies; • obtain the necessary regulatory clearances, approvals or certifications for expanded indications, new products or product modifications; • be fully FDA- compliant with marketing of new devices or modified products and be fully compliant with foreign requirements to market our new devices or modified products; • provide adequate training to potential users of our products; • receive adequate coverage and reimbursement for procedures performed with our products; and • develop an effective and dedicated sales and marketing team. If we are not successful in expanding our indications and developing and commercializing new products and product enhancements, our ability to increase our revenue may be impaired, which could have a material adverse effect on our business, financial condition, and results of operations. Our financial results may fluctuate significantly and may not fully reflect the underlying performance of our business. Our quarterly and annual results of operations have in the past and may in the future vary significantly and future period- to- period comparisons of our operating results may not be meaningful. Accordingly, the results of any one quarter or period should not be relied upon as an indication of future performance. Our quarterly and annual financial results may fluctuate as a result of a variety of factors, many of which are outside our control and, as a result, may not fully reflect the underlying performance of our business. Such factors may include, for example, seasonal variations in our sales or required postponements of elective surgical procedures effected during a health crisis, as was the case with ~~the~~ COVID- 19 ~~pandemic~~ . We generally experience and may in the future experience higher sales in the U. S. during the fourth quarter as a result of patients having paid their annual insurance deductibles in full, thereby reducing their out- of- pocket costs. Alternatively, in the first quarter, many U. S. patients' insurance deductibles reset, requiring more out- of- pocket costs, which negatively impacts our sales during this period. Other factors that may cause fluctuations in our quarterly and annual results include, but are not limited to: • changes in coverage policies by third- party payors that affect the reimbursement of procedures using our products **; • challenges experienced by patients in obtaining positive coverage and reimbursement decisions from payers, including necessary prior authorization approvals in advance of treatment** ; • timing of new product offerings, acquisitions, licenses or other significant events by us or our competitors; • unanticipated pricing pressure; • the hiring, retention, and continued productivity of our sales representatives; • our ability to expand the geographic reach of our sales and marketing efforts; • our ability to obtain regulatory clearance, approval, or certification for any products in development or for our current products for additional indications or in additional countries outside the U. S.; • results of clinical research and studies on our existing products and products in development; • delays in receipt of anticipated purchase orders; and • positive or negative coverage in the media or clinical publications of our products or products of our competitors or our industry. Because our quarterly and annual results may fluctuate, period- to- period comparisons may not be the best indication of the underlying results of our business and should only be relied upon as one factor in determining how our business is performing. These fluctuations may also increase the likelihood that we will not meet our forecasted performance, which could negatively affect the market price for our common stock. Our results of operations could be materially harmed if we are unable to accurately forecast customer demand for our Inspire system and manage our inventory. To ensure adequate inventory supply, we must forecast inventory needs and place orders with our suppliers based on our estimates of future demand for our Inspire system. Our ability to accurately forecast demand for our Inspire system could be negatively affected by many factors, including our failure to accurately manage our expansion strategy, product introductions by competitors, an increase or decrease in customer demand for our Inspire system or for products of our competitors, our failure to accurately forecast customer acceptance of new products, unanticipated changes in general market conditions or regulatory matters, and weakening of economic conditions or consumer confidence in future economic conditions. Inventory levels in excess of customer demand may result in inventory write- downs or write- offs, which would cause our gross margin to be adversely affected and could impair the strength of our brand. Conversely, if we underestimate customer demand for our Inspire system, our third- party contract manufacturers may not be able to deliver products to meet our requirements, and this could result in damage to our reputation and customer relationships. In addition, if we experience a significant increase in demand, additional supplies of raw materials or additional manufacturing capacity may not be available when required on terms that are acceptable to us, or at all, or suppliers or our third- party manufacturers may not be able to allocate sufficient capacity in order to meet our increased requirements, which could have an adverse effect on our ability to meet customer demand for our Inspire system and our results of operations. We seek to maintain sufficient levels of inventory in order to protect ourselves from supply interruptions. As a result, we are subject to the risk that a

portion of our inventory will become obsolete or expire, which could have a material adverse effect on our earnings and cash flows due to the resulting costs associated with the inventory impairment charges and costs required to replace such inventory. We have experienced and continue to experience supply disruptions which began during the COVID **- 19** pandemic ~~,~~ and **have continued as a result of not having received certification of silicone- based leads under the EU Medical Devices Regulation (See Part I.," Item 1A. Risk Factors — We may not receive the necessary approvals** ~~our~~ **or certifications for our future products or expanded indications, and failure to timely obtain necessary approvals or certifications for our future products or expanded indications would adversely affect our ability to grow our business. "). Our** efforts to maintain higher levels of inventory to protect ourselves from supply interruptions may not be successful in avoiding significant supply and inventory issues or delay in implant procedures. As a result, we are subject to the risk of inventory obsolescence and expiration, which could lead to inventory impairment charges. For example, during the three months ended September 30, 2022, we recorded a charge of $ 2. 8 million for obsolete inventory and component parts related to product introductions which were completed in October 2022, including the new silicone leads and the Bluetooth ®- enabled patient remote. We rely on a limited number of third- party suppliers and contract manufacturers for the manufacture and assembly of our products, and a loss or degradation in performance of these suppliers and contract manufacturers could have a material adverse effect on our business, financial condition, and results of operations. We rely on third- party suppliers and contract manufacturers for the raw materials and components used in our Inspire system and to manufacture and assemble our products. The suppliers that provide certain materials and components are sole suppliers. These sole suppliers, and any of our other suppliers or our third- party contract manufacturers, may be unwilling or unable to supply the necessary materials and components or manufacture and assemble our products reliably and at the levels we anticipate or that are required by the market. Our ability to supply our products commercially and to develop any future products depends, in part, on our ability to obtain these materials, components, and products in accordance with regulatory requirements and in sufficient quantities for commercialization and clinical testing. While our suppliers and contract manufacturers have generally met our demand for their products and services on a timely basis in the past, we cannot guarantee that they will in the future be able to meet our demand for their products or prevent delays in the delivery of their products, which could be adversely affected due to, for example, natural and man- made disasters, public health emergencies such as ~~the~~ COVID- 19 ~~pandemic~~, product quality issues, other catastrophic events, the macroeconomic environment including supply chain constraints, higher inflation and interest rates, the nature of our agreements with our contract manufacturers, our relative importance to such manufacturers as a customer or a contract manufacturer' s decision to discontinue or reduce the level of business they conduct with us. If we are required to change contract manufacturers due to any change in or termination of our relationships with these third parties, or if our manufacturers are unable to obtain the materials they need to produce our products at consistent prices or at all, we may lose sales, experience manufacturing or other delays, incur increased costs or otherwise experience impairment to our customer relationships. We cannot guarantee that we will be able to establish alternative relationships on similar terms, without delay or at all. Establishing additional or replacement suppliers for any of these materials, components or services, if required, could be time- consuming and expensive, may result in interruptions in our operations and product delivery, may affect the performance specifications of our Inspire system or could require that we modify its design. Even if we are able to find replacement suppliers or third- party contract manufacturers, we will be required to verify that the new supplier or third- party manufacturer maintains facilities, procedures, and operations that comply with our quality expectations and applicable regulatory requirements. Furthermore, our contract manufacturers could require us to move to another one of their production facilities or use alternative materials or components. Any of these events could require that we obtain a new regulatory authority approval **or notified body certification** before we implement the change, which could result in further delay and which may not be obtained at all. While we seek to maintain sufficient levels of inventory as discussed above, those inventories may not fully protect us from supply interruptions. If our third- party suppliers fail to deliver the required commercial quantities of materials on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement suppliers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality on a timely basis, the continued commercialization of our Inspire system, the supply of our products to customers, and the development of any future products will be delayed, limited or prevented, which could have material adverse effect on our business, financial condition, and results of operations. Performance issues, service interruptions or price increases by our shipping carriers could adversely affect our business and harm our reputation and ability to provide our services on a timely basis. Expedited, reliable shipping is essential to our operations. We rely heavily on providers of transport services for reliable and secure point- to- point transport of our Inspire system to our customers and for tracking of these shipments. Should a carrier encounter delivery performance issues such as delivery delays or loss, damage or destruction of any systems, such occurrences may damage our reputation and lead to decreased demand for our Inspire system and increased cost and expense to our business. Similarly, strikes, severe weather, natural disasters, public health crises or other service interruptions affecting delivery services we use would adversely affect our ability to process orders for our Inspire system on a timely basis. Consolidation in the healthcare industry or group purchasing organizations could lead to demands for price concessions, which may affect our ability to sell our products at prices necessary to support our current business strategies. Healthcare costs have risen significantly over the past decade, which has resulted in or led to numerous cost reform initiatives by legislators, regulators, and third- party payors. Cost reform has triggered a consolidation trend in the healthcare industry to aggregate purchasing power, which may create more requests for pricing concessions in the future. Additionally, group purchasing organizations, independent delivery networks, and large single accounts may continue to use their market power to consolidate purchasing decisions for hospitals and ASCs. We expect that market demand, government regulation, third- party coverage, and reimbursement policies and societal pressures will continue to change the healthcare industry worldwide, resulting in further business consolidations and alliances among our customers, which may exert further downward pressure on the prices of our products. If we are unable to expand, manage and maintain our direct sales and marketing organization we may

not be able to generate revenue growth. We currently sell our Inspire system through a direct sales force that targets ENT physicians and sleep centers in the U. S. ~~and~~ **,** Europe **, and Japan** , and also utilize various direct- to- consumer marketing initiatives, including paid online search, radio, television, social media, and online videos. In ~~Japan and Singapore~~ **certain Asia Pacific markets** , we sell our products through ~~a distributor~~ **distributors** . As of December 31, ~~2022~~ **2023** , our direct sales and marketing organization, including reimbursement personnel, consisted of ~~523~~ **728** employees, having increased from ~~72~~ **129** employees as of December 31, ~~2017~~ **2018** . Our operating results are directly dependent upon the efforts of these employees. If our direct sales force fails to adequately promote, market and sell our Inspire system, our revenue may be adversely affected. In order to generate future revenue growth, we plan to continue to expand the size and geographic scope of our direct sales organization. This growth may require us to split or adjust existing sales territories, which may adversely affect our ability to retain customers in those territories. Additionally, our future success will depend largely on our ability to continue to hire, train, retain, and motivate skilled sales and reimbursement personnel with significant industry experience and technical knowledge of implantable devices and related products. Because the competition for their services is high, we cannot ensure that we will be able to hire and retain additional personnel on favorable or commercially reasonable terms, if at all. Failure to hire or retain qualified sales and reimbursement personnel would prevent us from expanding our business and generating revenue. If we are unable to expand our sales and marketing capabilities, we may not be able to effectively commercialize our Inspire system, which could have an adverse effect on our business, financial condition, and results of operations. To successfully market and sell our Inspire system in markets outside of the U. S., we must address many international business risks. Sales in markets outside of the U. S. accounted for approximately 3. **0 %, 3.** 2 %, **and** 5. 3 ~~%, and 8. 0~~ % of our revenue for the years ended December 31, **2023,** 2022, **and** 2021 ~~, and 2020~~ , respectively. Our strategy is to increase our international presence in Europe, including Germany and the Netherlands, as well as other international markets, such as Japan, Singapore, **and** Hong Kong ~~, and Australia~~ . This strategy is subject to a number of risks, including: • difficulties in staffing and managing our international operations; • increased competition as a result of more products and procedures receiving regulatory approval or otherwise free to market in international markets; • longer accounts receivable payment cycles and difficulties in collecting accounts receivable; • reduced or varied protection for intellectual property rights in some countries; • trade export restrictions, trade regulations, and foreign tax laws; • fluctuations in currency exchange rates; • foreign certification and regulatory clearance or approval requirements; • difficulties in developing effective marketing campaigns in unfamiliar foreign countries; • customs clearance and shipping delays; • political, social, and economic instability abroad, terrorist attacks, and security concerns in general; • preference for locally produced products; • potentially adverse tax consequences, including the complexities of foreign value- added tax systems, tax inefficiencies related to our corporate structure, and restrictions on the repatriation of earnings; • the burdens of complying with a wide variety of foreign laws and different legal standards; and • increased financial accounting and reporting burdens and complexities. If one or more of these risks are realized, our business, financial condition, and results of operations could be adversely affected. We primarily rely on our own direct sales force for our Inspire system, which may result in higher fixed costs than our competitors and may slow our ability to reduce costs in the face of a sudden decline in demand for our products. We primarily rely on our own direct sales force, which as of December 31, ~~2022~~ **2023** , covered ~~225~~ **287** territories in the U. S. and ~~12 in Europe~~ **19 outside of the U. S.** , to market and sell our Inspire system. Some of our competitors rely predominantly on independent sales agents and third- party distributors. A direct sales force has in the past and may in the future subject us to higher fixed costs than those of companies that market competing products through independent third parties, due to the costs that we bear associated with employee benefits, training, and managing sales personnel. As a result, we could be at a competitive disadvantage. Additionally, these fixed costs may slow our ability to reduce costs in the face of a sudden decline in demand for our Inspire system, which could have a material adverse effect on our business, financial condition, and results of operations. We face the risk of product liability claims that could be expensive, divert management' s attention and harm our reputation and business. We may not be able to maintain adequate product liability insurance. Our business exposes us to the risk of product liability claims that are inherent in the testing, manufacturing and marketing of medical devices. This risk exists even if a device is cleared, approved, or certified for commercial sale by the FDA or foreign regulatory authorities or notified bodies and manufactured in facilities regulated by the FDA or an applicable foreign regulatory authority. Our Inspire system is designed to affect, and any future products will be designed to affect, important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with our Inspire system could result in patient injury or death. The medical device industry has historically been subject to extensive litigation over product liability claims, and we cannot offer any assurance that we will not face product liability suits. We may be subject to product liability claims if our Inspire system causes, or is alleged to have caused, patient injury or death. In addition, an injury that is caused by the activities of our suppliers, such as those who provide us with components and raw materials, may be the basis for a claim against us. Product liability claims may be brought against us by patients, healthcare providers or others selling or otherwise coming into contact with our Inspire system, among others. If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in: • costs of litigation; • distraction of management' s attention from our primary business; • the inability to commercialize our Inspire system or new products; • decreased demand for our Inspire system; • damage to our business reputation; • product recalls or withdrawals from the market; • withdrawal of clinical study participants; • substantial monetary awards to patients or other claimants; or • loss of sales. We can provide no assurance that we will be successful in initiating appropriate market recall or market withdrawal efforts that may be required in the future or that these efforts will have the intended effect of preventing product malfunctions and the accompanying product liability that may result. Such recalls and withdrawals may also be used by our competitors to harm our reputation for safety or be perceived by patients as a safety risk when considering the use of our products, either of which could have a material adverse effect on our business, financial condition and results of operations. Although we have product liability and clinical study liability insurance, this

insurance is subject to deductibles and coverage limitations. Our current product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, coverage may not be adequate to protect us against any future product liability claims. If we are unable to obtain insurance at an acceptable cost or on acceptable terms 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 have a material adverse effect on our business, financial condition and results of operations. If the quality of our Inspire system does not meet the expectations of physicians or patients, then our brand and reputation or our business could be adversely affected. In the course of conducting our business, we must adequately address quality issues that may arise with our Inspire system, including defects in third- party components included in our Inspire system. There can be no assurance that we will be able to eliminate or mitigate occurrences of quality issues and associated liabilities. In addition, even in the absence of quality issues, we may be subject to claims and liability if the performance of our Inspire system does not live up to the expectations of physicians or patients as a result of the patient' s use of the product. For example, battery life will vary based on usage and therapy settings. Based on STAR trial therapy settings at the 12- month endpoint, the battery in our current generation neurostimulator is generally expected to last for approximately 11 years, but it may not last that long if a patient' s use of the device or chosen level of stimulation is greater than expected. The minimum estimated longevity based on STAR trial results is seven years. If the quality of our Inspire system does not meet the expectations of physicians or patients, then our brand and reputation with those physicians or patients, or our business, financial condition and results of operations, could be adversely affected. If we choose to acquire new and complementary businesses, products or technologies, we may be unable to complete these acquisitions or to successfully integrate them in a cost- effective and non- disruptive manner. Our success depends, in part, on our ability to continually enhance and broaden our product offerings in response to changing customer demands, competitive pressures and advances in technologies. Accordingly, we may in the future pursue the acquisition of, or joint ventures relating to, complementary businesses, products or technologies instead of developing them ourselves. We do not know if we will be able to successfully complete any future acquisitions or joint ventures, or whether we will be able to successfully integrate any acquired business, product or technology or retain any key employees related thereto. Integrating any business, product or technology we acquire could be expensive and time- consuming, disrupt our ongoing business and distract our management. If we are unable to integrate any acquired businesses, products or technologies effectively, our business will be adversely affected. In addition, any amortization or charges resulting from the costs of acquisitions could increase our expenses. Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations. Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. ~~The global financial crisis caused extreme volatility and disruptions in the capital and credit markets.~~ Factors such as geopolitical events (including the ongoing ~~war~~ **wars** in Ukraine **and Israel**), inflationary pressures, impacts from ~~the~~ COVID- 19 ~~pandemic~~ , and ~~the~~ U. S. election cycles have **caused extreme** ~~contributed to this~~ volatility **and disruptions in the capital and credit markets** . These global economic conditions could result in a variety of risks to our business, including weakened demand for our Inspire system, and adversely impact our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy has strained in the past and may in the future strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the economic climate and financial market conditions could adversely affect our business. Failure of a key information technology system, process or site **, cyberattacks, or other deficiencies in our cybersecurity** could have an adverse effect on our business **and operations** . We rely extensively on information technology systems to conduct our business **and collect, store and transmit confidential information, including personal information of customers and our employees and contractors** . These systems affect, among other things, ordering and managing materials from suppliers, shipping products to customers, processing transactions, summarizing and reporting results of operations, complying with regulatory, legal or tax requirements, data security and other processes necessary to manage our business. Our information technology systems and those of our third- party service providers, vendors, strategic partners and other contractors or consultants are vulnerable to damage or interruption from computer viruses and malware (e. g. ransomware), natural disasters, terrorism, war, telecommunication and electrical failures, hacking, cyberattacks, phishing attacks and other social engineering schemes, malicious code, employee theft or misuse, human error, fraud, denial or degradation of service attacks, sophisticated nation- state and nation- state- supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization. **There can be no assurance that our cybersecurity risk management program and processes, including our policies, controls or procedures, will be fully implemented, complied with or effective in protecting our information technology systems and information.** The risk of a security breach or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased and evolved. **We** ~~As a result of the COVID- 19 pandemic, we~~ and our third- party service providers and partners may also face increased cybersecurity risks due to our reliance on internet technology and ~~the number of our~~ employees who **work** ~~are working~~ remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. Our third- party service providers and partners are also subject to these heightened risks. If our systems are damaged or cease to function properly due to any number of causes, ranging from catastrophic events to power outages to

security breaches, and our business continuity plans do not effectively compensate on a timely basis, we may experience interruptions in our operations, which could have an adverse effect on our business **and financial condition** . We and certain of our service providers are from time to time subject to cyberattacks and security incidents. While we do not believe that we have experienced any significant system failure, accident or security breach to date, if such an event were to occur, it could lead to unauthorized access, disclosure and use of **confidential** ~~non- public~~ information, including **personal** information from our ADHERE patient registry or other patient information we create, receive, maintain or transmit, including with respect to our Inspire Cloud, SleepSync ™ **platform** , or the Inspire Sleep app, which ~~are~~ **may be** governed by HIPAA and other laws. **If a security breach or other incident were to result in the unauthorized access to or unauthorized use, disclosure, release or other processing of personal information, it may be necessary to notify individuals, governmental authorities, supervisory bodies, the media and other parties pursuant to privacy and security laws.** Any such access, disclosure, or other loss of information could result in **regulatory action or investigation,** legal claims or proceedings, liability under laws that protect the privacy of personal information, and damage to our reputation. In addition, we accept payments for our sales through credit and debit card transactions, which are handled through a third- party payment processor. As a result, we are subject to a number of risks related to credit and debit card payments. As a result of these transactions, we pay interchange and other fees, which may increase over time and could require us to either increase the prices we charge for our Inspire system or experience an increase in our costs and expenses. In addition, as part of the payment processing process, we transmit our customers' credit and debit card information to our third- party payment processor. We may in the future become subject to lawsuits or other proceedings for purportedly fraudulent transactions arising out of the actual or alleged theft of our customers' credit or debit card information if the security of our third- party credit card payment processor is breached. We and our third- party credit card payment processor are also subject to payment card association operating rules, certification requirements and rules governing electronic funds transfers, which could change or be reinterpreted to make it difficult or impossible for us to comply. If we or our third- party credit card payment processor fail to comply with these rules or requirements, we may be subject to fines and higher transaction fees and lose our ability to accept credit and debit card payments from our customers, and there may be an adverse effect on our business. **Further, our insurance coverage may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems.** If our facilities are damaged or become inoperable, we may be unable to continue to research, develop, and supply our Inspire system and, as a result, there could be an adverse effect on our business until we are able to secure a new facility and rebuild our inventory. We do not have redundant facilities. We perform substantially all of our research and development and back- office activity at **two** ~~a single location~~ **locations** in Golden Valley, Minnesota. The majority of our finished goods inventory is maintained at a third **-** party location in Tennessee. Our facility, equipment and inventory would be costly to replace and could require substantial lead time to repair or replace. These facilities may be harmed or rendered inoperable by natural or man- made disasters, including, but not limited to, tornadoes, flooding, ~~fire~~ **fires and other events, including climate change- related severe weather or disasters** , power outages, and public health crises, which may render it difficult or impossible for us to perform our research, development and commercialization activities for some period of time. The inability to perform those activities, combined with the time it may take to rebuild our inventory of finished product, may result in the loss of customers or harm to our reputation. Although we possess insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and this insurance may not continue to be available to us on acceptable terms, or at all. We rely on third- party distributors to effectively distribute our products in certain markets. We depend or expect to depend in the future on qualified distributors for the marketing and selling of our products in certain markets. Currently, the markets in which we market and sell our products through distributors include ~~Japan,~~ Singapore ~~,~~ and Hong Kong. If our distributors fail to effectively market and sell our Inspire system in full compliance with applicable laws, our operating results and business may suffer. Recruiting and retaining qualified third- party distributors and training them in our technology and product offering requires significant time and resources. To develop and expand our distribution, we may be required to scale and improve our processes and procedures that support our distributors. Further, if our relationship with a distributor in a given market terminates, we may be unable to replace that distributor without disruption to our business, or we may decide to transition to a direct sales force in that market. If we fail to develop or maintain positive relationships with our distributors, including in new markets, fail to manage, train or incentivize these distributors effectively, or fail to provide distributors with competitive products on attractive terms, or if these distributors are not successful in their sales efforts, or if we are unable to successfully transition to a direct sales force in markets previously served by distributors, we may not achieve expected revenues or may have a reduction in revenue and our operating results, reputation and business would be harmed. We are subject to anti- bribery, anti- corruption, and anti- money laundering laws, including the U. S. Foreign Corrupt Practices Act, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses, which could adversely affect our business, results of operations and financial condition. As we grow our international presence and global operations, we will have increasing obligations to comply with trade and economic sanctions and other restrictions imposed by the U. S., the EU, and other governments and organizations. During the year ended December 31, ~~2022~~ **2023** , approximately 3. ~~2~~ **0** % of our total sales were made in EU member states ~~, Japan,~~ and ~~Singapore~~ **certain Asia Pacific regions** . The U. S. Departments of Justice, Commerce, State and Treasury and other federal agencies and authorities have a broad range of civil and criminal penalties they may seek to impose against corporations and individuals for violations of economic sanctions laws, export control laws, the U. S. Foreign Corrupt Practices Act (" FCPA") and other federal statutes and regulations, including those established by the Office of Foreign Assets Control (" OFAC"). In addition, the U. K. Bribery Act of 2010 (the" Bribery Act") prohibits both domestic and international bribery, as well as bribery across both private and public sectors. An organization that " fails to prevent bribery " by anyone associated with the organization can be charged under the Bribery Act unless the organization can establish the

defense of having implemented " adequate procedures " to prevent bribery. Under these laws and regulations, as well as other anti- corruption laws, anti- money laundering laws, export control laws, customs laws, sanctions laws and other laws governing our operations, various government agencies may require export licenses, may seek to impose modifications to business practices, including cessation of business activities in sanctioned countries or with sanctioned persons or entities and modifications to compliance programs, which may increase compliance costs, and may subject us to fines, penalties and other sanctions. A violation of these laws or regulations would negatively affect our business, financial condition and results of operations. We have implemented policies and procedures designed to ensure compliance by us and our directors, officers, employees, representatives, consultants and agents with the FCPA, OFAC restrictions, the Bribery Act and other export control, anti- corruption, anti- money- laundering and anti- terrorism laws and regulations. We cannot ensure, however, that our policies and procedures are or will be sufficient or that directors, officers, employees, representatives, consultants and agents have not engaged and will not engage in conduct for which we may be held responsible, nor can we ensure that our business partners have not engaged and will not engage in conduct that could materially affect their ability to perform their contractual obligations to us or even result in our being held liable for such conduct. Violations of the FCPA, OFAC restrictions, the Bribery Act or other export control, anti- corruption, anti- money laundering and anti- terrorism laws or regulations may result in severe criminal or civil sanctions, and we may be subject to other liabilities, which could have a material adverse effect on our business, financial condition and results of operations. We bear the risk of warranty claims on our Inspire system. We bear the risk of warranty claims on our Inspire system. We may not be successful in claiming recovery under any warranty or indemnity provided to us by our suppliers or vendors in the event of a successful warranty claim against us by a customer or that any recovery from such vendor or supplier would be adequate. In addition, warranty claims brought by our customers related to third- party components may arise after our ability to bring corresponding warranty claims against such suppliers expires, which could result in costs to us. We may need substantial additional funding beyond our existing cash resources and may be unable to raise capital when needed, which could force us to delay or reduce our commercialization efforts or product development programs. Our existing cash, cash equivalents, short- term investments and revenue will be sufficient to meet our capital requirements and fund our operations for at least 12 months. However, we have based these estimates on assumptions that may prove to be incorrect, and we could spend our available financial resources much faster than we currently expect. Any future funding requirements will depend on many factors, including: • patient, physician and market acceptance of our Inspire therapy; • the scope, rate of progress and cost of our current or future clinical studies; • the cost of our research and development activities; • the cost of filing and prosecuting patent applications and defending and enforcing our patent or other intellectual property rights; • the cost of defending, in litigation or otherwise, any claims that we infringe third- party patents or other intellectual property rights; • the cost and timing of additional regulatory clearances, approvals or certifications; • the cost and timing of establishing additional sales and marketing capabilities; • costs associated with any product recall that may occur; • the effect of competing technological and market developments; and • the extent to which we acquire or invest in products, technologies and businesses, although we currently have no commitments or agreements relating to any of these types of transactions. Any additional equity or debt financing that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds by selling additional shares of our common stock or other securities convertible into or exercisable or exchangeable for shares of our common stock, the issuance of such securities will result in dilution to our stockholders. The price per share at which we sell additional shares of our common stock, or securities convertible into or exercisable or exchangeable for shares of our common stock, in future transactions may be higher or lower than the price per share paid by investors in previous offerings of shares of our common stock. Furthermore, investors purchasing any securities we may issue in the future may have rights superior to the rights of a holder of our common stock. In addition, any future debt financing into which we enter may impose upon us covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. If we raise additional funds through collaboration and licensing arrangements with third- parties, it may be necessary to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favorable to us. Furthermore, we cannot be certain that additional funding will be available on acceptable terms, if at all. If we do not have, or are not able to obtain, sufficient funds, we may have to delay development or commercialization of our products or license to third- parties the rights to commercialize products or technologies that we would otherwise seek to commercialize. We also may have to reduce marketing, customer support or other resources devoted to our products or cease operations. Any of these factors could harm our business, financial condition and results of operations. Our ability to use our net operating losses and research and development credit carryforwards to offset future taxable income may be subject to certain limitations. In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the" Code"), a corporation that undergoes an " ownership change, " generally defined as a greater than 50 % change by value in its equity ownership over a three- year period, is subject to limitations on its ability to utilize its pre- change net operating losses (" NOLs") and its research and development credit carryforwards to offset future taxable income. ~~We are currently performing~~ **During 2023, we finalized** a detailed analysis to determine whether an ownership change has occurred **through December 31, 2022,** and if a limitation exists. **It was determined** ~~Based on the preliminary results of the analysis, we believe there is no evidence~~ that ~~this limitation would hinder~~ **December 11, 2018 was** the ~~utilization~~ **only date that we experienced an ownership change. The study concluded that none** of ~~our~~ **the federal** net operating ~~loss~~ **losses** ~~carryforwards or~~ **nor the federal** R & D ~~credit~~ **credits** ~~carryforwards in~~ **that were accumulated on December 11, 2018 will expire unused solely due to** the ~~future. As~~ **limitations under Sections 382 and 383** of **the Code. We are in the process of updating the analysis through** December 31, ~~2022~~ **2023 . Although unexpected, if we experienced an ownership change during 2023, the timing of our ability to utilize the tax attributes may be affected. As of December 31, 2023** , our gross federal NOL carryforward was $ ~~257~~ **226** . ~~4~~ **1** million ~~. Our existing NOLs and research and development credit carryforwards may be subject to~~

~~limitations arising from previous ownership changes, and if we undergo an ownership change, our ability to utilize NOLs and research and development credit carryforwards could be further limited by Sections 382 and 383 of the Code~~ . In addition, our ability to deduct net interest expense may be limited if we have insufficient taxable income for the year during which the interest is incurred, and any carryovers of such disallowed interest would be subject to the limitation rules similar to those applicable to NOLs and other attributes. Future changes in our stock ownership, some of which might be beyond our control, could result in an ownership change under Section 382 of the Code. For these reasons, in the event we experience a change of ~~control~~ **ownership within the definition of Section 382 of the Code** , we may not be able to utilize a material portion of the NOLs, research and development credit carryforwards or disallowed interest expense carryovers, even if we attain profitability. If we were deemed to be an investment company under the Investment Company Act of 1940, as amended (the " 1940 Act "), applicable restrictions could make it impractical for us to continue our business as contemplated and could have a material adverse effect on our business, financial condition and results of operations. Under Sections 3 (a) (1) (A) and (C) of the 1940 Act, a company generally will be deemed to be an " investment company " for purposes of the 1940 Act if (1) it is, or holds itself out as being, engaged primarily, or proposes to engage primarily, in the business of investing, reinvesting or trading in securities or (2) it engages, or proposes to engage, in the business of investing, reinvesting, owning, holding or trading in securities and it owns or proposes to acquire investment securities having a value exceeding 40 % of the value of its total assets (exclusive of U. S. government securities and cash items) on an unconsolidated basis. We do not believe that we are an " investment company, " as such term is defined in either of those sections of the 1940 Act. We intend to conduct our operations so that we will not be deemed an investment company. However, if we were to be deemed an investment company, restrictions imposed by the 1940 Act, including limitations on our capital structure and our ability to transact with affiliates, could make it impractical for us to continue our business as contemplated and could have a material adverse effect on our business, financial condition and results of operations. The increasing and evolving focus on sustainability and environmental, social, and governance initiatives from regulators and stakeholders could increase our costs **, expose us to new risks** , harm our reputation and adversely impact our financial results. There has been increasing and evolving public focus by investors, customers, environmental and social activists, the media, politicians, and governmental and nongovernmental organizations and other stakeholders on a variety of environmental, social, and governance (" ESG ") matters. We experience pressure to make commitments relating to ESG matters that affect us, including the design and implementation of specific risk mitigation strategic initiatives relating to ESG. If we are not effective in addressing ESG matters relevant to business, including meeting stakeholder expectations regarding relevant ESG goals, practices, initiatives, commitments, performance and / or public disclosures, our reputation and financial results may suffer. We may experience increased costs in order to execute upon our ESG goals, initiatives, and commitments and measure achievement of those goals, initiatives, and commitments which could have an adverse impact on our business and financial condition. Moreover, the increasing attention to corporate ESG initiatives could also result in reduced demand for products, reduced profits, and increased investigations and litigation. In addition, organizations that provide information to investors on corporate governance and related matters have developed ratings processes for evaluating companies on ESG matters. Such ratings are used by some investors to inform their investment or voting decisions. Unfavorable ESG ratings could lead to negative investor sentiment toward us and / or our industry, which could have a negative impact on our access to and costs of capital. To the extent ESG matters negatively impact our reputation, we may also not be able to compete as effectively to recruit or retain employees. This emphasis on ESG matters has resulted and may result in the adoption of new laws and regulations, including new reporting requirements. **For example, the SEC has announced proposed rules that, among other matters, would establish a framework for reporting climate- related risks. To the extent the proposed rules impose additional reporting obligations, we could face increased costs. Separately, the SEC has also announced that it is scrutinizing existing climate- change related disclosures in public filings, increasing the potential for enforcement if the SEC were to allege our existing climate disclosures are misleading or deficient.** As we continue to focus on our ESG goals, initiatives, commitments, performance, and disclosures, and as ESG- related laws, regulations, and voluntary and required disclosure standards and frameworks continue to evolve, we have expanded our public disclosures in these areas. Such disclosures may reflect goals, aspirations, commitments, and other expectations and assumptions, which are necessarily uncertain and may not be realized. If we fail to comply with new laws or regulations or accurately disclose against voluntary or required reporting standards or frameworks, our reputation and business could be adversely impacted. Climate- related events and other events could harm our business. Natural disasters, disease outbreaks and pandemics, power shortages, terrorism, political unrest, telecommunications failure, vandalism, geopolitical instability, war, climate- related events, and other events beyond our control could negatively impact our operations or otherwise harm our business. Such events may result in damage or loss of service to assets that our operations rely on, cause delays in product development or availability, or result in losses of critical data, any of which may adversely impact our operations. In addition, the impacts of climate- related events on the global economy and our industry are rapidly evolving. Physical impacts of climate- related events (including but not limited to floods, droughts, more frequent and / or intense storms and wildfires), ~~may disrupt~~ **or chronic changes (such as droughts, heat waves or sea level changes) in climate patterns can adversely impact** our operations, as well as the operations of our suppliers and customers **. Our facilities and offices may be adversely impacted by natural disasters, including those intensified by climate change. Our locations, and those of our customers and suppliers, can be disrupted by droughts, extreme temperatures, fires, flooding and other climate change- related risks, as well as earthquakes, actions by utility providers, and other catastrophic events such as an actual or threatened public health emergency. If a catastrophic event occurs at or near any of our offices, or utility providers or public health officials take certain actions (e. g., shut off power to our facilities), our operations may be interrupted, which could adversely impact our business and results of operations. If a catastrophic event impacts a significant number of our suppliers or customers, or our ability to provide services to our customers, our business and results of operations could be adversely**

impacted . Longer term physical impacts may also result in changing consumer preferences, which may adversely impact demand for certain of our products. Transition impacts of climate- related events may subject us to increased regulations, reporting requirements, standards or expectations regarding the environmental impacts of our business. Failure to disclose accurate climate- related events information in a timely manner may also adversely affect our reputation, business, or financial performance. Risks Related to Government Regulation Our products and operations are subject to extensive government regulation and oversight both in the U. S. and abroad, and our failure to comply with applicable requirements could harm our business. We and our products are subject to extensive regulation in the U. S. and elsewhere, including by the FDA and its foreign counterparts. The FDA and foreign regulatory agencies regulate, among other things, with respect to medical devices: design, development and manufacturing; testing, labeling, content and language of instructions for use and storage; clinical studies; product safety; establishment registration and device listing; marketing, sales and distribution; pre- market clearance, approval, and certification; record keeping procedures; advertising and promotion; recalls and field safety corrective actions; post- market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; post- market approval studies; and product import and export. The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales. The FDA, foreign regulatory authorities, and notified bodies enforce these regulatory requirements through periodic unannounced inspections **or audits** . Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as: warning letters; fines; injunctions; civil penalties; termination of distribution; recalls or seizures of products; delays in the introduction of products into the market; total or partial suspension of production; refusal to grant future clearances, approval, or certifications; withdrawals or suspensions of current approvals **or certifications** , resulting in prohibitions on sales of our products; and in the most serious cases, criminal penalties. We may not receive the necessary approvals or certifications for our future products or expanded indications, and failure to timely obtain necessary approvals or certifications for our future products or expanded indications would adversely affect our ability to grow our business **and our results of operations** . An element of our strategy is to continue to upgrade our products, add new features and expand the indications and uses for our current products. In the U. S., before we can market a new medical device, or a new use of, or claim for, or significant modification to, an existing product, we must first receive PMA from the FDA. In the process of obtaining PMA, which was required for our Inspire system, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, pre- clinical, clinical study, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life- sustaining, life- supporting or implantable devices. ~~Modifications to products that are approved through a PMA application generally require FDA approval. PMA can be expensive, lengthy and uncertain.~~ The process of obtaining a PMA is costly and more uncertain **and time consuming** than the 510 (k) clearance process used for lower risk devices. Despite the time, effort and cost, a device may not be approved by the FDA. Any delay or failure to obtain necessary regulatory approvals could harm our business **and results of operations** . Furthermore, even if we are granted regulatory approval, it may include significant limitations on the indicated uses for the device, which may limit the market for the device. The FDA and other regulatory authorities or notified bodies outside the U. S. can delay, limit or deny approval or certification of a device for many reasons, including: • our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory entity or notified body that our products are safe or effective for their intended uses; • the disagreement of the FDA or the applicable foreign regulatory authority or notified body with the design or implementation of our clinical studies or the interpretation of data from pre- clinical studies or clinical studies; • serious and unexpected adverse device effects experienced by participants in our clinical studies; • the data from our pre- clinical studies and clinical studies may be insufficient to support approval or certification, where required; • our inability to demonstrate that the clinical and other benefits of the device outweigh the risks; • the manufacturing process or facilities we use may not meet applicable requirements; and • the potential for approval policies or regulations of the FDA or applicable foreign regulatory authorities to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance, approval or certification. In addition, the FDA **or other regulatory authorities or notified bodies outside the U. S.** may change ~~its~~ **their** approval **or certification** policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval **or certification** of our future products under development or impact our ability to modify our currently cleared **or certified** products on a timely basis. Such policy or regulatory changes could impose additional requirements **or time delays** upon us that could delay our ability to obtain new approvals **or certifications** , increase the costs of compliance **and our operating expenses, adversely impact our revenues or inventory forecasting** or restrict our ability to maintain our current approval **or certification. The timing of FDA approval of a next generation product could have a significant impact on the carrying value of the inventory of our previous generation product, and therefore our results of operations** . Subject to the transitional provisions, in order to sell our products in EU member states, our products must comply with the general safety and performance requirements of the EU Medical Devices Regulation, which repeals and replaces EU Medical Devices Directive and the AIMDD. Compliance with these requirements is a prerequisite to be able to affix the European Conformity (" CE ") mark to our products, without which they cannot be sold or marketed in the EU ~~. See — Government Regulation~~ . To demonstrate compliance with the general safety and performance requirements, we must undergo a conformity assessment procedure, which varies according to the type of medical device and its (risk) classification. Except for low risk medical devices (Class I), where the manufacturer can self- assess the conformity of its products with the general safety and performance requirements (except for any parts which relate to sterility, metrology or reuse aspects), a conformity assessment procedure requires the intervention of a notified body. The notified body would typically audit and examine the technical file and the quality system for the manufacture, design and final inspection of our devices. If satisfied that the relevant product conforms to the relevant general safety and performance requirements, the

notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE mark to the device, which allows the device to be placed on the market throughout the EU. If we fail to comply with applicable laws and regulations, we would be unable to affix the CE mark to our products, which would prevent us from selling them within the EU. The aforementioned EU rules are generally applicable in the EEA, and non-compliance with the above requirements would also prevent us from selling our products in these three countries. ~~We~~ **Once devices are certified under the EU Medical Devices Regulation, we** must inform the notified body that carried out the conformity assessment of the medical devices that we market or sell in the EU and the EEA of any planned substantial changes to our quality system or substantial changes to our medical devices that could affect compliance with the general safety and performance requirements laid down in Annex I to the EU Medical Devices Regulation or cause a substantial change to the intended use for which the device has been CE marked. The notified body will then assess the planned changes and verify whether they affect the products' ongoing conformity with the EU Medical Devices Regulation. If the assessment is favorable, the notified body will issue a new certificate of conformity or an addendum to the existing certificate attesting compliance with the general safety and performance requirements and quality system requirements laid down in the Annexes to the EU Medical Devices Regulation **. The notified body may disagree with our proposed changes or take more time than anticipated to review and assess applications resulting in regulatory delays. See Part I.," Item 1A. Risk Factors — Risks Related to Government Regulation ". For example, we applied for certification of silicone- based leads under the EU Medical Devices Regulation in December 2021 in order to replace the polyurethane- based leads, two components of the Inspire system currently used only in the European market. However, designated notified bodies currently have severe capacity constraints, and review times have lengthened significantly, including for our certification application. As a result of these delays, we have experienced inventory shortages and related adverse impacts on our results of operations that are expected to continue** . Modifications to our products may require us to obtain new PMAs or approvals of a PMA supplement or certification, and if we market modified products without obtaining necessary approvals or certifications, we may be required to cease marketing or recall the modified products until required approvals are obtained. Certain modifications to a PMA-approved device may require approval of a new PMA or a PMA supplement, or alternatively a notification or other submission to the FDA. The FDA may not agree with our decisions regarding whether a new PMA or PMA supplement is necessary. We may make modifications to our approved devices in the future that we believe do not require approval of a new PMA or PMA supplement. If the FDA disagrees with our determination and requires us to submit a new PMA or PMA supplement for modifications to our previously approved products, we may be required to cease marketing or to recall the modified product until we obtain approval, and we may be subject to significant regulatory fines or penalties. In addition, the FDA may not approve our products for the indications that are necessary or desirable for successful commercialization or could require clinical studies to support any modifications. Similar requirements may apply in foreign jurisdictions where we market our products. Any delay or failure in obtaining required approvals or certifications would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. Failure to comply with post-marketing regulatory requirements could subject us to enforcement actions, including substantial penalties, and might require us to recall or withdraw a product from the market. Even though we have obtained approval for the Inspire system, we are subject to ongoing and pervasive regulatory requirements governing, among other things, the manufacture, marketing, advertising, medical device reporting, sale, promotion, registration, and listing of devices. For example, we must submit periodic reports to the FDA as a condition of PMA. These reports include safety and effectiveness information about the device after its approval. Failure to submit such reports, or failure to submit the reports in a timely manner, could result in enforcement action by the FDA. Following its review of the periodic reports, the FDA might ask for additional information or initiate further investigation. Similar requirements may apply in foreign jurisdictions where we market our products. In addition, the PMA for our Inspire system was subject to several conditions of approval, including a post- market long- term study. Though we believe we have complied with these conditions to date, any failure to comply with the conditions of approval could result in the withdrawal of PMA and the inability to continue to market the device. Failure to conduct the required studies in accordance with institutional review board (" IRB") and informed consent requirements, or adverse findings in these studies, could also be grounds for withdrawal of approval of the PMA. The regulations to which we are subject are complex and have become more stringent over time. Regulatory changes could result in restrictions on our ability to continue or expand our operations, higher than anticipated costs, or lower than anticipated sales. Even after we have obtained the proper regulatory approval or certification to market a device, we have ongoing responsibilities under FDA regulations and applicable foreign laws and regulations. The FDA, state and foreign regulatory authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, state or foreign regulatory authorities, which may include any of the following sanctions: • untitled letters or warning letters; • fines, injunctions, consent decrees and civil penalties; • recalls, termination of distribution, administrative detention, or seizure of our products; • customer notifications or repair, replacement or refunds; • operating restrictions or partial suspension or total shutdown of production; • delays in or refusal to grant our requests for future PMAs or foreign regulatory approvals or certifications of new products, new intended uses, or modifications to existing products; • withdrawals or suspensions of our current PMA or foreign regulatory approvals or certifications, resulting in prohibitions on sales of our products; • FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries; and • criminal prosecution. Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, financial condition and results of operations. Our products must be manufactured in accordance with foreign, federal and state regulations, and we or any of our suppliers or third- party manufacturers could be forced to recall our installed systems or terminate production if we fail to comply with these regulations. The methods used in, and the facilities used for, the manufacture of our products must comply with the FDA' s Quality System Regulation (" QSR") which is a complex regulatory scheme that covers the procedures and

documentation of the design, testing, production, process controls, quality assurance, labeling, packaging, handling, storage, distribution, installation, servicing and shipping of medical devices. Furthermore, we are required to verify that our suppliers maintain facilities, procedures and operations that comply with our quality standards and applicable regulatory requirements. The FDA enforces the QSR through periodic announced or unannounced inspections of medical device manufacturing facilities, which may include the facilities of subcontractors. Our products are also subject to similar state regulations and various laws and regulations of foreign countries governing manufacturing. Our third- party manufacturers may not take the necessary steps to comply with applicable regulations, which could cause delays in the delivery of our products. In addition, failure to comply with applicable FDA and foreign requirements or later discovery of previously unknown problems with our products or manufacturing processes could result in, among other things: warning letters or untitled letters; fines, injunctions or civil penalties; suspension or withdrawal of approvals or certifications; seizures or recalls of our products; total or partial suspension of production or distribution; administrative or judicially imposed sanctions; the FDA' s or applicable foreign regulatory authority' s or notified body' s refusal to grant pending or future clearances, approvals or certifications for our products; clinical holds; refusal to permit the import or export of our products; and criminal prosecution of us or our employees. Any of these actions could significantly and negatively affect supply of our products. If any of these events ~~occurs~~ **occur**, our reputation could be harmed, we could be exposed to product liability claims and we could lose customers and experience reduced sales and increased costs. The misuse or off- label use of our Inspire system may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business. Our Inspire system has been approved by the FDA for specific indications. We train our marketing personnel and direct sales force to not promote our Inspire system for uses outside of the FDA- approved indications for use, known as " off- label uses. " We cannot, however, prevent a physician from using our Inspire system off- label, when in the physician' s independent professional medical judgment he or she deems it appropriate. There may be increased risk of injury to patients if physicians attempt to use our Inspire system off- label. Furthermore, the use of our Inspire system for indications other than those approved by the FDA, approved by any foreign regulatory authority or certified by a notified body, may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients. If the FDA or any foreign regulatory authority determines that our promotional materials or training constitute promotion of an off- label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter, which is used for violators that do not necessitate a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as false claims laws, if they consider our business activities to constitute promotion of an off- label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations. In addition, physicians may misuse our Inspire system or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our Inspire system is misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. Similarly, in an effort to decrease costs, physicians may also reuse our Inspire system despite it being intended for a single use or may purchase reprocessed Inspire systems from third- party reprocessors in lieu of purchasing a new Inspire system from us, which could result in product failure and liability. As described above, product liability claims could divert management' s attention from our core business, be expensive to defend and result in sizable damage awards against us that may not be covered by insurance. Our products may cause or contribute to adverse medical events or be subject to failures or malfunctions that we are required to report to the FDA and foreign regulatory authorities, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us. We are subject to the FDA' s medical device reporting regulations and similar foreign regulations, which require us to report to the FDA and foreign regulatory authorities when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, the FDA and foreign regulatory authorities could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device approval or certification, seizure of our products or delay in clearance, approval or certification of future products. The FDA and foreign regulatory bodies have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA' s and foreign regulatory bodies' authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found. A government- mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future. Depending on the corrective action we take to redress a product' s deficiencies or defects, the FDA or foreign regulatory authorities may require, or we may decide, that we will need to obtain new approvals for the device before we may market or distribute the corrected device. Seeking such approvals may delay our ability to replace the

recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA or foreign regulatory authority warning letters, product seizure, injunctions, administrative penalties or civil or criminal fines. Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA or foreign regulatory authorities. We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification to the FDA or foreign regulatory authorities. If the FDA or a foreign regulatory authority disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results. If we do not obtain and maintain international regulatory registrations, approvals or certifications for our products, we will be unable to market and sell our products outside of the U. S. Sales of our products outside of the U. S. are subject to foreign regulatory requirements that vary widely from country to country. In addition, the FDA regulates exports of medical devices from the U. S. While the regulations of some countries may not impose barriers to marketing and selling our products or only require notification, others require that we obtain the approval of or certification by a specified body (e. g., notified bodies in Europe). Complying with foreign regulatory requirements, including obtaining registrations, approvals or certifications, can be expensive and time- consuming, and we may not receive regulatory approvals or certifications in each country in which we plan to market our products or we may be unable to do so on a timely basis. The time required to obtain registrations, approvals or certifications, if required by other countries, may be longer than that required for FDA approval, and requirements for such registrations, clearances, approvals or certifications may significantly differ from FDA requirements. If we modify our products, we may need to apply for additional regulatory approvals or certifications before we are permitted to sell the modified product. In addition, we may not continue to meet the quality and safety standards required to maintain the authorizations or certifications that we have received. If we are unable to maintain our authorizations or certifications in a particular country, we will no longer be able to sell the applicable product in that country. Regulatory approval by the FDA does not ensure registration, clearance, approval or certification by regulatory authorities or notified bodies in other countries, and registration, clearance, approval or certification by one or more foreign regulatory authorities or notified bodies does not ensure registration, clearance, approval or certification by regulatory authorities or notified bodies in other foreign countries or by the FDA. However, a failure or delay in obtaining registration, regulatory clearance, approval or certification in one country may have a negative effect on the regulatory process in others. **The FDA may modify its enforcement policies with respect to medical software products, and our software products may become subject to extensive regulatory requirements, which may increase the cost of conducting, or otherwise harm, our business. We develop and offer certain software applications in connection with our business, including our SleepSync ™ cloud- based patient management platform, which is designed to function as a medical device data system (“ MDDS ”). For its part, the FDA may regulate medical or health- related software, including machine learning functionality and predictive algorithms, if such software falls within the definition of a “ medical device ” under the FDCA. However, historically, the FDA has exercised enforcement discretion for certain low- risk software functions, and has issued several guidance documents that establish enforcement discretion policies and / or otherwise outline the FDA’ s approach to the regulation of software as a medical device. For example, in September 2022 the FDA issued a guidance entitled: “ Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices, ” which among other things, announced the FDA’ s intent not to enforce compliance with certain FDCA requirements with respect to medical device MDDS functions, including those requirements relating to registration and listing, premarket review, post- market reporting and compliance with the QSR. In addition, the 21st Century Cures Act (" Cures Act ”) amended the FDCA to exclude from the definition of “ medical device ” certain medical- related software, including certain software used for administrative support functions at a healthcare facility, software intended for maintaining or encouraging a healthy lifestyle, software designed to store electronic health records, certain clinical decision support software, and software for transferring, storing, or displaying medical device data or in vitro diagnostic data, including certain MDDS functionality. We believe our currently marketed applications, including the SleepSync ™ platform, provide functionality that either qualifies for FDA enforcement discretion under the September 2022 policy for device MDDS, or is otherwise exempt from the FDCA’ s definition of a “ medical device ” pursuant to the Cures Act amendments, and therefore that our products are subject to the FDA’ s current enforcement discretion policy applicable to MDDS software functions or otherwise provide functions that are not currently regulated by the FDA as a medical device. However, there is a risk that the FDA could disagree with our determinations, or that the FDA could alter its enforcement discretion policies, and in either case, subject our software to more stringent medical device regulations. If the FDA determines that any of our current or future software applications, including the SleepSync ™ platform, are regulated as medical devices and not otherwise subject to enforcement discretion, we would become subject to various requirements under the FDCA and the FDA’ s implementing regulations. If this occurs, we may be required to cease marketing or to recall our software products until we obtain the requisite clearances or approvals, and we may be subject to enforcement action. In addition, as we continue to update and improve our SleepSync ™ platform, we are also continuing to integrate certain software functions we utilize for compliance, quality oversight and product surveillance into the SleepSync ™ platform. As such, any enforcement action with respect to our SleepSync ™ software platform, or any requirements for us to obtain clearances or approvals for our software applications would also affect the speed at which we could update and modify these systems, and in any case, would entail significant cost and could harm our reputation, business, financial condition, and results of operations.** Legislative or regulatory reforms in the U. S. or the EU may make it more difficult and costly for us to obtain regulatory clearances, approvals or certification for our products or to

manufacture, market or distribute our products after clearance, approval or certification is obtained. From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulation of medical devices. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any future products or make it more difficult to obtain approval for, manufacture, market or distribute our products. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require: additional testing prior to obtaining clearance or approval; changes to manufacturing methods; recall, replacement or discontinuance of our products; or additional record keeping. ~~In addition~~ **For example** , **in February 2024, the FDA issued a final rule to amend and replace the Quality System** ~~legislation~~ **Regulation** ~~in~~ **, or QSR, which sets forth the FDA' s current good manufacturing practice requirements for medical devices, to align more closely with the International Organization for Standardization standards. Specifically, this final rule, which the FDA expects to go into effect on February 2, 2026, establishes the " Quality Management System Regulation, " or QMSR, which among** ~~the~~ **other** ~~U~~ **things, incorporates by reference the quality management system requirements of ISO 13485: 2016** . ~~S. and~~ **Although the FDA has stated that the standards contained in ISO 13485: 2016 are substantially similar to** ~~the~~ **those** ~~EU may~~ **set forth in the QSR, and although our quality system is currently designed to comply with ISO standards in connection with our device certifications outside the United States, it is unclear the extent to which this final rule, once effective, could** impose additional or different regulatory requirements on us that could increase the costs of compliance or otherwise ~~create competition that may~~ negatively affect our business **. If we are unable to comply with QMSR, once effective, or with any other changes in the laws or regulations enforced by FDA or comparable regulatory authorities, we may be subject to enforcement action, which could have an adverse effect on our business, financial condition and results of operations** . Similarly, the EU landscape concerning medical devices recently evolved. On May 25, 2017, the EU Medical Devices Regulation entered into force, which repeals and replaces the EU Medical Devices Directive and the AIMDD. See Part I, Item I, " Business – Government Regulation " for additional information on these reforms. These modifications are likely to have an effect on the way we conduct our business in the EEA. For example, as a result of the transition towards the new regime, notified body review times have lengthened, and product introductions or modifications could be delayed or canceled, which could adversely affect our ability to grow our business. We are subject to federal, state and foreign fraud and abuse laws, and transparency laws, which, if violated, could subject us to substantial penalties. Additionally, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business. There are numerous U. S. federal and state, as well as foreign, laws pertaining to healthcare fraud and abuse, including anti- kickback, false claims and physician transparency laws. Our business practices and relationships with providers are subject to scrutiny under these laws. The healthcare laws and regulations that may affect our ability to operate include, but are not limited to: the federal Anti- Kickback Statute, the federal civil and criminal false claims laws and civil monetary penalties laws, including the federal civil False Claims Act, the federal Civil Monetary Penalties Law, federal criminal fraud and abuse laws under HIPAA, analogous state and foreign law equivalents of each of the foregoing. See Part I, Item 1." Business — Government Regulation." These laws and regulations, among other things, constrain our business, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, physicians or other potential purchasers of our products. Similar laws may exist in other jurisdictions where we operate, such as in the EU. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws. To enforce compliance with the healthcare regulatory laws, certain enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. 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 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. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to respond to. If our operations are found to be in violation of any of the healthcare laws or regulations described above or any other healthcare regulations that apply to us, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment, contractual damages, reputational harm, disgorgement and the curtailment or restructuring of our operations. We are **or may be** subject to U. S. federal, state, and foreign laws and regulations ~~imposing~~ **which impose** obligations on how we collect, store and process health- related and other personal information. Our actual or perceived failure to comply with such obligations could harm our business **, operations, and financial condition** . Ensuring compliance with such laws could also impair our efforts to maintain and expand our customer base, and thereby decrease our revenue. In the conduct of our business, we process health- related and other personal information. The U. S. federal government ~~and~~ **,** various states **, and foreign governments** have adopted or proposed laws, regulations, guidelines and rules for the collection, distribution, use and storage of personal information of individuals. For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and regulations implemented thereunder (collectively" HIPAA"), imposes privacy, security and breach notification obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services that involve creating, receiving, maintaining or transmitting individually identifiable health information for or on behalf of such covered entities, and their covered subcontractors. HIPAA requires covered entities

and business associates to develop and maintain policies with respect to the protection of, use and disclosure of **protected health information ("** PHI **")** , including the adoption of administrative, physical and technical safeguards to protect such information, and certain notification requirements in the event of a breach of unsecured PHI. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured PHI, a complaint about privacy practices or an audit by the U. S. Department of Health and Human Services ~~, or~~ **("** HHS **")** , may be subject to significant civil, criminal and administrative fines and penalties and / or additional reporting and oversight obligations. HIPAA also authorizes state Attorneys General to file suit on behalf of their residents. Courts may award damages, costs and attorneys' fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to sue us in civil court for violations of HIPAA, its standards have been used as the basis for duty of care in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI. Further, the Federal Trade Commission (the" FTC") and many state Attorneys General continue to enforce federal and state consumer protection laws against companies for online collection, use, dissemination and security practices that appear to be unfair or deceptive. For example, according to the FTC, failing to take appropriate steps to keep consumers' personal information secure can constitute unfair acts or practices in or affecting commerce in violation of Section 5 (a) of the Federal Trade Commission Act. The FTC expects a company' s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. We may also be subject to U. S. federal rules, regulations, and guidance concerning data security for medical devices, including guidance from the FDA. State privacy and security laws **which govern the privacy, processing and protection of health- related and other personal information** vary from state to state and, in some cases, can impose more restrictive requirements than U. S. federal law. Where state laws are more protective, we must comply with the stricter provisions. In addition to fines and penalties that may be imposed for failure to comply with state law, some states also provide for private rights of action to individuals for **certain** ~~misuse~~ **misuses** of personal information. For example, the California Consumer Privacy Act of 2018 (the" CCPA") went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. **The CCPA provides for civil penalties for violations, as well as a private right of action for certain data breaches that has increased the likelihood of, and risks associated with data breach litigation.** Further, the California Privacy Rights Act (the" CPRA") **generally** went into effect on January 1, 2023 and **significantly amends the CCPA. The CPRA** imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It ~~will~~ also ~~create~~ **created** a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Similar laws have passed in ~~Virginia and Colorado, and have been proposed in~~ other states **,** and **are continuing to be proposed** at the **state and** federal level, reflecting a trend toward more stringent privacy legislation in the U. S. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging and additional compliance investment and potential business process changes may be required. **We also expect that there will continue to be new laws, regulations and industry standards concerning privacy, data protection and information security proposed and enacted in various jurisdictions. For example, Washington State enacted a broadly applicable law to protect the privacy of personal health information known as the " My Health My Data Act, " which generally requires affirmative consent for the collection, use, or sharing of any " consumer health data. " Consumer health data is defined to include personal information that is linked or reasonably linkable to a consumer and that identifies a consumer' s past, present, or future physical or mental health status; consumer health data also includes information that is derived or extrapolated from non- health information, such as algorithms and machine learning. Other states, including Connecticut and Nevada, have also passed consumer health data laws, and given the increased focus on the use of health data by entities that are not subject to HIPAA, additional states are expected to pass consumer health privacy laws.** In **the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition. We are also or may become subject to rapidly evolving data protection laws, rules and regulations in foreign jurisdictions. For example, in** Europe, we are subject to the requirements of the GDPR (and national laws implementing the GDPR) because we are " established " in certain EU countries and we are processing personal data of individuals located in the EU and EEA in the context of these establishments, as well as offering of goods to, and / or monitoring the behavior of, individuals in the EU and EEA in connection with our clinical investigations. The GDPR, which went into effect in May 2018, imposes strict requirements for processing the personal data subject to the GDPR. If we do not comply with our obligations under the GDPR, we could be exposed to significant fines the greater of EUR 20 million or 4 % of total global annual turnover for certain breaches. In addition to the foregoing, a breach of the GDPR could result in regulatory investigations, reputational damage, orders to cease / change our use of data, enforcement notices, as well potential civil claims including class action type litigation where individuals suffer harm. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States. Recent legal developments in Europe have created complexity and uncertainty regarding such transfers, in particular in relation to transfers to the United States ~~. On July 16~~ , ~~2020~~ **and the efficacy and longevity of current transfer mechanisms between the EEA** , **and the United States remains uncertain. Case law from** the Court of Justice of the European Union (" CJEU ") **states** ~~invalidated the EU- US Privacy Shield Framework, or Privacy Shield, under which personal information could be transferred from the EEA (and the UK) to relevant self- certified U. S. entities. The CJEU further noted~~ that reliance on the standard contractual clauses **(SCCs)** (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism ~~and potential alternative to the Privacy Shield~~) alone may not necessarily be sufficient in all circumstances and that transfers

must be assessed on a case- by- case basis. **We expect** ~~European court and regulatory decisions subsequent to~~ the **existing legal complexity and uncertainty regarding** ~~CJEU decision of July 16, 2020 have taken a restrictive approach to~~ international **personal** data transfers **to continue** . As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the standard contract clauses cannot be used, and / or start taking enforcement action, we could suffer additional costs, complaints and / or regulatory investigations or fines, and / or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results. Further, from January 1, 2021, we have to comply with both the GDPR and the GDPR as incorporated into United Kingdom national law, **under** the ~~latter regime having~~ **United Kingdom General Data Protection Regulation and Data Protection Act 2018 (collectively,** the ~~ability to~~ **" UK GDPR ") which imposes** ~~separately~~ -- **separate but similar** ~~fine~~ **fines** up to the greater of £ 17. 5 million or 4 % of global turnover. ~~The relationship between~~ **On October 12, 2023,** the **UK Extension** ~~United Kingdom and the EU in relation~~ to ~~certain aspects of~~ **the DPF came into effect (as approved by the UK Government), as a UK GDPR** data ~~protection law remains unclear, for example around how data can lawfully be transferred~~ -- - **transfer mechanism** ~~between each jurisdiction, which may expose us~~ to ~~further compliance risk~~ **U. S. entities self- certified under the UK Extension to the DPF** . We are also subject to evolving EU and EEA privacy laws on cookies and e- marketing. In the EU and the UK, informed consent is required for the placement of ~~a~~ **certain** cookie or similar technologies on an individual' s device and for direct electronic marketing. The GDPR also imposes conditions on obtaining valid consent for cookies, such as a prohibition on pre- checked consents and a requirement to ensure separate consents are sought for each type of cookie or similar technology. Recent European court and regulator decisions **and guidance** are driving increased attention to cookies and tracking technologies. If the trend of increasing enforcement by regulators of the strict approach to opt- in consent for all but essential use cases, as seen in recent guidance and decisions continues, this could lead to substantial costs, require significant systems changes, limit the effectiveness of our marketing activities, divert the attention of our technology personnel, adversely affect our margins, and subject us to additional liabilities. In light of the complex and evolving nature of EU, EU Member State, and UK privacy laws on cookies and tracking technologies, there can be no assurances that we will be successful in our efforts to comply with such laws; violations of such laws could result in regulatory investigations, fines, orders to cease / change our use of such technologies, as well as civil claims including class actions, and reputational damage. Any actual or perceived failure by us, our employees or contractors, our partners, our service providers, or the third parties with whom we work, to comply with privacy or security laws, policies, legal obligations or industry standards, or any security incident that results in the unauthorized release or transfer of personal information, may result in governmental enforcement actions and investigations including by EU regulators and U. S. federal and state regulatory authorities as well as fines and penalties, litigation, including by consumer advocacy groups, and / or adverse publicity and could cause our customers, their patients and other healthcare professionals to lose trust in us, which could harm our reputation and have a material adverse effect on our business, financial condition and results of operations. Healthcare policy changes, including recently enacted legislation reforming the U. S. healthcare system, could harm our business, financial condition and results of operations. In the U. S., there have been and continue to be a number of legislative initiatives to contain healthcare costs. In ~~March~~ 2010, the Affordable Care Act (the" ACA") was enacted in the U. S., which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Among other ways in which it may affect our business, the ACA: • established a new Patient- Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research; • implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models; and • expanded the eligibility criteria for Medicaid programs. In addition, other legislative changes have been proposed and adopted since the ACA was enacted, such as the Budget Control Act of 2011, the American Taxpayer Relief Act of 2012, and the Medicare Access and CHIP Reauthorization Act of 2015, among others. See Part I, Item 1. " Business — Government Regulation. " The expansion in the government' s role in the U. S. healthcare industry may result in decreased profits to us, lower reimbursement by payors for our Inspire system, and / or reduced medical procedure volumes, all of which may have a material adverse effect on our business, financial condition and results of operations. We expect additional state, federal, and foreign healthcare policies and reform measures to be adopted in the future, any of which could limit reimbursement for healthcare products and services or otherwise result in reduced demand for our Inspire system or additional pricing pressure and have a material adverse effect on our industry generally and on our customers. Any changes of, or uncertainty with respect to, future coverage or reimbursement rates could affect demand for our Inspire system, which in turn could impact our ability to successfully commercialize our Inspire system and could have a material adverse effect on our business, financial condition and results of operations. Our business involves the use of hazardous materials and our third- party manufacturers must comply with environmental laws and regulations, which may be expensive and restrict how we do business. Our third- party manufacturers' activities may involve the controlled storage, use and disposal of hazardous materials. Our manufacturers are subject to federal, state, local, and foreign laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these hazardous materials. We currently carry no insurance specifically covering environmental claims relating to the use of hazardous materials. Although we believe the safety procedures of our manufacturers for handling and disposing of these materials and waste products comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of hazardous materials. In the event of an accident, state or federal or other applicable authorities may curtail our manufacturers' use of these materials and interrupt their business operations which could adversely affect our business **. Environmental laws and regulations could change or become more stringent over time, imposing greater compliance costs, and increasing risks and penalties associated with violations. We cannot assure you that violations of these laws**

and regulations will not occur in the future or have not occurred in the past as a result of human error, accidents, equipment failure or other causes. The expense associated with environmental regulation and remediation could harm our business, financial condition, and results of operations . The clinical study process required to obtain regulatory approvals or certifications is lengthy and expensive with uncertain outcomes. If clinical studies of our future products do not produce results necessary to support regulatory clearance or approval in the U. S. or foreign approval or certification, with respect to our current or future products, elsewhere, we will be unable to expand the indications for or commercialize these products and may incur additional costs or experience delays in completing, or ultimately be unable to complete, the commercialization of those products. We have obtained PMA for our Inspire system. In order to obtain PMA for a device, the sponsor must conduct well- controlled clinical studies designed to assess the safety and efficacy of the product candidate. Conducting clinical studies is a complex and expensive process, can take many years, and outcomes are inherently uncertain. We incur substantial expense for, and devote significant time to, clinical studies but cannot be certain that the studies will ever result in commercial revenue. We may experience significant setbacks in clinical studies, even after earlier clinical studies showed promising results, and failure can occur at any time during the clinical study process. Any of our products may malfunction or may produce undesirable adverse effects that could cause us or regulatory authorities to interrupt, delay or halt clinical studies. We will likely need to conduct additional clinical studies in the future to support new indications for our products or for approvals, clearances or certifications of new product lines, or for the approval of the use of our products in some foreign countries. Clinical testing is difficult to design and implement, can take many years, can be expensive and carries uncertain outcomes. The initiation and completion of any of these studies may be prevented, delayed, or halted for numerous reasons. We may experience a number of events during that could adversely affect the costs, timing or successful completion of our clinical studies, including: • we may be required to submit an IDE application or similar application to the FDA or a foreign regulatory authority, which must become effective prior to commencing human clinical studies, and the FDA or foreign regulatory authority may reject our IDE or similar application and notify us that we may not begin investigational studies; • regulators and other comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical studies; • regulators and / or IRBs, or other reviewing bodies may not authorize us or our investigators to commence a clinical study, or to conduct or continue a clinical study at a prospective or specific study site; • we may not reach agreement on acceptable terms with prospective contract research organizations (" CROs") and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and study sites; • clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical studies or abandon product development programs; • the number of subjects or patients required for clinical studies may be larger than we anticipate, enrollment in these clinical studies may be insufficient or slower than we anticipate, and the number of clinical studies being conducted at any given time may be high and result in fewer available patients for any given clinical study, or patients may drop out of these clinical studies at a higher rate than we anticipate; • our third- party contractors, including those manufacturing products or conducting clinical studies on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; • we might have to suspend or terminate clinical studies for various reasons, including a finding that the subjects are being exposed to unacceptable health risks; • we may have to amend clinical study protocols or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to submit to an IRB or other review bodies and / or regulatory authorities for re- examination; • regulators, IRBs, or other parties may require or recommend that we or our investigators suspend or terminate clinical research for various reasons, including safety signals or noncompliance with regulatory requirements; • the cost of clinical studies may be greater than we anticipate; • clinical sites may not adhere to the clinical protocol or may drop out of a clinical study; • we may be unable to recruit a sufficient number of clinical study sites; • regulators, IRBs, or other reviewing bodies may fail to approve or subsequently find fault with our manufacturing processes or facilities of third- party manufacturers with which we enter into agreement for clinical and commercial supplies, the supply of devices or other materials necessary to conduct clinical studies may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply; • approval policies or regulations of FDA or applicable foreign regulatory agencies may change in a manner rendering our clinical data insufficient for approval or certification; and • our current or future products may have undesirable side effects or other unexpected characteristics. Patient enrollment in clinical studies and completion of patient follow- up depend on many factors, including the size of the patient population, the nature of the study protocol, the proximity of patients to clinical sites, the eligibility criteria for the clinical study, patient compliance, competing clinical studies and clinicians' and patients' perceptions as to the potential advantages of the product being studied in relation to other available therapies, including any new treatments that may be approved for the indications we are investigating. For example, patients may be discouraged from enrolling in our clinical studies if the study protocol requires them to undergo extensive post- treatment procedures or follow- up to assess the safety and efficacy of a product candidate, or they may be persuaded to participate in contemporaneous clinical studies of a competitor' s product candidate. In addition, patients participating in our clinical studies may drop out before completion of the study or experience adverse medical events unrelated to our products. Delays in patient enrollment or failure of patients to continue to participate in a clinical study may delay commencement or completion of the clinical study, cause an increase in the costs of the clinical study and delays, or result in the failure of the clinical study. Clinical studies must be conducted in accordance with the laws and regulations of the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and IRBs and other reviewing bodies at the medical institutions where the clinical studies are conducted. In addition, clinical studies must be conducted with supplies of our devices produced under current good manufacturing practice requirements and other regulations. Furthermore, we rely on CROs, and clinical study sites to ensure the proper and timely conduct of our clinical studies and while we have agreements governing their committed activities, we have limited influence over their actual performance. We depend on our collaborators and on medical

institutions and CROs to conduct our clinical studies in compliance with good clinical practice (" GCP") requirements. To the extent our collaborators or the CROs fail to enroll participants for our clinical studies, fail to conduct the study in accordance with GCP requirements or are delayed for a significant time in the execution of studies, including achieving full enrollment, we may be affected by increased costs, program delays or both. In addition, clinical studies that are conducted in countries outside the U. S. may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements and the engagement of non- U. S. CROs, as well as expose us to risks associated with clinical investigators who are unknown to the FDA, and different standards of diagnosis, screening and medical care. Failure can occur at any stage of clinical testing. Our clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and non- clinical testing in addition to those we have planned. Our failure to adequately demonstrate the safety and efficacy of our system or any product we may develop in the future would prevent receipt of regulatory clearance, approval or certification and, ultimately, the commercialization of that product or indication for use. Even if our future products are cleared or approved in the U. S., commercialization of our products in foreign countries would require approval by regulatory authorities or certification by notified bodies in those countries. Approval and certification procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the U. S., including additional preclinical studies or clinical studies. Any of these occurrences could have an adverse effect on our business, financial condition and results of operations. Disruptions at the FDA, other government agencies or notified bodies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business. The ability of the FDA, foreign regulatory authorities and notified bodies to review and approve or certify new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies or notified bodies may also slow the time necessary for new medical devices and modifications to cleared or approved medical devices to be reviewed and / or cleared, approved or certified by necessary government agencies or notified bodies, which would adversely affect our business. For example, over the last several years, the U. S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Similarly, a prolonged government shutdown could prevent the timely review of our patent applications by the United States Patent and Trademark Office (" USPTO"), which could delay the issuance of any U. S. patents to which we might otherwise be entitled. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly fund our business. In the EU, notified bodies must be officially designated to certify products and services in accordance with the EU Medical Devices Regulation. ~~While several~~ **Their designation process, which is significantly stricter under the new Regulation, has experienced considerable delays in recent years. Despite a recent increase in designations, the current number of** notified bodies ~~have been~~ designated ~~,~~ **under** the **new Regulation remains** ~~COVID- 19 pandemic has~~ significantly ~~slowed down~~ **lower than** the **number of notified bodies** ~~designation~~ **designated** ~~process~~ **under the previous regime** . **The** ~~Currently~~ -- **current** designated notified bodies ~~have severe capacity constraints and~~ are **therefore** facing a **backlog** ~~large amount~~ of requests ~~for recertification of products under the MDR~~ as a consequence of which review times have lengthened. This situation **may** ~~could significantly~~ impact **the way we are conducting** our **business in the EU and the EEA and the** ability **of** ~~to grow~~ our ~~business in the EU~~ **notified body to timely review** and ~~EEA~~ **process our regulatory submissions and perform its audits** . Separately, in response to the global COVID- 19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Any resurgence of the virus or emergence of new variants may lead to further inspectional **or administrative** delays ~~. Regulatory authorities outside the U. S. have adopted similar restrictions or other policy measures in response to the COVID- 19 pandemic~~ . If a prolonged government shutdown occurs, or if global health concerns ~~continue to~~ prevent the FDA, other regulatory authorities and notified bodies from conducting their regular inspections or audits, reviews, or other regulatory activities, it could significantly impact the ability of the FDA, other regulatory authorities or notified bodies to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Risks Related to Intellectual Property Matters If we are unable to adequately protect our intellectual property rights, or if we are accused of infringing on the intellectual property rights of others, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights. Our commercial success depends in part on our success in obtaining and maintaining issued patents, trademarks and other intellectual property rights in the U. S. and elsewhere and protecting our proprietary technology. If we do not adequately protect our intellectual property and proprietary technology, competitors may be able to use our technologies or the goodwill we have acquired in the marketplace and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. Some of our intellectual property rights depend on a licensing agreement with a third party, and our patent coverage includes protection provided by licensed patents. Many of these licensed patents are over ten years old and the standard life of a patent is 20 years from its initial filing date. If in the future we no longer have rights to one or more of these licensed patents, our patent coverage may be compromised, which in turn could affect our ability to protect our Inspire system or defend against competitors. We own numerous issued patents and pending patent applications that relate to our system. As of December 31, ~~2022~~ **2023** , we had rights to ~~66~~ **80** issued U. S. patents, ~~43~~ **55** issued foreign patents, ~~80~~ **81** pending U. S. patent applications, and ~~73~~ **79** pending foreign patent applications. Assuming all required fees are paid, issued U. S. patents owned by us will expire between ~~2023~~ **2029** and ~~2040~~ **2041** . We cannot provide any

assurances that any of our patents have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect our Inspire system, any additional features we develop for our Inspire system or any new products. Other parties may have developed technologies that may be related or competitive to our system, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent applications, either by claiming the same methods or devices or by claiming subject matter that could dominate our patent position. The patent positions of medical device companies, including our patent position, may involve complex legal and factual questions, and, therefore, the scope, validity and enforceability of any patent claims that we may obtain cannot be predicted with certainty. Patents, if issued, may be challenged, deemed unenforceable, invalidated or circumvented. Proceedings challenging our patents could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such proceedings may be costly. Thus, any patents that we may own may not provide any protection against competitors. Furthermore, an adverse decision in an interference proceeding can result in a third party receiving the patent right sought by us, which in turn could affect our ability to commercialize our products. Though an issued patent is presumed valid and enforceable, its issuance is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Competitors could purchase our Inspire system and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our patents, or develop and obtain patent protection for more effective technologies, designs or methods. We may be unable to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, suppliers, vendors, former employees and current employees. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the U. S., and we may encounter significant problems in protecting our proprietary rights in these countries. Our ability to enforce our patent rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor' s or potential competitor' s product. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful. In addition, proceedings to enforce or defend our patents could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. If any of our patents covering our Inspire system are invalidated or found unenforceable, or if a court found that valid, enforceable patents held by third parties covered one or more of our products, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights. The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that: • any of our patents, or any of our pending patent applications, if issued, will include claims having a scope sufficient to protect our Inspire system; • any of our pending patent applications will issue as patents; • we will be able to successfully commercialize our products on a substantial scale, if approved, before our relevant patents we may have expire; • we were the first to make the inventions covered by each of our patents and pending patent applications; • we were the first to file patent applications for these inventions; • others will not develop similar or alternative technologies that do not infringe our patents; any of our patents will be found to ultimately be valid and enforceable; • any patents issued to us will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties; • we will develop additional proprietary technologies or products that are separately patentable; or • our commercial activities or products will not infringe upon the patents of others. We rely, in part, upon unpatented trade secrets, unpatented know- how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our employees and our collaborators and consultants. We also have agreements with our employees and consultants that obligate them to assign their inventions to us and have non- compete agreements with some, but not all, of our consultants. It is possible that technology relevant to our business will be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees and consultants who are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could otherwise become known or be independently discovered by our competitors. Litigation or other proceedings or third- party claims of intellectual property infringement could require us to spend significant time and money and could prevent us from selling our products or affect our stock price. Our commercial success will depend in part on not infringing the patents or violating the other proprietary rights of others. Significant litigation regarding patent rights occurs in our industry. Our competitors in both the U. S. 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. We do not always conduct independent reviews of patents issued to third parties. In addition, patent applications in the U. S. and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived, so there may be applications of others now pending or recently revived patents of which we are unaware. These applications may later result in issued patents, or the revival of previously abandoned patents, that will prevent, limit or otherwise interfere with our ability to make, use or sell our products. Third parties may, in the future, assert claims that we are employing their proprietary technology without authorization, including claims from competitors or from non- practicing entities that have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. As we continue to commercialize our products in their current or updated forms, launch new products and enter new markets, competitors may claim that one or more of our products infringe their intellectual property rights as part of business strategies designed to impede our successful commercialization and entry into new markets. The large number of patents, the rapid rate of new patent applications and issuances, the complexities of the technology involved, and the uncertainty of litigation

may increase the risk of business resources and management' s attention being diverted to patent litigation. We have, and we may in the future, receive letters or other threats or claims from third parties inviting us to take licenses under, or alleging that we infringe, their patents. Moreover, we may become party to future adversarial proceedings regarding our patent portfolio or the patents of third parties. Such proceedings could include supplemental examination or contested post- grant proceedings such as review, reexamination, inter partes review, interference or derivation proceedings before the USPTO and challenges in U. S. District Court. Patents may be subjected to opposition, post- grant review or comparable proceedings lodged in various foreign, both national and regional, patent offices. The legal threshold for initiating litigation or contested proceedings may be low, so that even lawsuits or proceedings with a low probability of success might be initiated. Litigation and contested proceedings can also be expensive and time- consuming, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. We may also occasionally use these proceedings to challenge the patent rights of others. We cannot be certain that any particular challenge will be successful in limiting or eliminating the challenged patent rights of the third party. Any lawsuits resulting from such allegations could subject us to significant liability for damages and invalidate our proprietary rights. Any potential intellectual property litigation also could force us to do one or more of the following: • stop making, selling or using products or technologies that allegedly infringe the asserted intellectual property; • lose the opportunity to license our technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property rights against others; incur significant legal expenses; • pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing; • pay the attorney' s fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing; • redesign those products that contain the allegedly infringing intellectual property, which could be costly, disruptive and infeasible; and • attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms or at all, or from third parties who may attempt to license rights that they do not have. Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. If we are found to infringe the intellectual property rights of third parties, we could be required to pay substantial damages (which may be increased up to three times of awarded damages) and / or substantial royalties and could be prevented from selling our products unless we obtain a license or are able to redesign our products to avoid infringement. Any such license may not be available on reasonable terms, if at all, and there can be no assurance that we would be able to redesign our products in a way that would not infringe the intellectual property rights of others. We could encounter delays in product introductions while we attempt to develop alternative methods or products. If we fail to obtain any required licenses or make any necessary changes to our products or technologies, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products. In addition, we generally indemnify our customers with respect to infringement by our products of the proprietary rights of third parties. Third parties may assert infringement claims against our customers. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers, regardless of the merits of these claims. If any of these claims succeed or settle, we may be forced to pay damages or settlement payments on behalf of our customers 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. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position could be harmed. In addition to patent protection for our issued patents and pending patent applications related to our system, we also rely upon copyright and trade secret protection for our Inspire therapy, as well as non- disclosure agreements and invention assignment agreements with our employees, consultants and third parties, to protect our confidential and proprietary information. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time- consuming, and the outcome is unpredictable. Even though we use commonly accepted security measures, trade secret violations are often a matter of state law, and the criteria for protection of trade secrets can vary among different jurisdictions. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our business and competitive position could be harmed. We may be unable to enforce our intellectual property rights throughout the world. The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the U. S. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. This could make it difficult for us to stop infringement of our foreign patents, if obtained, or the misappropriation of our other intellectual property rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country- by- country basis, which is an expensive and time- consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the U. S. and foreign

countries may affect our ability to obtain adequate protection for our technology and the enforcement of our intellectual property. Third parties may assert ownership or commercial rights to inventions we develop. Third parties may in the future make claims challenging the inventorship or ownership of our intellectual property. We have written agreements with collaborators that provide for the ownership of intellectual property arising from our collaborations. In addition, we may face claims by third parties that our agreements with employees, contractors or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such intellectual property. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property or may lose our exclusive rights in that intellectual property. Either outcome could harm our business and competitive position. Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets. We employ individuals who previously worked with other companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property or personal ~~data~~ **information** , including trade secrets or other proprietary information, of a former employer or other third party. Litigation may be necessary to defend against these claims. If we fail in defending any such claims or settling those claims, in addition to paying monetary damages or a settlement payment, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Recent changes in U. S. patent laws may limit our ability to obtain, defend and / or enforce our patents. Recent 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. The Leahy- Smith America Invents Act (" the Leahy- Smith Act") includes a number of significant changes to U. S. patent law. These include provisions that affect the way patent applications are prosecuted and also affect patent litigation. The USPTO recently developed new regulations and procedures to govern administration of the Leahy- Smith Act, and many of the substantive changes to patent law associated with the Leahy- Smith Act, and in particular, the first to file provisions, which became effective on March 16, 2013. The first to file provisions limit the rights of an inventor to patent an invention if not the first to file an application for patenting that invention, even if such invention was the first invention. Accordingly, it is not clear what, if any, impact the Leahy- Smith Act will have on the operation of our business. However, the Leahy- Smith Act and its implementation could increase the uncertainties and costs surrounding the enforcement and defense of our issued patents. For example, the Leahy- Smith Act provides that an administrative tribunal known as the Patent Trial and Appeals Board (" PTAB") provides a venue for challenging the validity of patents at a cost that is much lower than district court litigation and on timelines that are much faster. Although it is not clear what, if any, long- term impact the PTAB proceedings will have on the operation of our business, the initial results of patent challenge proceedings before the PTAB since its inception in 2013 have resulted in the invalidation of many U. S. patent claims. The availability of the PTAB as a lower- cost, faster and potentially more potent tribunal for challenging patents could increase the likelihood that our own patents will be challenged, thereby increasing the uncertainties and costs of maintaining and enforcing them. Risks Related to Our Common Stock The market price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock The market price of our common stock is likely to be highly volatile and may fluctuate substantially due to many factors, including, for example: • the volume and timing of sales of our products; • the introduction of new products or product enhancements by us or others in our industry; • disputes or other developments with respect to our or others' intellectual property rights; • our ability to develop, obtain regulatory clearance or approval for, and market new and enhanced products on a timely basis; • regulatory actions with respect to our therapy or those of our competitors or companies perceived to be similar to ours; • product liability claims or other litigation; • changes in physician, hospital, healthcare provider practices; • quarterly variations in our results of operations or those of others in our industry; • media exposure of our products or of those of others in our industry; • changes in governmental regulations • changes in the structure of healthcare payment systems; • changes in earnings estimates or recommendations by securities analysts; and • general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors. In recent years, the stock markets generally have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors may significantly affect the market price of our common stock, regardless of our actual operating performance. In addition, in the past, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Securities litigation brought against us following volatility in our stock price, regardless of the merit or ultimate results of such litigation, could result in substantial costs, which would hurt our financial condition and operating results and divert management' s attention and resources from our business. Provisions in our governing documents and under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our current management. Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. 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 members of our board of directors. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. These provisions provide, among other things, that: •

our board of directors has the exclusive right to expand the size of our board of directors and to elect directors to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors; • our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered three- year terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors; • our stockholders may not act by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders; • a special meeting of stockholders may be called only by the chair of our board of directors, our chief executive officer or a majority of our board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; • our amended and restated certificate of incorporation prohibits cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates; • our board of directors may alter certain provisions of our bylaws without obtaining stockholder approval; • the approval of the holders of at least two- thirds of the shares entitled to vote at an election of directors is required to adopt, amend or repeal our bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors; • stockholders must provide advance notice and additional disclosures in order to nominate individuals for election to the board of directors or to propose matters that can be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror' s own slate of directors or otherwise attempting to obtain control of our Company; and • our board of directors is authorized to issue shares of preferred stock and to determine the terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror. Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15 % of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15 % of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL or our amended and restated certificate of incorporation or amended and restated bylaws or (iv) any action asserting a claim governed by the internal affairs doctrine. We believe this provision benefits us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi- forum litigation. However, this 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. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions. Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain. We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the agreement governing our former credit facility precluded, and any future debt agreements may preclude, us from paying cash dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. General Risk Factors Changes in U. S. and foreign tax laws could have a material adverse effect on our business, cash flow, results of operations and financial condition. We are subject to taxation in several countries, and changes in tax laws or challenges to our tax positions could adversely affect our business, results of operations and financial condition. As such, we are subject to tax laws, regulations, and policies of the U. S. federal, state, and local governments and of comparable taxing authorities in foreign jurisdictions. Changes in tax laws in one or more jurisdictions, as well as other factors, could cause us to experience fluctuations in our tax obligations and effective tax rates in the future and otherwise adversely affect our tax positions and / or our tax liabilities. We are currently unable to predict what changes will occur and, if so, the ultimate impact on our business. To the extent that such changes have a negative impact on us or our consumers, including as a result of related uncertainty, these changes may materially and adversely impact our business, financial condition, results of operations and cash flow. There can be no assurance that our effective tax rates, tax payments or tax credits will not be adversely affected by changes in tax laws in various jurisdictions. Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud. We have designed our disclosure controls and procedures to provide reasonable assurance that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures, no matter how well- conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision- making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. Securities analysts may not publish favorable research or reports about our business or may publish no information at all, which could cause our stock price or trading volume to decline. The trading market for our common stock relies in part on the research and reports that securities or industry analysts publish about us or our

business. We do not control these analysts. If any of the analysts who cover us provide inaccurate or unfavorable research or issue an adverse opinion regarding our stock price, our stock price could decline. If one or more of the analysts covering our business downgrade our stock or change their opinion of our stock, our stock price would likely decline. In addition, if one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.