

Risk Factors Comparison 2025-03-20 to 2024-04-16 Form: 10-K

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We rely on a sole manufacturer for the production of our products. We do not have control over the operations of the facilities of the third- party manufacturer that we use. A significant disruption to our manufacturer could have a material adverse effect on our business, financial condition and results of operations. Our reliance on our manufacturer poses a number of risks, including lack of control over the manufacturing process and ultimately over the quality and timing of delivery of our product. A change in our relationship with our manufacturer could result in a material adverse effect on our business, financial condition and results of operations. A decision to change manufacturers would result in longer times for design and production as we secure any necessary licenses or clearances, develop quality control measures, and implement manufacturing processes. Continued testing of our products may not yield successful results and could reveal currently unknown aspects or safety hazards associated with our products. Our research and development programs are designed to test the safety and efficacy of our products through extensive pre- clinical and clinical testing. Even if our ongoing and future pre- clinical and clinical studies are completed as planned, we cannot be certain that their results will support our claims or that the FDA and other regulatory authorities will agree with our conclusions. Success in pre- clinical studies and early clinical studies does not ensure that later clinical studies will be successful, and we cannot be sure that the later studies will replicate the results of prior studies and pre- clinical studies. The clinical study process may fail to demonstrate that our device candidates are safe and effective for the proposed indicated uses, which could cause us to abandon a device candidate and may delay development of others. It is also possible that patients enrolled in clinical studies will experience adverse side effects that have not been previously observed. In addition, our pre- clinical and clinical studies for our device candidates involve a relatively small patient population and, as a result, these studies may not be indicative of future results. We may experience numerous unforeseen events during, or as a result of, the testing process that could delay or prevent further commercialization of our products, including the following: • pre- clinical and clinical testing for our products may not produce the desired effect, may be inconclusive or may not be predictive of safety or efficacy results obtained in future clinical studies, following long- term use or in much larger populations; • unanticipated adverse events or other side effects that are not currently known may occur during our clinical studies that may preclude additional regulatory approval or result in additional limitations to commercial use if approved; and • the data collected from our clinical studies may not reach statistical significance or otherwise not be sufficient to support FDA or other regulatory approval. If unacceptable side effects arise in the development of our products for future indications, we could suspend or terminate our clinical studies or the FDA or other regulatory authorities could order us to cease clinical studies or deny approval of our device candidates for any or all targeted indications, narrow the approved indications for use or otherwise require restrictive product labeling or marketing or require further clinical studies, which may be time- consuming and expensive and may not produce results supporting FDA or other regulatory approval of our products in a specific indication. Treatment- related side effects could also affect patient recruitment or the ability of enrolled patients to complete the study or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have a need to train medical personnel using our devices for clinical studies and upon any commercialization of our products for future indications. Inadequate training in recognizing or managing the potential side effects of our products could result in patient injury or death. Any of these occurrences may harm our business, prospects and financial condition significantly. Any delay or termination of our clinical studies will delay the filing of submissions for regulatory approvals of our products and ultimately our ability to commercialize our products and generate revenues. Furthermore, we may abandon our products for indications that we previously believed to be promising. Any of these events could have a material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline. As we expand, we may experience difficulties managing our growth. Our anticipated growth will place a significant strain on our management and on our operational and financial resources and systems. We could face challenges inherent in efficiently managing a more complex business with an increased number of employees over large geographic distances, including the need to implement appropriate systems, policies, benefits and compliance programs. Failure to manage our growth effectively could materially adversely affect our business. Additionally, our anticipated growth will increase the demands placed on our third- party suppliers, resulting in an increased need to carefully monitor the available supply of components and services and to scale up our quality assurance programs. There is no guarantee that our suppliers will be able to support our anticipated growth. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our development and commercialization goals. The size and expected growth of our available market has not been established with precision and may be smaller than we estimate. Our data on the available market for our current products and future products is based on a number of internal and third- party research reports, estimates and assumptions. While we believe that such research, our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct. In addition, the statements in this prospectus relating to, among other things, the expected growth in the market for our IB- Stim are based on a number of internal and third- party data, estimates and assumptions, and may prove to be inaccurate. If the actual number of consumers who would benefit from our products, the price at which we can sell future products or the available market for our products is smaller than we estimate, it could have a material adverse effect on our business, financial condition and results of operations. If physicians and patients do not accept our current and future products or if the market for indications for which any product candidate is approved is smaller than expected, we may be unable to generate significant revenue, if any. Even when any of our product candidates obtain regulatory approval, they may not gain market acceptance among physicians, patients, and

third- party payers. Physicians may decide not to recommend our treatments for a variety of reasons including: • timing of market introduction of competitive products; • demonstration of clinical safety and efficacy compared to other products; • cost-effectiveness; • limited or no coverage by third- party payers; • convenience and ease of administration; • prevalence and severity of adverse side effects; • restrictions in the label of the device; • other potential advantages of alternative treatment methods; and • ineffective marketing and distribution support of its products. If any of our product candidates is approved but fails to achieve market acceptance or such market is smaller than anticipated, we may not be able to generate significant revenue and our business would suffer. Because of the specialized nature of our business, the termination of relationships with our key employees, consultants and advisors may prevent us from successfully operating our business, including developing our products, conducting clinical studies, commercializing our products and obtaining any necessary financing. We are highly dependent on the members of our executive team, the loss of whose services may adversely impact the achievement of our objectives. While we have entered into employment agreements with each of our key executives, any of them could leave our employment at any time. We do not have “key person” insurance on any of our employees. The loss of the services of one or more of our current employees might impede the achievement of our business objectives. The competition for qualified personnel in the medical device fields is intense, and we rely heavily on our ability to attract and retain qualified scientific, technical and managerial personnel. Our future success depends upon our ability to attract, retain and motivate highly skilled employees. In order to commercialize our products successfully, we will be required to expand our workforce, particularly in the areas of research and development and clinical studies, sales and marketing and supply chain management. These activities will require the addition of new personnel and the development of additional expertise by existing management personnel. We face intense competition for qualified individuals from numerous pharmaceutical, biopharmaceutical and biotechnology companies, as well as academic and other research institutions. We may not be able to attract and retain these individuals on acceptable terms or at all. Failure to do so could materially harm our business. Customer or third- party complaints or negative reviews or publicity about our company or our products could harm our reputation and brand. We are heavily dependent on customers who use our IB- Stim device to provide good reviews and word- of- mouth recommendations to contribute to our growth. Customers who are dissatisfied with their experiences with our products or services may post negative reviews. We may also be the subject of blog, forum or other media postings that include inaccurate statements and / or create negative publicity. In addition, any negative news regarding similar products may adversely impact our business. Any negative reviews or publicity, whether real or perceived, disseminated by word- of- mouth, by the general media, by electronic or social networking means or by other methods, could harm our reputation and brand and could severely diminish consumer confidence in our products. Adverse global economic conditions could have a negative effect on our business, results of operations and financial condition and liquidity. A general slowdown in the global economy, including a recession, or in a particular region or industry, an increase in trade tensions with U. S. trading partners, inflation or a tightening of the credit markets could negatively impact our business, financial condition and liquidity. Adverse global economic conditions have from time to time caused or exacerbated significant slowdowns in the industries and markets in which we operate, which have adversely affected our business and results of operations. Macroeconomic weakness and uncertainty also make it more difficult for us to accurately forecast revenue, gross profit and expenses, and may make it more difficult to raise or refinance debt. Sustained uncertainty about, or worsening of, current global economic conditions and further escalation of trade tensions between the U. S. and its trading partners, could result in a global economic slowdown and long- term changes to global trade. Such events may also (i) cause our customers and consumers to reduce, delay or forgo spending, (ii) result in customers sourcing products from other suppliers not subject to such restrictions or tariffs, (iii) lead to the insolvency or consolidation of key suppliers and customers, and (iv) intensify pricing pressures. Any or all of these factors could negatively affect demand for our products and our business, financial condition and results of operations. Additionally, economic conditions in certain regions may also be affected by natural disasters and public health emergencies, such as extreme weather events, and could have a significant adverse effect on our business, including interruption of our commercial and clinical operations, supply chain disruption, endangerment of our personnel, fewer patient visits, increased patient drop- out rates, delays in recruitment of new patients, and other delays or losses of materials and results.

~~A The COVID-19 pandemic could materially adversely impact our business. A As the COVID-19 pandemic continues around the globe, we have experienced and will likely continue to experience disruptions that~~ **disruption and** ~~could severely~~ **disruption and** ~~impact our~~ **disruption and** ~~business and clinical studies, which could include: • delays and / or difficulties in onboarding active patients and enrolling patients in our clinical studies; • delays and / or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff; • declines in prescriptions written due to a perception that our products are difficult to administer remotely or if patients are unwilling to travel to treatment sites or receive in- home treatment assistance from us or other caregivers; • reductions in third- party reimbursements, which could materially affect our revenue, as most of our patients rely on third- party payers to cover the cost of our products and a material number of our patients could lose access to their private health insurance plan if they or someone in their family lose their job; • diversion of healthcare resources away from conducting clinical studies, including the diversion of hospitals serving as our clinical study sites and hospital staff supporting the conduct of our clinical studies; • interruption of key clinical study activities, such as clinical study site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others; • staff disruptions and turnover internally and at treatment sites and third- party providers who provide support, either directly as a result of illness or indirectly as a result of vaccine mandates and other changes in terms of employment; • delays in receiving approval from local regulatory authorities or IRBs to initiate our planned clinical studies; • delays in clinical sites receiving the supplies and materials needed to conduct our clinical studies; • interruption in shipping that may affect the transport of active patient and clinical study materials; • changes in local regulations as part of a response to~~ **a pandemic** ~~the COVID-19 outbreak~~ **a pandemic** ~~that may require us to change the ways in which our clinical studies are conducted, which may result in unexpected costs, or to discontinue the clinical studies altogether; • delays in necessary interactions with local regulators, ethics committees and other~~

important agencies and contractors due to limitations in employee resources or forced furlough of government employees; • disruption of our supply chain as our suppliers and common carriers are unable to meet our requirements to provide us the materials we need for clinical study and active patient care needs; • indirect consequences of ~~a~~ the COVID-19 pandemic on the economy in general, such as an increase in bankruptcies of our key suppliers, or the inability of our third- party payers to meet their obligations reimburse us in a timely fashion or at all; • postponements and cancellations of key conferences and meetings and travel restrictions could interfere with our ability to interact with key thought leaders in the field, leading to a disruption in the rate of adoption of our technology; • access restrictions at offices, hospitals, and treatment centers, and stakeholder illness could interfere with the ability of our sales force to engage in face- to- face visits with providers, leading to a disruption in the rate of adoption of our technology; • increases in expenditures for technology and other tools necessary to provide patient care in an environment where both patient and care- giver travel is restricted and access to in- person interaction is limited; • refusal of the FDA to accept data from clinical studies in affected geographies outside the United States; and • patient delays in seeking or receiving treatment, either due to fear of infection or lack of access to treatment and study sites, leading to fewer diagnoses of the indications our products are approved to treat or more advanced procession of the disease, which may contraindicate the use of our products or disqualify the patient from participating in a given study. ~~The global status of the COVID-19 pandemic continues to rapidly evolve. The extent to which the a~~ pandemic may impact our business and clinical studies will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing guidelines, business closures or business disruptions and the effectiveness of actions taken to contain and treat the disease. The response to ~~the a~~ pandemic may result in permanent changes to the environment in which we operate as described above in ways we are unable to predict. ~~A~~ ~~The COVID-19~~ pandemic may also have the effect of heightening many of the other risks described herein. Developing medical technology entails significant technical, regulatory and business risks. We may fail to adapt our technology to user requirements or emerging treatment standards. Neuromodulation therapies are not currently considered standard of care for IBS and may not ever be considered standard of care. Treatment standards may not evolve to incorporate our product. New industry standards for the development, manufacture and marketing of medical devices may evolve and we may not be able to conform to the changes, meet new standards in a timely fashion or maintain a competitive position in the market. In particular, regulatory standards for electrical treatments of medical conditions are evolving. If we face material delays in introducing our products and new technology, we may fail to attract new customers. Our Company has an evolving business strategy and investors must be willing to accept a substantial degree of uncertainty. The Company' s strategic focus is on the development of developing neuromodulation therapies to address chronic and debilitating conditions in children. The Company may engage in ongoing discussions with potential licensees, other strategic partners and institutional or private financing sources, the result of which could add to or alter its current strategic focus, cash needs or ownership structure. Investors must be willing to accept a substantial degree of uncertainty and must be willing to rely upon the Company' s board of directors and management to complete an appropriate business strategy to commercially exploit targeted business opportunities. We may not be able to compete with treatments now being marketed and developed, or which may be developed and marketed in the future by other companies. Our products will compete with existing and new therapies and treatments for chronic and debilitating conditions in children. We are aware of a number of companies currently seeking to develop alternative therapies or treatment for such diseases and conditions at least in part. Numerous pharmaceutical, biotechnology, drug delivery and medical device companies, hospitals, research organizations, individual scientists, and nonprofit organizations are engaged in the development of alternatives to our technology. Some of these companies have greater research and development capabilities, experience, manufacturing, marketing, financial, and managerial resources than we do. Collaborations or mergers between large pharmaceutical or biotechnology companies with competing treatment technologies could enhance our competitors' financial, marketing, and other resources. Developments by other medical device companies could make our products or technologies uncompetitive or obsolete. Accordingly, our competitors may succeed in developing competing technologies, obtaining FDA clearances and / or approval for products or gaining market acceptance more rapidly than we can. Due in part to our limited financial resources, we may fail to select or capitalize on the most scientifically, clinically or commercially promising or profitable indications or therapeutic areas for our product candidates, and / or we may be unable to pursue the clinical trials that we would like to pursue. We have limited technical, managerial, and financial resources to determine the indications on which we should focus the development efforts related to our product candidates. Due to our limited available financial resources, we may have curtailed clinical development programs and activities that might otherwise have led to more rapid progress of our product candidates through the regulatory and development processes. We may make incorrect determinations with regard to the indications and clinical trials on which to focus the available resources that we do have. Furthermore, we cannot assure you that we will be able to retain adequate staffing levels to run our operations and / or to accomplish all of the objectives that we otherwise would seek to accomplish. Our decisions to allocate our research, management, and financial resources toward particular indications or therapeutic areas for our product candidates may not lead to the development of viable commercial products and may divert resources from better opportunities. Similarly, our decisions to delay or terminate product development programs may also cause us to miss valuable opportunities. We ~~have had~~ material weaknesses in our internal control over financing reporting **during the years ended December 31, 2024 and 2023, that are unremediated as of December 31, 2024**. If we fail to establish and maintain proper and effective internal control over financial reporting, our operating results and our ability to operate our business could be harmed. Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time- consuming effort that needs to be re- evaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. ~~Due to accounting resource constraints, we have had limited review controls.~~

These constraints have resulted in (1) a lack of segregation of duties, since we have a limited administrative staff, (2) lack of internal controls structure review and (3) misapplication of U. S. GAAP. As a result of these constraints and the restatement our unaudited financial statements as of and for the three and nine month periods ended September 30, 2023, management concluded material weaknesses in our internal control over financial reporting existed as of December 31, 2023 and, accordingly, our internal control over financial reporting and disclosure controls and procedures were not effective as of such date. Specifically, management identified a material accounting error that understated extinguishment of debt expense and net loss in the Statements of Operations and understated additional paid in capital in the Balance Sheet as of and for the three and nine month periods ended September 30, 2023 as described and restated in Note 19 to the audited financial statements included in this Form 10-K. Our management is composed of a small number of individuals resulting in a situation where limitations on segregation of duties exist. All responsibility for accounting entries and the creation of financial statements is held by a single person, though the Company engages multiple accounting consultants for accounting, tax and audit support. To remedy this situation, we would need to hire additional staff or financial consultant support. We document, review and improve our internal controls and procedures for compliance with Section 404 of the Sarbanes- Oxley Act, which require requires annual management assessment of the effectiveness of our internal control over financial reporting. To comply with the requirements of being a public company, the Company has undertaken various actions to, and will take additional actions, such as remediating the material weaknesses described above, implementing implement additional internal controls and procedures and hiring internal audit staff or financial consultants. Testing and maintaining internal controls can divert our management's attention from other matters that are important to the operation of our business. Additionally, when evaluating internal controls over financial reporting, the Company may identify additional material weaknesses that it may not be able to remediate in time to meet the applicable deadline imposed upon us for compliance with the requirements of Section 404 of the Sarbanes- Oxley Act. If the Company identifies any additional material weaknesses in its internal control over financial reporting or is unable to remediate the material weakness described above or comply with the requirements of Section 404 of the Sarbanes- Oxley Act in a timely manner or if the Company's independent registered public accounting firm is unable to express an unqualified opinion as to the effectiveness of our internal control over financial reporting once it is no longer an emerging growth company, or if the Company is unable to conclude in our quarterly and annual reports that our disclosure controls and procedures are effective, investors may lose confidence in the accuracy and completeness of the Company's financial reports and the market price of our common stock could be negatively affected, and the Company may become subject to investigations by the stock exchange on which our securities are listed, the SEC or other regulatory authorities, which could require additional financial and management resources. In addition, if the Company fails to remediate any identified material weakness, including the material weaknesses described above, our financial statements could be inaccurate and the Company could face restricted access to capital markets. Our small size and internal control deficiencies may adversely affect our financial condition, results of operation and access to capital. Moreover, our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. If we cannot provide reliable financial reports or prevent fraud, we may not be able to manage our business as effectively as we would if an effective control environment existed, and our business and reputation with investors may be harmed. Risks Related to Legal and Regulatory Matters Product liability suits, whether or not meritorious, could be brought against us due to alleged defective devices or for the misuse of our products, which could result in expensive and time-consuming litigation, payment of substantial damages and / or expenses and an increase in our insurance rates. If our current or future devices are defectively designed or manufactured, contain defective components or are misused, or if someone claims any of the foregoing, whether or not meritorious, we may become subject to substantial and costly litigation. For example, we may be sued if our products cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. This may occur if our products are misused or damaged, have a sudden failure or malfunction (including with respect to safety features) or are otherwise impaired due to wear and tear. Even absent a product liability suit, malfunctions of our products or misuse by physicians or patients would need to be remedied swiftly in order to maintain continuous use and ensure efficacy of our products. Any product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the device, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products. Even successful defense may 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 reputation; • withdrawal of clinical study participants and inability to continue clinical studies; • initiation of investigations by regulators; • costs to prepare for and defend the related litigation; • a diversion of management's time and our resources; • substantial monetary awards to study participants or patients; • product recalls, withdrawals or labeling, marketing or promotional restrictions; • loss of revenues; • exhaustion of any available insurance and our capital resources; • the inability to commercialize any device candidate; and • a decline in our share price. Product liability claims could divert management's attention from our core business, be expensive to defend and result in sizable damage awards against us. We may not have sufficient insurance coverage for all claims. 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, could harm our reputation in the industry and could reduce revenues. Product liability claims in excess of our insurance coverage would be paid out of cash reserves, if any, which could have a material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline. Even if our agreements with our third- party manufacturers and suppliers entitle us to indemnification against losses,

such indemnification may not be available or adequate should any claim arise. Other future litigation and regulatory actions could have a material adverse impact on the Company. From time to time, we may be subject to litigation and other legal and regulatory proceedings relating to our business or investigations or other actions by governmental agencies. No assurances can be given that the results of these or new matters will be favorable to us. An adverse resolution of lawsuits, arbitrations, investigations or other proceedings or actions could have a material adverse effect on our financial condition and results of operations, including as a result of non-monetary remedies. Defending ourselves in these matters may be time-consuming, expensive and disruptive to normal business operations and may result in significant expense and a diversion of management's time and attention from the operation of our business, which could impede our ability to achieve our business objectives. Additionally, any amount that we may be required to pay to satisfy a judgment, settlement, fine or penalty may not be covered by insurance. Subject to the Delaware General Corporation Law, our certificate of incorporation permit us to indemnify any director against any liability, to purchase and maintain insurance against any liability for any director and to provide any director with funds (whether by loan or otherwise) to meet expenditures incurred or to be incurred by such director in defending any criminal, regulatory or civil proceedings or in connection with an application for relief (or to enable any such director to avoid incurring such expenditure). In addition, under our Articles of Incorporation and bylaws (the "Bylaws") we are obligated to indemnify each of our directors and officers against certain liabilities and expenses arising from their being a director or officer to the maximum extent permitted by Delaware law. In the event we are required to make such payments to our directors and officers, there can be no assurance that any of these payments will not be material. We are subject to consumer protection laws that regulate our marketing practices and prohibit unfair or deceptive acts or practices. Our actual or perceived failure to comply with such obligations could harm our business, and changes in such regulations or laws could require us to modify our products or marketing or advertising efforts. In connection with the marketing or advertisement of our products, we could be the target of claims relating to false, misleading, deceptive or otherwise noncompliant advertising or marketing practices, including under the auspices of the FTC and state consumer protection statutes. If we rely on third parties to provide any marketing and advertising of our products, we could be liable for, or face reputational harm as a result of, their marketing practices if, for example, they fail to comply with applicable statutory and regulatory requirements. If we are found to have breached any consumer protection, advertising, unfair competition or other laws or regulations, we may be subject to enforcement actions that require us to change our marketing and business practices in a manner that may negatively impact us. This could also result in litigation, fines, penalties and adverse publicity that could cause reputational harm and loss of customer trust, which could have a material adverse effect on our business, financial condition and results of operations. We are increasingly dependent on information technology systems and are subject to privacy and security laws. Our products and our systems and infrastructure face certain risks, including from cyber security breaches and data leakage. We increasingly rely upon technology systems and infrastructure. Our technology systems, including our products, are potentially vulnerable to breakdown or other interruption by fire, power loss, system malfunction, unauthorized access and other events. Likewise, data privacy breaches by employees and others with both permitted and unauthorized access to our products and our systems may pose a risk that protected patient information ("PI") may be exposed to unauthorized persons or to the public, or may be permanently lost. The increasing use and evolution of technology, including cloud-based computing, creates additional opportunities for the unintentional dissemination of information, intentional destruction of confidential information stored in our systems or in non-encrypted portable media or storage devices. We could also experience a business interruption, information theft of confidential information, or reputational damage from industrial espionage attacks, malware or other cyber incidents, which may compromise our system infrastructure or lead to data leakage, either internally or at our third-party service providers or other business partners. The size and complexity of our computer systems, and scope of our geographic reach, make us potentially vulnerable to information technology system breakdowns, internal and external malicious intrusion, cyberattacks and computer viruses. Because the techniques used to obtain unauthorized access, or to sabotage systems, change frequently and generally are not recognized until launched against a target, we may be unable to anticipate these techniques or to implement adequate preventative measures. If we do not allocate and effectively manage the resources necessary to build and sustain the proper technology infrastructure or properly manage third-party contractors who perform data management services on our behalf, then a security breach could subject us to, among other things, transaction errors, business process inefficiencies, the loss of customers, damage to our reputation, business disruptions or the loss of or damage to intellectual property. Such security breaches could expose us to a risk of loss of information, litigation, penalties, remediation costs and potentially significant liability to customers, employees, business partners and regulatory authorities, including, for example, under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") in the United States and Regulation 2016 / 679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data under GDPR in the EU. If our data management systems (including third party data management systems) do not effectively collect, secure, store, process and report relevant data for the operation of our business, whether due to equipment malfunction or constraints, software deficiencies, or human error, our ability to effectively plan, forecast and execute our business plan and comply with applicable laws and regulations will be impaired. Any such impairment could materially and adversely affect our financial condition and results of operations. While we have invested heavily in the protection of data and information technology and in related training, there can be no assurance that our efforts will prevent significant breakdowns, breaches in our systems or other cyber incidents or ensure compliance with all applicable security and privacy laws, regulations, and standards, including with respect to third-party service providers that utilize sensitive personal information, including PI, on our behalf. A security breach, whether of our products, systems or third-party hosting services we utilize, could disrupt treatments being provided by our products, disrupt access to our customers' stored information, such as patient treatment data and health information, and could lead to the loss of, damage to or public disclosure of such data and information, including patient health information. Such an event could have serious negative consequences, including possible patient injury, regulatory action, fines, penalties and

damages, reduced demand for our products, an unwillingness of customers to use our products, harm to our reputation and brand and time-consuming and expensive litigation, any of which could have a material adverse effect on our financial results. We currently carry cyber and privacy liability insurance with an aggregate limit of \$ 1,000,000, but the amount of insurance coverage that we purchased and may purchase in the future may be inadequate. In the future, our insurance coverage may be expensive or not be available on acceptable terms or in sufficient amounts, if at all. We may choose to, or may be required to, suspend, repeat or terminate our clinical studies if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive or the studies are not well designed. Clinical studies must be conducted in accordance with the FDA's cGCPs and the equivalent laws and regulations applicable in other jurisdictions in which the clinical studies are conducted. The clinical studies are subject to oversight by the FDA, regulatory agencies in other jurisdictions, ethics committees and institutional review boards at the medical institutions where the clinical studies are conducted. In addition, clinical studies must be conducted with device candidates produced under the FDA's QSR and in accordance with the applicable regulatory requirements in the other jurisdictions in which the clinical studies are conducted. The conduct of clinical studies may require large numbers of test patients. The FDA or regulatory agencies in other jurisdictions might delay or terminate our clinical studies of a device candidate for various reasons, including: • the device candidate may have unforeseen adverse side effects or may not appear to be more effective than current therapies; • we may not agree with the FDA, a regulatory authority in another jurisdiction or an ethics committee regarding the protocol for the conduct of a clinical study; • new therapies may become the standard of care while we are conducting our clinical studies, which may require us to revise or amend our clinical study protocols or terminate a clinical study; or • fatalities may occur during a clinical study due to medical problems that may or may not be related to clinical study treatments. Furthermore, the process of obtaining and maintaining regulatory approvals in the U. S. and other jurisdictions is lengthy, expensive and uncertain. It can vary substantially, based on the type, complexity and novelty of the product involved. Accordingly, any of our device candidates could take a significantly longer time than we expect to, or may never, gain regulatory approval, which could have a material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline. Legislative and regulatory changes in the U. S. and in other countries regarding healthcare insurance and government-sponsored reimbursement programs (such as Medicare in the United States) may adversely affect our business and financial results. We rely to a material degree on highly regulated private and government-run health insurance programs for our revenue in most of the countries in which we operate. The laws and regulations regarding health care programs, both public and private, are driven by public policy considerations that may be unrelated to the direct provision of patient care, such as lowering costs or requiring or limiting access to healthcare options. These laws and regulations are very complicated and there are many requirements we must satisfy in order for our products to become and remain eligible for reimbursement under these programs. In many cases we may have limited negotiating power when negotiating reimbursement rates for our products. In the future, lawmakers and regulators could also pass additional healthcare laws and implement other regulatory changes at both the national and local levels. These laws and regulations could potentially affect coverage and reimbursement for our products. However, we cannot predict the ultimate content, timing or effect of any future healthcare initiatives or the impact any future legislation or regulation will have on us. With respect to countries outside the U. S., the national competent authorities in the EU member states, the UK, Switzerland, Israel, Japan, and other jurisdictions are also increasingly active in their goal of reducing public spending on healthcare. We cannot, therefore, guarantee that the treatment of patients with our products would be reimbursed in any particular country or, if successfully included on reimbursement lists, whether we will remain on such lists. We are subject to extensive post-marketing regulation by the FDA and comparable authorities in other jurisdictions, which could impact the sales and marketing of our products and could cause us to incur significant costs to maintain compliance. In addition, we may become subject to additional regulation in other jurisdictions if we market and sell our products outside of the U. S. We market and sell our products subject to extensive regulation by the FDA and numerous other federal, state and governmental authorities in other jurisdictions. These regulations are broad and relate to, among other things, the conduct of pre-clinical and clinical studies, product design, development, manufacturing, labeling, testing, product storage and shipping, premarket clearance and approval, conformity assessment procedures, premarket clearance and approval of modifications introduced in marketed products, post-market surveillance and monitoring, reporting of adverse events and incidents, pricing and reimbursement, interactions with healthcare professionals, interactions with patients, information security, advertising and promotion and product sales and distribution. Although IB-Stim already has market clearance from FDA for functional abdominal pain associated with IBS in children, we will require additional FDA clearances to market our products for treating other indications. In addition, before our products can be marketed in the EU, our products must obtain a CE Certificate from a notified body. New intended uses of CE marked medical devices falling outside the scope of the current CE Certificate require a completely new conformity assessment before the device can be CE marked and marketed in the EU for the new intended use. The process required to gather necessary information and draw up documentation in order to obtain CE Certification of a medical device in the EU can be expensive and lengthy and its outcome can be uncertain. We may make modifications to our products in the future that we believe do not or will not require notifications to our notified body or new conformity assessments to permit the maintenance of our current CE Certificate. If the competent authorities of the EU member states or our notified body disagree and require the conduct of a new conformity assessment, the modification of the existing CE Certificate or the issuance of a new CE Certificate, we may be required to recall or suspend the marketing of the modified versions of our products. In Japan, new medical devices or new therapeutic uses of medical devices falling outside the scope of the existing approval by the MHLW require a new assessment and approval for each such new device or use. Accordingly, we may be required to obtain a new approval from MHLW before we launch a modified version of our products or the use of our products for additional indications. Approval time frames from the MHLW vary from simple notifications to review periods of one or more years, depending on the complexity and risk level of the device. In addition, importation into Japan of medical devices is subject to "Quality Management System (QMS) Ordinance," which

includes the equivalent of “ Good Import ” regulations in the U. S. As with any highly regulated market, significant changes in the regulatory environment could adversely affect our ability to commercialize our products in Japan. In the U. S. and other jurisdictions, we also are subject to numerous post- marketing regulatory requirements, which include regulations under the QSR related to the manufacturing of our products, labeling regulations and medical device reporting regulations, which require us to report to the FDA or comparable regulatory authorities in other jurisdictions and our notified body if our products cause or contribute to a death or serious injury, or malfunction in a way that would likely cause or contribute to a death or serious injury. In addition, these regulatory requirements may in the future change in a way that adversely affects us. If we fail to comply with present or future regulatory requirements that are applicable to us, we may be subject to enforcement action by the FDA or comparable regulatory authorities in other jurisdictions and notified bodies, which may include any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- patient notification, or orders for repair, replacement or refunds;
- voluntary or mandatory recall, withdrawal or seizure of our current or future devices;
- administrative detention by the FDA or other regulatory authority in another jurisdiction of medical devices believed to be adulterated or misbranded;
- operating restrictions, suspension or shutdown of production;
- refusal or delay of our requests for approval for new intended uses for or modifications to our products or for approval of new devices;
- refusal or delay in obtaining CE Certificates for new intended uses for or modifications to our products;
- suspension, variation or withdrawal of the CE Certificates granted by our notified body in the EU;
- prohibition or restriction of products being placed on the market;
- operating restrictions;
- suspension or withdrawal of approvals that have already been granted;
- refusal to grant export approval for our products or any device candidates; or
- criminal prosecution.

The occurrence of any of these events could have a material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline. Over time, we expect to make modifications to our products that are designed to improve efficacy, reduce side effects, enhance the user experience or for other purposes. Modifications to our products may require approvals, modified or new CE Certificates and analogous regulatory approvals in other jurisdictions or even require us to cease promoting or to recall the modified versions of our products until such clearances, approvals or modified or new CE Certificates are obtained, and the FDA, comparable regulatory authorities in other jurisdictions or our notified body may not agree with our conclusions regarding whether new approvals are required. In addition, any substantial change introduced to a medical device or to the quality system certified by our notified body requires a new conformity assessment of the device and can lead to changes to the CE Certificates or the preparation of a new CE Certificate of Conformity. Substantial changes may include, among others, the introduction of a new intended use of the device, a change in its design or a change in the Company’ s suppliers. Responsibility for determination that a modification constitutes a substantial change lies with the manufacturer of the medical device. We must inform the notified body that conducted the conformity assessment of the products we market or sell in the EU of any planned substantial changes to our quality system or changes to our products that could, among other things, affect compliance with the MDR or the devices’ intended use. The notified body will then assess the changes and verify whether they affect the product’ s conformity with the Essential Requirements laid down in Annex I to the MDD or the conditions for the use of the device. If the assessment is favorable, the notified body will issue a new CE Certificate or an addendum to the existing CE Certificate attesting compliance with the Essential Requirements laid down in Annex I to the MDD. There is a risk that the competent authorities of the EU member states or our notified body may disagree with our assessment of the changes introduced to our products. The competent authorities of the EU member states or our notified body also may come to a different conclusion than the FDA on any given product modification. In addition, medical devices that have obtained a CE Certification under the MDD may in principle continue to be marketed under such CE Certificate until the CE Certificate expires and at the latest until May 27, 2024, provided that the manufacturer complies with the MDR’ s additional requirements related to post- marketing surveillance, market surveillance, vigilance, and registration of economic operators and of devices. However, if such medical devices undergo a significant change in their design or intended use, we would need to obtain a new CE Certificate under the MDR for these devices. If the FDA disagrees with us and requires us to submit a new application for then- existing modifications and / or the competent authorities of the EU member states or our notified body disagree with our assessment of the change introduced in a product, its design or its intended use, we may be required to cease promoting or to recall the modified product until we obtain approval and / or until a new conformity assessment has been conducted in relation to the product, as applicable. In addition, we could be subject to significant regulatory fines or other penalties. Furthermore, our products could be subject to recall if the FDA, comparable regulatory authorities in other jurisdictions, or our notified body determine, for any reason, that our products are not safe or effective or that appropriate regulatory submissions were not made. Any recall or requirement that we seek additional approvals or clearances could result in significant delays, fines, increased costs associated with modification of a product, loss of revenues and potential operating restrictions imposed by the FDA, comparable foreign regulatory authorities in other jurisdictions, or our notified body. Delays in receipt or failure to receive approvals / certification, or the failure to comply with any other existing or future regulatory requirements, could reduce our sales, profitability and future growth prospects. In addition to FDA requirements, we will spend considerable time and money complying with other federal, state, local and foreign rules, regulations and guidance and, if we are unable to fully comply with such rules, regulations and guidance, we could face substantial penalties. We are subject to extensive regulation by the U. S. federal government and the states and other countries in which we conduct our business. U. S. federal government healthcare laws apply when we submit a claim on behalf of a U. S. federal healthcare program beneficiary, or when a customer submits a claim for an item or service that is reimbursed under a U. S. federal government- funded healthcare program, such as Medicare or Medicaid. The laws that affect our ability to operate our business in addition to the Federal Food, Drug, and Cosmetic Act and FDA regulations include, but are not limited to, the following:

- the U. S. federal Anti- Kickback Statute, an intent- based federal criminal statute which prohibits knowingly and willfully offering, providing, soliciting or receiving remuneration of any kind to induce or reward, or in return for, referrals or the purchase, lease, order or

recommendation or arranging of any items or services reimbursable by a federal healthcare program; ● the Federal Civil False Claims Act, which imposes civil penalties, including through civil whistleblower or “ qui tam ” actions, for knowingly submitting or causing the submission of false or fraudulent claims of payment to the federal government, knowingly making, using or causing to be made or used a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government; ● the Federal Criminal False Claims Act, which is similar to the Federal Civil False Claims Act and imposes criminal liability on those that make or present a false, fictitious or fraudulent claim to the federal government; ● Medicare laws and regulations that prescribe requirements for coverage and reimbursement, and laws prohibiting false claims or unduly influencing selection of products for reimbursement under Medicare and Medicaid; ● healthcare fraud statutes that prohibit false statements and improper claims to any third- party payer; ● the Federal Physician Self- Referral Law, commonly known as the Stark law, which, absent an applicable exception, prohibits physicians from referring Medicare and Medicaid patients to an entity for the provision of certain designated health services (“ DHS ”), if the physician (or a member of the physician’ s immediate family) has an impermissible financial relationship with that entity and prohibits the DHS entity from billing for such improperly referred services; ● the Federal Beneficiary Anti- Inducement Statute, which prohibits the offering of any remuneration to a beneficiary of Medicare or Medicaid that is likely to influence that beneficiary’ s choice of provider or supplier. This can include, but is not limited to, inappropriate provision of patient services including financial assistance. Recent government investigations have focused on this particular prohibition. There are established exceptions from liability, but we cannot guarantee that all of our practices will fall squarely within those exceptions; ● the U. S. Foreign Corrupt Practices Act, which can be used to prosecute companies in the U. S. for arrangements with physicians or other parties outside the U. S. if the physician or party is a government official of another country and the arrangement violates the law of that country; ● the Federal Trade Commission Act, the Lanham Act and similar federal and state laws regulating truthfulness in advertising and consumer protection; and ● the Federal Physician Payments Sunshine Act, the French Sunshine Act and similar state and foreign laws, which require periodic reporting of payments and other transfers of value made to U. S. and French- licensed physicians, teaching hospitals, and in the U. S., physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse- midwives. Similar laws exist in the EU, individual EU member states and other countries. These laws are complemented by EU or national professional codes of practices. HIPAA provides data privacy and security provisions for safeguarding medical information. Additionally, states in the U. S. are enacting local privacy laws (e. g., California). In the EU, the GDPR harmonizes data privacy laws and rules on the processing of personal data, including patient and employee data, across the EU. The GDPR has a number of strict data protection and security requirements for companies processing data of EU residents, including when such data is transferred outside of the EU. Additionally, we need to comply with analogous privacy laws in other jurisdictions in which we operate, such as the Israeli Privacy Protection Law, the Asia Pacific Economic Cooperation Privacy Framework, and Japan’ s Act on the Protection of Personal Information. The laws and codes of practices applicable to us are subject to evolving interpretations. Moreover, certain U. S. federal and state laws regarding healthcare fraud and abuse and certain laws in other jurisdictions regarding interactions with healthcare professionals and patients are broad and we may be required to restrict certain of our practices to be in compliance with these laws. Healthcare fraud and abuse laws also are complex and even minor, inadvertent irregularities, or even the perception of impropriety, can potentially give rise to claims that a statute has been violated. Any violation of these laws could have a material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline. Similarly, if there is a change in law, regulation or administrative or judicial interpretations, we may have to change our business practices or our existing business practices could be challenged as unlawful, which likewise could have a material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline. Fines and penalties for violations of these laws and regulations could include severe criminal and civil penalties, including, for example, significant monetary damages, exclusion from participation in the federal healthcare programs and permanent disbarment of key employees. Any penalties, damages, fines, curtailment or restructuring of our operations would adversely affect our ability to operate our business, our prospects and our financial results. In addition, any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management’ s attention from the operation of our business and damage our reputation. In addition, although we believe that we have the required licenses, permits and accreditation to dispense our products in the future, a regulator could find that we need to obtain additional licenses or permits. We also may be subject to mandatory reaccreditation and other requirements in order to maintain our billing privileges. Failure to satisfy those requirements could cause us to lose our privileges to bill governmental and private payers. If we are required to obtain permits or licenses that we do not already possess, we also may become subject to substantial additional regulation or incur significant expense. To ensure compliance with Medicare, Medicaid and other regulations, federal and state governmental agencies and their agents, including MACs, may conduct audits of our operations to support our claims submitted for reimbursement of items furnished to beneficiaries and health care providers. Depending on the nature of the conduct found in such audits and whether the underlying conduct could be considered systemic, the resolution of these audits could adversely impact our revenue, financial condition and results of operations. If we, our collaborative partners, our contract manufacturers or our component suppliers fail to comply with the FDA’ s QSR or equivalent regulations established in other countries, the manufacturing and distribution of our products could be interrupted, and our product sales and results of operations could suffer. We, our collaborative partners, our contract manufacturers and our component suppliers are required to comply with the FDA’ s QSR and the equivalent quality system requirements imposed by the laws and regulations in other jurisdictions, which are a complex regulatory framework that covers the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products. We cannot assure you that our facilities or our contract manufacturers’ or component suppliers’ facilities would pass any future quality system inspection. If our or any of our contract manufacturers’ or

component suppliers' facilities fails a quality system inspection, the manufacturing or distribution of our products could be interrupted and our operations disrupted. Failure to take adequate and timely corrective action in response to an adverse quality system inspection could force a suspension or shutdown of our packaging and labeling operations or the manufacturing operations of our contract manufacturers, and lead to suspension, variation or withdrawal of our regulatory approvals or a recall of our products. If any of these events occurs, we may not be able to provide our customers with our products on a timely basis, our reputation could be harmed and we could lose customers, any or all of which could have a material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline. Our products may in the future be subject to recalls that could harm our reputation, business and financial results. The FDA and similar governmental authorities in other jurisdictions have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. In addition, governmental bodies in other jurisdictions have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Distributors and manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government- mandated or voluntary recall by us or one of our manufacturers could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. The FDA requires that certain classifications of recalls be reported to the FDA within ten working days after the recall is initiated. Requirements for the reporting of product recalls to the competent authorities are imposed in other jurisdictions in which our products are or would be marketed in the future. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA or to the competent authorities of other countries. In the future, we may initiate voluntary recalls involving our products that we determine do not require notification of the FDA or to other equivalent non- U. S. authorities. If the FDA or the equivalent non- U. S. authorities disagree with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA and the equivalent non- U. S. authorities could take enforcement action if we fail to report the recalls when they were conducted. Recalls of our products would divert managerial and financial resources and could have a material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline. If our products cause or contribute to a death or a serious injury, or malfunction in certain ways, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions. Under the FDA Medical Device Reporting regulations and the equivalent regulations applicable in other jurisdictions in which our products are or may be marketed in the future, medical device manufacturers are required to report to the FDA and to the equivalent non- U. S. authorities 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 these events to the FDA or to the equivalent authorities in other jurisdictions within the required time frames, or at all, the FDA or the equivalent authorities in other jurisdictions could take enforcement action 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, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results. We may be subject to fines, penalties or injunctions if we are determined to be promoting the use of our products for unapproved or off- label uses. Medical devices may be marketed only for the indications for which they are approved. Our promotional materials and training materials must comply with FDA regulations and other applicable laws and regulations governing the promotion of our products in the U. S. and other jurisdictions. If the FDA or the competent authorities in other jurisdictions determine that our promotional materials or training constitutes promotion of an unapproved use, they could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled or warning letter, an injunction, seizure, civil fines and criminal penalties. It is also possible that authorities in other federal, state or national enforcement in other jurisdictions might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and the commercialization of our products could be impaired. We are affected by and subject to environmental laws and regulations that could be costly to comply with or that may result in costly liabilities. We are subject to environmental laws and regulations, including those that impose various environmental controls on the manufacturing, transportation, storage, use and disposal of hazardous chemicals and other materials used in, and hazardous waste produced by, the manufacturing of our products. We incur and expect to continue to incur costs to comply with these environmental laws and regulations. Additional or modified environmental laws and regulations, including those relating to the manufacture, transportation, storage, use and disposal of materials used to manufacture our products or restricting disposal or transportation of batteries, may be imposed that may result in higher costs. In addition, we cannot predict the effect that additional or modified environmental laws and regulations may have on us, our third- party suppliers of equipment and our products or our customers. The pediatrics and medical device industries are characterized by patent and other intellectual property litigation and disputes, and any litigation, dispute or claim against us may cause us to incur substantial costs, could place a significant strain on our financial resources, divert the attention of management from our business, harm our reputation and require us to remove certain devices from the market. Whether a product infringes a patent or violates other intellectual property rights involves complex legal and factual issues, the determination of which is often uncertain. Any intellectual property dispute, even a meritless or unsuccessful one, would be time consuming and expensive to defend and could result in the diversion of our management' s attention from our business and result in adverse publicity, the disruption of research and development and marketing efforts, injury to our reputation and loss of revenues. Any of these events could negatively affect

our business, prospects, financial condition and results of operations. Third parties may assert that our products, the methods employed in the use of our products or other activities infringe on their patents. Such claims may be made by competitors seeking to obtain a competitive advantage or by other parties, many of whom have significantly larger intellectual property portfolios than we have. Additionally, in recent years, individuals and groups have begun purchasing intellectual property assets for the purpose of making claims of infringement and attempting to extract settlements from companies like ours. With respect to our current products, the risk of infringement claims is exacerbated by the fact that there are numerous issued and pending patents relating to the treatment of cancer. Because patent applications can take many years to issue, and in many cases remain unpublished for many months after filing, there may be applications now pending of which we are unaware that may later result in issued patents that our products may infringe. There could also be existing patents that one or more components of our products or other device candidates may inadvertently infringe. As the number of competitors in the market or other device candidates grows, the possibility of inadvertent patent infringement by us or a patent infringement claim against us increases. To the extent we gain greater market visibility, our risk of being subject to such claims is also likely to increase. If a third party's patent was upheld as valid and enforceable and we were found to be infringing, we could be prevented from making, using, selling, offering to sell or importing our products or other device candidates, unless we were able to obtain a license under that patent or to redesign our systems to avoid infringement. A license may not be available at all or on terms acceptable to us, and we may not be able to redesign our products to avoid any infringement. Modification of our products or development of device candidates to avoid infringement could require us to conduct additional clinical studies and to revise our filings with the FDA and other regulatory bodies, which would be time-consuming and expensive. If we are not successful in obtaining a license or redesigning our devices, we may be unable to make, use, sell, offer to sell or import our devices and our business could suffer. We may also be required to pay substantial damages and undertake remedial activities, which could cause our business to suffer. We may also be subject to claims alleging that we infringe or violate other intellectual property rights, such as copyrights or trademarks, may have to defend against allegations that we misappropriated trade secrets, and may face claims based on competing claims of ownership of our intellectual property. The confidentiality and assignment of inventions agreements that our employees, consultants and other third parties sign may not in all cases be enforceable or sufficient to protect our intellectual property rights. In addition, we may face claims from third parties based on competing claims to ownership of our intellectual property. We may employ individuals who were previously employed at other medical device companies, and as such we may be subject to claims that such employees have inadvertently or otherwise used or disclosed the alleged trade secrets or other proprietary information of their former employers. Any such litigation, dispute or claim could be costly to defend and could subject us to substantial damages, injunctions or other remedies, which could have a material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline. Changes in U. S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our devices. As is the case with other medical device companies, our success is heavily dependent on our intellectual property rights, and particularly on our patent rights. Obtaining and enforcing patents in the medical device industry involves both technological and legal complexity, and is therefore costly, time consuming and inherently uncertain. In addition, the U. S. has recently enacted and is currently implementing wide-ranging patent reform legislation. Certain 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 value of patents once obtained. Depending on decisions by the U. S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could further negatively impact the value of our patents, narrow the scope of available patent protection or weaken the rights of patent owners. Future regulatory action remains uncertain. We operate in a highly regulated and evolving environment with rigorous regulatory enforcement. Any legal or regulatory action could be time-consuming and costly. If we or the manufacturers or distributors that supply our products fail to comply with all applicable laws, standards, and regulations, action by the FDA or other regulatory agencies could result in significant restrictions, including restrictions on the marketing or use of the products we sell or the withdrawal of the products we sell from the market. Any such restrictions or withdrawals could materially affect our reputation, business and operations. Our product candidates will remain subject to ongoing regulatory review even after they receive marketing clearances, and if we fail to comply with continuing regulations, we could lose these clearances and the sale of any of our approved commercial products could be suspended. Even as we received regulatory clearance to market the IB- Stim, the manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, and record keeping related to IB- Stim will remain subject to extensive regulatory requirements. If we fail to comply with the regulatory requirements of the FDA and other applicable domestic and foreign regulatory authorities or discover any previously unknown problems with any approved product, manufacturer, or manufacturing process, we could be subject to administrative or judicially imposed sanctions, including: ● restrictions on the products, manufacturers, or manufacturing processes; ● warning letters; ● civil or criminal penalties; ● fines; ● injunctions; ● product seizures or detentions; ● pressure to initiate voluntary product recalls; ● suspension or withdrawal of regulatory clearances and / or approvals; and ● refusal to approve pending applications for marketing clearances and / or approval of new products or supplements to approved applications. Intellectual property litigation and infringement claims could cause us to incur significant expenses or prevent us from selling certain of our products. The therapeutic medical device and pharmaceutical industries are characterized by extensive intellectual property litigation and, from time to time, we may become the subject of claims of infringement or misappropriation. Regardless of outcome, such claims are expensive to defend and divert management and operating personnel from other business issues. A successful claim or claims of patent or other intellectual property infringement against us could result in payment of significant monetary damages and / or royalty payments or negatively impact our ability to sell current or future products in the affected category. We depend extensively on our patents and proprietary technology and the patents, and we must protect those assets in order to

preserve our business. Although we expect to seek patent protection for any devices, in silico products (if any), systems, and processes we discover and / or for any specific use we discover for new or previously known compounds, devices, biologics, products, systems, or processes, any or all of these may not be subject to effective patent protection. In addition, our issued patents may be declared invalid or our competitors may find ways to avoid the claims in the patents. Our success will depend, in part, on our ability to obtain patents, protect our trade secrets and proprietary knowledge and operate without infringing on the proprietary rights of others. We are the sole assignee of numerous granted United States patents, pending United States patent applications and international patents. The patent position of pharmaceutical and biotechnology firms like us are generally highly uncertain and involves complex legal and factual questions, resulting in both an apparent inconsistency regarding the breadth of claims allowed in United States patents and general uncertainty as to their legal interpretation and enforceability. Accordingly, patent applications assigned to us may not result in patents being issued, any issued patents assigned to us may not provide us with competitive protection or may be challenged by others, and the current or future granted patents of others may have an adverse effect on our ability to do business and achieve profitability. Moreover, others may independently develop similar products, may duplicate our products, or may design around our patent rights. In addition, as a result of the assertion of rights by a third- party or otherwise, we may be required to obtain licenses to patents or other proprietary rights of others in or outside of the United States. Any licenses required under any such patents or proprietary rights may not be made available on terms acceptable to us, if at all. If we do not obtain such licenses, we could encounter delays in product market introductions during our attempts to design around such patents or could find that the development, manufacture or sale of products requiring such licenses is foreclosed. In addition, we could incur substantial costs in defending suits brought against us or in connection with patents to which we hold licenses or in bringing suit to protect our own patents against infringement. Due to legal and factual uncertainties regarding the scope and protection afforded by patents and other proprietary rights, we may not have meaningful protection from competition. Our long- term success will substantially depend upon our ability to protect our proprietary technologies from infringement, misappropriation, discovery and duplication, and avoid infringing the proprietary rights of others. Our patent rights and the patent rights of biotechnology and pharmaceutical companies in general, are highly uncertain and include complex legal and factual issues. Because of this, our pending patent applications may not be granted. These uncertainties also mean that any patents that we own or will obtain in the future could be subject to challenge, and even if not challenged, may not provide us with meaningful protection from competition. Due to our financial uncertainties, we may not possess the financial resources necessary to enforce our patents. Patents already issued to us or our pending applications may become subject to dispute, and any dispute could be resolved against us. Because a substantial number of patents have been issued in the field of neuromodulation therapy and because patent positions can be highly uncertain and frequently involve complex legal and factual questions, the breadth of claims obtained in any application or the enforceability of our patents cannot be predicted. Consequently, we do not know whether any of our pending or future patent applications will result in the issuance of patents or, to the extent patents have been issued or will be issued, whether these patents will be subject to further proceedings limiting their scope, will provide significant proprietary protection or competitive advantage, or will be circumvented or invalidated. Also, because of these legal and factual uncertainties, and because pending patent applications are held in secrecy for varying periods in the United States and other countries, even after reasonable investigation, we may not know with certainty whether any products that we (or a licensee) may develop will infringe upon any patent or other intellectual property right of a third party. We believe that the patents that we own or have applied for do not infringe any third- party patents; however, we cannot know for certain whether we could successfully defend our position, if challenged. We may incur substantial costs if we are required to defend our intellectual property in patent suits brought by third parties. These legal actions could seek damages and seek to enjoin testing, manufacturing and marketing of the accused product or process. In addition to potential liability for significant damages, we could be required to obtain a license to continue to manufacture or market the accused product or process. If the third parties on which we rely for the conduct of our clinical trials and results do not perform our clinical trial activities in accordance with good clinical practices and related regulatory requirements, we may be unable to obtain regulatory approval for or commercialize our product candidates. We may use independent clinical investigators and other third- party service providers to conduct and / or oversee the clinical trials of our product candidates for the foreseeable future. The FDA requires us and our clinical investigators to comply with regulations and standards, commonly referred to as good clinical practices, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate, and that the trial participants are adequately protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Third parties may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory requirements or the respective trial plans and protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval, and commercialization of our product candidates or result in enforcement action against us. Risks Related to Our Common Stock We may not be able to maintain a listing of our common stock on NYSE American. Our common stock is listed on NYSE American. We must meet certain financial and liquidity criteria to maintain such listing. If we violate NYSE American's listing requirements, or if we fail to meet any of NYSE American's listing standards, our common stock may be delisted. In addition, our board of directors may determine that the cost of maintaining our listing on a national securities exchange outweighs the benefits of such listing. A delisting of our common stock from NYSE American may materially impair our stockholders' ability to buy and sell our common stock and could have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock. The delisting of our common stock could significantly impair our ability to raise capital and the value of your investment. We do not expect to declare or pay dividends in the foreseeable future. We do not expect to declare or pay dividends in the foreseeable future, as we anticipate that we will invest future earnings in the development and growth of our business. Therefore, holders of our common stock will not receive any return on their investment unless they sell their securities, and holders may be unable to sell their securities on favorable terms or at all. If securities industry analysts do not

publish research reports on us, or publish unfavorable reports on us, then the market price and market trading volume of our common stock could be negatively affected. Any trading market for our common stock may be influenced in part by any research reports that securities industry analysts publish about us. We do not currently have and may never obtain research coverage by securities industry analysts. If no securities industry analysts commence coverage of us, the market price and market trading volume of our common stock could be negatively affected. In the event we are covered by analysts, and one or more of such analysts downgrade our securities, or otherwise reports on us unfavorably, or discontinues coverage of us, the market price and market trading volume of our common stock could be negatively affected. Future issuances of our common stock or securities convertible into, or exercisable or exchangeable for, our common stock, or the expiration of lock- up agreements that restrict the issuance of new common stock or the trading of outstanding common stock, could cause the market price of our common stock to decline and would result in the dilution of your holdings. Future issuances of our common stock or securities convertible into, or exercisable or exchangeable for, our common stock, or the expiration of lock- up agreements that restrict the issuance of new common stock or the trading of outstanding common stock, could cause the market price of our common stock to decline. We cannot predict the effect, if any, of future issuances of our securities, or the future expirations of lock- up agreements, on the price of our common stock. In all events, future issuances of our common stock would result in the dilution of your holdings. In addition, the perception that new issuances of our securities could occur, or the perception that locked- up parties will sell their securities when the lock- ups expire, could adversely affect the market price of our common stock. In addition to any adverse effects that may arise upon the expiration of these lock- up agreements, the lock- up provisions in these agreements may be waived, at any time and without notice. If the restrictions under the lock- up agreements are waived, our common stock may become available for resale, subject to applicable law, including without notice, which could reduce the market price for our common stock. Future issuances of debt securities, which would rank senior to our common stock upon our bankruptcy or liquidation, and future issuances of preferred stock, which could rank senior to our common stock for the purposes of dividends and liquidating distributions, may adversely affect the level of return you may be able to achieve from an investment in our common stock. In the future, we may attempt to increase our capital resources by offering debt securities. Upon bankruptcy or liquidation, holders of our debt securities, and lenders with respect to other borrowings we may make, would receive distributions of our available assets prior to any distributions being made to holders of our common stock. Moreover, if we issue preferred stock, the holders of such preferred stock could be entitled to preferences over holders of common stock in respect of the payment of dividends and the payment of liquidating distributions. Because our decision to issue debt or preferred stock in any future offering, or borrow money from lenders, will depend in part on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of any such future offerings or borrowings. Holders of our common stock must bear the risk that any future offerings we conduct or borrowings we make may adversely affect the level of return, if any, they may be able to achieve from an investment in our common stock. If our shares of common stock become subject to the penny stock rules, it would become more difficult to trade our shares. The SEC has adopted rules that regulate broker- dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than \$ 5. 00, other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system. If we do not retain a listing on NYSE American or another national securities exchange and if the price of our common stock is less than \$ 5. 00, our common stock could be deemed a penny stock. The penny stock rules require a broker- dealer, before a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document containing specified information. In addition, the penny stock rules require that before effecting any transaction in a penny stock not otherwise exempt from those rules, a broker- dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive (i) the purchaser' s written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our common stock, and therefore stockholders may have difficulty selling their shares. We are subject to ongoing public reporting requirements that are less rigorous than Exchange Act rules for companies that are not emerging growth companies, and our stockholders could receive less information than they might expect to receive from more mature public companies. We are required to publicly report on an ongoing basis as an “ emerging growth company ” (as defined in the JOBS Act) under the reporting rules set forth under the Exchange Act. For so long as we remain an emerging growth company, we may take advantage of certain exemptions from various reporting requirements that are applicable to other Exchange Act reporting companies that are not emerging growth companies, including but not limited to: ● not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act; ● being permitted to comply with reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and ● being exempt from the requirement to hold a non- binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We expect to take advantage of these reporting exemptions until we are no longer an emerging growth company. We would remain an emerging growth company for up to five years, although if the market value of our common stock that is held by non- affiliates exceeds \$ 700 million as of any June 30 before that time, we would cease to be an emerging growth company as of the following December 31. Because we are subject to ongoing public reporting requirements that are less rigorous than Exchange Act rules for companies that are not emerging growth companies, our stockholders could receive less information than they might expect to receive from more mature public companies. We cannot predict if investors will find our common stock less attractive if we elect to rely on these exemptions, or if taking advantage of these exemptions would result in less active trading or more volatility in the price of our common stock. Because the Company is a “ smaller reporting company, ” we may take advantage of certain scaled disclosures available to us, resulting in holders of our securities receiving less Company information than they

would receive from a public company that is not a smaller reporting company. We are a “ smaller reporting company ” as defined in the Exchange Act. As a smaller reporting company, we may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as (i) our common stock held by non- affiliates is less than \$ 250 million measured on the last business day of our second fiscal quarter, or (ii) our annual revenue is less than \$ 100 million during the most recently completed fiscal year and our common stock held by non- affiliates is less than \$ 700 million measured on the last business day of our second fiscal quarter. To the extent we take advantage of any reduced disclosure obligations, it may make it harder for investors to analyze the Company’ s results of operations and financial prospectus in comparison with other public companies. As a smaller reporting company, we are permitted to comply with scaled- back disclosure obligations in our SEC filings compared to other issuers, including with respect to disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We have elected to adopt the accommodations available to smaller reporting companies. Until we cease to be a smaller reporting company, the scaled- back disclosure in our SEC filings will result in less information about our company being available than for other public companies. If investors consider our common stock less attractive as a result of our election to use the scaled- back disclosure permitted for smaller reporting companies, there may be a less active trading market for our common stock and our share price may be more volatile. As a “ smaller reporting company, ” we may at some time in the future choose to exempt our Company from certain corporate governance requirements that could have an adverse effect on our public shareholders. Under NYSE American rules, a “ smaller reporting company, ” as defined in Rule 12b- 2 under the Exchange Act, is not subject to certain corporate governance requirements otherwise applicable to companies listed on NYSE American. For example, a smaller reporting company is exempt from the requirement of having a compensation committee composed solely of directors meeting certain enhanced independence standards, as long as the compensation committee has at least two members who do meet such standards. Although we have determined not to avail ourselves of this or other exemptions from NYSE American requirements that are or may be afforded to smaller reporting companies while we will seek to maintain our shares on NYSE American, in the future we may elect to rely on any or all of these exemptions. By electing to utilize any such exemptions, our Company may be subject to greater risks of poor corporate governance, poorer management decision- making processes, and reduced results of operations from problems in our corporate organization. Consequently, if we were to avail ourselves of these exemptions, our stock price might suffer, and there is no assurance that we would be able to continue to meet all continuing listing requirements of NYSE American from which we would not be exempt, including minimum stock price requirements. ITEM 1B.

UNRESOLVED STAFF COMMENTS