Risk Factors Comparison 2024-03-05 to 2023-03-02 Form: 10-K

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Our business involves significant risks, some of which are described below. You should carefully consider these risks, as well as the other information in this Annual Report on Form 10- K, including our audited financial statements and the related notes and " Management' s Discussion and Analysis of Financial Condition and Results of Operations. " The occurrence of any of the events or developments described below could have a material adverse effect on our business, results of operations, financial condition, prospects and stock price. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. You should not interpret our disclosure of any of the following risks to imply that such risks have not already materialized. Risks related to operational, commercial and manufacturing matters We currently rely on our RNS System, which can only be marketed in the United States for use in adults with drug- resistant focal epilepsy, ~~and is~~ **as our primary source of revenue. Our RNS System was historically** recommended as well as implanted primarily at Level 4 CECs **and has recently expanded outside of Level 4 CECs and into the community setting** . If we are not successful in enhancing awareness of our RNS System, driving **utilization and** adoption across ~~our current target population~~ **Level 4 CECs, growing utilization and adoption in the community setting** , expanding referral pathways to increase referrals to Level 4 CECs, reaching beyond Level 4 CECs and expanding the population of eligible patients, our sales, business, financial condition and results of operations will be negatively affected. Our business currently depends primarily on our ability to successfully market our RNS System, which includes increasing the number of patients treated at CECs, increasing adoption of our RNS System across CECs ~~,~~ and **in the community setting, as well as** driving utilization by clinicians within CECs **and in the community setting** . Currently, our RNS System can only be marketed for use in adults with drug- resistant focal epilepsy in the United States. **Historically** ~~Additionally,~~ our RNS System ~~is~~ **was** primarily recommended and implanted at Level 4 CECs, which provide advanced diagnosis and management of epilepsy. **We only recently began expanding our commercial efforts to target and be able to qualify the additional 1, 800 epileptologists outside of Level 4 CECs and the entire population of functional neurosurgeons as a result of the FDA approval of a PMA- S in 2023, which updated the qualification criteria for centers and clinicians that may prescribe and implant the RNS System.** Therefore, we ~~are~~ **have been** dependent on widespread market adoption of our RNS System within a limited number of accounts. We are aiming to increase awareness about our RNS System, including earlier in the diagnostic process through our partnership with DIXI Medical, expand the population of patients we can treat with our RNS System, ~~as well as the number of~~ **and increase utilization and adoption across** physicians that ~~can~~ prescribe and ~~the number of centers at which neurosurgeons can~~ implant our RNS System **both within Level 4 CECs and outside of Level 4 CECs, in the community setting** , but there can be no assurance that we will succeed. The commercial success of our RNS System will continue to depend on a number of factors, including the following: • the degree to which drug- resistant epilepsy remains a chronic and debilitating condition; • the actual and perceived effectiveness, safety and reliability, and clinical benefit, of our RNS System, especially relative to alternative neuromodulation devices such as VNS or DBS; • the prevalence and severity of any adverse patient events involving our RNS System; • our ability to provide earlier awareness of and education about our RNS System to patients and clinicians, including through our partnership with DIXI Medical; • the degree to which clinicians, patients and hospital facilities, **including at** ~~primarily Level 4~~ CECs **and outside of CECs, in the community setting** , adopt our RNS System ~~; • the continued effects of the COVID- 19 pandemic~~ ; • the availability, relative cost and perceived advantages and disadvantages of alternative technologies or treatment methods for epilepsy; • the results of additional clinical and other studies relating to the health, safety, economic or other benefits of our RNS System; • whether key thought leaders in the medical community accept that our clinical efficacy and safety results are sufficiently meaningful to influence their decision to adopt our RNS System over other neuromodulation therapies; • the extent to which we are successful in educating clinicians, patients, and hospital facilities about the benefits of our RNS System, including as a result of the extended battery life of the neurostimulator; • our reputation among clinicians, patients and hospital facilities; • our ability to predict product performance; • the strength of our marketing and distribution infrastructure, including our ability to drive adoption and utilization of our RNS System, our ability to ~~develop and maintain relationships with programming centers, and our ability to~~ expand referral pathways to CECs **and beyond, and our ability to grow the market outside of Level 4 CECs, in the community** ; • our ability to obtain, maintain, protect, enforce and defend our intellectual property rights, including in and to our RNS System; • our ability to maintain compliance with all legal and regulatory requirements, including those applicable to our RNS System; • our ability to continue to maintain a commercially viable manufacturing process at our manufacturing facility that is compliant with current Good Manufacturing Practices, or cGMP, and Quality Systems Regulations, or QSR; • our ability to maintain our contractual relationships with our vendors and component suppliers, including single- source vendors and suppliers, through which we obtain critical components for our RNS System; • the continued coverage of and adequate payment for the implantation procedure and for clinicians to provide ongoing care for patients implanted with our RNS System by third **-** party payors, including both private and government payors; and • our ability to continue to attract and retain key talent. If we fail to successfully market and sell our RNS System cost- effectively and maintain and expand our market share, our sales, business, financial condition and results of operations will be negatively affected. Our commercial success will continue to depend on attaining significant market acceptance of our RNS System among patients, clinicians and hospital facilities and increasing the number of patients treated. If we are unable to successfully achieve substantial market acceptance and adoption of our RNS System, our sales, business, financial condition and results of operations would be harmed. Our commercial success will depend in large part on the further acceptance by clinicians, patients and

hospital facilities of our RNS System as safe, useful, and cost- effective, and increasing the number of patients treated at Level 4 CECs and **in** ~~other -~~ **the** ~~facilities~~ **community setting** . We cannot predict how quickly, if at all, additional clinicians, patients, and hospital facilities will adopt our RNS System over continued noninterventional therapies or competing neuromodulation devices or surgical treatment options ~~at Level 4 CECs and other facilities~~ . For example, clinicians may be reluctant to use our RNS System due to familiarity with neuromodulation devices that are more established **. Alternatively, in the community setting, neuromodulation may not be a common practice, if it is done at all** . Clinicians, patients, and hospital facilities may continue to prefer noninvasive therapeutic options, resective or ablative surgery, or alternative neuromodulation therapies such as VNS and DBS. Moreover, we cannot predict how quickly, if at all, those currently living with epilepsy but who are not being treated will seek treatment ~~or utilize Level 4 CECs for treatment~~ . Our ability to grow sales of our RNS System and drive market acceptance will depend on successfully educating clinicians, patients, and hospital facilities of the relative benefits of our RNS System. Additionally, patients rely on their healthcare providers, including epileptologists and neurosurgeons to recommend a course of treatment. If we are unable to successfully achieve substantial market acceptance and adoption of our RNS System by additional clinicians, patients, and hospital facilities, **or to expand the clinicians' perspective as to the types of patients that can benefit from our RNS System,** patients may be reluctant to use our products over alternative neuromodulation therapies. If we are unable to successfully drive patient interest in our RNS System, including through our partnership with DIXI Medical, our business, financial condition and results of operations would be harmed. Our commercial success will depend on a continued flow of patient referrals to ~~Level 4~~ CECs from treating primary care physicians, neurologists, and other healthcare providers and from caregiver support and encouragement around physician referrals and self- referrals to ~~Level 4~~ CECs. If we are unable to successfully expand our referral pathways to achieve an increased patient referral pipeline into **CECs or develop opportunities outside of** Level 4 CECs **, in the community setting** , our sales, business, financial condition and results of operations would be harmed. Our commercial success will depend in large part on continued referrals of appropriate patients from treating primary care physicians, neurologists, and other healthcare providers to epileptologists, neurosurgeons, and other clinicians, primarily at Level 4 CECs. We ~~estimate that of the approximately 575, 000 adults with drug- resistant focal epilepsy in the United States, approximately 24, 000 adult drug- resistant focal epilepsy patients are treated in Level 4 CECs annually. We~~ cannot predict how quickly, if at all, we can **grow utilization and adoption at the Level 4 CECs and in the community setting to** build ~~that~~ **a** pipeline through our sales and marketing efforts and whether primary care physicians, neurologists, and other healthcare providers, as well as caregivers will support **use of our RNS System in the community setting or** patient referrals to epileptologists and neurosurgeons at ~~Level 4~~ CECs over other therapy options. Primary care physicians, neurologists, and other healthcare providers may continue to prefer traditional treatments, such as additional attempts to treat with new therapeutic drugs that become available from time to time, including for fear of losing management of the patient' s care. If we are unable to educate clinicians to follow national guidelines, which recommend that patients whose seizures have not been brought under control after three months of care by a primary care physician or after 12 months of seeing a general neurologist be referred to a CEC, **or that patients that are considered drug resistant because they failed to achieve sustained seizure freedom after trying two antiseizure medications be referred to a tertiary epilepsy center to evaluate potential interventions, or if we are unable to convince them as to the merits of our RNS System inside a CEC or in the community setting,** we may be unable to successfully build our patient pipeline. This could harm our business, financial condition and results of operations. Various factors outside our direct control ~~, including the COVID- 19 pandemic,~~ may negatively impact our manufacturing of our RNS System, which could harm our business, financial condition, and results of operations. We manufacture our RNS System at our manufacturing facility in Mountain View, California. This facility supports our production operations, including manufacturing, quality control, and raw material and finished goods storage. We believe that we currently have adequate manufacturing capacity and supplies for our products sufficient to meet our demand forecasts. If demand for our RNS System increases more rapidly than we anticipate, if we encounter problems with one or more of our suppliers, or if we secure regulatory approval to commercialize our products in additional geographies or indications, we may need to either expand our manufacturing capabilities, qualify new suppliers, or outsource to other manufacturers. Our manufacturing and distribution operations are subject to regulatory requirements of the FDA' s Quality System Regulation, or QSR, for medical devices sold in the United States. Manufacturers of medical device products often encounter difficulties in production, including difficulties with production costs and yields, quality control, quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced FDA requirements, other federal and state regulatory requirements, and foreign regulations, to the extent applicable. If we fail to manufacture our products in compliance with QSR, or if our manufacturing facility suffers disruptions, supply chain issues, machine failures, slowdowns or disrepair, we may not be able to fulfill customer demand and our business would be harmed. Further, we typically do not maintain more than several months of inventory on hand and we manufacture our products using near term demand forecasts. As a result, deviations from our forecasts could cause us to fail to meet demand for our products. Since we produce our products in one manufacturing facility, any contamination of the controlled environment, equipment malfunction, supply issues, personnel issues, including human error, or failure to strictly follow procedures can significantly reduce our yield. A drop in yield can increase our cost to manufacture our products or, in more severe cases, require us to halt the manufacture of our products until the problem is resolved. Identifying and resolving the cause of a drop in yield can require substantial time and resources. In addition, if demand for our products shifts such that our manufacturing facility is operated below our forecasts for an extended period, we may adjust our manufacturing operations to reduce fixed costs, which could lead to uncertainty and delays in manufacturing times and quality during any transition period. The manufacturing, sterilization and distribution of our products are technically challenging. Changes that our suppliers may make, or additional requirements from regulatory agencies, outside of our direct control can have an impact on our processes, on quality and on the successful or timely delivery of our products to our customers. Mistakes and mishandling may occur, which can affect supply and delivery. As a result, our dependence on third- party, including single source, suppliers, subjects us to a

number of risks that could impact our ability to manufacture our products and harm our business, financial condition, and results of operations, including: • interruption of supply resulting from modifications to, or discontinuation of, a supplier' s operations ~~, including due to the COVID- 19 pandemic~~ ; • delays in product shipments resulting from uncorrected defects, reliability issues or a supplier' s failure to produce components that consistently meet our quality specifications; • delays in analytical results or failure of analytical techniques that we depend on for quality control and release of our products; • price fluctuations due to a lack of long- term supply arrangements with our suppliers for key components; • inability to obtain adequate supply in a timely manner or on commercially reasonable terms; • difficulty identifying and qualifying alternative suppliers for components in a timely manner; • inability of suppliers to comply with applicable provisions of the QSR or other applicable laws or regulations enforced by the FDA and other Federal and state regulatory authorities; • delays in regulatory approvals of any changes to manufacturing, including the use of new suppliers; • latent defects that may become apparent after our products have been released and that may result in an adverse event or a recall of such products; • inclusion of vendors of raw materials not in compliance with regulatory requirements; • natural or other disasters, global pandemics, labor disputes, financial distress, lack of raw material supply, issues with facilities and equipment, international conflict or war, or other forms of disruption to business operations affecting our manufacturer or its suppliers; • production delays related to the evaluation and testing of our products or the use of components from alternative suppliers; • failure to complete sterilization on time or in compliance with the required regulatory standards; and • delays in delivery by our suppliers of components, materials, or services due to changes in demand from us or their other customers. The occurrence of any of these issues could significantly harm our ability to manufacture our products and maintain sufficient quality standards, which would negatively impact our sales, business, financial condition, and results of operations. We depend on a limited number of single- source suppliers and vendors in connection with the manufacture of our RNS System, which makes us vulnerable to supply shortages and price fluctuations that could harm our business, financial condition, and results of operations. We source and rely upon materials, components, and sub- assemblies of our RNS System, as well as manufacturing services from approved suppliers, most of which are single source suppliers. For example, Micro Systems Technologies Management AG and Greatbatch Ltd are single source suppliers of several key components of our products, including printed circuit assemblies and batteries. In addition, certain of our suppliers are not under long- term contracts with us. These components, materials, and services, which also include silicone adhesive, integrated circuits, and other components, are critical and there are relatively few alternative sources of supply. We believe our single source suppliers are capable of continuing to meet our specifications and maintaining quality, but any significant problem experienced by one of our single source suppliers may result in a delay or interruption in the supply of components, materials, or services to us. Our suppliers may experience manufacturing delays or issues, stop producing our components, materials, or services, increase the prices they charge us, or elect to terminate their relationships with us. In any of these cases, we could face a delay of several months to identify, perform appropriate testing, and qualify alternative suppliers and service providers with regulatory authorities, as we do not currently have supplier transition plans. In addition, the failure of our third- party suppliers and service providers to maintain acceptable quality requirements could result in the recall of our products. If one of our suppliers fails to maintain acceptable quality requirements, we may have to identify and qualify a new supplier. Although we require our third- party suppliers to supply us with materials, components and services that meet our specifications and comply with applicable provisions of the FDA' s QSR and other applicable legal and regulatory requirements in our agreements and contracts, and we perform incoming inspection, testing or other acceptance activities to ensure the materials and components meet our requirements, there is a risk that our suppliers will not always act consistent with our best interests, and may not always supply components that meet our requirements or supply components in a timely manner. The number of third- party suppliers with the necessary manufacturing and regulatory expertise and facilities is limited and certification of a new supplier may be complex and time consuming. Any delay or interruption would likely lead to a delay or interruption in our manufacturing operations. The inclusion of substitute components must meet our product specifications and could require us to qualify the new supplier with the appropriate regulatory authorities, including the FDA. The added time and cost to arrange for alternative suppliers could harm our business. New manufacturers of any planned product would be required to qualify under applicable regulatory requirements and would need to have sufficient rights under applicable intellectual property laws to the method of manufacturing the planned product. Obtaining the necessary FDA or international approvals or other qualifications under applicable regulatory requirements and ensuring non- infringement of third- party intellectual property or other proprietary rights could result in a significant interruption of supply and could require the new manufacturer to bear significant additional costs that may be passed on to us. **and results of operations.** Our results of operations may be harmed if we are unable to accurately forecast customer demand for our products.We do not maintain large amounts of excess inventory at any given time.To ensure adequate supply,we must forecast inventory needs and manufacture our products based on our estimates of future demand.Our ability to accurately forecast demand for our products ~~,including our distributed DIXI Medical products,~~ could be negatively affected by many factors,including our failure to accurately manage our expansion strategy,product introductions by competitors,our inability to forecast the lifecycle of our products,an increase or decrease in customer demand for our products or for competitor products,our failure to accurately forecast customer adoption of new products,unanticipated changes in general market conditions or regulatory matters and weakening of economic conditions or consumer confidence in future economic conditions **,as well as the ongoing COVID- 19 pandemic** .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 products,our manufacturing team ~~,or that of DIXI Medical,~~ 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 components,materials,or services,or additional manufacturing capacity may not be available when required on terms that are acceptable to us,or at all,which may negatively affect our business,financial condition, If we fail to optimize our sales and

marketing capabilities and develop widespread brand awareness cost- effectively, our growth will be impeded and our business may suffer. We are actively expanding our presence in the United States through additional sales and education efforts to drive awareness of our RNS System amongst patients, clinicians and hospital facilities, to drive adoption of our RNS System at Level 4 CECs and **in the community setting and to** increase utilization **and adoption** of our RNS System within new and existing accounts. We also plan to explore regulatory and reimbursement approval pathways to expand our presence in international territories. We take a measured approach to optimize our sales infrastructure to grow our customer base and our business. Identifying and recruiting qualified personnel and training them on the use of our RNS System, on applicable federal and state laws and regulations and on our internal policies and procedures, requires significant time, expense and attention, particularly given our strategy of having each Therapy Consultant, or sales representative, cover many accounts. It can take significant time before our Therapy Consultants are fully trained and productive and before they have established relationships with their target accounts. Our business may be harmed if our efforts to optimize do not generate a corresponding increase in revenue or result in a decrease in our operating margin. In particular, if we are unable to hire, develop and retain talented sales personnel or if new sales personnel are unable to achieve desired productivity levels in a reasonable period of time, we may not be able to realize the expected benefits of this investment or increase our revenue. **Additionally, if we do not hire the correct type of or appropriate number of sales personnel as we expand into the community setting, our efforts to grow our market and business outside of the Level 4 CECs may be harmed.** We dedicate significant financial and other resources to our customer outreach and training programs, which may require us to incur significant upfront costs. For example, we may need to conduct additional physician trainings across hospital facilities, **both at** ~~including Level 4~~ CECs **and as we expand into the community setting** . Our sales force may also need to develop additional efficiencies and approaches to address potential growth as we expand referral pathways, expand into additional existing Level 4 CECs as well as new ~~Level 4~~ CECs **, grow our presence in the community setting** , offer new products, including those distributed through our partnership with DIXI Medical, ~~and~~ increase the number of epileptologists recommending, and neurosurgeons implanting, our RNS System **, and increase the numbers and types of patients being prescribed and implanted** ~~within~~ -- **with** ~~each Level 4 CEC~~ **the RNS System by current clinicians** . Our business would be harmed if our programs and associated expenditures do not generate a corresponding increase in revenue. In addition, we believe that developing and maintaining awareness of our brand in a cost- effective manner is critical to achieving broad acceptance of our products and attracting new customers. Brand promotion activities may not generate customer awareness or increase revenue and, even if they do, any increase in revenue may not offset the costs and expenses we incur in building our brand. If we fail to successfully promote, maintain and protect our brand, we may fail to realize a sufficient return on our brand- building efforts, or to achieve the widespread brand awareness that is critical for broad adoption of our RNS System. We may be unable to compete successfully with other treatment options for drug- resistant focal epilepsy, which could harm our sales, business, financial condition and results of operations. Our industry is competitive and has been evolving rapidly with not only existing treatment options, but also the introduction of new products and technologies as well as the market activities of industry participants. Our RNS System is indicated for adult patients with drug- resistant focal epilepsy in the United States and we **have historically** primarily ~~market~~ **marketed** our device to ~~customers, primarily consisting of the~~ clinicians within Level 4 CECs that treat these patients **. As a result of the recent approval of a PMA- S, we are now able to expand our commercial efforts to the additional epileptologists and functional neurosurgeons practicing outside of Level 4 CECs, in the community setting** . In our target patient population, there are two primary treatment options (i) an ablative or resective surgery, or (ii) implantation of a neuromodulation device. Patients may also choose not to actively seek additional treatment for epilepsy or may choose to try new therapeutic drugs that become available from time to time. We estimate that approximately 80 % of drug- resistant focal epilepsy patients are either not ideal candidates for ablative or resective surgery or are unwilling to undergo a destructive surgical procedure and we compete primarily with two manufacturers of neuromodulation devices for the treatment of these patients. Our primary competitors are LivaNova plc, which manufactures the VNS System, and Medtronic plc, which manufactures the DBS System. Third- party payors may encourage the use of competitors' products or other neuromodulation therapies due to lower costs of competing products or alternatives. Additionally, treating physicians, including epileptologists and neurosurgeons may promote the use of other competitors' products or alternative therapies. Further, as existing competitors and other companies develop new or improved products, we cannot predict what the standard of care will be in the future. Our primary competitors are large, well- capitalized companies with significant market share and resources. They have more established sales and marketing programs than we do and have greater name recognition. These competitors also have long operating histories and may have more established relationships with potential customers. In addition to competing for market share, competitors may develop or acquire patents or other rights that may limit our ability to compete. The medical device industry is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. There can be no assurance that other companies or institutions will not succeed in developing or marketing devices and products that are more effective or safer than our RNS System or that would render our RNS System obsolete or noncompetitive. We believe that the clinical advantages of our RNS System and our focus on neuromodulation will be important factors in our future success. Our continued success depends on, among other things, our ability to: • continue to demonstrate safety and efficacy in our Post- Approval Study and in ongoing commercial use; • expand our referral pathways; • expand the number of **CECs implanting our RNS System and increase utilization across existing clinicians using the RNS System and adoption across new clinicians within these CECs; • increase the utilization and adoption of our RNS System outside of** Level 4 CECs **, in** ~~implanting our RNS System and increase utilization across these~~ -- **the community setting** ~~Level 4 CECs~~ ; • drive awareness to increase the number of drug- resistant epilepsy patients referred to ~~Level 4~~ CECs **and treated outside of CECs, in the community setting** ; • maintain adequate reimbursement for implant procedures and for clinicians to provide ongoing care of patients treated with our RNS System; • attract and retain skilled research, development, sales, marketing and clinical personnel; • continue to innovate in

order to improve therapy effectiveness and enhance the patient and provider experience; • adequately predict product performance; • obtain and maintain regulatory clearances and approvals, including for expanded indications; • cost- effectively manufacture, market and sell our RNS System; • obtain, maintain, protect, enforce and defend our intellectual property rights and operate our business without infringing, misappropriating or otherwise violating the intellectual property rights of others; • acquire products or technologies complementary to or necessary for our business; and • source materials, components, and sub-assemblies from suppliers on a cost- effective and timely basis. Adoption of our RNS System depends on positive clinical data as well as clinician acceptance of the data and our products, and negative clinical data or perceptions among these clinicians would harm our sales, business, financial condition, and results of operations. The rate of adoption and sales of our products are heavily influenced by clinical data. Although we have positive clinical data across four multi- center FDA approved prospective clinical studies going out as far as nine years, there can be no assurance that clinical data will continue to be positive for our ongoing studies, such as our Post- Approval Study. Additionally, there can be no assurance that future clinical studies, including those to continue demonstrating the efficacy of our products in currently approved patient populations and those to support label retention and expansion for our products will demonstrate safety and effectiveness. Unfavorable or inconsistent clinical data from ongoing or future clinical studies conducted by us, our competitors, or third parties, the negative interpretation of our clinical data internally and externally, including by customers, competitors, patients, and regulators, or findings of new or more frequent adverse events, could harm our business, financial condition, and results of operations. The rate of adoption and sales of our products are also influenced by clinician perceptions. Negative perceptions of our products by clinicians, including due to negative clinical data, could result in decreased adoption or use of our products, which would harm our business, financial condition, and results of operations. Additionally, if key opinion leaders who support our products cease to recommend our products, our business, financial condition and results of operations will be harmed. Further, if we cannot maintain strong working relationships with clinicians and continue to receive their advice and input, the marketing of our products could suffer, which could harm our business, financial condition and results of operations. **Certain** ~~The COVID- 19 pandemic and related~~ restrictions on access to clinicians as well as hospital staffing shortages have impacted, and will likely continue to impact, our ability to maintain such relationships. Finally, although we have demonstrated the safety, effectiveness and clinical advantages of our products in pivotal clinical studies, neuromodulation is still a relatively new approach to treating drug- resistant focal epilepsy. The results of clinical studies of the products conducted to date and from commercial use do not necessarily predict future results. Any negative long- term results or adverse events from use of our products that arise in the future could harm our business, financial condition, and results of operations. Our future success also depends upon patients having an understanding of how to properly use our RNS System and an experience with our products that meets their expectations in order to increase clinician demand for our products as a result of positive feedback and word- of- mouth. Patients may be dissatisfied if their expectations of the procedure and results are not met or if they are not adequately trained on use of our RNS System. Patients may be dissatisfied if they experience adverse events or insufficient reduction in frequency of seizures. If the results of our products do not meet the expectations of the patients, or the patient experiences adverse events, it could discourage the patient from continuing to use our device or referring our products to others. Dissatisfied patients may express negative opinions through social media, advocacy, or other publicity. Any failure to meet patient expectations and any resulting negative publicity could harm our reputation and future sales. ~~Our sales, business, financial condition and results of operations have been and continue to be impacted by the COVID- 19 pandemic. The global spread of the COVID- 19 pandemic, including the different COVID- 19 variants and measures introduced by local, state and federal governments to contain the virus and mitigate its public health effects have significantly impacted the global economy and negatively impacted our business. We have seen and may continue to be negatively impacted by decreased and delayed procedures being performed to implant our RNS System, hospital staffing shortages, delayed and decreased epilepsy diagnostic evaluations at epilepsy monitoring units, or EMUs, which create the majority of our pipeline for new RNS System implants and increased vacation demand by both patients and clinicians as a result of loosening travel restrictions, Given the uncertainty around the duration and extent of the COVID- 19 pandemic, we expect continued, lingering, and far- reaching adverse impacts to our business, results of operations, financial condition, and liquidity, but cannot accurately predict at this time the extent of the future potential impacts. The widespread pandemic has also had a significant negative effect on the U. S. and global economies and, if the COVID- 19 pandemic results in a prolonged economic recession, it would continue to harm our sales, business, operating results, and financial condition. Additionally, quarantines or government reaction or shutdowns for COVID- 19 have disrupted and may disrupt our supply chain, especially for components we source from single- source suppliers. Travel and cargo restrictions may also disrupt our ability to distribute our RNS System or engage with our customers in the ordinary course of business. Any cargo restrictions related to raw materials used to manufacture our RNS System or its components may restrict our ability to manufacture and ship devices and harm our sales, business, operating results, and financial condition.~~ If adequate reimbursement becomes unavailable for the procedures to implant our RNS System and for clinicians to provide ongoing care for patients treated with our RNS System, it could diminish our sales or affect our ability to sell our RNS System profitably. The implant procedure for our RNS System and the ongoing patient care provided by clinicians, including monitoring and programming, are reimbursed under well- established physician and hospital codes. Our ability to increase sales of our RNS System depends, in significant part, on the availability of adequate financial coverage and reimbursement from third- party payors, including governmental payors (such as the Medicare and Medicaid programs in the United States), managed care organizations, and private health insurers. Third- party payors decide which treatments they will cover and establish reimbursement rates for those treatments. We do not bill any third- party payors for our RNS System. Instead, we invoice healthcare providers for our RNS System and the cost is bundled into the reimbursement received by healthcare providers for the procedures in which our RNS System is used. We expect our RNS System will continue to be purchased by hospital facilities ~~, primarily Level 4 CECs, and other providers~~ who will then seek reimbursement from third- party payors for brain- responsive neuromodulation for drug resistant focal epilepsy. While third-

party payors currently cover and provide reimbursement for both implant procedures of our RNS System as well as for clinicians providing ongoing patient care, we can give no assurance that these third- party payors will continue to provide coverage and adequate reimbursement, or that current reimbursement levels for **diagnostic,** implant **or replacement** procedures as well as clinician- provided ongoing patient care will continue. Furthermore, the overall amount of reimbursement available for brain- responsive neuromodulation for drug resistant focal epilepsy could decrease in the future. Changes in reimbursement may not necessarily impact our sales. Additionally, we cannot be sure that the reimbursement amounts available for brain-responsive neuromodulation for drug resistant focal epilepsy will not reduce or otherwise negatively impact the demand for our marketed RNS System. Failure by ~~Level 4 CECs and other~~ users of our RNS System to obtain coverage and adequate reimbursement for the implant procedures or for clinicians providing ongoing patient care would cause our business, financial condition, and results of operations to suffer. **Additionally, a third- party payor' s decision to provide coverage for a brain-responsive neuromodulation for drug resistant focal epilepsy does not imply that an adequate reimbursement rate will be approved. Further, coverage policies and third- party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.** Use of our RNS System requires appropriate neurosurgeon training for implantation and epileptologist training for programming and ongoing patient care, and inadequate training may lead to negative patient outcomes, which could harm our business, financial condition, and results of operations. The successful use of our RNS System depends in part on the training and skill of the neurosurgeon performing the implant procedure as well as the clinician, typically an epileptologist, performing the subsequent programming of our RNS System and monitoring the patient response. Clinicians **, including those practicing outside of Level 4 CECs and in the community setting,** could experience difficulty with the technique necessary to successfully implant and program our RNS System, and monitor patients if they do not receive appropriate training. Moreover, clinicians rely on their previous medical training and experience when recommending or implanting our RNS System, and we cannot guarantee that all neurosurgeons will have the necessary implantation skills to properly perform the procedure. We cannot be certain that physicians or healthcare providers that use our RNS System have received sufficient training, and physicians or healthcare providers who have not received adequate training may nonetheless attempt to use our RNS System with their patients. If clinicians implant or utilize our RNS System incorrectly, or without adhering to or completing all relevant training, their patient outcomes may not be consistent with the outcomes achieved in our clinical studies. Adverse safety outcomes that arise from improper or incorrect use of our RNS System may negatively impact the perception of patient benefit and safety of our RNS System, notwithstanding results from our clinical studies. These results could limit adoption of our RNS System in treatment for drug- resistant focal epilepsy, which would harm our sales, business, financial condition, and results of operations. We are highly dependent on our senior management team and key personnel, and our business could be harmed if we are unable to attract and retain personnel necessary for our success. We are highly dependent on our senior management and key personnel. Our success will depend on our ability to retain senior management and to attract and retain qualified personnel in the future, including sales and marketing professionals, engineers, scientists, clinical trial specialists and other highly skilled personnel and to integrate current and additional personnel in all departments. As part of our expense management initiatives, we recently implemented a pause on hiring for certain open positions and implemented or may implement additional cost saving measures that lead to reductions in force, furloughs, or altered job responsibilities across the entire organization. The pause on hiring, or turnover or reductions of members of our senior management, sales and marketing professionals, engineers, scientists and clinical trial specialists could impact decision- making as well as efficiency and could result in delays in product development and harm our business. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms, or at all. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have issued stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by fluctuations in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management and other key personnel may terminate their employment with us on short notice. Our employment arrangements with our employees provide for at- will employment, which means that any of our employees could leave our employment at any time, with or without notice. We also do not maintain " key man " insurance policies on the lives of these individuals or the lives of any of our other employees. We rely on our own direct sales force to market and sell our RNS System, and if we are unable to optimize our sales force, it could harm our business. Our operating results are directly dependent upon the sales and marketing efforts of our sales and customer support team. If our employees fail to adequately promote, market and sell our products, our sales could significantly decrease. As we launch new products, expand our product offerings and increase our marketing efforts with respect to existing products, we will need to expand the reach of our marketing and sales networks. Our future success will depend largely on our ability to continue to hire, train, retain and motivate skilled employees with significant technical knowledge in various areas. An inability to attract, hire, train and retain employees will harm our sales, business, financial condition, and results of operations. We expect to increase the size of our organization in the future, and we may experience difficulties in managing the operational elements or timing of this growth. If we are unable to manage or appropriately time the anticipated growth of our business, our future revenue and operating results may be harmed. As of December 31, ~~2022~~ **2023**, we had ~~167~~ **171** employees. As our sales and marketing strategies evolve and as we continue operating as a public company, we may need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including: • identifying, recruiting, integrating, maintaining and motivating additional employees; • managing our internal development efforts effectively, while complying with our contractual obligations to contractors and other third parties; and • improving our operational, financial and management controls, reporting systems and procedures. Our future financial performance and our ability to successfully market and sell our RNS System will depend, in

part, on our ability to effectively manage or time any future growth, and our management may also have to divert a disproportionate amount of attention away from day- to- day activities in order to devote a substantial amount of time to managing these growth activities. As demand for our RNS System increases, we will need to continue to scale our capacity at our manufacturing facility, expand customer service, billing and systems processes and enhance our internal quality assurance program. We cannot be certain that any increases in scale, related improvements and quality assurance will be successfully implemented or that appropriate personnel will be available to facilitate the growth of our business. If we encounter difficulty meeting market demand, quality standards or physician expectations, our reputation will be harmed and our business will suffer. Additionally, additional growth may result in higher fixed costs and may slow our ability to reduce costs in the face of a sudden decline in demand for our products. We may not be able to achieve or maintain satisfactory pricing and margins for our RNS System, which could harm our business and results of operations. Manufacturers of medical devices have a history of price competition, and we can give no assurance that we will be able to maintain satisfactory prices for our RNS System at the levels we have historically achieved. The pricing of our products could be impacted by several factors, including pressure to reduce prices by our customers due to a decline in the amount that third- party payors reimburse for implant procedures using our RNS System for clinicians providing ongoing patient care. A decline in the amount that third- party payors reimburse our customers for ongoing patient care could also make it difficult for programming centers to conduct ongoing patient support without a corresponding reduction in prices for our products. If we are forced to lower or are unable to increase the price we charge for our RNS System, our gross margins will decrease, which will harm our ability to invest in and grow our business. If we are unable to maintain our prices, or if our costs increase and we are unable to offset such increase with an increase in our prices, our margins could erode, which could harm our business and results of operations. Our results..... affect our business, financial condition, and results of operations. We are seeking expanded FDA labeling for our RNS System to be able to treat patients with generalized drug- resistant epilepsy as well as patients between the age of 12 and 17 with drug- resistant focal epilepsy, but if we are unable to broaden the indications for our RNS System to include these patients, our growth potential could be harmed. Our products are subject to extensive regulation by the FDA in the United States. Before a new medical device or a new intended use for an existing medical device can be marketed in the United States, we must first submit and receive either 510 (k) clearance pursuant to Section 510 (k) of the Food, Drug and Cosmetic Act, or the FDCA, or approval of a PMA application from the FDA, unless an exemption applies. If clinical studies do not produce results necessary to support regulatory clearance or approval to expand our indications to include patients with generalized drug- resistant epilepsy as well as patients age 12 to 17 with drug- resistant focal epilepsy, we will be unable to obtain and maintain necessary approvals to expand our indications to include these patients in accordance with our expected timelines, which could harm our growth potential. Furthermore, we could incur substantial costs and the attention of management could be diverted throughout this process. We may expand sales of our RNS System internationally in the future, but we may experience difficulties in obtaining regulatory clearance or approval or in successfully marketing our RNS System internationally even if approved. A variety of risks associated with marketing our RNS System internationally could harm our growth potential. While our RNS System is not yet approved for sale outside the United States, we may pursue regulatory and reimbursement approval pathways in markets outside of the United States. Sales of our RNS System outside of the United States will be subject to foreign regulatory requirements governing clinical studies and marketing approval, as well as additional post- approval requirements. We would incur substantial expenses in connection with any international expansion. Additional risks related to operating in foreign countries include: • differing regulatory requirements in foreign countries, including with respect to data privacy and security; • differing reimbursement regimes in foreign countries, including price controls; • unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements; • economic weakness, including inflation, or political instability in particular foreign economies and markets; • compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; • foreign taxes, including withholding of payroll taxes; • foreign currency fluctuations, which could result in increased operating expenses or reduced revenue; • difficulties staffing and managing foreign operations; • workforce uncertainty in countries where labor unrest is more common than in the United States; • potential liability under the U. S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, or comparable foreign regulations; • challenges enforcing our contractual and intellectual property rights as well as intellectual property theft or compulsory licensing, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States; and • business interruptions resulting from geopolitical actions, including tariffs, war and terrorism. These and other risks associated with international operations may harm our ability to attain or maintain profitable operations internationally, which would harm our growth potential. In addition, there can be no guarantee that we will receive approval to sell our RNS System in every international market we target, nor can there be any guarantee that any sales would result even if such approval is received. Approval in the United States, or in any other jurisdiction, does not ensure approval in other jurisdictions. Obtaining foreign approvals could result in significant delays, difficulties and costs for us and require additional studies and additional expenses. Regulatory requirements can vary widely from country to country and could delay the introduction of our RNS System in those countries. If we fail to comply with these regulatory requirements or to obtain and maintain required approvals, our target market will be reduced and our ability to generate revenue will be diminished. Our inability to successfully enter all our desired international markets and manage business on a global scale could harm our growth potential. ~~Further, there are foreign privacy laws and regulations that impose restrictions on the collection, use, storage, disclosure, transfer and other processing of personal data, including health information. For example, the European Union General Data Protection Regulation, or the GDPR, imposes stringent data protection requirements, including, for example, more robust disclosures to individuals, a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention of information, increased requirements pertaining to special categories of data, such as health data, and additional obligations regarding third- party processors in connection with the processing of the personal data. Our failure to comply with the GDPR or other applicable foreign privacy~~

~~laws or regulations or significant changes in the laws and regulations restricting our ability to obtain or use required patient information could significantly impact our business and our future business plans.~~ Risks related to government regulation and our industry If we fail to comply with U. S. federal and state laws and regulations, including fraud and abuse and other healthcare laws and regulations, such as those relating to kickbacks and false claims for reimbursement, we could face substantial penalties and our business, financial condition and results of operations could be harmed. Healthcare providers play a primary role in the distribution, recommendation, ordering and purchasing of any medical device for which we have or obtain marketing clearance or approval. Through our arrangements with healthcare professionals and hospital facilities, we are exposed to broadly applicable anti- fraud and abuse, anti- kickback, false claims and other healthcare laws and regulations that may constrain our business, our arrangements and relationships with customers, and how we market, sell and distribute our marketed medical devices. We have a compliance program, code of conduct and associated policies and procedures, but it is not always possible to identify and deter misconduct by our employees, contractors, and other third parties, including our customers, and the precautions we take to detect and prevent noncompliance may not be effective in protecting us from governmental investigations for failure to comply with applicable fraud and abuse or other healthcare laws and regulations. In the United States, we are subject to various state and federal anti- fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and federal civil False Claims Act, or the FCA. Our relationships with physicians, other health care professionals and hospitals are subject to scrutiny under these laws. There are also similar laws in other countries that we may become subject to if we expand internationally. The laws that may affect our ability to operate include, among others: • the Anti- Kickback Statute, which prohibits, among other things, knowingly and willingly soliciting, offering, receiving or paying remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual, or the purchase, order or recommendation of, items or services for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs; • federal civil and criminal false claims laws, including the FCA, and civil monetary penalties laws, which prohibits, among other things, persons or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds and knowingly making, using or causing to be made or used, a false record or statement to get a false claim paid or to avoid, decrease or conceal an obligation to pay money to the federal government; • the Health Insurance Portability & Accountability Act of 1996, or HIPAA, which applies to our customers and some of their downstream vendors and contractors, imposes criminal and civil liability for, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third- party payors, or knowingly and willfully falsifying, concealing or covering up a material fact or making a materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services ~~; • various state laws governing the privacy and security of personal information, including the California Consumer Privacy Act, or the CCPA, which became effective on January 1, 2020, and California Privacy Rights Act of 2020, or the CPRA, which amends and expands the CCPA and goes into effect in January 2023, which regulates the processing of personal information of California residents and increases the privacy and security obligations of covered companies handling such personal information. The CCPA and the CRPA requires covered companies to, amongst other things, provide new and additional disclosures to California residents, and affords such residents new abilities to access their personal information and opt out of certain sales of personal information~~ ; and • the federal Physician Payments Sunshine Act, also known as Open Payments, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program to report annually, with certain exceptions to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other " transfers of value " made to physicians, as defined by such law, other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members. State and federal regulatory and enforcement agencies continue to actively investigate violations of healthcare laws and regulations, and the U. S. Congress continues to strengthen the arsenal of enforcement tools. Most recently, the Bipartisan Budget Act of 2018, or the BBA, increased the criminal and civil penalties that can be imposed for violating certain federal health care laws, including the Anti- Kickback Statute. Enforcement agencies also continue to pursue novel theories of liability under these laws. In particular, government agencies have increased regulatory scrutiny and enforcement activity with respect to manufacturer reimbursement support activities and patient care programs, including bringing criminal charges or civil enforcement actions under the Anti-Kickback Statute, federal civil FCA and HIPAA' s healthcare fraud and privacy provisions. Achieving and sustaining compliance with applicable federal and state anti- fraud and abuse laws may prove costly. If we or our employees are found to have violated any of the above laws we may be subjected to substantial criminal, civil and administrative penalties, including imprisonment, exclusion from participation in federal healthcare programs, such as Medicare and Medicaid, and significant fines, monetary penalties, forfeiture, disgorgement and damages, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. Any action or investigation against us for the violation of these healthcare fraud and abuse laws, even if successfully defended, could result in significant legal expenses and could divert our management' s attention from the operation of our business. Companies settling federal civil FCA, Anti-Kickback Statute or civil monetary penalties law cases also may be required to enter into a Corporate Integrity Agreement with the Office of Inspector General, or OIG, in order to avoid exclusion from participation (such as loss of coverage for their products) in federal healthcare programs such as Medicare and Medicaid. Corporate Integrity Agreements typically impose substantial costs and operational burdens on companies to ensure compliance. Defending against any such actions can be detrimental to our reputation and brand and can otherwise be costly, time- consuming and may require significant personnel

resources, and may harm our business, financial condition and results of operations. In addition, the medical device industry' s relationship with physicians is under increasing scrutiny by the OIG, the U. S. Department of Justice, or the DOJ, the state attorney generals and other foreign and domestic government agencies. Our failure to comply with requirements governing the industry' s relationships with physicians or an investigation into our compliance by the OIG, the DOJ, state attorney generals and other government agencies, could harm our business, financial condition and results of operations. Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could harm our business, financial condition and results of operations. We are exposed to the risk that our employees, independent contractors, consultants, commercial partners and vendors may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or disclosure of unauthorized activities to us that violates: (i) the laws of the FDA and other similar foreign regulatory bodies, including those laws requiring the reporting of true, complete and accurate information to such regulators; (ii) manufacturing standards; (iii) healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or (iv) laws that require the true, complete and accurate reporting of financial information or data. These laws may impact, among other things, future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commissions, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical studies. We have adopted a code of conduct, employee handbook, and compliance policies, but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent these activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, imprisonment, reporting and oversight obligations, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, diminished profits and future earnings and curtailment of operations, any of which could adversely affect our ability to operate our business and our results of operations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in integrity issues, or a negative impact to our reputation or brand. Whether or not we are successful in defending against any such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations, which could harm our business, financial condition and results of operations. Regulatory compliance is expensive, complex and uncertain, and a failure to comply could lead to enforcement actions against us and other negative consequences for our business. The FDA and similar agencies regulate our products as medical devices. Complying with these regulations is costly, time- consuming, complex and uncertain. For instance, before a new medical device, or a new intended use for an existing device, can be marketed in the United States, a company must first submit and receive either 510 (k) clearance or approval of a PMA from the FDA, unless an exemption applies. FDA regulations and regulations of similar agencies are wide- ranging and include, among other things, oversight of: • product design, development, manufacturing (including suppliers **and materials**) and testing; • laboratory, preclinical and clinical studies; • product safety and effectiveness; • product labeling; • product storage and shipping; • record keeping; • pre- market clearance or approval; • marketing, advertising and promotion; • product sales and distribution; • product changes; • product recalls; and • post- market surveillance and reporting of deaths or serious injuries and certain malfunctions. Our products are subject to extensive regulation by the FDA and if we expand internationally in the future may be subject to extensive regulation by non- U. S. regulatory agencies. Further, improvements of **or changes to** our existing products, any potential new products, and new indications for use of our current products will be subject to extensive regulation, and we may require permission from regulatory agencies and ethics boards to conduct clinical studies, as well as clearance or approval from the FDA prior to commercial sale. In order to commercialize and distribute our products in markets outside of the United States, it will require approval from non- U. S. regulatory agencies. The FDA and foreign regulatory bodies can delay, limit or deny clearance or approval of a device for many reasons, including: • our inability to demonstrate to the satisfaction of the FDA or the applicable 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 body with the design or implementation of our clinical studies or the interpretation of data from clinical studies; • serious and unexpected adverse device effects experienced by participants in our clinical studies; • the data from our preclinical studies and clinical studies may be insufficient to support clearance or approval, 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 bodies to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance or approval. Failure to comply with applicable U. S. requirements regarding, for example, promoting, manufacturing or labeling our RNS System, may subject us to a variety of administrative or judicial actions and sanctions, such as Form 483 observations, warning letters, untitled letters, product recalls, product seizures, and total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution. Any enforcement action by the FDA and other comparable non- U. S. regulatory agencies could harm our business, financial condition and results of operations. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following actions: • untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties; • removal from FDA' s Voluntary Improvement Program

pilot; • unanticipated expenditures to address or defend such actions; • form 483s, or other compliance or enforcement notices, communications or correspondence, including customer notifications for repair, replacement or refunds; • recall, detention or seizure of our RNS System; • operating restrictions or partial suspension or total shutdown of production; • refusing or delaying our requests for 510 (k) clearance or PMA of new products or modified products; • operating restrictions; • seizure or detention of products; • withdrawing 510 (k) clearances or PMAs that have already been granted; • refusal to grant export approval for our RNS System; • criminal prosecution; or • civil penalties. If any of these events were to occur, it would have a negative impact on our business, financial condition and results of operations. The FDA also regulates the advertising and promotion of our RNS System to ensure that the claims we make are consistent with our regulatory clearances and approvals, that there are adequate and reasonable data to substantiate the claims and that our promotional labeling and advertising is neither false nor misleading in any respect. If the FDA determines that any of our advertising or promotional claims are misleading, not substantiated or not permissible, we may be subject to enforcement actions, including warning letters, and we may be required to revise our promotional claims and make other corrections or restitutions. Additionally, our manufacturing facility is required to comply with extensive requirements imposed by the FDA, including ensuring that quality control and manufacturing procedures conform to the QSR. As such, we will be subject to continual review and inspections to assess compliance with the QSR and adherence to commitments made in any 510 (k) or PMA application. The 510 (k) or PMA process can be expensive, lengthy and unpredictable and we will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. We may not be able to obtain necessary clearances or approvals or may be unduly delayed in doing so, which would negatively affect our business, financial condition and results of operations. Furthermore, even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the product, which may limit the market for the product. Although we have obtained PMA approval to market our RNS System, our approval can be revoked if safety or efficacy problems develop. Our operations are subject to pervasive and continuing FDA regulatory requirements, and failure to comply with these requirements could harm our business, financial condition and results of operations. Before a new medical device or service, or a new intended use for an existing product or service, **or a change to an existing product or service** can be marketed in the United States, a company must first submit and receive either 510 (k) clearance or PMA from the FDA, unless an exemption applies. In the 510 (k) clearance process, before a device may be marketed, the FDA must determine that a proposed device is substantially equivalent to a legally- marketed predicate device, which includes a device that has been previously cleared through the 510 (k) process, a device that was legally marketed prior to May 28, 1976 (pre- amendments device), a device that was originally on the U. S. market pursuant to an approved PMA and later down- classified, or a 510 (k)- exempt device. In the process of obtaining PMA approval, which was required for our RNS 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, preclinical, 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 device. The FDA and state and international authorities have broad enforcement powers. The medical device industry is now experiencing greater scrutiny and regulation by federal, state and foreign governmental authorities. Companies in our industry are subject to more frequent and more intensive reviews and investigations, often involving the marketing, business practices and product quality management. Such reviews and investigations may result in: civil and criminal proceedings; the imposition of substantial fines and penalties; the receipt of warning letters, untitled letters, demands for recalls or the seizure of our products; the requirement to enter into corporate integrity agreements, stipulated judgments or other administrative remedies; and result in our incurring substantial unanticipated costs and the diversion of key personnel and management' s attention from their regular duties, any of which may harm our business, financial condition and results of operations, and may result in greater and continuing governmental scrutiny of our business in the future. Additionally, federal, state and foreign governments and entities have enacted laws and issued regulations and other standards requiring increased visibility and transparency of interactions with healthcare providers. For example, Open Payments requires us to annually report to CMS payments and other transfers of value to U. S. physicians and certain other clinicians and U. S. teaching hospitals, with the reported information made publicly available on a searchable website. Failure to comply with these legal and regulatory requirements could impact our business, and we have had and will continue to spend substantial time and financial resources to develop and implement enhanced structures, policies, systems and processes to comply with these legal and regulatory requirements, which could harm our business, financial condition and results of operations. Modifications to our products or products we sell may require new 510 (k) clearances or PMAs or may require us to recall or cease marketing these products until clearances or approvals are obtained, which could harm our business, financial condition and results of operations. In the United States, our RNS System is marketed pursuant to a PMA order issued by the FDA. Any modifications to a PMA- approved device that could significantly affect its safety or effectiveness, including significant design and manufacturing changes, or that would constitute a major change in its intended use, manufacture, design, components, **materials,** or technology requires approval of a new PMA application or PMA supplement ~~. For instance, we believe that the change in the expected average battery life of our RNS System requires a label change, and we have submitted this to the FDA as a PMA supplement for review~~ . However, certain changes to a PMA- approved device do not require submission and approval of a new PMA or PMA supplement and may only require notice to FDA in a PMA 30- Day Notice, Special PMA Supplement- Changes Being Effected or PMA Annual Report. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer' s decision. The FDA may not agree with our decisions regarding whether new approvals are necessary **for products that we manufacture and distribute** . If the FDA disagrees with our determination and requires us to seek new PMA approvals for modifications to our previously approved products for which we have concluded that new approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties. For products that have received 510 (k) clearance,

such as our Burr Hole Cover product, modifications that could significantly affect safety and effectiveness, such as changes to the intended use or technological characteristics, may require new 510 (k) clearances or PMAs or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. Based on FDA published guidelines, the FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplemental approval or clearance; however, the FDA can review a manufacturer' s decision. Any modification to an FDA- cleared device that could significantly affect its safety or efficacy or that would constitute a major change in its intended use would require a new 510 (k) clearance, or if such modification put the device into Class III, possibly a PMA. We may not be able to obtain additional 510 (k) clearances or PMAs for new products or for modifications to, or additional indications for, our products in a timely fashion, or at all. Delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. We have made modifications to our RNS System in the past and expect to make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for these modifications, we may be required to recall and to stop selling or marketing such products as modified, which could harm our operating results and require us to redesign such products. In these circumstances, we may be subject to significant enforcement actions. The FDA may also change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may impact our ability to modify our currently approved or cleared products on a timely basis. Any of these actions could harm our business, financial condition and results of operations. Our products or products we ~~sell~~ **distribute** may be subject to recalls after receiving FDA approval or clearance, which could divert managerial and financial resources, harm our reputation and our business. The FDA has the authority to require the recall of our products or products we sell because of any failure to comply with applicable laws and regulations, or defects in design or manufacture. A government mandated or voluntary product recall by us could occur because of, for example, component failures, device malfunctions or other adverse events, such as serious injuries or deaths, or quality- related issues, such as manufacturing errors or design or labeling defects. Any future recalls of our products or products we ~~sell~~ **distribute** could divert managerial and financial resources, harm our reputation and negatively impact our business. If we initiate a correction or removal of one of our products to reduce a risk to health posed by the device, we would be required to submit a publicly available Correction and Removal report to the FDA and, in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device recall which could lead to increased scrutiny by the FDA and our customers regarding the quality and safety of our products. Furthermore, the submission of these reports has been and could be used by competitors against us and could harm our reputation, which could cause customers to delay purchase decisions, cancel orders or decide not to purchase our products and could cause patients to lose trust in and decide not to implant our RNS System. If any of our products **or products that we distribute** cause or contribute to a death or a serious injury or malfunction in certain ways, we will be required to report under applicable medical device reporting regulations, or MDRs, which can result in voluntary corrective actions or agency enforcement actions and harm our reputation, business, financial condition and results of operations. Under MDRs, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. If we fail to report events required to be reported to the FDA within the required timeframes, or at all, the FDA could take enforcement action and impose sanctions against us. Any such adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, would be costly, distract management from operating our business, could be used by competitors against us, and may harm our reputation, business, financial condition and results of operations. From time to time, we engage outside parties to perform services related to certain of our clinical studies. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to complete our clinical studies on our planned timelines, or at all, and may incur significant additional costs. From time to time, we engage consultants to help design, monitor and analyze the results of certain of our clinical studies and trials. The consultants we engage may interact with clinical investigators to enroll patients in our clinical studies. We depend on these consultants and clinical investigators to conduct clinical studies and trials and monitor and analyze data from these studies and trials under the investigational plan and protocol for the study or trial and in compliance with applicable regulations and standards, such as the FDA' s Good Clinical Practice, or GCP, guidelines and FDA human subject protection regulations. We may face delays in completing our clinical studies if these parties do not perform their obligations in a timely, compliant or competent manner. If these third parties do not successfully carry out their duties or meet expected deadlines, or if the quality, completeness or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical study protocols or for other reasons, our clinical studies or trials may need to be extended, delayed or terminated or may otherwise prove to be unsuccessful, and we may have to conduct additional studies, which would significantly increase our costs. Healthcare reform initiatives and other administrative and legislative proposals may harm our business, financial condition, results of operations and cash flows in our key markets. There have been and continue to be proposals by the federal government, state governments, regulators and third-party payors to control or manage the increased costs of healthcare and, more generally, to reform the U. S. healthcare system. Certain of these proposals could limit the prices we are able to charge for our products or the coverage and reimbursement available for our products and could limit the acceptance and availability of our products. The adoption of proposals to control costs could harm our business, financial condition and results of operations. There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future or their full impact. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may

harm: • our ability to set a price that we believe is fair for our products; • our ability to generate revenue and achieve or maintain profitability; and • the availability of capital. Further, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U. S. Congressional inquiries and proposed and enacted federal legislation designed to bring transparency to product pricing and reduce the cost of products and services under government healthcare programs, such as the recently enacted Inflation Reduction Act **of 2022** . Additionally, individual states in the United States have also increasingly passed legislation and implemented regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. Moreover, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what products to purchase and which suppliers will be included in their healthcare programs. Adoption of price controls and other cost- containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures may prevent or limit our ability to generate revenue and attain profitability. Various new healthcare reform proposals are emerging at the federal and state level. Any new federal and state healthcare initiatives that may be adopted could limit the amounts that federal and state governments will pay for healthcare products and services, and could harm our business, financial condition and results of operations. Our collection, use, storage, disclosure, transfer and other processing of sensitive and personal information **may** subject us to stringent and evolving U. S. and foreign laws, regulations ~~,~~ **and** rules, contractual obligations **, industry standards** , policies and other obligations related to data privacy and security ~~that~~ **. Our actual or perceived failure to comply with such obligations** could **lead** ~~give rise~~ to significant costs, liabilities and other risks, including as a result of investigations, inquiries, litigation, fines, legislative and regulatory action and negative press about our **data** privacy and **security** ~~data protection~~ practices, which may disrupt our business operations and harm our business and reputation, financial conditions, results of operations and prospects and cause other adverse business consequences. In the course of our operations, we receive, collect, use, generate, store, disclose, transfer, make accessible, protect, secure, dispose of, transmit, share and otherwise process **(collectively, process)** an increasing volume of sensitive ~~,~~ and personal information, including **proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, and** detailed recordings of iEEGs from patients as well as information from our employees and third parties with whom we conduct business. Our data processing activities may subject us to **numerous** data privacy and security obligations, such as various laws, rules, regulations, guidance and industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security. ~~When conducting clinical studies, we face risks associated with collecting trial participants' data, especially health data, in a manner consistent with applicable laws and regulations, such as GCP guidelines or FDA human subject protection regulations.~~ We are subject to many diverse laws and regulations relating to data privacy and security. In the United States, various federal and state regulators have adopted, or are considering adopting, laws and regulations concerning personal information and data security **, including data breach notification laws. In the past few years, numerous U. S. states — including California, Virginia, Colorado, Connecticut, and Utah — have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal information. As applicable, such rights may include the right to access, correct, or delete certain personal information, and to opt- out of certain data processing activities, such as targeted advertising, profiling, and automated decision- making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal information, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance** . Additionally, our customers may be subject to additional federal and state privacy and security laws, rules, regulations and standards, including HIPAA, that they may require us to comply with through contractual obligations. This patchwork of legislation and regulation may give rise to conflicts or differing views of personal privacy rights. ~~Additionally, new privacy rules are being enacted in the United States and globally, and existing ones are being updated and strengthened.~~ For example, the CCPA applies to personal information of consumers, business representatives, and employees, and requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights. The CCPA provides for **fines** ~~civil penalties~~ of up to $ 7, 500 per **intentional** violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA increases compliance costs and potential liability with respect to other personal ~~data~~ **information** we maintain about California residents. In addition, the California Privacy Rights Act of 2020, or CPRA, expands the CCPA' s requirements, including by adding a new right for individuals to correct their personal information and establishing a new regulatory agency to implement and enforce the law. **While** ~~Other~~ -- **the** ~~states, such as Virginia and Colorado, have also passed comprehensive privacy~~ laws ~~,~~ and **regulations of** ~~similar laws are being considered in several~~ other states ~~, as well as at the federal and local levels. While these states, like the CCPA,~~ also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us, **and** the third parties upon whom we rely. ~~In the event we expand our operations internationally, we may become subject to additional foreign data privacy and security laws, rules, regulations, requirements, and standards, which in the European Union, for instance, have been significantly reformed.~~ Outside the United States, an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, the ~~European Union' s General Data Protection Regulation, or~~ EU GDPR, the United Kingdom' s GDPR, or UK GDPR, and Canada' s Personal Information Protection and Electronic Documents Act, or PIPEDA, impose strict requirements for processing personal ~~data~~ **information** . Under ~~the~~ EU GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to € 20 million Euros **under the EU GDPR, 17. 5 million pounds sterling under the UK GDPR,** or **, in each case,** four percent of annual global revenues, whichever is greater; or private litigation related to processing of personal ~~data~~ **information**

brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the GDPR and the CCPA, require our customers to impose specific contractual restrictions on their service providers. We publish privacy policies, marketing materials, and other statements regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences. **In addition** ~~We make public statements about our use and disclosure of personal information through our privacy policies, information provided on our website and press statements. Although we endeavor~~ to ~~comply with our public statements and documentation, we may at times fail to do so or be alleged to have failed to do so. The publication of our privacy policies and other statements that provide promises and assurances about~~ data privacy and security ~~can~~ **laws, we are contractually** subject ~~us~~ to ~~potential government or legal action if they~~ **industry standards adopted by industry groups and, we** are ~~found to be deceptive~~ , ~~unfair or misrepresentative of our~~ **or may become subject to such obligations in** ~~actual practices. Any concerns about our data privacy and security practices, even if unfounded, could damage~~ the **future** ~~reputation of our business and harm our business, financial condition and results of operations~~ . Obligations related to data privacy and security are quickly changing, becoming increasingly stringent, and creating regulatory uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources and may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal ~~data~~ **information** on our behalf. We **or the third parties upon which we rely** may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties on whom we rely may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e. g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class- action claims) **and mass arbitration demands** ; additional reporting requirements and / or oversight; bans on processing personal ~~data~~ **information** ; and orders to destroy or not use personal **information. In particular, plaintiffs have become increasingly more active in bringing privacy- related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of** data **and the number of violations** . Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; inability to process personal ~~data~~ **information** or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations. ~~Significant disruptions~~ **Disruptions** in our information technology systems **or data** or those of third parties upon which we rely, whether through breaches or failures of our systems, **ransomware,** unauthorized access or otherwise, may result in both an adverse impact to our products, as well as the unauthorized use, disclosure, modification or misappropriation of patient **or other** personal **or sensitive** information, the occurrence of fraudulent activity, or other ~~data~~ **information** security- related incidents, all of which could result in adverse consequences, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences, which could have a material and adverse impact on our business, financial condition and results of operations. We are ~~increasingly~~ dependent on complex information technology systems for the ~~efficient~~ functioning of our business, including the manufacture, distribution and maintenance of our products, as well as for accounting, data storage, compliance, purchasing and inventory management purposes. **We process and** ~~Further, our products~~ collect ~~, use, store, disclose, transfer,~~ **data about trial participants in connection with clinical trials** and ~~otherwise process sensitive~~ patient data, such as detailed recordings of iEEGs to help clinicians make more informed treatment decisions and optimize their patients' care. These data are recorded by our RNS System and can be viewed by the physician during regular patient visits using the Physician Tablet or on demand through a secure website. **Further** ~~We also collect~~ , ~~use~~ **in the ordinary course of our business** , **we** ~~store, disclose, transfer,~~ and ~~otherwise~~ **the third parties upon which we rely** process a growing volume of ~~other~~ personal information and confidential, proprietary and sensitive ~~data~~ **information** , which may include procedure- based information and sensitive healthcare data, credit card ~~,~~ and other financial information, **and** insurance ~~information, and other potentially personally identifiable~~ information. Cyber- attacks, malicious internet- based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive ~~data~~ **information** and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer " hackers, " threat actors, " hacktivists, " organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation- state- supported actors. Some actors now engage and are expected to continue to engage in cyber- attacks, including without limitation nation- state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyber- attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our services. We and the third parties upon which we rely are subject to a variety of evolving threats, including but not limited to social- engineering attacks (including through **deep fakes, which may be increasingly more difficult to identify as fake, and** phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial- of- service attacks (such as credential stuffing), credential harvesting, personnel misconduct or error, ransomware attacks, supply- chain attacks, software

bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments **. Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations** . Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program. In addition, our reliance on third-party service providers could introduce new cybersecurity risks and vulnerabilities, including supply- chain attacks, and other threats to our business operations. We rely on third- party service providers and technologies to operate critical business systems to process sensitive ~~data~~ **information** in a variety of contexts, such as and without limitation, cloud- based infrastructure, data center facilities, encryption and authentication technology, employee email, content delivery to customers, and other functions. We also rely on third- party service providers to provide other products, services, parts, or otherwise to operate our business. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third- party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third- party service providers fail to satisfy their privacy or security- related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply- chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third- party partners' supply chains have not been compromised. ~~.~~We may expend significant resources or modify our business activities **(including our clinical trial activities)** to try to protect against security incidents.Additionally,certain data privacy and security obligations may require us to implement and maintain specific security measures or industry- standard or reasonable security measures to protect our information technology systems and sensitive ~~data~~ **information** .While we have implemented security measures designed to protect against security incidents,there can be no assurance that these measures will be effective.We take steps **designed** to detect **,mitigate** and remediate vulnerabilities **in our information systems (such as our hardware and / or software** , ~~but~~ **including that of third parties upon which** we **rely).We** may not ~~be able to~~ **,however,** detect and remediate all ~~vulnerabilities because the threats and techniques used to exploit the vulnerability change frequently and are often sophisticated in nature.Therefore,~~ such vulnerabilities **on** ~~could be exploited but may not be detected until after~~ a **timely basis** ~~security incident has occurred.These vulnerabilities pose material risks to our business~~ .Further,we may experience delays in ~~developing~~ **deploying remedial measures designed to address any such identified vulnerabilities.** Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive ~~data~~ **information** or our information technology systems, or those of the third parties upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to provide our services . We may expend significant resources or..... designed to address any such identified vulnerabilities . Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and / or oversight; restrictions on processing sensitive ~~data~~ **information** (including personal ~~data~~ **information**); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may cause customers to stop using our **products and** services, deter new customers from using our **products and** services, and negatively impact our ability to grow and operate our business. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We currently maintain a cybersecurity insurance policy and business interruption coverage to mitigate certain potential losses but this insurance is limited in amount, and we cannot be certain that such potential losses will not exceed our policy limits, or will cover all potential claims to which we are exposed and may not be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims. Therefore, failure to maintain or protect our information systems and data integrity effectively could harm our business, financial condition, and results of operations. In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. We face potential liability related to the privacy of health information we obtain. We may maintain, use, and share sensitive health information that we receive directly from patients that use our products, throughout the clinical study process, in the course of our research collaborations, and from healthcare providers in the course of using our products and systems. Most healthcare providers, including hospitals from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, as amended by the Health Information Technology for Economic and Clinical Health, or HITECH. We are not

currently classified as a covered entity or business associate under HIPAA and thus are not subject to its requirements or penalties. However, any person may be prosecuted under HIPAA' s criminal provisions either directly or under aiding- and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive, maintain, use, or transfer individually identifiable health information from a HIPAA- covered healthcare provider or research institution that has not satisfied HIPAA' s requirements for disclosure of individually identifiable health information. Furthermore, certain health privacy laws, data breach notification laws, consumer protection laws and genetic testing laws may apply directly to our operations or those of our collaborators and may impose restrictions on our collection, use and dissemination of individuals' health information As such, we may be subject to state laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, including certain health information, which is a broader class of information than the health information protected by HIPAA. ~~To the extent we engage in clinical studies outside the United States, we may implicate foreign data privacy and security laws and regulations, including the GDPR and legislation of the European Union member states implementing it. If we do business in international markets in the future, any failure by us or our third- party contractors to comply with the strict rules on the transfer of personal data outside of the European Union and the United Kingdom into the United States in accordance with such laws and regulations may result in the imposition of criminal and administrative sanctions on such contractors, which could adversely affect our business.~~ Moreover, patients about whom we or our contractors or collaborators obtain or share health information, as well as the providers who share this information with us or whom we share this data with, may have statutory or contractual rights that limit our ability to use and disclose the information. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could negatively affect our business, financial condition and results of operations. If we or third- party contractors or consultants fail to comply with applicable federal, state or local regulatory requirements, we could be subject to a range of regulatory actions that could affect our or our contractors' ability to develop and commercialize our products and could harm or prevent sales of our products, or could substantially increase the costs and expenses of developing, commercializing and marketing our products. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business. Additionally, data collection, privacy and security have become the subject of increasing public concern and changing preferences towards data collection, privacy and security could adversely affect patient willingness to consent to our collection of their health information. Patients may be reluctant or unwilling to consent to the collecting of their health information, and patients that have opted- in to the collection of their health information may revoke their consent at any time, including as a result of these concerns or as a result of changes to our data policies that we have implemented or may implement in the future. In particular, the success of our business depends in part on our ability to lawfully obtain health information from our patients. If patients choose not to consent to the collection of their health information as a result of these concerns, or our consent practices are found to be unlawful, this could negatively impact the growth potential for our business. Compliance with environmental laws and regulations could be expensive, and the failure to comply with these laws and regulations could subject us to significant liability. Our research, development and manufacturing operations involve the use of hazardous substances, and we are subject to a variety of federal, state and local environmental laws and regulations relating to the storage, use, handling, generation, manufacture, treatment, discharge and disposal of hazardous substances. Our products may also contain hazardous substances, and they are subject laws and regulations relating to labeling requirements and to their sale, collection, recycling, treatment, storage and disposal. Compliance with these laws and regulations may be expensive and noncompliance could result in substantial fines and penalties. Environmental laws and regulations also impose liability for the remediation of releases of hazardous substances into the environment and for personal injuries resulting from exposure to hazardous substances, and they can give rise to substantial remediation costs and to third- party claims, including for property damage and personal injury. Liability under environmental laws and regulations can be joint and several and without regard to fault or negligence, and they tend to become more stringent over time, imposing greater compliance costs and increased risks and penalties associated with violations. We cannot be certain that violations of these laws and regulations, or releases of or exposure to hazardous substances, will not occur in the future or have not occurred in the past, including as a result of human error, accidents, equipment failure or other causes. The costs of complying with environmental laws and regulations, and liabilities that may be imposed for violating them, or for remediation obligations or responding to third- party claims, could negatively affect our business, financial condition and results of operations. Clinical studies may be delayed, suspended or terminated for many reasons, which will increase our expenses and delay the time it takes to support label expansion for additional indications. We plan to continue to develop and execute clinical studies to support label retention for our products and label expansion for our products into additional epilepsy populations. We may also develop and execute clinical studies for new products or for label expansion for our current products into patient populations living with other neurologic conditions. We do not know whether future clinical studies will begin on time, need to be redesigned, enroll an adequate number of patients or be completed on schedule, if at all. The commencement and completion of clinical studies to support label retention and expansion for additional indications or for new products may be delayed, suspended or terminated as a result of many factors, including: • the delay or refusal of regulators or Institutional Review Boards, or IRBs, to authorize us to commence a clinical study at a prospective trial site; • changes in regulatory requirements, policies and guidelines; • delays or failure to reach agreement on acceptable terms with prospective clinical research organizations, or CROs, and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; • delays in patient enrollment and variability in the number and types of patients available for clinical studies ~~, including due to COVID- 19,~~ and delays in or the inability to monitor enrolled patients ~~, including due to COVID- 19~~ ; • the inability to enroll a sufficient number of patients in studies to observe statistically

significant treatment effects in the trial; • having clinical sites deviate from the trial protocol or dropping out of a study; • safety or tolerability concerns that could cause us to suspend or terminate a trial if we find that the participants are being exposed to unacceptable health risks; • regulators or IRBs requiring that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or safety concerns, among others; • lower than anticipated retention rates of patients and volunteers in clinical studies; • our CROs or clinical studies sites failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, deviating from the protocol or dropping out of a trial; • delays relating to adding new clinical study sites; and • exceeding budgeted costs due to difficulty in accurately predicting costs associated with clinical studies. We could also encounter delays if a clinical study is suspended or terminated by us, by the IRBs or the Ethics Committees of institutions at which such studies are being conducted, by the Data Safety Monitoring Board for such trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical study due to a number of factors, including failure to conduct the clinical study in accordance with regulatory requirements, including GCP regulations, or our clinical protocols, inspection of the clinical study operations or trial site by the FDA resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate safety and effectiveness, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical study. In addition, we may encounter delays if the FDA concludes that our financial relationships with investigators result in a perceived or actual conflict of interest that may have affected the interpretation of a study, the integrity of the data generated at the applicable clinical study site or the utility of the clinical study itself. Principal investigators for our clinical studies may serve as scientific advisors or consultants to us from time to time and receive cash compensation and / or stock options in connection with such services. If these relationships and any related compensation to or ownership interest by the clinical investigator carrying out the study result in perceived or actual conflicts of interest, or if the FDA concludes that the financial relationship may have affected interpretation of the study, the integrity of the data generated at the applicable clinical study site may be questioned and the utility of the clinical study itself may be jeopardized, which could result in the delay or rejection by the FDA. Any such delay or rejection could prevent us from supporting label retention and expansion for our RNS System. Risks related to our intellectual property If we are unable to obtain, maintain, protect, enforce and defend patent or other intellectual property protection for our products, or if the scope of the patent and other intellectual property protection obtained is not sufficiently broad, or as a result of our existing or any future out- licenses of our intellectual property, our competitors could develop and commercialize products similar to or competitive with our products, our ability to continue to commercialize our RNS System, or our other products, may be harmed. As with other medical device companies, our success depends in large part on our ability to obtain, maintain, protect, enforce and defend a proprietary position for our products, which will depend upon our success in obtaining and maintaining effective patent and other intellectual property protection in the United States and other countries into which we may expand our business in the future that covers our RNS System and any other products, their manufacturing processes and their intended methods of use. Furthermore, our success will also depend on our ability to enforce and defend those patents, as well as our other intellectual property. In some cases, we may not be able to obtain patents covering our products which are sufficient to prevent third parties, such as our competitors, from utilizing our products, or our competitors may have rights under current or future out- licenses of our intellectual property, which could result in our competitors developing and commercializing products similar to or competitive with our products. Any failure to obtain, maintain, protect, enforce or defend patent and other intellectual property protection with respect to our RNS System or other aspects of our business could harm our business, competitive position, financial condition and results of operations. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain, protect, enforce, and defend our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our patents. Additionally, we cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties. The patent prosecution process is expensive, time- consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection in one, several, or all geographies. Although we enter into non- disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, suppliers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, the publication of discoveries in scientific literature often lags behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. As such, we cannot be certain that we were the first to make the inventions claimed in any of our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties, including by way of our cross- license with Medtronic, and we are therefore reliant on our licensors or licensees. Therefore, these and any of our patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Furthermore, our license agreements may be terminated by the licensor. Defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example, with respect to proper priority claims, inventorship and the like, although we are unaware of any such defects that we believe are of importance. If we or any of our current or future licensors or licensees fail to obtain, maintain, protect, enforce or defend such patents and other intellectual

property rights, such rights may be reduced or eliminated. If any of our current or future licensors or licensees are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation or prosecution of our patents or patent applications, such patents or applications may be invalid and unenforceable. Any of these outcomes could impair our ability to prevent competition from third parties, which may harm our business. The strength of patent rights generally, and particularly the patent position of medical device companies, involves complex legal and scientific questions, can be uncertain, and has been the subject of much litigation in recent years. This uncertainty includes changes to the patent laws through either legislative action to change statutory patent law or court action that may reinterpret existing law or rules in ways affecting the scope or validity of issued patents. Our current or future patent applications may fail to result in issued patents in the United States or foreign countries with claims that cover our products, including our RNS System. Even if patents do successfully issue from our patent applications, third parties may challenge the validity, enforceability or scope of such patents, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful challenge to our patents could deprive us of exclusive rights necessary for the successful commercialization of our products, including our RNS System. Furthermore, even if they are unchallenged, our patents may not adequately protect our RNS System or any other products we develop, provide exclusivity for these products or prevent others from designing around our claims. If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical products could be adversely affected. If the breadth or strength of protection provided by the patents we hold or pursue with respect to our products is challenged, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize, our products. Patents have a limited lifespan. In the United States, the natural expiration of a utility patent is generally 20 years after its effective filing date and the natural expiration of a design patent is generally 14 years after its issue date, unless the filing date occurred on or after May 13, 2015, in which case the natural expiration of a design patent is generally 15 years after its issue date. However, the actual protection afforded by a patent varies from country to country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory- related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our products, we may be open to competition. Further, if we encounter delays in our development efforts, the period of time during which we could market our products under patent protection would be reduced and, given the amount of time required for the development, testing and regulatory review of planned or future products, patents protecting such products might expire before or shortly after such products are commercialized. ~~Our issued patents are expected to continue to expire through August 2038 without taking into account all possible patent term adjustments, extensions, or abandonments, and assuming payment of all appropriate maintenance, renewal, annuity, and other governmental fees.~~ As our patents expire, the scope of our patent protection will be reduced, which may reduce or eliminate any competitive advantage afforded by our patent portfolio. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or own, currently or in the future, issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own may be challenged, narrowed, circumvented or invalidated by third parties. Consequently, we do not know whether our RNS System or our other products will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative products in a non- infringing manner, which could harm our business, financial condition and results of operations. Some of our patents and patent applications may be co-owned or cross- licensed with third parties. If we give up, do not pursue, or are unable to obtain an exclusive license to any such third- party co- owners' or licensee' s interest in such patents or patent applications, such co- owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co- owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could harm our business, financial condition and results of operations. We may not be successful in obtaining necessary rights to any products or processes we may develop through acquisitions and in- licenses. We may find it necessary or prudent to acquire or obtain licenses to intellectual property or proprietary rights held by third parties that we may identify as necessary or important to our business operations. However, we may be unable to acquire or secure such licenses to any or all intellectual property or proprietary rights from third parties that we identify as necessary for our RNS System or any future products we may develop. The acquisition or licensing of third- party intellectual property or proprietary rights is a competitive area, and our competitors may pursue strategies to acquire or license third - party intellectual property or proprietary rights that we may consider attractive or necessary. Our competitors may have a competitive advantage over us due to their size, capital resources and greater development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to acquire or license third - party intellectual property or proprietary rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully acquire or license required third- party intellectual property or proprietary rights or maintain the existing licenses to intellectual property rights we have, we may have to spend time and resources to develop intellectual property ourselves or abandon development of the relevant product, both of which could harm our business, financial condition and results of operations. Patents covering our products, including our RNS System could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad, which could harm our business, financial condition and results of operations. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and

abroad. We may be subject to a third- party preissuance submission of prior art to the U. S. Patent and Trademark Office, or the USPTO, or become involved in opposition, derivation, revocation, reexamination, post- grant and inter partes review, or IPR, or interference proceedings or other similar proceedings challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, such patent rights, allow third parties to commercialize our products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third- party patent rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post- grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our priority of invention or other features of patentability with respect to our patents and patent applications. Such challenges may result in loss of patent rights, in loss of exclusivity, or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical products or limit the duration of the patent protection of our products. Such proceedings also may result in substantial cost and require significant time from our management, even if the eventual outcome is favorable to us. In addition, if we initiate legal proceedings against a third party to enforce a patent covering our products, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non- enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Defenses of these types of claims, regardless of their merit, would involve substantial litigation expense, would result in reputational harm, and would be a substantial diversion of employee resources from our business. Third parties may also raise claims challenging the validity or enforceability of our patents before administrative bodies in the United States or abroad, even outside the context of litigation, including through re- examination, post- grant review, IPR, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (such as opposition proceedings). Such proceedings could result in the revocation of, cancellation of or amendment to our patents in such a way that they no longer cover our products. The outcome for any particular patent following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant or other third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection for the patents raised in such a claim. Such a loss of patent protection would harm our business, financial condition and results of operations. The medical device industry is characterized by patent litigation and in the future we could become subject to patent or other intellectual property litigation that could be costly, result in the diversion of management' s time and efforts, require us to pay damages or prevent us from marketing our existing or future products. Patent litigation is prevalent in the medical device and diagnostic sectors. Our commercial success depends in part upon our ability and that of our suppliers to manufacture, market, sell, and use our proprietary products without infringing, misappropriating or otherwise violating the intellectual property or proprietary rights of third parties. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our products. Additional third parties may assert infringement claims against us based on existing or future intellectual property rights, regardless of merit. If we are found to infringe a third party' s intellectual property rights, we could be required to incur costs to obtain a license from such third party to continue developing and marketing our products. We may also elect to enter into such a license in order to settle pending or threatened litigation. However, we may not be able to obtain any required license on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be non- exclusive, thereby giving our competitors access to the same technologies licensed to us, and could require us to pay significant royalties and other fees. We could be forced, including by court order, to cease commercializing the infringing product. In addition, we could be found liable for monetary damages, which may be significant. If we are found to have willfully infringed a third- party patent, we could be required to pay treble damages and attorneys' fees. A finding of infringement could prevent us from commercializing our planned products in commercially important territories, or force us to cease some of our business operations, which could harm our business and cause brand and reputational harm. We could also be forced to redesign those products that contain the allegedly infringing intellectual property, which could be costly, disruptive and infeasible. Many of our employees were previously employed at, and many of our current advisors and consultants are employed by, universities or other biotechnology, medical device, healthcare, or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, advisors 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 these employees, have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee' s former employer. Furthermore, although these agreements may be difficult to enforce, we may in the future be subject to claims that these individuals are violating non- compete agreements with their former employers. These and other claims that we have misappropriated the confidential information or trade secrets of third parties can have a similar negative impact on our business to the infringement claims discussed above. Even if we are successful in defending against intellectual property claims, litigation or other legal proceedings relating to such claims may cause us to incur significant expenses, cause reputational harm, and could distract our technical and management personnel from their normal responsibilities. If we fail in defending any such claims, in addition to paying monetary damages or other settlements, we may lose valuable intellectual property rights or personnel, which could harm our business, financial condition and results of operations. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial negative impact on the price of our common shares. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately

conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of litigation or other intellectual property related proceedings could harm our business, financial condition and results of operations. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Obtaining and maintaining our patent protection depends on compliance with various procedural measures, document submissions, fee payments and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and patent applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our patents and applications. The USPTO and various non- U. S. government agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non- compliance can result in the abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could harm our business, financial condition and results of operations. Certain of our patents are, and our future owned and in- licensed patents may be, discovered through government funded programs and thus may subject to federal regulations such as " march- in " rights, certain reporting requirements and a preference for U. S.- based companies. Compliance with such regulations may limit our exclusive rights, and limit our ability to contract with non- U. S. manufacturers. Certain of our patents are, and our future owned and in-licensed patents may be, discovered through government funded programs. As a result, the U. S. government may have certain rights to intellectual property embodied in our current or future products pursuant to the Bayh- Dole Act of 1980, or the Bayh-Dole Act, and implementing regulations, which are amended from time to time. These U. S. government rights in certain inventions developed under a government- funded program include a non- exclusive, non- transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U. S. government has the right to require us or our licensors to grant exclusive, partially exclusive, or non- exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations, which are also referred to as " march- in rights. " The U. S. government also has the right to take title to these inventions if we, or the applicable licensor, fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. These time limits have recently been changed by regulation, and may change in the future. Intellectual property generated under or in collaboration with a government funded program is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. In addition, the U. S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U. S. manufacturers may limit our future ability to contract with non- U. S. product manufacturers for products covered by such intellectual property. If the U. S. government decides to exercise these rights, it is not required to engage us as its contractor in connection with doing so. These rights may permit the U. S. government to disclose our confidential information to third parties. To the extent any of our current or future intellectual property is generated through the use of U. S. government funding, the provisions of the Bayh- Dole Act may similarly apply. Any exercise by the government of any of the foregoing rights could harm our business, financial condition, results of operations and prospects. If we fail to comply with our obligations in any current or future agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business. We are and may become party to license or collaboration agreements with third parties **, such as our collaboration agreement with Rapport Therapeutics, Inc., or Rapport,** to advance our research or allow commercialization of our products. Such agreements may impose numerous obligations, such as development, diligence, payment, commercialization, funding, milestone, royalty, sublicensing, insurance, patent prosecution, enforcement and other obligations on us and may require us to meet development timelines, or to exercise certain efforts to develop and commercialize licensed products, in order to maintain the licenses. In spite of our best efforts, our licensors might conclude that we have materially breached such license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technologies covered by these license agreements. Any termination of these licenses could result in the loss of significant rights and could harm our ability to commercialize our products, and competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical to ours. We may further be required to cease our development and commercialization of certain of our products. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects. Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including: • the scope of rights granted under the license agreement and other interpretation- related issues; • whether and the extent to which our technology and processes infringe, misappropriate or otherwise violate intellectual property rights of the licensor that are not subject to the license agreement; • our right to sublicense patent and other rights to third parties under collaborative development relationships; • our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our products, and what activities satisfy those diligence

obligations; • the priority of invention of any patented technology; and • the ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our future licensors and us and our partners. In addition, the agreements under which we may license intellectual property or technology from third parties are likely to be complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our sales, business, financial condition or results of operations. Moreover, if disputes over intellectual property that we may license prevent or impair our ability to maintain future license agreements on acceptable terms, we may be unable to successfully develop and commercialize the affected products, which could have a material adverse effect on our sales, business, financial conditions or results of operations. If we are unable to obtain patent term extension under the Hatch- Waxman Amendments, our business may be materially harmed. Depending upon the timing, duration and specifics of FDA marketing approval of our products, one or more of the U. S. patents we own or license may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch- Waxman Amendments. The Hatch- Waxman Amendments permit a patent restoration term of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, even if, at the relevant time, we have an issued patent covering our product, we may not be granted an extension if we were, for example, to fail to exercise due diligence during the testing phase or regulatory review process, to fail to apply within applicable deadlines or prior to expiration of relevant patents or otherwise to fail to satisfy applicable requirements. Moreover, the time period of the extension or the scope of patent protection afforded could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval and only those claims covering the approved product, a method for using it or a method for manufacturing it may be extended. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product will be shortened and our competitors may obtain approval of competing products following our patent expiration. As a result, our ability to generate revenues could be adversely affected. Further, if this occurs, our competitors may take advantage of our investment in development and studies by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. If we do not have adequate patent protection or other exclusivity for our products, our business, financial condition or results of operations could be adversely affected. We have limited foreign intellectual property rights and may not be able to protect our intellectual property and proprietary rights throughout the world, which could harm our business, financial condition and results of operations. We have limited intellectual property rights outside the United States. Filing, prosecuting and defending patents on our products in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as in the United States. While we do not currently operate or sell our products outside of the United States, these products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. 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, which may impede on our ability to grow outside of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition and results of operations may be harmed. Changes in U. S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy- Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be

entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we could continue incurring costs without being certain that we were the first to file any patent application related to our products or invent any of the inventions claimed in our patents or patent applications. The America Invents Act also includes a number of significant changes that affect the way patent applications are prosecuted and also may affect patent litigation. These include allowing third- party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post- grant proceedings, including post- grant review, inter partes review and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U. S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Additionally, USPTO proceedings provide a venue for challenging the validity of patents at a cost must lower than district court litigation and on much faster timelines. This lower- cost, faster and potentially more potent tribunal for challenging patents could itself increase the likelihood that our own patents will be challenged. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In addition, future actions by the U. S. Congress, the federal courts and the USPTO could cause the laws and regulations governing patents to change in unpredictable ways. Any of the foregoing could harm our business, financial condition and results of operations. In addition, recent U. S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U. S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. We cannot predict how this and future decisions by the courts, the U. S. Congress or the USPTO may impact the value of our patents. Any similar adverse changes in the patent laws of other jurisdictions could also harm our business, financial condition, results of operations and prospects. We may be subject to claims, including third- party claims of intellectual property infringement, misappropriation or other violations against us or our collaborators, challenging the ownership or inventorship of our intellectual property and, if unsuccessful in any of these proceedings, we may be required to obtain licenses from third parties, which may not be available on commercially reasonable terms, or at all, or to cease the development, manufacture and commercialization of one or more of our products. The medical device industry is highly competitive and dynamic. Due to the focused research and development that is taking place by several companies, including us and our competitors, in this field, the intellectual property landscape is in flux, and it may remain uncertain in the future. As such, we may be subject to claims that current or former employees, collaborators or other third parties have an interest in our patents, trade secrets or other intellectual property as an inventor or co- inventor. Additionally, we could become subject to significant intellectual property- related litigation and proceedings relating to our or third- party intellectual property and proprietary rights. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our products, or could face third- party claims of intellectual property infringement, misappropriation or other violations, including by a licensor from whom we' ve licensed certain intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship of our patents, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our products. If we were to lose exclusive ownership of such intellectual property, other owners may be able to license their rights to other third parties, including our competitors. We also may be required to obtain and maintain licenses from third parties, including parties involved in any such disputes. Such licenses may not be available on commercially reasonable terms, or at all, or may be non- exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture and commercialization of one or more of our products. The loss of exclusivity or the narrowing of our patent claims could limit our ability to stop others from using or commercializing similar or identical technology and products. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could harm our business, financial condition and results of operations. Additionally, our commercial success depends in part on our and any potential future collaborators' ability to develop, manufacture, market and sell any products that we may develop and use our proprietary technologies without infringing, misappropriating or otherwise violating the patents and other intellectual property or proprietary rights of third parties. It is uncertain whether the issuance of any third- party patent would require us or any potential collaborators to alter our development or commercial strategies, obtain licenses or cease certain activities. The medical device industry is characterized by extensive litigation regarding patents and other intellectual property rights, as well as administrative proceedings for challenging patents, including interference, inter partes or post- grant review, derivation and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Third parties, including our competitors, may currently have patents or obtain patents in the future and claim that the manufacture, use or sale of our products infringes upon these patents. We have not conducted an extensive search of patents issued or assigned to other parties, including our competitors, and no assurance can be given that patents containing claims covering our products,

parts of our products, technology or methods do not exist, have not been filed or could not be filed or issued. In addition, because patent applications can take many years to issue and because publication schedules for pending patent applications vary by jurisdiction, there may be applications now pending of which we are unaware and which may result in issued patents which our current or future products infringe. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe. Unintentionally abandoned patents or applications can also be revived, so there may be recently revived patents or applications of which we are unaware. As the number of competitors in our market grows and the number of patents issued in this area increases, the possibility of patent infringement claims against us escalates. Moreover, we may face claims from non- practicing entities, or NPEs, which have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. Third parties, including NPEs, may in the future claim, that our products infringe or violate their patents or other intellectual property rights. In the event that any third- party claims that we infringe their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, even if we believe such claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. A court of competent jurisdiction could hold that these third- party patents are valid, enforceable and infringed by our products, which could harm our ability to commercialize any product we may develop and any other technologies covered by the asserted third- party patents. In order to successfully challenge the validity of any such U. S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U. S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U. S. patent. If we are found to infringe third- party intellectual property rights, including patents, and we are unsuccessful in demonstrating that such patents or other intellectual property rights are invalid or unenforceable, such third parties may be able to block our ability to commercialize the applicable products or technology unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be held invalid or unenforceable. Such a license may not be available on commercially reasonable terms, or at all. Even if we are able to obtain a license, the license would likely obligate us to pay significant license fees and / or royalties, and the rights granted to us might be non- exclusive, which could result in our competitors gaining access to the same technology. If we are unable to obtain a necessary license to a third- party patent on commercially reasonable terms, or at all, we may be unable to commercialize our products, or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business. Defense of infringement claims, regardless of their merit or outcome, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. In the event of a successful claim of infringement against us, we may be enjoined from further developing or commercializing the infringing products and / or have to pay substantial damages for use of the asserted intellectual property, including treble damages and attorneys' fees were we found to willfully infringe such intellectual property. Claims that we have misappropriated the confidential information or trade secrets of third parties could harm our business, financial condition and results of operations. We also might have to redesign our infringing products or technologies, which may be impossible or require substantial time and monetary expenditure. Engaging in litigation, including to defend against third- party infringement claims is very expensive, particularly for a company of our size, and time- consuming. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial negative impact on our common stock price. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings against us could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could harm our business, financial condition and results of operations. We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time- consuming and unsuccessful. Competitors may infringe our patents, or the patents of any current or future licensing partners, or we may be required to defend against claims of infringement. Our ability to enforce our patent rights against competitors who infringe our patents depends on our ability to detect such 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, our patents or the patents of our licensing partners also may become involved in inventorship, priority or validity disputes. For example, although we try to ensure that our employees, consultants and advisors are not in breach of any past contractual obligations and do not use the proprietary information or know- how of others in the work that they do for us, we may in the future become subject to claims that we or these individuals have, inadvertently or otherwise, used or disclosed intellectual property, including trade secrets or other proprietary information, of their former university or employer. Additionally, we may be subject to claims from third parties challenging intellectual property rights we regard as our own, based on claims that our agreements with employees or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations to assign inventions to a previous employer, or to another person or entity. Furthermore, while it is our policy to require all employees and contractors to execute agreements assigning relevant intellectual property to us, we may also be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. These assignment agreements may not be self- executing or adequate in scope, and may be breached or challenged, and we may be forced to bring claims against third

parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. We may not have adequate remedies for any such breaches, and such claims could harm our business, financial condition and results of operations. To counter or defend against such claims can be expensive and time- consuming and it may be necessary or we may desire to enter into a license to settle any such claims; however, there can be no assurance that we would be able to obtain a license on commercially reasonable terms, if at all. In an infringement proceeding, a court may decide that our patent is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover such technology. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our management and other personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial negative impact on our common stock price. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could harm our ability to compete in the marketplace, including ability to hire new employees or contract with independent sales representatives. Additionally, we may lose valuable intellectual property rights or personnel. Any of the foregoing could harm our business, financial condition and results of operations. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be harmed. Our registered and unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be violating or infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build or sustain name recognition among potential partners, customers and patients in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to continue to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement or dilution claims brought by owners of other trademarks. Over the long term, if we are unable to establish name recognition based on our trademarks, trade names, domain names or other intellectual property, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names or other intellectual property may be ineffective, could result in substantial costs, diversion of resources, or adverse impact to our brand and could harm our business, financial condition and results of operations. Intellectual property rights do not necessarily address all potential threats, and limitations in intellectual property rights could harm our business, financial condition and results of operations. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, may evolve, and may not adequately protect our business or permit us to maintain our competitive advantage. For example: • others may be able to make products that are similar to our products or utilize similar technology but that are not covered by the claims of our patents or that incorporate certain technology in our products that is in the public domain; • our intellectual property strategy may be limited, we may not seek protection for intellectual property that may ultimately become relevant to our business or our invention disclosure process may prove insufficient to encourage inventors to come forward with protectable intellectual property; • we, or our current or future licensors or collaborators, might not have been the first to make the inventions covered by the applicable issued patent or pending patent application that we own now or may own or license in the future; • we, or our current or future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions; • we, or our current or future licensors or collaborators, may fail to meet our obligations to the U. S. government regarding any future patents and patent applications funded by U. S. government grants, leading to the loss or unenforceability of patent rights; • others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights; • it is possible that our current or future pending patent applications will not lead to issued patents; • it is possible that there are prior public disclosures that could invalidate our patents, or parts of our patents; • it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours; • it is possible that our patents or patent applications omit individuals that should be listed as inventors or include individuals that should not be listed as inventors, which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable; • issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties; • the claims of our patents or patent applications, if and when issued, may not cover our products or technologies; • the laws of foreign countries may not protect our proprietary rights or the rights of current or future licensors or collaborators to the same extent as the laws of the United States; • the inventors of our patents or patent applications may become involved with competitors, develop products or processes that design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors; • our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; • we have engaged in scientific collaborations in the past and will continue to do so in the future and our collaborators may develop adjacent or competing products that are outside the scope of our patents; • we may not develop additional proprietary technologies that are patentable; • the patents of others may harm our business; or • we may choose not to file a patent in order

to maintain certain trade secrets or know- how, and a third party may subsequently file a patent covering such intellectual property. If we are unable to protect the confidentiality of our other proprietary information, our business and competitive position may be harmed. In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, know- how and other confidential or proprietary information that is not patentable or that we elect not to patent. However, such information can be difficult to protect, and some courts, for instance, are less willing or unwilling to protect trade secrets. To maintain the confidentiality of our trade secrets and proprietary information, we rely heavily on confidentiality provisions that we have in contracts with our employees, consultants, collaborators, suppliers, customers, and others upon the commencement of their relationship with us. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Furthermore, we may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by such third parties, despite the existence generally of these confidentiality restrictions. These contracts may not provide meaningful protection or equitable remedies for our trade secrets, know- how, or other proprietary information in the event of any unauthorized use, misappropriation, or disclosure of such trade secrets, know- how, or other proprietary information. There can be no assurance that such third parties will not breach their agreements with us, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known or independently developed by competitors. Despite the protections we do place on our intellectual property or other proprietary rights, monitoring unauthorized use and disclosure of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property or other proprietary rights have or will be adequate. 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, the laws of many foreign countries will not protect our intellectual property or other proprietary rights to the same extent as the laws of the United States. Consequently, we may be unable to prevent our proprietary technology from being exploited abroad, which could affect our ability to expand to foreign markets or require costly efforts to protect our products. We also license rights to use certain proprietary information and technology from third parties. The use of such proprietary information and technology is therefore subject to the obligations of the applicable license agreement between us and the owner. For example, the software we developed for our RNS System includes the use of open source software that is subject to the terms and conditions of the applicable open source software licenses that grant us permission to use such software. The owner of any such proprietary information or technology also might not enforce or otherwise protect its rights in the proprietary information or technology with the same vigilance that we would, which would allow competitors to use such proprietary information and technology without having to adhere to a license agreement with the owner. To the extent our intellectual property or other proprietary information protection is incomplete, we are exposed to a greater risk of direct competition. A third party could, without authorization, copy or otherwise obtain and use our products or technology, or develop similar products or technology. Our competitors could purchase our products and attempt to reverse engineer or replicate some or all of the competitive advantages we derive from our development efforts or design around our protected products or technology. Our failure to secure, protect and enforce our intellectual property rights could substantially harm the value of our products, brand and business. The theft or unauthorized use or publication of our trade secrets and other confidential business information could reduce the differentiation of our products, substantially and adversely impact our sales and commercial operations and harm our business. Additionally, the value of our investment in development or business acquisitions could be reduced and third parties might make claims against us related to losses of their confidential or proprietary information. Any of the foregoing could materially and adversely affect our business, financial condition and results of operations. Further, it is possible that others will independently develop the same or similar technology or product or otherwise obtain access to our unpatented technology, and in such cases, we could not assert any trade secret rights against such parties. Costly and time- consuming litigation could be necessary to enforce and determine the scope of our trade secret rights and related confidentiality and nondisclosure provisions. If we fail to obtain or maintain trade secret protection, or if our competitors otherwise obtain our trade secrets or independently develop technology or products similar to and potentially competing with our products, our competitive market position could be materially and adversely affected. In addition, some courts are less willing or unwilling to protect trade secrets and agreement terms that address non- competition are difficult to enforce in many jurisdictions and might not be enforceable in certain cases. We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations, systems and tools, agreements or security measures may be breached, whereby detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive and time-consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any breach. Our inability to use software licensed from third parties, or our use of open source software under license terms that interfere with our proprietary rights, could disrupt our business. Our products, including our RNS System, includes the use of open source software that is subject to the terms and conditions of the applicable open source software licenses that grant us permission to use such software. Although we monitor our use of open source software, the terms of many open source licenses to which we are subject have not been interpreted by U. S. or foreign courts, and there is a risk that such licenses could be construed in a manner that imposes unanticipated conditions or restrictions on our ability to provide our technology to our customers. Moreover, we cannot ensure that we have not incorporated additional open source software in our products in a manner that is inconsistent with the terms of the applicable license or our current policies and procedures. In the future, we could be required to seek licenses from third parties in order to continue offering our solutions, which licenses may not be available on terms that are acceptable to us, or at all. Claims related to our use of open source software could also result in litigation, require us to purchase costly licenses or require us to devote additional research and development resources to change the software underlying our technology, any of which would have a negative effect on our business, financial condition and operating results and may not be possible in a timely

manner. We and our customers may also be subject to suits by parties claiming infringement due to the reliance by our products on certain open source software, and such litigation could be costly for us to defend or subject us to injunctions enjoining us from the sale of our products that contain open source software. Alternatively, we may need to re- engineer our products or discontinue using portions of the functionality provided by our products. In addition, the terms of open source software licenses may require us to provide software that we develop using such software to others on unfavorable terms, such as by precluding us from charging license fees, requiring us to disclose our source code, requiring us to license certain of our own source code under the terms of the applicable open source license or requiring us to provide notice on our products using such code. Any such restriction on the use of our own software, or our inability to use open source or third- party software, could result in disruptions to our business or operations, or delays in our development of future products or enhancements of our existing products, such as our RNS System, which could impair our business. Risks related to financial matters We have a history of net losses, and we expect to continue to incur losses for the foreseeable future. If we do achieve profitability, we may not be able to sustain it. We have incurred losses since our inception and expect to continue to incur losses for the foreseeable future. For the years ended December 31, **2023 and** 2022 ~~and 2021~~, we reported net losses of $ **33. 0 million and $** 47 ~~. 1 million and $ 36~~. 1 million, respectively. As a result of these losses, as of December 31, ~~2022~~ **2023**, we had an accumulated deficit of approximately $ ~~470~~ **503**. ~~9~~ **8** million. We expect to continue to incur significant business expenses as we continue to enhance our efforts to promote our brand, increase sales, improve therapy effectiveness, enhance the patient and provider experience, and expand the population of eligible patients. In addition, we expect our selling, general and administrative expenses to increase as we continue to operate as a public company. The net losses that we incur may fluctuate significantly from period to period. We will need to generate significant additional revenue and improve our gross margins in order to achieve and sustain profitability. It is possible that we will not achieve profitability or that, even if we do achieve profitability, we may not remain profitable for any substantial period of time. Our failure to achieve or maintain profitability could negatively impact the value of our common stock. Our expected future capital requirements may and do depend on many factors including expanding our customer base, the expansion of our sales force, our efforts to manage our expenses, and the timing and extent of spending on updating our product to enhance our offering or expand our reach. We may need additional funding to fund our operations but additional funds may not be available to us on acceptable terms on a timely basis, if at all. We may seek funds through borrowings or through additional rounds of financing, including private or public equity or debt offerings. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Any future debt financing into which we enter may impose upon us additional covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay any dividends, repurchase our common stock, make certain investments, and engage in certain merger, consolidation or asset sale transactions. Any future debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. Furthermore, we cannot be certain that additional funding will be available on acceptable terms, if at all. If we are unable to raise additional capital or generate sufficient cash from operations to adequately fund our operations, we will need to curtail planned activities to reduce costs, which will likely harm our ability to execute on our business plan and continue operations. We are party to an existing Term Loan Agreement, which contains restrictive covenants as well as financial maintenance covenants, and if we are unable to comply with these covenants then the lenders could declare an event of default ~~wherein~~ **and** we may need to immediately repay the amounts due under the Term Loan Agreement. In September 2020, we entered into a Term Loan Agreement, or the Term Loan, pursuant to which the lender has made available to us an aggregate principal amount not to exceed $ 60. 0 million, of which, as of December 31, ~~2022~~ **2023**, we have drawn $ 50. 0 million and the remainder was available to be drawn only if we met certain financial thresholds, which we did not meet. The Term Loan contains customary affirmative and restrictive covenants, including with respect to our ability to enter into fundamental transactions, incur additional indebtedness, grant liens, pay any dividend or make any distributions to our holders, make investments, merge or consolidate with any other person or engage in transactions with our affiliates, as well as financial maintenance covenants, including minimum liquidity and annual revenue covenants. In February 2023, the Term Loan was amended to reduce the minimum annual revenue covenant **and increase the annual interest rate from 12. 5 % to 13. 5 %, effective March 1, 2023**. If we fail to comply with the covenants or payments specified in the Term Loan, the lenders could declare an event of default, which would give it the right to terminate its commitment to provide additional loans and declare all borrowings outstanding, together with accrued and unpaid interest and fees, to be immediately due and payable. In addition, borrowings under the Term Loan are secured by substantially all of our properties, rights and assets, including intellectual property. To support our continued operations and the growth of our business, we may need **access to our existing capital or** to seek additional capital through new equity or debt financings, which sources of **existing or** additional capital may not be available to us on acceptable terms or at all. If we are unable to obtain, if needed, adequate financing or financing on terms satisfactory to us, it could harm our business and growth prospects. Our operations have consumed substantial amounts of cash since inception and we intend to continue to make significant investments to support our continued business operations and growth, respond to business challenges or opportunities, enhance our products, expand the population of eligible patients, and potentially acquire complementary businesses and technologies. For the years ended December 31, **2023 and** 2022 ~~and 2021~~, our net cash used in operating activities was $ **19. 7 million and $** 36. 9 million ~~and $ 24. 6 million~~, respectively. As of December 31, ~~2022~~ **2023**, we had $ ~~77~~ **66**. ~~4~~ **5** million of cash, cash equivalents and short- term investments and $ ~~11~~ **16**. ~~0~~ **2** million in current liabilities **. Our cash is invested in major financial institutions in the United States and cash equivalents are invested in money market funds. Deposits in these financial institutions may exceed federally insured limits, and we may be exposed to credit risk on deposits in the event of default of the financial institutions to the extent account balances exceed the amount insured by the Federal Deposit Insurance Corporation**. Our future capital requirements may be significantly different from our current estimates and will depend on many factors, including our growth rate, the growth of sales and marketing teams and activities, our expense management initiatives, the expansion of the population of eligible patients, geographies we may choose to enter

and commercialize in, updates to our products, potential introduction of new products, either developed internally or acquired, the continued oversight of regulatory agencies, and the continuing market acceptance of our products. Accordingly, we may need to engage in equity or debt financings or collaborative arrangements to secure additional funds. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences and privileges superior to those of holders of our common stock. Any debt financing secured by us in the future could involve additional restrictive covenants relating to our capital- raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions. In addition, during times of economic instability, it has been difficult for many companies to obtain financing in the public markets or to obtain debt financing, and we may not be able to obtain additional financing, if needed, on commercially reasonable terms, if at all. If we are unable to **access our existing capital or** obtain adequate financing or financing on terms satisfactory to us, if needed, it could harm our business and growth prospects. Our ability to use our net operating losses to offset future taxable income may be subject to certain limitations. In general, under Section 382 of the U. S. Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an " ownership change " is subject to limitations on its ability to utilize its pre- change net operating losses, or NOLs, to offset future taxable income. A Section 382 " ownership change " generally occurs if one or more stockholders or groups of stockholders who own at least 5 % of our stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three- year period. Similar rules may apply under state tax laws. As of December 31, ~~2022~~ **2023**, we had $ ~~151~~ **155**. ~~6~~ **0** million of federal net operating loss carryforwards and $ ~~142~~ **150**. ~~6~~ **3** million of state net operating loss carryforwards. The federal and state NOL carryforwards began expiring in ~~2022~~ **2023** and 2028, for federal and state purposes, respectively. As of December 31, ~~2022~~ **2023**, the amount of federal NOL carryforwards that does not expire is $ ~~99~~ **103**. ~~1~~ **3** million (subject to certain utilization limitations). We have conducted Section 382 studies and determined that we experienced ownership changes in 2016 and in 2021 which resulted in permanent limitation of our pre- change NOL and research and development credit carryforwards. In addition, future changes in our stock ownership, some of which are outside of our control, could result in an additional ownership change under Section 382 of the Code, further limiting our ability to utilize NOLs arising prior to such ownership change in the future. There is also a risk that due to statutory or regulatory changes, such as suspensions on the use of NOLs (including California legislation enacted in June 2020 that limited the ability to use California net operating losses to offset California income for tax years beginning after 2019 and before 2023), or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities. If we identify any material weaknesses or otherwise fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately or timely report our financial condition or results of operations. We cannot be certain that the actions we may take in the future will prevent or avoid potential future material weaknesses. If we identify any material weaknesses in our internal control over financial reporting and are unable to successfully remediate them, the accuracy and timing of our financial reporting may be negatively impacted, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, investors may lose confidence in our financial reporting, and our stock price may decline as a result. Our history of recurring losses and anticipated expenditures as well as the significant amount of debt that we have incurred may affect our ability to operate our business and secure additional financing in the future. We have incurred operating losses to date and it is possible we may never generate a profit. Additionally, our obligations under the Term Loan Agreement are collateralized by substantially all of our assets, including our material intellectual property, and we are subject to customary financial and operating covenants limiting our ability to engage in various activities, which management may deem important for the business. The covenants related to the Term Loan Agreement, as well as any future financing agreements into which we may enter, may restrict our ability to finance our operations and engage in, expand or otherwise pursue our business activities and strategies. While we have not previously breached and are not currently in breach of these or any other covenants contained in our Term Loan Agreement, there can be no guarantee that we will not breach these covenants in the future. Our ability to comply with these covenants may be affected by events beyond our control, and future breaches of any of these covenants could result in a default under the loan agreement. If not waived, future defaults could cause all of the outstanding indebtedness under the term loan agreement to become immediately due and payable and terminate commitments to extend further credit. If we do not have or are unable to generate sufficient cash available to repay our debt obligations when they become due and payable, either upon maturity or in the event of a default, our assets could be foreclosed upon and we may not be able to obtain additional debt or equity financing on favorable terms, if at all, which may negatively impact our ability to operate and continue our business. Other risks facing our company ~~The~~ **Our** estimates of market opportunity and forecasts of market and revenue growth ~~included in this Annual Report on Form 10- K, including growth in the number of Level 4 CECs, epileptologists and neurosurgeons, as well as our projections related to the DIXI Medical distribution agreement,~~ may prove to be inaccurate, and even if the market in which we compete achieves the forecasted growth, our business could fail to grow at similar rates, if at all. Market opportunity estimates and growth forecasts are subject to significant uncertainty. Our estimates of the annual total addressable markets for our RNS System are based on a number of internal and third- party estimates and assumptions, including, without limitation, our assumptions relative to the number of adults with drug- resistant focal epilepsy in the United States who are treated at ~~Level 4~~ **CECs and outside of** CECs each year; the number of neuromodulation procedures annually in the United States; the **number and** growth in number of ~~Level 4~~ CECs, epileptologists, and neurosurgeons **, in the CECs and in the community setting**; the growth in number of patients referred to ~~Level 4~~ CECs **; the patients receiving neuromodulation therapy outside in the community setting**; and the potential growth of our market opportunity with the expansion of treatment to patients **in the community setting, as well as those suffering from generalized epilepsy or are** under age 18 ~~and with drug- resistant generalized epilepsy patients~~. In addition, our projections related to becoming the exclusive U. S. distributor of DIXI Medical

products are based on a number of estimates and assumptions, including, without limitation, information obtained from DIXI Medical related to historical performance and future projections. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, ~~including as a result of the COVID- 19 pandemic,~~ thereby reducing the predictive accuracy of these underlying factors. As a result, our estimates of the annual total addressable market for our RNS System may prove to be incorrect. If the actual annual total addressable market for our RNS System is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business. Alternatively, if the actual annual total addressable market for our RNS System is bigger than we have estimated, we may not be ready to manage such growth, which may impair our sales and have an adverse impact on our business **. Additionally, if our projections regarding the revenue we anticipate receiving from our collaboration with Rapport are inaccurate, we may not attain our revenue projections, which could harm our business, result in investors losing confidence in our financial reporting, and our stock price may decline** . If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit or halt the marketing and sale of our products. The expense and potential unavailability of insurance coverage for liabilities resulting from our products could harm our business and our ability to sell our products, including our RNS System. We face an inherent risk of product liability as a result of the marketing and sale of our products. Although we have established internal procedures designed to minimize risks that may arise from quality issues, there can be no assurance that we will eliminate or mitigate occurrences of these issues and associated liabilities. For example, we may be sued if our RNS System causes or is perceived to cause injury or is found to be otherwise unsuitable during manufacturing, marketing, sale, or distribution. Any such product liability claim may include, but not be limited to, allegations of defects in manufacturing, defects in design, defects in clinical study design or performance, a failure to warn of dangers inherent in the product, negligence, strict liability or a potential breach of implied or expressed warranties. In addition, we may be subject to claims against us even if the apparent injury is due to the actions of others or the pre- existing health of the patient. For example, we rely on healthcare providers to determine appropriate patients for our products and to properly and correctly implant and use our RNS System as part of a patient' s treatment protocol. If these healthcare providers are not properly trained, do not properly screen the patient, are negligent in implanting or using our RNS System or implant or use our RNS System " off- label, " the capabilities or reputation of our RNS System may be diminished or the patient may suffer critical injury. While we believe that we clearly describe the limitations of our label, we cannot prevent an epileptologist from referring a patient for an RNS System implant for off- label indications, prevent a neurosurgeon from implanting our RNS System for off- label applications, or having our RNS System programmed based on off- label considerations. In addition, we cannot guarantee that healthcare providers are adequately trained prior to incorporating our RNS System into their practice. Complications resulting from the use of our products, including use of our RNS System off- label or use by healthcare providers who have not been trained appropriately, or at all, may expose us to product liability claims and harm our reputation. We may also be subject to claims that are caused by the activities of our suppliers and vendors, such as those who provide us with components, materials, or services, which may have an impact on our products and result in product liability claims brought against us. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or halt commercialization of our products. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: • decreased demand for our products; • injury to our brand or reputation; • initiation of investigations by regulators; • costs to defend the related litigation; • increased insurance premiums; • a diversion of management' s time and our resources; • substantial monetary awards to trial participants or patients; • regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions; • loss of revenue; • exhaustion of any available insurance and our capital resources; and • the inability to market and sell our products. We believe we have adequate product liability insurance, but it may not prove to be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We currently carry product liability insurance in the amount of $ 7. 0 million in the aggregate. In the future, we may not be able to maintain or obtain insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Our insurance policy contains various exclusions, and we may be subject to a product liability claim for which we have no coverage. The potential inability to obtain sufficient product liability insurance at an acceptable cost to protect against product liability claims could prevent or inhibit the marketing and sale of products we may develop. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts, which would harm our business, financial condition and results of operations. In addition, any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, harm our patient- focused brand, negatively impact our reputation in the industry, significantly increase our expenses and reduce product sales. Some of our customers may also have difficulty in procuring or maintaining liability insurance to cover their operations, including their use of our products. Medical malpractice carriers are withdrawing coverage in certain states or substantially increasing premiums. If this trend continues or worsens, our customers may discontinue using our products and potential additional customers may opt against purchasing our products due to the cost or inability to procure insurance coverage. The failure of third parties to meet their contractual, regulatory and other obligations could adversely affect our business. We rely on suppliers, vendors, partners, consultants, and other third parties to research, develop, and partake in both the manufacturing and commercialization of our products, as well as manage certain parts of our business. In addition, in August 2022 we entered into a distribution agreement with DIXI Medical pursuant to which we became the exclusive U. S. distributor of DIXI Medical' s product line, under which DIXI Medical provides us with ongoing commercial support and supplies us with DIXI Medical products, as ordered by us. **Additionally, in November 2023, we entered into a collaboration agreement with Rapport, whereby we agreed to provide them certain data, biomarker monitoring and data analysis capabilities.** Using these third parties poses a number of risks, such as: • they may not perform

to our standards or legal requirements; • they may not produce reliable results; • they may not perform in a timely manner; • they may not maintain confidentiality of our proprietary information; • disputes may arise with respect to ownership of rights to products developed with our partners; and • disagreements could cause delays in, or termination of, the research, development or commercialization of our products or result in litigation or arbitration. Moreover, some third parties may be located in markets subject to political and social risk, corruption, infrastructure problems and natural disasters, in addition to country- specific privacy and data security risk given current legal and regulatory environments. Failure of third parties to meet their contractual, regulatory and other obligations may materially affect our business. Future legislation, potential changes in federal regulatory agency leadership, and new policies and priorities under the Biden Administration may adversely impact our company. Congress devoted substantial attention in 2021 to healthcare matters, through greater oversight of the FDA. Although the prospects for the imminent enactment of major legislation are not certain at this time, the enactment of more targeted measures may be more likely due to the increased possibility of bipartisan support for consideration of such measures. In addition, the Biden administration ~~could impose new or modified COVID- 19 programs and restrictions, and~~ may propose additional fiscal or tax measures, or additional regulatory requirements that would apply to us or our customers, thereby impacting our business, operations and profitability. Moreover, changes in the leadership and senior staffs of the FDA could impact the rulemaking, supervision, examination and enforcement priorities and policies of the agency. The potential impact of changes in agency personnel, policies and priorities on the medical device sector, including us, cannot be predicted at this time. In addition, the Biden administration has indicated an increased focus on enforcement of federal consumer protection laws and appoint consumer- oriented regulators. It is possible that regulators in the administration could promulgate rulemakings and bring enforcement actions that materially impact our business and the business of our customers. These regulators may, for example, augment requirements that apply to the medical device approval process, impose additional clinical studies requirements, or change privacy rules that impact how we maintain, use, and share sensitive healthcare data, and could otherwise revise or create new regulatory requirements that apply to us. We may not be able to respond quickly or effectively to regulatory, legislative, and other developments, and these changes may in turn impair our ability to offer our current or planned products, or increase our cost of doing business. In addition, if our practices are not consistent or viewed as not consistent with legal and regulatory requirements, we may become subject to audits, inquiries, whistleblower complaints, adverse media coverage, investigations, or criminal or civil sanctions, all of which may have an adverse effect on our reputation, business, financial condition and results of operations. Risks related to ownership of our common stock If we sell shares of our common stock in future financings, stockholders may experience immediate dilution and, as a result, our stock price may decline. We may, from time to time, issue additional shares of common stock at a discount from the current trading price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our common stockholders would experience additional dilution and, as a result, our stock price may decline. ~~We will continue to have broad discretion in the use of proceeds from our initial public offering and may invest or spend the proceeds in ways with which investors do not agree and in ways that may not yield a return. We will continue to have broad discretion over the use of proceeds from our initial public offering. Investors may not agree with our decisions, and our use of the proceeds may not yield any return on your investment. We currently are using or intend to use the net proceeds from our initial public offering to expand our sales and marketing efforts, increase our research and development activities, conduct or sponsor clinical studies, expand internationally, and provide for working capital and other general corporate purposes. We also used a portion of the net proceeds we received from our initial public offering to repay approximately $ 4. 0 million of principal indebtedness, plus accrued interest, under our Paycheck Protection Program loan. Our failure to apply the net proceeds of our initial public offering effectively could impair our ability to pursue our growth strategy or could require us to raise additional capital. In addition, pending their use, the proceeds of our initial public offering may have been or could be placed in investments which may not produce income or that may lose value.~~ Sales of a substantial number of shares of our common stock in the public market could cause the market price of our common stock to decline. Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock. As of December 31, ~~2022~~ **2023**, we had a total of approximately **27. 8 million** ~~25, 045, 751~~ shares outstanding of common stock, of which **11. 1 million** ~~15, 105, 804~~ shares are held by directors, executive officers and other affiliates. These shares will be subject to volume limitations under Rule 144 under the Securities Act, and may also be subject to vesting requirements. As of December 31, ~~2022~~ **2023**, there were approximately **6.** 7 **million** ~~, 076, 678~~ shares of common stock ~~subject to outstanding stock options and restricted stock units (RSUs) or~~ reserved for future issuance under our equity incentive plans. All of the shares of common stock issuable upon exercise of outstanding stock options, vesting and settlement of **restricted stock units, or** RSUs, and exercise ~~of~~ **or** settlement of any ~~options or~~ other equity incentives are registered for public resale under the Securities Act. Accordingly, these shares will be able to be freely sold in the public market upon issuance as permitted by any applicable vesting requirements, subject to the lock- up agreements and, for our affiliates, volume limitations described above. In addition, certain of our stockholders have registration rights that would require us to file registration statements for the public resale of the common stock issuable upon conversion of such shares or to include such shares in registration statements that we may file on our behalf or for other stockholders. Concentration of ownership of our common stock among our executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions. Based on the number of shares of common stock outstanding as of December 31, ~~2022~~ **2023**, our executive officers, directors and current beneficial owners of 5 % or more of our common stock, in the aggregate, beneficially own, approximately ~~85~~ **73**. ~~9~~ **0** % of our common stock. These stockholders,

acting together, will be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors and any merger or other significant corporate transactions. The interests of this group of stockholders may not coincide with the interests of other stockholders and they may want us to pursue strategies that deviate from the interests of other stockholders. We are an emerging growth company and a smaller reporting company, and our compliance with the reduced reporting and disclosure requirements applicable to emerging growth companies and smaller reporting companies could make our common stock less attractive to investors. We are an emerging growth company, as defined in the JOBS Act, and we expect to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved and extended adoption period for accounting pronouncements. Even after we no longer qualify as an emerging growth company, we may still qualify as a " smaller reporting company, " which would allow us to continue to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act and reduced disclosure obligations regarding executive compensation in this Annual Report on Form 10- K and our periodic reports and proxy statements. We cannot predict whether investors will find our common stock less attractive as a result of our reliance on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We will remain an emerging growth company until the earliest of (i) December 31, 2026, (ii) the first fiscal year after our annual gross revenues exceed $ 1. ~~07~~ **235** billion, (iii) the date on which we have, during the immediately preceding three- year period, issued more than $ 1. ~~00~~ **0** billion in non- convertible debt securities, or (iv) the end of any fiscal year in which the market value of our common stock held by non- affiliates exceeds $ 700 million as of the end of the second quarter of that fiscal year. ~~Anti- takeover provisions~~ **Provisions** in our **corporate** charter **documents** and under Delaware law could make an acquisition of **us, which may be beneficial to** our ~~company~~ **stockholders,** more difficult ~~, limit~~ **and may prevent** attempts by our stockholders to replace or remove our current management ~~and limit the market price of our common stock~~ . Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may have the effect of delaying or preventing a change of control or changes in our management without the consent of our board of directors. Our amended and restated certificate of incorporation and amended and restated bylaws include provisions that: • provide for a classified board of directors whose members serve staggered terms; • authorize our board of directors to issue, without further action by the stockholders, shares of undesignated convertible preferred stock with terms, rights, and preferences determined by our board of directors that may be senior to our common stock; • require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent; • specify that special meetings of our stockholders can be called only by our board of directors, the chairperson of our board of directors, or our chief executive officer; • establish an advance notice procedure for stockholder proposals to be brought before an annual meeting, including proposed nominations of persons for election to our board of directors; • prohibit cumulative voting in the election of directors; • provide that our directors may be removed for cause only upon the vote of the holders of at least 66 2 / 3 % of our outstanding shares of common stock; • provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum; and • require the approval of our board of directors or the holders of at least 66 2 / 3 % of our outstanding shares of common stock entitled to vote at an election of directors to adopt, to amend our bylaws and certain provisions of our certificate of incorporation. 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, which is responsible for appointing the members of our management. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally, subject to certain exceptions, prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any " interested " stockholder for a period of three years following the date on which the stockholder became an " interested " stockholder. Any delay or prevention of a change of control transaction or changes in our management could cause the market price of our common stock to decline. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware or, under certain circumstances, the federal district courts of the United States of America be the exclusive forums for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) is the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law for: • any derivative action or proceeding brought on our behalf; • any action asserting a breach of fiduciary duty; • any action arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation, or our amended and restated bylaws; and • any action asserting a claim against us that is governed by the internal- affairs doctrine. These provisions do not apply to suits brought to enforce a duty or liability created by the Exchange Act or any claim for which the federal district courts of the United States of America have exclusive jurisdiction. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. Our stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of, and consented to, the provisions of our amended and restated certificate of incorporation, including those described in the preceding sentences. To prevent having to litigate claims in multiple jurisdictions and the threat

of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provide that the federal district courts of the United States be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid and several state trial courts have enforced such provisions and required that suits asserting Securities Act claims be filed in federal court, there is no guarantee that courts of appeal will affirm the enforceability of such provisions and a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions. If a court were to find either exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with litigating Securities Act claims in state court, or both state and federal court, which could harm our business, financial condition, results of operations, and prospects. These exclusive forum provisions may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive- forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could harm our business and financial condition. General risk factors **Unstable market** ~~Unfavorable U. S.~~ and **economic conditions may have serious adverse consequences on our business, financial condition and share price. The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, increases in inflation rates, changes in interest rates and uncertainty about economic stability. For example, the Russia- Ukraine war and the conflict in the Middle East has created extreme volatility in the global capital markets and is expected to have further** global economic **consequences** ~~conditions could adversely affect our business~~ , **including disruptions** ~~financial condition or results~~ of ~~operations. Our results of operations could be adversely affected by general conditions in~~ the ~~U. S. economy and financial markets and adverse geopolitical and macroeconomic developments. U. S. and~~ global ~~market and economic conditions have been, and continue to be, disrupted and volatile due to many factors, including component shortages and related~~ supply chain ~~challenges, geopolitical developments~~ **and energy markets. Any** such **volatility** ~~as the ongoing COVID- 19 pandemic~~ and **disruptions may have adverse consequences on us** ~~the conflict between Ukraine and Russia and related sanctions, and increasing inflation rates and the responses by central banking authorities to control such inflation, among others. General business and economic conditions that could affect our~~ - **or** ~~business~~ **the third parties on whom we rely. If the equity and credit markets deteriorate** , **it may make any necessary** ~~financial condition or results of operations include fluctuations in economic growth,~~ debt ~~and~~ **or** equity ~~capital markets, liquidity of the global financial~~ **financing more difficult to obtain** ~~markets, the availability and cost of credit, investor and consumer confidence, and the strength of the economies~~ in ~~which we,~~ **a timely manner** ~~our~~ - **or** ~~manufacturers and~~ **on favorable terms, more costly** ~~our~~ - **or** ~~suppliers operate~~ **more dilutive** . A severe or prolonged global economic downturn could result in a variety of risks to our business. For example, inflation rates, particularly in the United States, have increased recently to levels not seen in years, and increased inflation may result in increases in our operating costs (including our labor costs), reduced liquidity and limits on our ability to access credit or otherwise raise capital on acceptable terms, if at all. In addition, the U. S. Federal Reserve has raised, and may again raise, interest rates in response to concerns about inflation, which ~~,~~ coupled with reduced government spending and volatility in financial markets may have the effect of further increasing economic uncertainty and heightening these risks. ~~Risks of a prolonged global economic downturn are particularly true in Europe, which is undergoing a continued severe economic crisis.~~ A weak or declining economy could also strain our suppliers and manufacturers, possibly resulting in supply ~~disruption~~ **disruptions** . Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business. ~~Additionally, financial markets around the world experienced volatility following the recent invasion of Ukraine by Russia. Our operations could be disrupted by tariffs, international conflict or war. For example, in late February 2022, Russia initiated significant military action against Ukraine. In response, the United States and certain other countries imposed significant sanctions and trade actions against Russia, and the United States and certain other countries could impose further sanctions, trade restrictions and other retaliatory actions should the conflict continue or worsen. It is not possible to predict the broader consequences of the conflict, including related geopolitical tensions, and the measures and retaliatory actions that may be taken by the United States and other countries in respect thereof, as well as any counter measures or retaliatory actions by Russia in response. Such conflict may cause regional instability, geopolitical shifts and could materially adversely affect global trade, currency exchange rates, regional economies and the global economy. In particular, while it is difficult to anticipate the impact of any of the foregoing on us, the conflict and actions taken in response to the conflict could increase our costs, disrupt our supply chain, reduce our sales and earnings, impair our ability to raise additional capital when needed on acceptable terms, if at all, or otherwise adversely affect our business, financial condition and results of operations.~~ Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses. Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, **public health crises** ~~medical epidemics or pandemics~~ , and other natural or man- made disasters or business interruptions, for which we are predominantly self- insured. Our ability to obtain components for our products could be disrupted if the operations of our suppliers were affected by a man- made or natural disaster or other business interruption. In addition, our corporate headquarters and manufacturing facility is located in Mountain View, California, near major earthquake faults and fire zones. Should our

facilities be significantly damaged or destroyed, it could take months to relocate or rebuild, during which time our manufacturing would cease or be delayed and our RNS System may be unavailable. Moreover, the use of a new facility or new manufacturing, quality control, or environmental control equipment or systems generally requires FDA review and approval of a PMA supplement. Because of the time required to authorize manufacturing in a new facility under FDA regulatory requirements, we may not be able to resume production on a timely basis even if we are able to replace production capacity. While we maintain property and business interruption insurance, such insurance has limits and would only cover the cost of rebuilding and relocating and, to some extent, lost revenue, but not general damage or losses caused by earthquakes or losses we may suffer due to our products being replaced by competitors' products. The inability to perform our manufacturing activities, combined with our limited inventory of materials and components and manufactured products, may cause physicians to discontinue using our products or harm our reputation, and we may be unable to reestablish relationships with such physicians in the future. Consequently, a catastrophic event at our facility could harm our business, financial condition, and results of operations. Litigation and other legal proceedings may harm our business. We are involved in, and from time to time in the future we may become involved in, legal proceedings relating to patent and other intellectual property matters, product liability claims, employee matters, tort or contract claims, federal regulatory investigations, private rights of action, securities matters and class actions as well as other legal proceedings or investigations, which could have a negative impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business. Litigation is inherently unpredictable and can result in excessive or unanticipated verdicts, judgements, and / or injunctive relief that affect how we operate our business. We could incur judgments or enter into settlements of claims for monetary damages or for agreements to change the way we operate our business, or both. We may fail to enter into settlements or to obtain rulings for matters we believe we have resolved. There may be an increase in the scope of these or other matters or there may be additional lawsuits, claims, proceedings or investigations in the future, which could harm our business, financial condition and results of operations. Adverse publicity about regulatory or legal action against us, irrespective of outcome, could damage our reputation and brand image, undermine our customers' confidence and reduce long- term demand for our products, even if the regulatory or legal action is unfounded or not material to our operations. Our stock price has been volatile, an active or liquid market in our common stock may not be sustainable and the value of our common stock may decline. Historically, our stock price has been volatile. During the year ended December 31, ~~2022~~ **2023** , our stock traded as high as $ ~~11~~ **10** . ~~57~~ **31** per share and as low as $ 1. ~~29~~ **44** per share. An active or liquid market in our common stock may not be sustainable and the market price of our common stock may continue to be highly volatile and may fluctuate or decline substantially as a result of a variety of factors, some of which are beyond our control or are related in complex ways, including: • actual or anticipated fluctuations in our financial condition and results of operations; • variance in our financial performance from expectations of securities analysts or investors; • changes in the coverage decisions, reimbursement or pricing of our products; • changes in our projected operating and financial results; • changes in laws or regulations applicable to our products; • announcements by us or our competitors of significant business developments, acquisitions, or new offerings; • publicity associated with issues related to our products; • our involvement in regulatory investigations or litigation; • future sales of our common stock or other securities, by us or our stockholders, as well as the anticipation of lock- up releases; • changes in senior management or key personnel; • the trading volume of our common stock; • changes in the anticipated future size and growth rate of our market; • general economic, regulatory, and market conditions, including economic recessions or slowdowns ~~; • the impact of the COVID- 19 pandemic~~ ; • changes in the structure of healthcare payment systems; and • developments or disputes concerning our intellectual property or other proprietary rights. Broad market and industry fluctuations, as well as general economic, political, regulatory, and market conditions, may negatively impact the market price of our common stock. In addition, given the relatively small public float of shares of our common stock on the Nasdaq Global Market, the trading market for our shares may be subject to increased volatility. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us, because medical device companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management' s attention and resources, which could harm our reputation and our business. If securities or industry analysts do not continue to publish research or publish unfavorable or inaccurate research about our business, our common stock price and trading volume could decline. Our stock price and trading volume will be heavily influenced by the way analysts and investors interpret our financial information and other disclosures. If securities or industry analysts do not continue to publish research or reports about our business, delay publishing reports about our business or publish negative or unfavorable reports about our business, regardless of accuracy, our common stock price and trading volume could decline. The trading market for our common stock depends, in part, on the research and reports that securities or industry analysts publish about us or our business. We expect that only a limited number of analysts will cover our company and we do not have any control over these analysts. If the number of analysts that cover us declines, demand for our common stock could decrease and our common stock price and trading volume may decline. Even if our common stock is actively covered by analysts, we do not have any control over the analysts or the measures that analysts or investors may rely upon to forecast our future results. Over- reliance by analysts or investors on any particular metric to forecast our future results may result in forecasts that differ significantly from our own. Regardless of accuracy, unfavorable interpretations of our financial information and other public disclosures could have a negative impact on our stock price. If our financial performance fails to meet analyst estimates, for any of the reasons discussed above or otherwise, or one or more of the analysts who cover us downgrade our common stock or change their opinion of our common stock, our reputation may be adversely impacted and our stock price would likely decline. We are obligated to develop and maintain proper and effective internal control over financial reporting and any failure to maintain the adequacy of these internal controls may negatively impact investor confidence in our company and, as a result, the value of our common stock. We are required pursuant to Section 404 of the Sarbanes- Oxley Act to include in our annual reports ~~, the first of which being for~~

~~the year ending December 31, 2022,~~ a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment needs to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. In addition, our independent registered public accounting firm is required to attest to the effectiveness of our internal control over financial reporting in our first annual report required to be filed with the Securities and Exchange Commission, or the SEC, following the date we are no longer an emerging growth company. We have not yet commenced the costly and challenging process of compiling the system and process documentation necessary to perform the evaluation required under Section 404. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge and compile the system and process documentation necessary to perform the evaluation needed to comply with Section 404. Any failure to maintain effective internal control over financial reporting could severely inhibit our ability to accurately report our financial condition or results of operations. If we are unable to conclude that our internal control over financial reporting is effective, or if we identify additional material weaknesses in our internal control over financial reporting, our reputation could be negatively impacted, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, we could be subject to sanctions or investigations by the Nasdaq Global Market, the SEC or other regulatory authorities and our access to the capital markets could be restricted in the future. Our operating results may fluctuate across periods, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations ~~or any guidance we may provide~~ . Our quarterly and annual operating results may fluctuate across periods, which makes it difficult for us to predict our future operating results. Accordingly, the results of any one quarter or period should not be relied upon as an indication of future performance. Our quarterly and annual operating results may fluctuate due to a variety of factors, many of which are outside of our control, including, but not limited to: • the level of demand for our products and any future products, which may vary significantly from period to period; • expenditures that we may incur to acquire, develop or commercialize additional products and technologies; • the timing and cost of obtaining regulatory approvals or clearances to expand our indications and get future approvals of any future products or features; • pricing pressures; • our ability to expand the geographic reach of our commercial efforts; • the degree of competition in our industry and any change in the competitive landscape of our industry, including consolidation among our competitors or future partners; • coverage and reimbursement policies with respect to our products, and potential future products that compete with our products; • the timing and success or failure of preclinical or clinical studies for expanding the indications of our RNS System or any future products we develop or competing products; • positive or negative coverage in the media or clinical publications of our products or products of our competitors or our industry; • the timing of customer orders or scheduling of implants using our products and the number of available selling days in any quarterly period, which can be impacted by holidays, vacations, the mix of products sold and the geographic mix of where products are sold, including any related foreign currency impact; • the impact of ~~COVID- 19~~ **hospital accessibility and staffing shortages** on procedure volume or otherwise; • the timing and cost of, and level of investment in, research, development, licenses, regulatory approval, commercialization activities, acquisitions and other strategic transactions, or other significant events relating to our products, which may change from time to time; • the cost of manufacturing our products, which may vary depending on the quantity of production and the terms of our agreements with third- party suppliers; and • future accounting pronouncements or changes in our accounting policies. The cumulative effects of these factors could result in fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period- to- period basis may not be meaningful. Further, our historical results are not necessarily indicative of results expected for any future period, and quarterly results are not necessarily indicative of the results to be expected for the full year or any other period. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, it could harm our business, financial condition, and results or operations **. Our actual operating results may differ significantly from any guidance provided. Our guidance, including forward- looking statements, is prepared by management and is qualified by, and subject to, a number of assumptions and estimates that, while presented with numerical specificity, are inherently subject to significant business, economic and competitive uncertainties and contingencies. Many of these uncertainties and contingencies are beyond our control and are based upon specific assumptions with respect to future business decisions, some of which will change. We generally state possible outcomes as high and low ranges, which are intended to provide a sensitivity analysis as variables are changed but are not intended to represent that actual results could not fall outside of the suggested ranges. Guidance is necessarily speculative in nature, and it can be expected that some or all of the assumptions of the guidance furnished by us will not materialize or will vary significantly from actual results. In particular, guidance offered in periods of extreme uncertainty, such as the uncertainty caused by macroeconomic conditions, is inherently more speculative in nature than guidance offered in periods of relative stability. Accordingly, any guidance with respect to our projected financial performance is necessarily only an estimate of what management believes is realizable as of the date the guidance is given. Actual results will vary from the guidance and the variations may be material. Investors should also recognize that the reliability of any forecasted financial data will diminish the farther in the future that the data is forecasted. Actual operating results may be different from our guidance, and such differences may be adverse and material. In light of the foregoing, investors are urged to put the guidance in context and not to place undue reliance on it. In addition, the market price of our common stock may reflect various market assumptions as to the accuracy of our guidance. If our actual results of operations fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially** . We will continue to incur increased costs as a result of operating as a public company, and our management and board of directors will be required to devote substantial time to compliance with our public company responsibilities and corporate governance

practices. As a public company, we have and will continue to incur significant legal, accounting, and other expenses. We expect such expenses to further increase after we are no longer an emerging growth company. The Sarbanes- Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Market, and other applicable securities rules and regulations impose various requirements on public companies. Furthermore, most senior members of our management team as well as our board of directors do not have significant experience with operating a public company. As a result, our management, board of directors, and other personnel will have to devote a substantial amount of time to compliance with these requirements. Moreover, these rules and regulations will drive high legal and financial compliance costs and will make some activities more time- consuming and costly. We cannot predict or estimate the amount of these additional costs or the timing of such costs. We may become subject to numerous laws and regulations related to anti- bribery and anti-corruption laws, such as the FCPA and the U. K. Bribery Act, in which violations of these laws could result in substantial penalties and prosecution. We currently do not market and sell our products outside the United States. However, if we choose to conduct business outside the United States, our business will be subject to various heavily- enforced anti- bribery and anti-corruption laws, such as the FCPA and similar laws around the world. These laws generally prohibit U. S. companies and their employees and intermediaries from offering, promising, authorizing or making improper payments to foreign government officials for the purpose of obtaining or retaining business or gaining any advantage. We face significant risks if we, which includes our third- party business partners and intermediaries, fail to comply with the FCPA or other anti- corruption and anti-bribery laws. In many foreign countries, particularly in countries with developing economies, it may be a local custom that businesses engage in practices that are prohibited by the FCPA or other applicable laws and regulations. To that end, we may have to incur substantial costs to enhance our controls if we begin doing business outside the United States, and even so, such compliance measures ultimately may not be effective in prohibiting our employees, contractors, business partners, intermediaries or agents from violating or circumventing our policies and / or the law. Responding to any enforcement action or related investigation may result in a significant diversion of management' s attention and resources and significant defense costs and other professional fees. Any violation of the FCPA or other applicable anti- bribery, anti- corruption or anti- money laundering laws to which we become subject could result in whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and, in the case of the FCPA, suspension or debarment from U. S. government contracts, which could harm our business, financial condition and results of operations. We may partner with or acquire other businesses, which could require significant management attention, disrupt our business, dilute stockholder value and harm our results of operations. As part of our business strategy, we may in the future partner with, make acquisitions of or investments in complementary companies, products or technologies that we believe fit within our business model and can address the needs of our customers and the patients they serve. In the future, we may not be able to acquire and integrate other companies, products or technologies in a successful manner. We may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such partnership or acquisitions in an appropriate timeframe and on favorable terms, if at all. In addition, the pursuit of potential acquisitions may divert the attention of management and cause us to incur additional expenses in identifying, investigating and pursuing suitable partnerships or acquisitions, whether or not they are consummated. If we do complete partnerships or acquisitions, we may not ultimately strengthen our competitive position or achieve our goals, including increases in revenue, and any acquisitions we complete could be viewed negatively by management, as well as our employees, customers, investors and industry analysts. Future partnerships or acquisitions may reduce our cash available for operations and other uses and could result in amortization expense related to identifiable assets acquired. We may have to pay cash, incur debt or issue equity securities to pay into or for any such partnerships or acquisition, each of which could adversely affect our financial condition or the value of our common stock. The sale or issuance of equity to finance any such partnerships or acquisitions would result in dilution to our stockholders. The incurrence of indebtedness to finance any such partnerships or acquisition would result in fixed obligations and could also include covenants or other restrictions that could impede our ability to manage our operations. In addition, our future results of operations may be harmed by the dilutive effect of an acquisition, performance earn- outs or contingent bonuses associated with an acquisition. Furthermore, partnerships or acquisitions may require large, one- time charges and can result in increased debt or contingent liabilities, a negative impact to our gross margins, adverse tax consequences, additional stock- based compensation expenses and the recording and subsequent amortization of amounts related to certain purchased intangible assets, any of which items could negatively affect our future results of operations.