Risk Factors Comparison 2025-03-25 to 2024-03-28 Form: 10-K

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Risks Related to Our Financial Position and Need for Capital We have incurred substantial net losses since our inception and anticipate that we will continue to incur substantial net losses for the foreseeable future. We may never achieve or sustain profitability. We have incurred substantial net losses since our inception. For the years ended December 31, **2024 and** 2023 ~~and 2022~~ , we incurred a net loss of $ **11. 7 million and $** 8. 9 million **, respectively,** and **used cash in operating activities of** $ ~~14~~ **11** . 1 million ~~, respectively,~~ and ~~used cash in operating activities of~~ $ 10. 4 ~~million and $ 14. 3~~ million, respectively. We have an accumulated deficit of $ ~~160~~ **171** . ~~0~~ **7** million as of December 31, ~~2023~~ **2024** . Our losses have resulted primarily from costs incurred in connection with our design, manufacturing and development activities, research and development activities, building our commercial infrastructure, stock- based compensation, legal, advertising, marketing and investor relations, and general and administrative expenses associated with our operations. Although we have received a medical device license from Health Canada to market the PoNS device in Canada, marketing authorization from the FDA for the sale of our PoNS device in the U. S. and market authorization from the TGA in Australia, we expect to continue to incur substantial losses for the foreseeable future as we continue to expand our commercialization efforts. We will require additional financing to carry out our plan of operations and if we are unable to obtain such financing, our business may fail. During the year ended December 31, ~~2023~~ **2024** , we generated approximately $ 0. ~~6~~ **5** million in revenue from the commercial sales of products in the United States and Canada. Because we have generated limited revenues from commercialization, our operations to date have been principally financed through public and private offerings of our common stocks, warrants and convertible debt and exercises of options and warrants. There are a number of conditions that we must satisfy before we will be able to generate sufficient revenue to fund our operations, including but not limited to the recruitment of patients for treatment, and demonstration of effectiveness sufficient to generate commercial orders by customers for our product. These factors raise substantial doubt about our ability to continue as a going concern through at least 12 months from the date of this Form 10- K. **We** ~~While we~~ had $ ~~5~~ **1** . ~~2~~ **1** million of cash as of December 31, ~~2023~~ **2024** , **and** we do not currently have sufficient resources to accomplish all of the above conditions necessary for us to generate sufficient revenues to achieve profitability, and we will require additional financing to fund our operations beyond the second quarter of ~~2024~~ **2025** . There is no guarantee that such funding will be available at all or in sufficient amounts to satisfy our required expenditures. If we are unable to obtain additional financing as needed, we may be forced to reduce the scope of our operations and planned capital expenditures or sell certain assets, including intellectual property, and we may be forced to cease or wind down operations, seek protection under the provisions of the U. S. Bankruptcy Code, or liquidate and dissolve our company, which would have a material adverse effect on the value of our common stock. Raising additional capital by issuing securities or through debt financings or licensing arrangements may cause significant dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product on terms unfavorable to us. Our operations to date have principally been financed by public and private offerings of our common stock warrants and convertible debt and exercises of warrants and options. Until we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings, or other capital sources, including potential collaborations with other companies or other strategic transactions. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of such securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through strategic partnerships with third parties, we may have to relinquish valuable rights to our technologies or product, future revenue streams, research programs or product candidates, or otherwise grant licenses on terms that are not favorable to us. If we are unable to raise additional capital when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts, or grant rights to develop and market potential future product candidates that we would otherwise prefer to develop and market ourselves. Any of these events could adversely affect our ability to achieve our product development and commercialization goals and have a material adverse effect on our business, financial condition and results of operations. Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements. We may be unable to continue to operate without the threat of liquidation for the foreseeable future. In connection with our management' s assessment, our report from our independent registered public accounting firm for the ~~fiscal~~ year ended December 31, ~~2023~~ **2024** includes an explanatory paragraph stating that our recurring losses from operations and net capital deficiency raise substantial doubt about our ability to continue as a going concern. If we are unable to obtain sufficient funding, our business, prospects, financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. Future reports from our independent registered public accounting firm may also contain statements expressing substantial doubt about our ability to continue as a going concern. We believe our existing capital resources will be sufficient to fund our operations ~~through~~ **into** the second quarter of ~~2024~~ **2025** . We also expect our expenses to increase as we continue to conduct trials of PoNS Therapy ® and as we pursue further regulatory approvals, and maintain, expand and protect our intellectual property portfolio. There can be no assurance that we will be successful in raising additional capital or that such capital, if available, will be on terms that are acceptable to us. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our consolidated financial statements, and investors will likely lose all or a part of their investment. If

we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all. Global macroeconomic instability could adversely affect our ability to raise additional financing. Generally, global macroeconomic conditions remain uncertain, largely due to the effects of geopolitical conflicts in the Ukraine and in the Middle East, disruptions in the banking system and financial markets, increased inflation ~~and~~ **,** sustained high interest rates **and unpredictable trade policies, including tariffs, customs regulations and other trade restrictions** . The general economic and capital market conditions, both in the U. S. and worldwide, have been volatile in the past and at times have adversely affected the Company' s access to capital and increased the cost of capital. The capital and credit markets may not be available to support future capital raising activity on favorable terms. If economic conditions decline, the Company' s future cost of equity or debt capital and access to the capital markets could be adversely affected. Risks Related to the Development and Commercialization of our ProductWe currently only have one product which is approved in the U. S. only for treatment of gait deficit, for MS and otherwise only in Canada and Australia. We currently have no products CE certified and CE marked for commercial distribution in Europe, or in any other country outside of Canada, the U. S. and Australia. In the U. S. we have not received marketing authorization for use of the PoNS device other than for MS. In addition, the FDA has previously rejected our de novo application for marketing authorization of the PoNS device for mmTBI. In Europe, we are developing the PoNS device for use in the ~~34neuromodulation~~ **neuromodulation** market, but we cannot begin marketing and selling the device in Europe until we obtain applicable CE ~~certificate~~ **39certificate** of conformity from a notified body in the EU after successful completion of a conformity assessment procedure. The process of obtaining regulatory authorization and / or certification is expensive and time- consuming and can vary substantially based upon, among other things, the type, complexity and novelty of a product. Changes in regulatory policy, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application may cause delays in the authorization and / or certification of a product or rejection of a regulatory application altogether. We are developing the PoNS device for other indications, or symptoms caused by neurological disorders, and will be required to commit our own resources to fund development of any other indications and each would require separate regulatory clearance, certification or other marketing authorization in other territories. The costs of such development efforts and regulatory clearance, certification or other marketing authorization could be substantial and would likely require additional funding, and each such indication would be subject to the same foregoing risks and uncertainties for FDA clearance / authorization. Obtaining FDA marketing authorization is expensive and uncertain, generally takes several years, and generally requires detailed and comprehensive scientific and clinical data. Notwithstanding the expense, these efforts may never result in FDA authorization for commercial distribution. Even if we were to obtain regulatory authorization, it may not be for the uses we believe are important or commercially attractive, in which case we would not be permitted to market our product for those uses. Our PoNS technology is a novel form of neurostimulation therapy, and the medical community tends not to adopt new therapies very rapidly. If physicians elect not to prescribe the PoNS Therapy, we will be unable to generate significant revenue. Our continued deployment strategy depends on physicians prescribing the PoNS Therapy to patients with relevant neurological disorders and physical therapists being trained in the supervision of patients' use of our treatment. Novel technologies are usually more slowly adopted by the medical community, as the medical community tends to be very conservative. Physicians may elect not to use our products for a variety of reasons, including: ● lack or perceived lack of evidence supporting the beneficial characteristics of our technology; ● limited long- term data on the use of PoNS technology for therapy; ● physicians' perception that there are insufficient advantages of our product relative to currently available products or compared to supervised therapeutic exercise alone; ● our inability to effectively train physical therapists in the supervision of patients' use of PoNS Therapy; ● hospitals may choose not to purchase our product; ● group purchasing organizations may choose not to contract for our product, thus limiting availability of our products to hospital purchasers; ● lack of coverage or adequate payment from managed care plans and other third- party payers for our product; ● Medicare, Medicaid or other third- party payers may limit or not permit reimbursement for our product; and ● the development or improvement of competitive products. If the medical community is slow to adopt ~~,~~ or declines to adopt our PoNS device for neurostimulation therapy, we will not be able to generate significant revenues which would have a material adverse effect on our business. There is limited market awareness of our product, and the neuromodulation market is new and uncertain. There is currently limited market awareness of our product. In order to succeed, we must, among other things, increase market awareness of our PoNS Therapy and expand our sales and marketing strategy. If we fail in any of these endeavors or experience delays in pursuing them, we will not generate revenues as planned and will need to curtail operations or seek additional financing earlier than otherwise anticipated. In addition, if the neuromodulation market ~~35fails~~ **40fails** to become more integrated in neurological therapy, it could have a materially adverse effect on our business and financial position. We face significant competition in an environment of rapid technological change, and our competitors may develop devices or products that are more advanced or more effective than ours are which may adversely affect our financial condition and our ability to successfully market the PoNS device. The neurostimulation market involves rapidly developing technology. Our competitors in the industry are predominantly large companies with longer operating histories, with significantly easier access to capital and other resources and an established product pipeline than us. The combined clinical research and product development done by the industry, including by us and all of our competitors, is foundational, and neurostimulation has slowly become integrated into neurological therapy. This foundation has allowed new and innovative neurostimulation companies to enter the market. New developments occur rapidly, and we anticipate that we will face increasing competition as new companies enter our market. There can be no assurance that we will be able to establish ourselves in the neurostimulation market, or, if established, that we will be able to maintain our market position. Our commercial opportunity may be reduced if our competitors develop new or improved products that are more convenient, more effective or less expensive than our product is. Additionally, technologies developed by our competitors may render the PoNS device uneconomical or obsolete. **Our product is currently made available to authorized users of the**

Department of Veterans Affairs Federal Supply Schedule and if we were no longer eligible to sell our products through such channel, our business may be adversely affected. Our PoNS device is eligible for reimbursement by the Department of Veterans Affairs and included on the Federal Supply Schedule pricing program. We must comply with additional laws and requirements applicable to our operations and manufacturing processes in order to remain eligible for this program. Our PoNS device is available for purchase by the Department of Veterans Affairs off contract. If we were to lose eligibility for reimbursement by the Department of Veterans Affairs, our business, financial condition and results of operations could be adversely affected. Additionally, in February 2025, large layoffs were conducted in the Department of Veterans Affairs, which could significantly delay and impede our interactions with the Department of Veterans Affairs. Risks Related to our Reliance on Third PartiesWe are, and will continue to be, dependent in significant part on outside scientists and third- party research institutions for our research and development in order to be able to commercialize our product. We rely, and will continue to rely, on third- party research institutions, collaborators and consultants. Such third- party research institutions, collaborators and consultants may determine to cease providing services to us at any time, which would delay our product development and commercialization efforts. We depend on third parties for the manufacture and distribution of our product and the loss of our third- party manufacturer and distributor could harm our business. We depend on our third-party contract manufacturing partner to manufacture and supply our PoNS device for clinical and commercial purposes. Additionally, we depend on a different third- party distribution partner to warehouse and ship our products to customers. Our reliance on a third- party manufacturer and a distribution provider to supply us with our PoNS device and to provide such other distribution services exposes us to risks that could delay our sales or result in higher costs or lost product revenues. In addition, our manufacturers have experienced and could continue to experience difficulties in securing long- lead time components, achieving volume production, quality control and quality assurance or suffer shortages of qualified personnel, or fail to follow and remain in compliance with the FDA- mandated Quality System Regulations, or QSR, compliance which is required for all medical devices, or fail to document their compliance to the QSR, any of which could result in their inability to manufacture sufficient quantities of our commercially available ~~product~~ **41product** to meet market demand or lead to significant delays in the availability of materials for our product and / or FDA enforcement actions against them and / or us **. Production of therapeutic products may require raw materials for which the sources and amount of supply are limited or may be hindered by quality or scheduling issues in respect of the third- party suppliers over which the Company has limited control. An inability to obtain adequate supplies of raw materials could significantly delay the development, regulatory approval and sales and marketing of a product** . If we are unable to obtain adequate supplies of our product that meet our specifications and quality standards, it will be difficult for us to compete effectively. While we have supply and quality agreements in place with our manufacturer, they may change the terms of our future orders or choose not to supply us with products in the future. Furthermore, if our manufacturer fails to perform its obligations, we may be forced to purchase our product from other third-party manufacturers, which we may not be able to do on reasonable terms or in sufficient time, if at all. In addition, if we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer or the reverification of an existing manufacturer could negatively affect our ability to produce and distribute our product in a timely manner ~~. 36We are currently in the process of transitioning our manufacturing functions to a new contract manufacturer and any delays in the manufacturing process as a result of this transition could harm our business. During the third quarter of 2023, the Company began implementing the transition of the manufacturing of PoNS device controllers and mouthpieces from its third- party contract manufacturing partner, Key Tronic Corporation, to Minnetronix, Inc. The Company expects this transition to be fully completed by mid- 2024, but it is possible that completing the transition could create delays or disruptions in the manufacturing process, or could affect the performance specifications of our PoNS device. Any delays or disruptions in the manufacturing of our PoNS device during the completion of this transition could negatively impact our business. The occurrence of any delay, assurance of quality standards and applicable regulatory requirements and any terms that our new contract manufacturer may require us, could harm our ability to meet the demand for our products in a timely and cost- effective manner, which could have a material adverse effect on our business, financial condition and results of operations~~ . Risks Related to Intellectual Property If our intellectual property protection is inadequate, competitors may gain access to our technology and undermine our competitive position. We regard our intended and future intellectual property as important to our success, and we intend to rely on patent law to protect our proprietary rights. Despite our precautions, unauthorized third parties may copy certain portions of our devices or products or reverse engineer or obtain and use information that we regard as proprietary. We may seek additional patents in the future. We do not know if any future patent application will be issued with the scope of the claims we seek, if at all or whether any patents we receive will be challenged or invalidated. Thus, we cannot assure you that any intellectual property rights that we may receive can be successfully asserted in the future or that they will not be invalidated, circumvented or challenged. In addition, the laws of some foreign countries do not protect proprietary rights to the same extent, as do the laws of the U. S. Our means of protecting any proprietary rights we may receive in the U. S. or abroad may not be adequate and competitors may independently develop a similar technology. Any failure to protect our proprietary information and any successful intellectual property challenges or infringement proceedings against us could have a material adverse effect on our business, financial condition and results of operations. We may be subject to various litigation claims and legal proceedings, including intellectual property litigation, such as patent infringement claims, which could adversely affect our business. We, as well as certain of our directors and officers, may be subject to claims or lawsuits. These lawsuits may result in significant legal fees and expenses and could divert management' s time and other resources. If the claims contained in these lawsuits are successfully asserted against us, we could be liable for damages and be required to alter or cease certain of our business practices or product lines. Any of these outcomes could cause our business, financial performance and cash position to be negatively impacted. Additionally, our commercial success will also depend, in

part, on not infringing on the patents or proprietary rights of others. There can be no assurance that the technologies and products used or developed by us will not infringe such rights. If such infringement occurs and we are not able to obtain a license from the relevant third party, we will not be able to continue the development, manufacture, use, or sale of any such infringing technology or product. There can be no assurance that necessary licenses to third- party technology will be available at all or on commercially reasonable terms. In some cases, litigation or other proceedings may be necessary to defend against or assert claims of infringement or to determine the scope and validity of the proprietary rights of third parties. Any potential litigation could result in substantial costs to, and diversion of, our resources and could have a material and adverse impact on us. ~~An~~ **42An** adverse outcome in any such litigation or proceeding could subject us to significant liabilities, require us to cease using the subject technology or require us to license the subject technology from the third party, all of which could have a material adverse effect on our business. ~~37There~~ -- **There** are risks to our intellectual property based on our international business operations. We may face risks to our technology and intellectual property as a result of our conducting business outside of the U. S., including as a result of our strategic arrangement with A & B (and subsequent transfer of assets to CMS and CMS Medical Hong Kong Limited), and particularly in jurisdictions that do not have comparable levels of protection of corporate proprietary information and assets such as intellectual property, trademarks, trade secrets, know- how and customer information and records. While these risks are common to many companies, conducting business in certain foreign jurisdictions, housing technology, data and intellectual property abroad, or licensing technology to joint ventures with foreign partners may have more significant exposure. Pursuant to our agreement with A & B, we transferred ownership of certain of our Asian patents, patent applications, and product support material for the PoNS device from us to A & B and granted to A & B, among other things, an exclusive license to market, promote, distribute and sell the PoNS device solely within specified Asian territories. Subsequently, A & B partnered with other companies in other foreign jurisdictions in connection with the development and manufacturing of the PoNS device, which may expose us to material risks of theft of our proprietary information and other intellectual property, including technical data, manufacturing processes, data sets or other sensitive information. For example, our product or components may be reverse engineered by other business partners or other parties, which could result in our patents being infringed or our know- how or trade secrets stolen. The risk can be by direct intrusion wherein technology and intellectual property is stolen or compromised through cyber intrusions or physical theft through corporate espionage, including with the assistance of insiders, or via more indirect routes. Risks Related to Government RegulationBefore we can market and sell our products for additional indications, we are required to obtain marketing authorization and / or certification from the FDA and foreign regulatory authorities. These authorizations and / or certifications will take significant time and require significant research, development, and clinical study expenditures, and ultimately may not succeed. Before we begin to label and market the PoNS Therapy for new uses in the U. S., we are required to obtain marketing authorization via a de novo classification and clearance request for our product or approval of pre- market approval application from the FDA, unless an exemption from pre- market review applies. While we have marketing authorization for the PoNS Therapy in the U. S. for use as a short- term treatment of gait deficit due to mild- to- moderate symptoms of MS, we have not received regulatory authorization or approval for any other indication. The process of obtaining regulatory authorizations or approvals, including completion of the de novo classification process, to market a medical device can be costly and time consuming, and we may not be able to successfully obtain pre- market reviews on a timely basis, if at all. In April 2019, the FDA declined our request for de novo classification and clearance for mmTBI, in part due to insufficient clinical evidence regarding effectiveness of our product from mmTBI. Following a pre- submission meeting with the FDA, we are assessing the feasibility of a clinical program to advance the development of a study aimed to obtain clearance for gait and balance deficits in mmTBI if nondilutive financing to fund the program becomes available. The FDA has substantial discretion in the de novo review process and may refuse to accept any future application (s) or may decide that our data are insufficient to grant the de novo request and require additional pre- clinical, clinical, or other studies. In addition, varying interpretations of the data obtained from pre- clinical and clinical testing could delay, limit, or prevent marketing authorization and / or certification from the FDA or other regulatory authorities. Moreover, in addition to continuing our pursuit of an indication for stroke and mmTBI with the FDA, we are currently considering the development of the PoNS device for other potential indications, including cerebral palsy, Parkinson' s disease, baby boomers balance, and neurological wellness, as well as expanding the label of our current indications. ~~If~~ **43If** the FDA requires us to go through a lengthier, more rigorous examination for the PoNS device for any of these indications or any other indications we may pursue, as it has for the PoNS device in the indication for mmTBI, introducing the product could be delayed or canceled, which would cause our launch to be delayed or cancelled. In addition, the FDA may determine that the PoNS device requires the more costly, lengthy and uncertain pre- market approval process. For example, if the FDA disagrees with our determination that the de novo classification procedures ~~38are~~ -- **are** the appropriate path to obtain marketing authorization for the PoNS device, the FDA may require us to submit a PMA application, which is generally more costly and more burdensome and can take several years from the time the application is submitted to the FDA until an approval is obtained. Obtaining and maintaining FDA marketing authorization will be costly, may result in time- consuming delays and will subject us to ongoing compliance costs and regulatory risk for non- compliance. Even though we have obtained FDA market clearance for our product as a treatment for MS, obtaining FDA marketing authorization, de novo classification and clearance, or PMA approval for medical devices for additional indications can be expensive and uncertain, generally takes from several months to several years, and generally requires detailed and comprehensive scientific and clinical data. Notwithstanding the expense, these efforts may never result in FDA authorization. The FDA can delay, limit or deny authorization of a device for many reasons, including: ● we may not be able to demonstrate to the FDA' s satisfaction that our product candidate is safe and effective for its intended users; ● the data from our pre- clinical studies and clinical trials may be insufficient to support authorization, where required; and ● the manufacturing process or facilities we use may not meet applicable requirements. In addition, the FDA may change its authorization policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or

delay marketing authorization of our products under development. Any delay in, or failure to receive or maintain clearance or approval for our product candidate could prevent us from generating revenue from our product candidate and adversely affect our business operations and financial results. Obtaining market authorization for our product as a treatment for additional indications will require a 510 (k) clearance, de novo classification and clearance, or pre- market approval under which the FDA will likely place substantial restrictions on how our device is marketed or sold. Moreover, the manufacture of medical devices must comply with the FDA' s QSR. In addition, manufacturers must register their manufacturing facilities, list the products with the FDA, and comply with requirements relating to labeling, marketing, complaint handling, adverse event and medical device reporting, reporting of corrections and removals, and import and export. The FDA monitors compliance with the QSR and these other requirements through periodic inspections. If our facilities or those of our manufacturers or suppliers are found to be in violation of applicable laws and regulations, or if we or our manufacturers or suppliers fail to take satisfactory corrective action in response to an adverse inspection, the regulatory authority could take enforcement action, including any of the following sanctions: ● untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties; ● customer notifications of repair, replacement, refunds, detention or seizure of our products; ● product recalls; ● operating restrictions or partial suspension or total shutdown of production; ● refusing or delaying requests for marketing authorization of new products or modified products; ● withdrawing marketing authorizations that have already been granted; ● refusing to provide Certificates for Foreign Government; ● refusing to grant export approval for our products; or ● pursuing criminal prosecution. ~~Regulatory~~ **44Regulatory** enforcement or inquiries, or other increased scrutiny on us, could affect the perceived safety and efficacy of our product candidate and dissuade our customers from using our product candidate, if and when it is authorized for marketing. ~~39We~~ **Once commercialized, modifications to our marketed products may require new 510 (k) clearances or approval of PMA supplements or may require us to cease marketing or recall the modified products until clearances or regulatory approvals are obtained. Modifications to any of our products once they are commercialized may require new regulatory approvals or clearances, including 510 (k) clearances or approval of PMAs or PMA supplements, or require us to recall or cease marketing the modified systems until these clearances or approvals are obtained. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance. A manufacturer may determine that a modification could not affect safety or efficacy and does not represent a major change in its intended use, so that no new clearance or approval is necessary. However, the FDA can review a manufacturer' s decision and may disagree. The FDA may also on its own initiative determine that a new clearance or approval of a PMA supplement is required. We may make modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing our products as modified, which could require us to redesign our products and / or seek new marketing authorizations and harm our operating results. In these circumstances, we may be subject to significant enforcement actions. The transition to the new presidential administration could hinder the FDA' s ability to perform normal business functions on which our business may rely, which could negatively impact our business. The ability of the FDA to review and approve new products, provide feedback on clinical trials and development programs, meet with sponsors and otherwise review regulatory submissions can be affected by a variety of factors, including government budget and funding levels; ability to hire and retain key personnel and accept the payment of user fees; and statutory, regulatory, and policy changes, among other factors. Average review times at the agency may fluctuate as a result. In addition, government funding of other government agencies on which our operations may rely is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA may also increase the time necessary for market authorization submissions for additional indications for our product to be reviewed and / or approved by the FDA, which would adversely affect our business. For example, the Trump Administration has discussed several changes to the reach and oversight of the FDA, which could affect its relationship with the medical device industry and transparency in decision making. Additionally, over the last several years, the U. S. government has shut down multiple times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA and other government employees and stop critical activities. If funding for the FDA is reduced, FDA priorities change, or a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Additionally, recent actions by the United States federal government have caused concern in the industry that this may occur. For example, beginning on February 13, 2025, the Department of Health and Human Services began firing a large number of its probationary employees, a category that includes new federal employees and employees recently promoted or transferred to new positions or agencies. Larger layoffs may follow, according to a memorandum issued by the Office of Personnel Management on February 26, 2025. These terminations, if they withstand legal challenges, may significantly delay and impede our interactions with FDA. Similar results may stem from the recent confirmed resignations of some senior FDA employees with responsibility for regulation of drugs and biologics, as well as possible future layoffs and resignations. There are also reports that the United States federal government intends to request Congress to reduce FDA funding in upcoming budgets. Such funding cuts may also delay the development and approval of new indications for PoNS. 45We** have in the past and may be required to conduct clinical trials to support a de novo submission or PMA application for the PoNS device with respect to one or more indications and we expect to be required to conduct clinical trials to support regulatory marketing authorization for future product candidates. In order to commercialize our product candidate in the U. S. with respect to specified indications, we may be required by the FDA to submit an application for premarket approval, or PMA, for review and approval by the FDA. A PMA application must be submitted to the FDA if our device cannot be cleared through the 510 (k) clearance process, down classified via the de novo process, or is not exempt from premarket review by the FDA. We could also be required to submit a PMA application for potential future product candidates.

If we are required by the FDA to submit a PMA application, the FDA will also require us to conduct clinical trials. We will receive marketing authorization from the FDA to commercialize products requiring a clinical trial only if we can demonstrate to the satisfaction of the FDA, through well designed and properly conducted clinical trials, that our product candidate is safe, effective, and otherwise meet the appropriate standards required for marketing authorization for specified indications. We have and may continue to encounter substantial delays in planned clinical trials, or our planned clinical trials for other indications using the PoNS device may fail to demonstrate the safety and efficacy of the PoNS device to the satisfaction of applicable regulatory authorities. We are currently engaged in multiple clinical trials and may continue to pursue additional clinical trials in the future. Clinical trials are complex, expensive, time consuming, uncertain as to outcome and are subject to substantial and unanticipated delays. Before we may begin clinical trials, if a clinical trial is determined to present a significant risk, we may be required to submit and obtain approval for an investigational device exemption, or IDE, that describes, among other things, the manufacture of, and controls for, the device and a complete investigational plan. Clinical trials generally involve a substantial number of patients in a multi- year study. Because we do not have the infrastructure necessary to conduct clinical trials, we will have to hire one or more contract research organizations, or CROs, to conduct trials on our behalf. CRO contract negotiations may be costly and time consuming and we will rely heavily on the CRO to ensure that our trials are conducted in accordance with regulatory and industry standards. We may encounter problems with our clinical trials and any of those problems could cause us or the FDA to suspend those trials or delay the analysis of the data derived from them. Moreover, any failure to abide by the applicable regulatory requirements by us, our CROs, and / or clinical trial sites may result in regulatory enforcement action against such third parties or us. We cannot guarantee that clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of testing. Delays can be costly and could negatively affect our ability to complete a clinical trial and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize the PoNS device. If we are unable to complete such planned clinical trials, or are unsuccessful in doing so, we may be unable to advance the PoNS device to regulatory authorization and / or certification, and commercialization, which would harm our business, financial condition, and results of operations. We are, and will continue to be, dependent in significant part on outside scientists and third- party research institutions for our research and development in order to be able to commercialize our product. We are and will continue to conduct clinical trials to obtain FDA marketing authorization. We rely heavily on third parties over the course of our clinical trials, and as a result will have limited control over the clinical investigators and limited visibility into their day- to- day activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. These third parties and we are required to comply with current good clinical practices, or cGCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these cGCPs through periodic inspections of trial sponsors, principal investigators, and trial sites. If we or any of these third parties fail to comply with applicable cGCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional nonclinical or clinical trials before approving our marketing applications or may subject them or us to regulatory enforcement actions. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the cGCP ~~40regulations~~ **46regulations** . In addition, our clinical trials may be required to be conducted with a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory marketing authorization and / or certification process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws. Any third parties conducting our clinical trials are not and will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical, clinical, and nonclinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies or other drug development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed, or terminated and we may not be able to complete development of, obtain regulatory marketing authorization and / or certification of or successfully commercialize our product candidate. As a result, our financial results and the commercial prospects for our product candidate would be harmed, our costs could increase, and our ability to generate revenue could be delayed. If any of our relationships terminate with these third- party CROs, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management' s time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays occur, which can materially affect our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition, and prospects. We may be required to suspend or discontinue clinical trials due to side effects or other safety risks that could preclude approval of our products. Our clinical trials may be suspended at any time for a number of reasons. We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to participants. In addition, regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to participants. If we are unable to obtain coverage or adequate reimbursement for our products, use of our products may

decline and our ability to generate revenue may be decreased. In the U. S., the commercial success of our existing product and any future products will depend, in part, on the extent to which governmental payers at the federal and state levels, including Medicare and Medicaid, private health insurers and other third- party payers provide coverage for and establish adequate reimbursement levels for our products. The existence of coverage and adequate reimbursement for our products by government and private payers is critical to market acceptance of our existing and future products. Suppliers are not likely to furnish our existing and any future products if they do not receive adequate reimbursement for our products. Many private payers currently base their reimbursement policies on the coverage decisions and payment amounts determined by CMS, which administers the Medicare program. Others may adopt different coverage or reimbursement policies for our products, while some governmental programs, such as Medicaid, have reimbursement policies that vary from state to state, some of which may not pay for our products in an adequate amount, if at all. A Medicare national or local coverage decision denying coverage for one or more of our products could result in private and other third- party payers also denying coverage for our products. Third- party payers also may deny reimbursement for our products if they determine that a product was not medically necessary, was not used in accordance with cost- effective treatment methods, as determined by the third- party payer, or was used for an unapproved use. Unfavorable coverage or reimbursement ~~41decisions~~ **47decisions** by government programs or private payers underscore the uncertainty that our products face in the market and could have a material adverse effect on our business. The healthcare industry in the U. S. has experienced a trend toward cost containment as government and private payers seek to control healthcare costs by paying service providers lower rates. While we believe that suppliers will be able to obtain coverage for our products, the level of payment available to them for our products may change over time. Federal and state healthcare programs, such as Medicare and Medicaid, closely regulate program payment levels and have sought to contain, and sometimes reduce, payment levels. Private payers frequently follow government payment policies and are likewise interested in controlling increases in the cost of medical care. In addition, some payers are adopting pay- for- performance programs that differentiate payments to suppliers based on the achievement of documented quality- of- care metrics, cost efficiencies, or patient outcomes. These programs are intended to provide incentives to providers to deliver the same or better results while consuming fewer resources. Because of these programs, and related payer efforts to reduce payment levels, suppliers are seeking ways to reduce their costs, including the amounts they pay to medical device manufacturers. We may not be able to sell our product profitably if third- party payers deny or discontinue coverage or reduce their levels of payment below that which we project, or if our production costs increase at a greater rate than payment levels. Adverse changes in payment rates by payers to suppliers could adversely affect our ability to market, sell our products, and negatively affect our financial performance. In international markets, medical device regulatory requirements and healthcare payment systems vary significantly from country to country, and many countries have instituted price ceilings on specific product lines. We cannot assure you that our products will be considered cost- effective by international third- party payers, that reimbursement will be available or, if available, that the third- party payers' reimbursement policies will not adversely affect our ability to sell our product profitably. Any failure to receive regulatory or reimbursement approvals would negatively affect market acceptance of our products in any international markets in which those approvals are being sought. If we fail to comply with healthcare laws, we could face substantial penalties and financial exposure, and our business, operations and financial condition could be adversely affected. We are subject to numerous healthcare laws that place limitations and requirements on the manner in which we conduct our business, including our sales and promotional activities and interactions with healthcare professionals and facilities. In some instances, our interactions with healthcare professionals and facilities that occurred prior to commercialization (e. g., the granting of stock options) could have implications at a later date. The laws that may affect our ability to operate include, among others: ● The US federal healthcare Anti- Kickback Statute prohibits any person from, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchasing, leasing, ordering or arranging for or recommending of any good or service for which payment may be made, in whole or in part, under federal and state healthcare programs such as Medicare and Medicaid. The term " remuneration " has been broadly interpreted to include anything of value. The Anti- Kickback Statute is subject to evolving interpretation and has been applied by government enforcement officials to a number of common business arrangements in the medical device industry. The government can establish a violation of the Anti- Kickback Statute without proving that a person or entity had actual knowledge of the statute or specific intent to violate it. There are a number of statutory exemptions and regulatory safe harbors protecting some common activities from prosecution; however, those exceptions and safe harbors are drawn narrowly. Failure to meet all of the requirements of a particular statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti- Kickback Statute, but the legality of the arrangement will be evaluated on a case- by- case basis based on the totality of the facts and circumstances. Penalties for violations of the Anti- Kickback Statute include, but are not limited to, criminal, civil and / or administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from Medicare, Medicaid and other federal healthcare programs, and the curtailment or restructuring of operations. ● The federal civil False Claims Act prohibits, among other things, knowingly presenting, or causing to be presented, claims for payment of government funds that are false or fraudulent, or knowingly making, or using or causing to be made or used, a false record or statement material to an obligation to pay money to the ~~42government~~ **48government** , or false or fraudulent claim to knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. Private individuals, commonly known as " whistleblowers, " can bring civil False Claims Act qui tam actions, on behalf of the government and such individuals may share in amounts paid by the entity to the government in recovery or settlement. In addition, a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and significant mandatory penalties per false claim or statement for violations. Criminal penalties, including imprisonment and criminal fines, are also possible for

making or presenting a false, fictitious or fraudulent claim to the federal government. ● HIPAA, among other things, imposes criminal and civil liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third party ~~payors~~ **payers**, knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal healthcare Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. ● The federal Physician Payment Sunshine Act, implemented as the Open Payments Program, requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare and Medicaid Services information related to payments and other transfers of value, directly or indirectly, to physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse midwives, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. ● Analogous state laws and regulations, such as state anti- kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by any third- party ~~payors~~ **payers**, including private insurers or patients. If our operations are found to be in violation of any of the laws described above or any other domestic or foreign laws and governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, exclusion from participation in government healthcare programs, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that their provisions are open to a variety of evolving interpretations and enforcement discretion. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management' s attention from the operation of our business. Our communications regarding products and product candidates, even while in development, are subject to extensive government scrutiny. We may be subject to governmental, regulatory and other legal proceedings relative to advertising, promotion, and marketing, and communications with study subjects and healthcare professionals, which could have a significant negative effect on our business. We are subject to governmental oversight and associated civil and criminal enforcement relating to medical device advertising, promotion, and marketing, and such enforcement is evolving and intensifying. Communications regarding our products in development and regarding our clinical trials may subject us to enforcement if they do not comply with applicable laws. In the U. S., we are potentially subject to enforcement from the FDA, other divisions of the Department of Health and Human Services, the U. S. Federal Trade Commission, or the FTC, the Department of Justice, and state and local governments. Other parties, including private plaintiffs, also are commonly bringing suit against pharmaceutical and medical device companies. We may be subject to liability based on the actions of individual employees and third- party contractors carrying out activities on our behalf. ~~43Even~~ **49Even** after marketing authorization and / or certification for our product is obtained, we are subject to extensive post- market regulation by the FDA and equivalent foreign competent authorities. Our failure to meet strict regulatory requirements could require us to pay fines, incur other costs or even close our facilities. Even after we have obtained the proper regulatory clearance or approval to market a product, the FDA has the power to require us to conduct post- market studies. These studies can be very expensive and time- consuming to conduct. Failure to complete such studies in a timely manner could result in the revocation of clearance or approval and the recall or withdrawal of the product, which could prevent us from generating sales from that product in the U. S. The FDA has broad enforcement powers, and any regulatory enforcement actions or inquiries, or other increased scrutiny on us, could dissuade some healthcare professionals from using our products and adversely affect our reputation and the perceived safety and efficacy of our products. We are also required to comply with the FDA' s Quality System Regulation, or QSR, which covers the methods used in, and the facilities and controls used for, the design, manufacture, quality assurance, labeling, packaging, sterilization, storage, shipping, installation and servicing of our marketed products. The FDA enforces these requirements via periodic announced and unannounced inspections of manufacturing facilities. In addition, in the future, regulatory authorities and / or customers may require specific packaging of sterile products, which could increase our costs and the price of our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the product from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects. After commercialization, our products may cause or contribute to adverse medical events or be subject to failures or malfunctions that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us. The FDA and similar foreign governmental authorities such as the competent authorities of the European Economic Area countries or Health Canada have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture or in the event that a product poses an unacceptable risk to health. Manufacturers may, under their own initiative, recall a product if any material deficiencies in our products are found. A government- mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. We are subject to the FDA' s medical device reporting regulations and similar foreign regulations, which require us to report to the FDA when we receive or become aware of information that reasonably suggests that one or

more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance or approval, seizure of our products or delay in clearance or approval of future products. The FDA and foreign regulatory bodies have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an ~~44unacceptable~~ **50unacceptable** risk to health. The FDA' s authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found. A government- mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future. Depending on the corrective action we take to redress a product' s deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new clearances or approvals for the device before we may market or distribute the corrected device. Seeking such clearances or approvals may delay our ability to replace the recalled devices in a timely manner. Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, will distract management from operating our business and may harm our reputation and financial results. Any future failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in any of the following enforcement actions: ● untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties; ● unanticipated expenditures to address or defend such actions; ● customer notifications or repair, replacement, refund, recall, detention or seizure of our products; ● operating restrictions or partial suspension or total shutdown of production; ● refusing or delaying our requests for 510 (k) clearance, de novo clearance, PMA approval, NDA, or BLA of new products or modified products; ● withdrawing clearances or approvals that have already been granted; ● refusal to grant export approval for our products; or ● criminal prosecution. Any of these sanctions could have a material adverse effect on our reputation, business, results of operations and financial condition. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements, which could result in our failure to produce our products on a timely basis and in the required quantities, if at all. U. S. legislative or FDA regulatory reforms may make it more difficult and costly for us to obtain regulatory approval of our product and to manufacture, market and distribute our products after marketing authorization is obtained. From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of future products. **For example, In January of 2024, FDA issued a final rule to replace the QSR with the adoption of ISO 13485, known as the Quality Management System Regulation, or QMSR. The new rule comes into effect in February if 2026.** ~~Any~~ **51Any** changes in the laws or regulations that govern the clearance and approval processes relating to our current, planned and future products could make it more difficult and costly to obtain clearance or approval for new products or to ~~45produce~~ **produce** , market and distribute existing products. Significant delays in receiving clearance or approval or the failure to receive clearance or approval for any new products would have an adverse effect on our ability to expand our business. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing clearance that we may have obtained and we may not achieve or sustain profitability. **The policies of the Trump Administration and their impact on the regulation of our products in the United States remain uncertain. For example, efforts to reduce the size of government could lead to fewer government personnel and reviewers for our product candidates or product modifications. Any such reduction in the size of review teams could lead to longer review times, fewer opportunities for interactive communications with the FDA, and fewer medical devices being cleared or approved. Any change in the laws or regulations that govern the clearance and approval processes relating to our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market and distribute existing products. Significant delays in receiving clearance or approval, or the failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business. Moreover, the imposition of tariffs on foreign goods could impact our supply chain leading to fewer suppliers in the marketplace or make it more difficult or expensive to import components or parts needed for our medical devices.** Risks Related to our Business OperationsWorldwide economic and social instability could adversely affect our revenue, financial condition, or results of operations. The health of the global economy as well as the

stability of the social fabric of our society affects our business and operating results. Global economic conditions in recent years have been volatile and disruptive due a number of factors such as geopolitical conflicts including those in Ukraine and in the Middle East, disruptions in the banking system and financial markets, supply chain disruptions, labor shortages, increased inflation ~~and~~ **,** sustained high interest rates **and unpredictable trade policies, including tariffs, customs regulations and other trade restrictions** . These conditions from time to time have, and could in the future, caused or exacerbated significant slowdowns in our industry and in the markets in which we operate, negatively impacting our business and results of operations. Our customers may experience financial difficulties or be unable to borrow money to fund their operations, which may adversely impact their ability to purchase our products or to pay for our products on a timely basis, if at all. In addition, adverse economic conditions have impacted ~~,~~ and may continue to adversely impact our suppliers' ability to provide our manufacturer with materials and components, which may negatively impact our business. Furthermore, these economic conditions make it more difficult for us to accurately forecast and plan our future business activities. If our expenses are greater than anticipated, then we will have fewer funds with which to pursue our plan of operations and our financing requirements will be greater than anticipated. We may find that the costs of carrying out our plan of operations are greater than we anticipate. We expect our expenses to increase over time in connection with our ongoing activities, particularly if and as we: expand our commercialization efforts of our PoNS device in the U. S. for MS; make improvements to our manufacturing process and product design; launch clinical trials for stroke and other indications; pursue further regulatory approvals; maintain, expand and protect our intellectual property portfolio; and add additional personnel. Increased operating costs may cause the amount of financing that we require to increase. Investors may be more reluctant to provide additional financing if we cannot demonstrate that we can control our operating costs. There is no assurance that additional financing required as a result of our operating costs being greater than anticipated will be available to us. If we do not control our operating expenses, then we will have fewer funds with which to carry out our plan of operations with the result that our business may fail. ~~Our~~ **52Our** ability to use net operating losses to offset future taxable income may be subject to certain limitations. Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code substantial changes in a corporation' s ownership may limit the amount of net operating losses, or NOLs, that can be utilized annually in the future to offset the corporation' s (and the corporation' s affiliates') U. S. federal and state taxable income. Specifically, this limitation may arise in the event of a cumulative change in ownership of more than 50 % within any three- year period. The amount of the annual limitation is determined based on the value of the corporation that underwent the ownership change, immediately before the ownership change. Subsequent ownership changes may further affect any limitation in future years (including by way of exercising of warrants). We may undertake a study to analyze and determine if any historical ownership changes of us or our subsidiary HMI have occurred to determine if there are any permanent limitations on our ability to utilize NOLs in the future. If we determine that an ownership change has occurred, the limitations on the use of our NOLs could increase our U. S. federal and state tax liability and reduce the amount of cash available for distribution to shareholders or otherwise adversely affect the value of an investment in our common stock or warrants. ~~46As~~ **As** a result of the use of our product in clinical trials, and through the sale of our products, we may be liable for product liability claims and we may not carry sufficient product liability insurance. The PoNS device and any devices and product candidates that we may develop in the future may expose us to potential liability from personal injury claims by clinical trial subjects and, if commercially sold, end- users of the product. We maintain clinical trial liability insurance and carry product liability insurance to protect us against the risk that in the future a product liability claim or product recall could materially and adversely affect our business. Inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of our intended product. We cannot assure you that when we commence distribution of our product that we will be able to obtain or maintain adequate coverage on acceptable terms, or that such insurance will provide adequate coverage against all potential claims. Moreover, even if we maintain adequate insurance, any successful claim could materially and adversely affect our reputation and prospects and divert management' s time and attention. If we are sued for any injury allegedly caused by our future products, our liability could exceed our total assets and our ability to pay the liability. We are a " smaller reporting company " under federal securities laws and we cannot be certain whether the reduced reporting requirements applicable to such companies will make our common stock less attractive to investors. We are a " smaller reporting company " under federal securities laws. For as long as we continue to be a smaller reporting company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies, including, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non- affiliates is less than $ 250 million or (ii) our annual revenue was less than $ 100 million during the most recently completed fiscal year and the market value of our stock held by non- affiliates is less than $ 700 million. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may decline or be more volatile. Investors could lose confidence in our financial reports, and the value of our common stock may be adversely affected, if our internal controls over financial reporting are found not to be effective by management or by our independent registered public accounting firm. As long as we remain a non- accelerated filer, we are exempt from the attestation requirement in the assessment of our internal control over financial reporting by our independent auditors pursuant to section 404 (b) of the Sarbanes- Oxley Act of 2002 but are required to make our own internal assessment of the effectiveness of our internal controls over financial reporting. The existence of one or more material weaknesses could affect the accuracy and timing of our financial reporting. ~~Investors~~ **53Investors** could lose confidence in our financial reports, and the value of our common stock may be harmed, if our internal controls over financial reporting are found not to be effective by management or by our independent registered public accounting firm. Several people who work for us on a part- time consulting basis may be subject to conflicts of interest. Several people who provide services to us are part- time consultants. Each may devote part of his working time to other

business endeavors, including consulting relationships with other corporate entities, and may have responsibilities to these other entities. Because of these relationships, some of the persons who provide services to us may be subject to conflicts of interest. Such conflicts may include deciding how much time to devote to our affairs, as well as what business opportunities should be presented to us. ~~47Our~~ -- **Our** business and operations would suffer in the event of computer system failures, cyber- attacks or a deficiency in our cyber- security. Despite the implementation of security measures, our information technology, communication networks and related systems, and those of third parties on which we rely, could be damaged, disrupted, breached or otherwise compromised from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber- attacks or cyber- intrusions (including ransomware attacks) over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. No network or system can ever be completely secure, and the risk of a security breach or disruption, particularly through cyber- attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. For example, in October 2019, we were the victim of a business email compromise fraud which resulted in our incurring a loss of approximately $ 0. 1 million. If any such attack, intrusion or other event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs for an indeterminate period of time. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In some cases, data cannot be reproduced. To the extent that any disruption or cybersecurity incident was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur material legal claims and liability, damage to our reputation, and the further development of the PoNS device or any future product candidate could be delayed. If a cybersecurity incident results in the exposure or unauthorized disclosure of personal information, we could incur additional costs associated with data breach notification and remediation expenses, investigation costs, regulatory penalties and fines, and legal proceedings. Our insurance coverage may not be adequate to cover all the costs related to such cybersecurity incidents. Challenges to our tax positions in U. S. or non- U. S. jurisdictions, the interpretation and application of recent U. S. tax legislation or other changes in U. S. or non- U. S. taxation of our operations could harm our business, revenue and financial results. We operate, or intend to operate, in a number of tax jurisdictions globally, including in the U. S. at the federal, state and local levels, and in several other countries, and we therefore are or will be subject to review and potential audit by tax authorities in these various jurisdictions. Significant judgment is required in determining our worldwide provision for income taxes and other tax liabilities, and tax authorities may disagree with tax positions we take and challenge our tax positions. Successful unilateral or multi- jurisdictional actions by various tax authorities may increase our worldwide effective tax rate, result in additional taxes or other costs or have other material consequences, which could harm our business, revenue and financial results. Our effective tax rate may also change from year to year or vary materially from our expectations based on changes or uncertainties in the mix of activities and income allocated or earned among various jurisdictions, changes in tax laws and the applicable tax rates in these jurisdictions (including future tax laws that may become material), tax treaties between countries, our eligibility for benefits under those tax treaties and the valuation of deferred tax assets and liabilities. Such changes could result in an increase in the effective tax rate applicable to all or a portion of our income, impose new limitations on deductions, credits or other tax benefits or make other changes that may adversely affect our business, ~~eash~~ **54cash** flows or financial performance. For example, if we are unable to fully realize the benefit of interest expense incurred in future periods as a result of recent tax law changes (as discussed below), we may need to recognize a valuation allowance on any related deferred tax assets, which would impact our annual effective income tax rate. The cumulative impact of these and other changes in tax law is uncertain and our business and financial condition could be adversely affected. The impact of these changes on holders of our securities is also uncertain and could be adverse. ~~48Risks~~ -- **Risks** Related to Our Common StockWe could be delisted from The Nasdaq Capital Market, which could seriously harm the liquidity of our stock and our ability to raise capital **or complete a strategic transaction** . Our common stock is listed on the Nasdaq Capital Market under the symbol " HSDT ". In order to maintain that listing, we must satisfy minimum financial and other requirements including, without limitation, the minimum stockholders **'** equity requirement and the minimum bid price requirement. There can be no assurances that we will be successful in maintaining, or if we fall out of compliance, in regaining compliance with the continued listing requirements and maintaining the listing of our common stock on the Nasdaq Capital Market. Delisting from Nasdaq could adversely affect our ability to raise additional financing through the public or private sale of equity securities and we would incur additional costs under requirements of state " blue sky " laws in connection with any sales of our securities. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities. **On August 9, 2024, we received a Notification Letter from the Listing Qualifications Staff (the " Staff ") of Nasdaq notifying us that because the closing bid price of our common stock was below $ 1. 00 per share for the prior 30 consecutive business days, we are not in compliance with the minimum bid price requirement for continued listing on The Nasdaq Capital Market, as set forth in Nasdaq Marketplace Rule 5550 (a) (2) (the " Minimum Bid Price Requirement "). On February 7, 2025, we received a second Notification Letter from the Staff notifying us that the 180- day compliance period had expired and that we are ineligible for an additional 180- day period due to the Company' s noncompliance with the $ 5, 000, 000 minimum stockholders' equity initial listing requirement for the Nasdaq Capital Market. As a result, the second Notification Letter informed us that our listed common stock would be subject to delisting pending the request of an appeal with regards to this determination. The Company had a hearing with the Nasdaq Hearing Panel on March 18, 2025. At the hearing, we presented our plan for regaining compliance with the Minimum Bid Price Requirement and requested a further extension so that we may complete the execution of our plan. Although we believe our plan will be sufficient to enable us to regain compliance, no assurance can be provided that Nasdaq will ultimately accept our plan or that we will**

ultimately regain compliance with the Minimum Bid Price Requirement. As of the date of this report, we have not received a determination from the hearings panel. Our common stock will remain listed and eligible for trading on Nasdaq pending the ultimate conclusion of the hearing process. If our common stock is delisted by Nasdaq, the price of our common stock may decline and our common stock may be eligible to be quoted on the OTC Bulletin Board, another over- the- counter quotation system, or on the pink sheets, which would negatively affect the liquidity of our common stock and an investor may find it more difficult to dispose of their common stock or obtain accurate quotations as to the market value of our common stock **. Any such delisting action may materially adversely affect our ability to raise capital or pursue strategic transactions on acceptable terms, or at all** . In addition, if our common stock is delisted from the Nasdaq Capital Market and the trading price remains below $ 5. 00 per share, trading in our common stock might also become subject to the requirements of certain rules promulgated under the Exchange Act, which require additional disclosure by broker- dealers in connection with any trade involving a stock defined as a " penny stock " (generally, any equity security not listed on a national securities exchange ~~or quoted on Nasdaq~~ that has a market price of less than $ 5. 00 per share, subject to certain exceptions). We continue to actively monitor our performance with respect to the listing standards and will consider available options to resolve any deficiency and maintain compliance with the Nasdaq rules. There can be no assurance that we will be able to maintain compliance or, if we fall out of compliance, regain compliance with any deficiency, or if we implement an option that regains our compliance, maintain compliance thereafter. ~~An~~ **55An** active trading market for our common stock on The Nasdaq Capital Market may not continue to develop or be sustained. Although our common stock is listed on The Nasdaq Capital Market, we cannot assure you that an active trading market for our common stock will continue to develop or be sustained. If an active market for our common stock does not continue to develop or is not sustained, it may be difficult for investors in our common stock to sell their shares of our common stock without depressing the market price for the shares or to sell the shares at all. Trading of our common stock could be sporadic, and the price of our common stock may be volatile; we caution you as to the highly illiquid nature of an investment in our shares. Our common stock has been listed on The Nasdaq Capital Market since April 11, 2018. Securities of microcap and small- cap companies have experienced substantial volatility in the past, often based on factors unrelated to the companies' financial performance or prospects. We believe that trading in our stock has been and will likely continue to be subject to significant volatility. These factors include macroeconomic developments in North America and globally and market perceptions of the attractiveness of particular industries. Factors unrelated to our performance that may affect the price of our common stock include the following: the extent of analytical coverage available to investors concerning our business may be limited if investment banks with research capabilities do not follow us, a reduction in trading volume and general market interest in our common stock may affect an investor' s ability to trade significant numbers of shares of our common stock; the size of our public float may limit the ability of some institutions to invest in our common stock. As a result of any of these factors, the market price of our common stock at any given point in time may not accurately reflect our long- term value. The price of our common stock may increase or decrease in response to a number of events and factors, including: changes in financial estimates; our acquisitions and financings; quarterly ~~49variations~~ -- **variations** in our operating results; the operating and share price performance of other companies that investors may deem comparable; and purchase or sale of blocks of our common stock. These factors, or any of them, may materially adversely affect the prices of our common shares regardless of our operating performance. The market price of our common stock is affected by many other variables which are not directly related to our success and are, therefore, not within our control. These include other developments that affect the breadth of the public market for shares of our common stock and the attractiveness of alternative investments. The effect of these and other factors on the market price of our common stock is expected to make our common stock price volatile in the future, which may result in losses to investors. Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our common stock may be lower as a result. There are provisions in our certificate of incorporation and bylaws that may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change of control was considered favorable by you and other stockholders. For example, our board of directors has the authority to issue up to 10, 000, 000 shares of preferred stock. The board of directors can fix the price, rights, preferences, privileges, and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change of control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders. Our charter documents also contain other provisions that could have an anti- takeover effect, including: ● stockholders are not entitled to remove directors other than by a 66 2 ⁄ 3 % vote and only for cause; ● stockholders are not be permitted to take actions by written consent; ● stockholders cannot call a special meeting of stockholders; and ● stockholders must give advance notice to nominate directors or submit proposals for consideration at stockholder meetings. ~~In~~ **56In** addition, we are subject to the anti- takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions by prohibiting Delaware corporations from engaging in specified business combinations with particular stockholders of those companies. These provisions could discourage potential acquisition proposals and could delay or prevent a change of control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock. Our certificate of incorporation provides that the Court of Chancery of the State of Delaware and, to the extent enforceable, the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim for breach of a fiduciary duty owed by any of our directors, officers or other employees

to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws or (iv) any action asserting a claim governed by the internal affairs doctrine. Our certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, subject to and contingent upon a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision. These exclusive forum provisions may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. For example, stockholders who do bring a claim in the Court of Chancery could face ~~50additional~~ -- **additional** litigation costs in pursuing any such claim, particularly if they do not reside in or near the State of Delaware. The Court of Chancery and federal district courts may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our stockholders. Some companies that adopted a similar federal district court forum selection provision are currently subject to a suit in the Chancery Court of Delaware by stockholders who assert that the provision is not enforceable. If a court were to find either choice of forum provision contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition. For example, the Court of Chancery of the State of Delaware recently determined that the exclusive forum provision of federal district courts of the United States of America for resolving any complaint asserting a cause of action arising under the Securities Act is not enforceable. As a result of this decision, we do not currently intend to enforce the federal forum selection provision in our certificate of incorporation, unless the decision is reversed on appeal. However, if the decision is reviewed on appeal and ultimately overturned by the Delaware Supreme Court, we would enforce the federal district court exclusive forum provision. If securities or industry analysts do not publish or cease publishing research or reports about us, our business or our market, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline. The trading market for our common stock will be influenced by the research and reports that industry or securities analysts may publish about us, our business, our market or our competitors. If any of the analysts who may cover us change their recommendation regarding our stock adversely, or provide more favorable relative recommendations about our competitors, our stock price would likely decline. If any analyst who may cover us were to cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. **57** ~~General RisksWe have not paid any dividends and do not foresee paying dividends in the future. We intend to retain earnings, if any, to finance the growth and development of our business and do not intend to pay cash dividends on shares of our common stock in the foreseeable future. The payment of future cash dividends, if any, will be reviewed periodically by the board of directors and will depend upon, among other things, conditions then existing including earnings, financial condition and capital requirements, restrictions in financing agreements, business opportunities and other factors. A decline in the price of our common stock could affect our ability to raise any required working capital and adversely affect our operations. A decline in the price of our common stock could result in a reduction in the liquidity of our common stock and a reduction in our ability to raise any required capital for our operations. Because our operations to date have been principally financed through public and private offerings of our common stock and warrants and exercises of options and warrants, a decline in the price of our common stock could have an adverse effect upon our liquidity and our continued operations. A reduction in our ability to raise equity capital in the future may have a material adverse effect upon our business plans and operations. If our stock price declines, we may not be able to raise additional capital or generate funds from operations sufficient to meet our obligations. We are heavily dependent upon the ability and expertise of our management team and a very limited number of employees and the loss of such individuals could have a material adverse effect on our business, operating results or financial condition. We currently have a very small management team. Our success is dependent upon the ability, expertise and judgment of our senior management. While employment agreements are customarily used as a primary method of retaining the services 51~~