UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ **Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.**

For the Fiscal Year Ended December 31, 2024
or

☐ **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.**

For the transition period from _____ to _____
Commission File No. 001-38445

HELIUS MEDICAL TECHNOLOGIES, INC.
(Exact name of registrant as specified in its charter)

Delaware	**36-4787690**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
642 Newtown Yardley Road, Suite 100 Newtown, Pennsylvania	**18940**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (215) 944-6100

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Class A Common Stock, $0.001 par value per share	**HSDT**	**The Nasdaq Stock Market LLC**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☐

Non-accelerated filer ☒ Smaller reporting company ☒

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. Yes ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the common equity held by non-affiliates of the registrant on June 30, 2024, based on the closing price on that date of $0.98 per share, was approximately $3,094,103. As of March 18, 2025, there were 6,126,778 shares of the registrant's Class A common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the proxy statement for the 2025 annual meeting of stockholders are incorporated by reference into Part III of this Annual Report to the extent described herein.

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In this Annual Report on Form 10-K, ("Form 10-K") unless otherwise specified, references to "we," "us," "our," "Helius" or "the Company" mean Helius Medical Technologies, Inc. and its wholly owned subsidiaries, Helius Medical, Inc. ("HMI"), Helius Medical Technologies (Canada), Inc. ("HMC") and Revelation Neuro, Inc. ("Revelation Neuro") unless the context otherwise requires. Our financial statements are prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP").

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K includes certain statements that may constitute "forward-looking statements." All statements contained in this Form 10-K, other than statements of historical facts, that address events or developments that the Company expects to occur, are forward-looking statements. These statements are based on management's expectations at the time the statements are made and are subject to risks, uncertainty, and changes in circumstances, which may cause actual results, performance, financial condition or achievements to differ materially from anticipated results, performance, financial condition or achievements. All statements contained herein that are not clearly historical in nature are forward-looking and the words "anticipate," "believe," "calls for," "could" "depends," "estimate," "expect," "extrapolate," "foresee," "goal," "intend," "likely," "might," "plan," "project," "propose," "potential," "target," "think," and similar expressions, or that events or conditions "may," "should occur" "will," "would," or any similar expressions are generally intended to identify forward-looking statements.

The forward-looking statements in this Form 10-K include but are not limited to statements relating to: the Company's future growth and operational progress, including manufacturing activities for the PoNS device, receipt of prescriptions and progress of commercialization of the PoNS device in the U.S., our ability to receive adequate reimbursement coverage under Medicare, Medicaid or under other insurance plans, clinical development plans, product development activities, plans for U.S. Food and Drug Administration, or FDA, filings and their subsequent approvals, other foreign or domestic regulatory filings, the safety and effectiveness of our product, our market awareness, our ability to compete effectively, the ability and limitation of our manufacturing sources, our distribution network, the adequacy of our intellectual property protection, our future patent approvals, our future expenses and cash flow, our ability to become profitable, our future financing arrangements, our accountants' future perspective including any going concerns, any future stock price, and our ability to build commercial infrastructure.

Such forward-looking statements are necessarily based upon a number of estimates and assumptions that, while considered reasonable by Helius, are inherently subject to significant business, economic, competitive political and social uncertainties and contingencies. The factors and assumptions used by management of the Company to develop such forward-looking statements include, but are not limited to, uncertainties associated with the Company's capital requirements to achieve its business objectives, availability of funds, the ability to find additional sources of funding, manufacturing, labor shortage and supply chain risks, including risks related to manufacturing delays, the Company's ability to obtain national Medicare insurance coverage and to obtain a reimbursement code, the Company's ability to continue to build internal commercial infrastructure, secure state distribution licenses, market awareness of the PoNS device, future clinical trials and the clinical development process, the product development process and FDA regulatory submission review and approval process, other development activities, ongoing government regulation and other factors included in the section entitled "Risk Factors."

Although we believe the expectations expressed in such forward-looking statements are based on reasonable assumptions at the time they were made, they are subject to risks and uncertainties, known and unknown, which could cause actual results and developments to differ materially from those expressed or implied in such statements. Forward-looking statements are not guarantees of future performance and actual results may differ significantly from such forward-looking statements.

You should refer to the "Risk Factors" section of this Form 10-K for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Form 10-K will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all.

These forward-looking statements speak only as of the date of this Form 10-K. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future. You should, however, review the factors and risks and other information we describe in the reports we will file from time to time with the Securities and Exchange Commission (the "SEC") after the date of this Form 10-K.

SUMMARY RISK FACTORS

Our business is subject to a number of risks, as fully described in "Item 1A. Risk Factors" in this Annual Report. The principal factors and uncertainties include, among others:

- We have a history of losses and may not achieve or sustain profitability in the future;
- We 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;
- We will require additional financing to carry out our plan of operations, and failure to obtain such financing may cause our business to fail;
- Global macroeconomic conditions remain volatile and uncertain due in part to geopolitical conflicts, banking and financial markets disruptions, supply chain disruptions, labor shortages, increased inflation, high interest rates and various trade restrictions, and any adverse impacts of such conditions could significantly harm our business or negatively affect our ability to obtain financing;
- We currently only have one product, the PoNS device, which is authorized for commercial distribution in Canada, Australia, and in the U.S. for treatment of MS, and we have not obtained authorization and/or certification to distribute the PoNS device commercially in Europe or in the U.S. for other indications and may never obtain such authorizations and/or certifications;
- Generation of revenue related to the PoNS technology is dependent on the PoNS Therapy® being prescribed by physicians in the U.S. and our ability to train physical therapists in the supervision of the use of the PoNS Therapy;
- Market awareness of the PoNS device is limited, and the neuromodulation market is new and uncertain;
- 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;
- We are dependent on third-party scientists and research institutions, in part, for research and development and on third parties for the manufacture and distribution of our product;
- Third parties may gain access to our technology if our intellectual property protection is insufficient;
- We may be subject to various litigation claims and legal proceedings, including intellectual property litigation, which may adversely affect our business;
- Commercialization of our product outside of Canada, Australia, and the U.S. for indications other than MS is dependent on obtaining market authorization and/or certification from the FDA and foreign regulatory authorities, which will require significant time, research, development, and clinical study expenditures and ultimately may not be successful;
- 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;
- We have not received adequate reimbursement rates from CMS and failure to obtain adequate reimbursement rates from other third parties could have a negative impact on our intended sales and would have a material adverse effect on our business, financial condition and operating results;
- We may encounter substantial delays in planned clinical trials, and planned clinical trials may fail to demonstrate the safety and efficacy of the PoNS device in new indications to the satisfaction of regulatory authorities;
- If we fail to comply with healthcare laws, we could face substantial penalties and financial exposure;
- We face ongoing government scrutiny and regulation in connection with the development of product candidates and following marketing authorization and/or certification;
- After commercialization, a product recall or the discovery of serious safety issues with our products could have a significant adverse impact on us;
- Our controls and security measures may not be successful in avoiding cybersecurity incidents;

- We are reliant on third-party, single-sourced contract manufacturing, exposing us to risks that could delay our sales or result in higher costs or lost product revenues including additional related risks resulting from the transition of our manufacturer;
- Our common stock is subject to various challenges that could cause its value to decrease; and
- We face various tax risks that could negatively affect our ability to conduct our business.

INDUSTRY AND MARKET DATA

In this Form 10-K, we reference information, statistics and estimates regarding the medical devices and healthcare industries. We have obtained this information from various third-party sources, including industry and general publications, reports by market research firms and other sources. This information involves a number of assumptions and limitations, and we have not independently verified the accuracy or completeness of this information. Some data and other information are also based on the good faith estimates of management, which are derived from our research, review of internal surveys, general information discussed in the industry, and third-party sources. We believe that these external sources and estimates are reliable but have not independently verified them. The industries in which we operate are subject to a high degree of uncertainty, change, and risk due to a variety of factors, including those described in "Item 1A. Risk Factors." These and other factors could cause results to differ materially from those expressed in this Form 10-K and other publications.

PART I

ITEM 1. BUSINESS

Overview

We are a neurotechnology company focused on neurological wellness. Our purpose is to develop, license or acquire non-implantable technologies targeted at reducing symptoms of neurological disease or trauma.

Our product, known as the Portable Neuromodulation Stimulator, or PoNS®, is an innovative non-implantable medical device, inclusive of a controller and mouthpiece, which delivers mild electrical stimulation to the surface of the tongue to provide treatment of gait deficit and chronic balance deficit. PoNS Therapy is integral to the overall PoNS solution and is the physical therapy applied by patients during use of the PoNS device. PoNS has marketing clearance in the U.S. for use in the U.S. as a short-term treatment of gait deficit due to mild-to-moderate symptoms for multiple sclerosis ("MS") and is to be used as an adjunct to a supervised therapeutic exercise program in patients 22 years of age and over by prescription only. We began accepting prescriptions for PoNS in the U.S. in March 2022, and commercial sales of PoNS commenced in April 2022. PoNS is authorized for sale in Canada for three indications: (i) as a short term treatment (14 weeks) of chronic balance deficit due to mild-to-moderate traumatic brain injury, or mmTBI, and is to be used in conjunction with physical therapy; (ii) as a short term treatment (14 weeks) of gait deficit due to mild and moderate symptoms from MS and it is to be used in conjunction with physical therapy; and (iii) for use as a short term treatment (14 weeks) of gait deficit due to mild and moderate symptoms from stroke, to be used in conjunction with physical therapy. It has been commercially available in Canada since March 2019. PoNS is authorized for sale as a Class IIa medical device in Australia and we have been seeking a business partner to commercialize and distribute PoNS in Australia.

PoNS Device

The PoNS device is a non-implantable medical device comprised of a controller and a mouthpiece that are connected by a cord. The controller is worn around the neck and the mouthpiece sits on the tongue during treatment. PoNS Therapy utilizes the PoNS device in conjunction with supervised therapeutic exercise. The PoNS Therapy consists of condition specific exercises for movement control, including balance and gait training and breathing and awareness training, which are tailored to focus on the individual patient's functional deficits. The PoNS Therapy is completed over a period of 14 weeks. During the first 2 weeks, the PoNS Therapy is mostly administered in a rehabilitation or physical therapy clinic by a PoNS trained therapist and, to a lesser extent, performed at home. The remaining 12 weeks are completed at home with weekly clinic visits to monitor rehabilitation progress, assess improvements and ensure the therapy intensity remains appropriate. When the device is on, the 143 gold-plated electrodes on the mouthpiece send mild electrical signals to the tongue. These impulses stimulate sensory nerves in the tongue that have direct pathways to the brain, through the brain stem. The combination of mild stimulation with supervised therapeutic exercise promotes neuromodulation and likely trigger neuroplastic effects, which potentially lead to functional improvements in balance and gait. During each clinic visit and at the end of the 14-week therapy, the clinic downloads and reviews the PoNS usage data from the device. This usage data in combination with details of completed treatment assessments gives the clinician and the patient a unique and powerful method to assess treatment progress. The patient initiates their PoNS Therapy sessions with the PoNS device initially under the supervision of the clinicians, then through regular check-ins.

Clinical research has shown that translingual neurostimulation activates two major cranial nerves – the trigeminal nerve, and the facial nerve, which creates a flow of neural impulses that are delivered directly into the brain stem and cerebellum – the main control centers for multiple functions including sensory perception and movement. From the brain stem, these impulses travel throughout the brain and may activate or reactivate signaling pathways involved in human function. Researchers believe that supervised therapeutic exercise with neurostimulation can modulate neural activity and initiate adaptive changes in the brain that lead to restructuring and reorganization (neuroplasticity) processes in specific areas of the brain.

Design

The PoNS device is ergonomically designed for patient comfort, is relatively light, contains a replaceable hygienic mouthpiece and a rechargeable battery with built-in technology to allow for tracking of the patient's usage, including time and intensity of treatments. See Figure 1.

Figure 1
The Portable Neuromodulation Stimulator, PoNS device

The mouthpiece of the PoNS device sits on the front third of the tongue and is held in place by the lips and closed mouth. See Figure 2.

Figure 2

A rechargeable lithium polymer battery with built-in charge safety circuitry provides power. While the voltage and pulse timing to each electrode are programmed into the device and cannot be altered, the user can adjust the stimulus intensity, which is achieved by adjusting the electrical pulse width. The sensation produced by the mouthpiece is similar to the feeling of drinking a carbonated beverage. The patented waveform is specifically designed to minimize the potential for tissue irritation.

Overview of MS and Current Available Treatments

MS is currently classified as an autoimmune disease of the central nervous system. The disease attacks the myelin, the protective covering of the nerve necessary for the transmission of nerve impulses through nerve fibers, causing inflammation and often damaging the myelin. Damage to the myelin is variable, depending on the course of the disease, which influences the type and severity of symptoms. MS is unpredictable and can cause symptoms such as extreme fatigue, lack of coordination, weakness, tingling, impaired sensation, vision problems, bladder problems, cognitive impairment and mood changes. Its effects can be physical and emotional with a substantial financial burden. Currently there is no cure and patients with MS experience a progressive decline in health over time. There are a variety of treatments available for MS, some of which are experimental, including pharmaceutical, dietary, and surgical, which may or may not be covered by government or private health insurance.

Findings from a 2019 National MS Society study (Wallin et al, 2019) estimate that nearly 1 million people in the U.S. are living with MS of which approximately 25-30% are on Medicare. The National MS Society estimates that 2.9 million people live with MS globally. The U.S. and Canada have the highest rates of MS, with 337.9 to 362.6 cases per 100,000 in the U.S. In Canada, 93,000 people are living with MS with 290 cases per 100,000 in Canada (Statistics Canada, Gilmour et al, 2018). Given the nature of this neurodegenerative disease, these individuals and their caretakers are active in exploring treatment options that may resolve or delay the progression of symptoms. There is also a well-established advocacy framework.

Mobility disability and walking impairment are among the most debilitating consequences of MS with approximately 72% of individuals diagnosed with MS reporting gait impairment as a major limitation in their daily lives (Williams et al, 2014). Gait is one of the most important bodily functions for MS patients and gait parameters, such as walking speed and stride length, have been shown to be significant predictors of patient's independence in daily activities. A survey of 436 patients found that 45% reported a mobility disability in the first month following diagnosis, with upwards of 90% of patients reporting a mobility disability within 10 years of their diagnosis (Baird et al, 2019). Additionally, 50-80% of MS patients suffer from balance and gait dysfunction (Cameron et al, 2018) and over 56% fall at least once within a three-month period (Carlin et al, 2018). It has also been reported that unemployment rates in MS patients range from 24-80% with higher rates associated with decreased ambulation and mobility (Julian et al, 2008). The Centers for Disease Control, or CDC, reports that individuals with disabilities, like MS, that result in limited mobility are at greater risk for health problems including injury, mental health and depression, overweight and obesity, pain, pressure sores or ulcers and other issues.

A 2016 economic analysis of MS found the total lifetime costs per person with MS to be $4.1 million (Owens, 2016), with average yearly healthcare costs ranging from $57 thousand to $93 thousand based on the severity of the disease, and averaging $65 thousand more in yearly healthcare costs than that of someone without MS (Bebo et al, 2022). In 2019, the total economic burden attributed to MS in the U.S was $85.4 billion and the average annual cost of living with MS was $88 thousand (Bebo et al, 2022).

Since the exact cause of MS is still unknown, there is no known prevention. Although there is no cure for MS yet, immunotherapy can provide disease-modifying effects, and other pharmacological and non-pharmacological treatments can manage symptoms. MS medications are designed to lessen the frequency of relapses and slow the progression of the disease, but none have been proven to halt progression of the disease. While there are several disease-modifying medications approved by the FDA to treat MS, only one drug approved by FDA and Heath Canada, Ampyra® (dalfampridine), which is indicated for the improvement of gait speed in conjunction with physical therapy in patients with MS, offers the closest, albeit limited only to speed, comparison to PoNS Therapy on improvement in gait.

Overview of TBI and Current Available Treatments

There are an estimated 49.0 million people globally (Guan et al, 2023), with 5.3 million in the U.S. (Centers for Disease Control and Prevention, 2015) and 2% of Canadians estimated to be 760,000 (Brain Injury Canada, N.D.), living with a TBI-related disability. Every year there are 27.2 million newly diagnosed TBIs globally (Guan et al, 2023), of which 2.8 million (Taylor et al, 2017) and 165,000 (Brain Injury Canada, N.D.) occur in the U.S. and Canada, respectively. This condition often has a significant impact on one's quality of life, negatively affecting independence, employability,

productivity, mental health and participation in the community. Rehabilitation is often required following a TBI for resulting motor, cognitive and behavioral impairments. Approximately 80% of individuals who sustain a TBI report balance impairment (Dever et al, 2022). The current standard of care to address balance issues following a TBI is supervised therapeutic exercise. While supervised therapeutic exercise can help to promote balance recovery, individuals are often unable to return to their full function and are left living with a balance deficit.

Prior to the development of the PoNS device, there were no cleared treatments that were clinically indicated to treat balance deficit. A few studies have suggested that supervised therapeutic exercise aimed at improving balance and gait may be mildly effective for rehabilitation in the mmTBI population. Given the small number of published studies, the small number of patients enrolled in the studies of which we are aware, the varying range of interventional protocols employed in such studies and the lower levels of study design, it is difficult to draw any conclusions regarding the effectiveness and dosing parameters of using supervised therapeutic exercise alone for the treatment of balance deficit following mmTBI. Consequently, we believe that there is a large potential commercial opportunity for the PoNS Therapy in the treatment of balance deficit due to mmTBI. Our goal is to establish the PoNS Therapy as the standard of care for this condition all over the world.

Overview of Stroke and Current Available Treatments

According to the World Stroke Organization, there are more than 101 million people across the globe who have experienced a stroke, and over 12 million new strokes occur each year (Feigin et al, 2022). In the U.S., approximately 650,000 people survive a new stroke each year and an estimated 7 million Americans live with ongoing complications of stroke (Dobkin, 2013). The Canadian Chronic Disease Surveillance System states that stroke is the third leading cause of death in Canada and the tenth largest contributor to disability-adjusted life years (the number of years lost due to ill-health, disability or early death). About 878,000 Canadian adults aged 20+ have experienced a stroke (Heran et al, 2022) and with the population aging, more and more Canadians are at risk. This condition often has a significant impact on one's functional ability, negatively affecting independence, employability, productivity, mental health and participation in the community. In addition, more than 80% of the survivors have gait impairment (Carmen, 2020). Rehabilitation is required following a stroke for resulting motor, cognitive and behavioral impairments. Most province public health systems in Canada offers stroke rehabilitation services along with private establishments. The potential for commercial opportunity for PoNS to support all these public and private establishments is wide. PoNS Therapy offers new opportunities for this type of service by enhancing physical rehabilitation and helping attain the desired goals.

PoNS Clinical Trials and Scientific Support in MS

There are two peer-reviewed published studies reporting on the results of clinical trials comparing active PoNS + PT vs a no frequency pulse sham device (placebo PoNS) + PT in subjects with mild and moderate MS: Tyler et al. Journal of Neuro Engineering and Rehabilitation 2014, 11:79 and Leonard et al. Multiple Sclerosis Journal Experimental, Translational and Clinical January-March 2017: 19 DOI: 10.1177/ 2055217317690561.

Summary results of the Tyler study in 20 subjects with mild and moderate MS:

- The study was designed as a between-group comparison of the Dynamic Gait Index (DGI) score improvement in 10 subjects treated with active PoNS, in conjunction with two weeks of treatment in clinic under supervision of a registered PoNS trainer, and, individually, at home over 12 weeks, as compared to 10 subjects treated with placebo PoNS and the same physical therapy regimen, after a total of 14 weeks of treatment.
- The primary endpoint demonstrated a statistically significant improvement greater than 4 points in the DGI score from baseline in the active PoNS group as compared to placebo at endpoint (Week 14) ($p<0.005$).
- The DGI improvement was already clinically meaningful at 2 weeks of treatment and continued to increase over the following 8 weeks of therapy with an average improvement of 7.7 points, which was then maintained (slightly increased) through week 14.

Summary results from the Leonard study in 14 patients treated with mild and moderate MS:

- A statistically significant improvement in the NeuroCom Sensory Organization Test (SOT), a test of subject's ability to balance, from baseline to week 14 of treatment in 7 subjects treated with active PoNS as compared to the 7 subjects in placebo PoNS group (p=0.001).
- Functional MRI data showed an increased blood oxygen dependent level (BOLD) signal in specific brain cortical areas, suggesting that sustained PoNS neuromodulation-induced activation of these cortical areas is likely to trigger a series of adaptive changes (neuroplasticity), expected to rehabilitate existing pathways as well as engage new mechanisms to deliver functional signals to the spinal cord, that may correlate with PoNS therapeutic outcomes observed in the Tyler study.

Summary of Real-World Evidence (RWE) in MS patients treated with PoNS in Canada.

- Gait deficit treatment outcomes for PoNS-treated individuals are routinely captured through a proprietary validated data capture software. At the time of this retrospective analysis, all data from the MS treated subjects available in our database, specifically 43 MS subjects treated with PoNS for gait deficit in Canada between March 2019 and December 2019, were utilized.
- The mean improvement in the FGA (functional gait assessment) from baseline to Week 14 was 4.53 (95% CI 3.35 to 5.72) with a median improvement of 5 points.
- A minimal detectable change, greater or equal to 4-point FGA improvement, was met by 56.7% of subjects, most of whom had chronic MS with long durations of the disease.
- An analysis of the surveillance safety database demonstrated an excellent safety profile supporting a positive benefit-risk ratio in the real-world clinical utilization setting.

Summary of PoNS Therapeutic Experience Program (PoNSTEP) study in MS.

- PoNSTEP study assesses the adherence to on-label PoNS® Therapy for improvement of gait in people with multiple sclerosis (MS) in a real-world clinical setting, and aims at understanding the utilization, treatment compliance, and the short/long-term clinical benefits of PoNS Therapy.

- The study enrolled 43 patients with gait deficit due to mild-to-moderate MS into the study who were receiving standard clinical care for their medical condition. The recommended dose of PoNS Therapy was 100-120 min per day for 14 weeks, performed 5 days/week in the clinic for the first 2 weeks (Phase 1), followed by a 12-week unsupervised therapy at home (Phase 2). Participants were also evaluated after a 6-month post-treatment observation period (Phase 3).

- The primary endpoint was maintenance of gait improvement from the end of supervised therapy (Phase 1) to the end of unsupervised therapy (Phase 2) in relation to the subject's adherence to PoNS therapy. Secondary endpoints included, among others, maintenance of improvement of gait and balance deficit over time.

- 41 patients started treatment, 38 completed the 14-week treatment protocol, and 29 of 38 were evaluated at the 6-month follow-up. Participants who declined 30% or more in their functional improvement from the end of Phase 2, were eligible for an additional 12-wk course of PoNS Therapy at home.

- The mean improvement in DGI during Phase 1 and Phase 2, among the 38 subjects completing the protocol, was 5.00 points (4.1 to 5.9, $p<0.001$) at week 14. Average therapy adherence was almost 90% in Phase 1 (with no significant association with DGI improvement [$r=0.14$; $p=0.42$]), whereas in Phase 2, adherence was over 67% with a significant linear correlation with DGI improvement ($r=0.345$; $p=0.034$). The mean changes [SD] in Phase 2 for subjects with ≥85% and <85% adherence were 3.7 [1.8] and 2.0 [1.8] points, respectively ($p=0.008$).

- 70.7% participants were evaluated Week 26 and the mean percentage decline in DGI was -4.1% (95% CI -9.4% to 1.1%) with only 1/28 (3.6%) experiencing at least a 30% decline in DGI (95% exact binomial confidence interval: 0.09% to 18.4%). No correlations between the mean decline from Week 14 to Week 26 and the treatment adherence metrics was observed (0.16 for Phase 1, 0.20 for Phase 2, and 0.20 for the whole 14-wk treatment period, all with p>0.30).

PoNS Clinical Trials and Scientific Support in mmTBI

There are two peer-reviewed published studies reporting on the clinical trials' results of the PoNS Therapy in people with mmTBI. The first is from our registrational clinical trial (TBI-001): Ptito A, Papa, L, Gregory, K, Folmer, RL, Walker, WC, Prabhakaran, V, Wardini, R, Skinner, KL, Yochelson, M, (2020). "A Prospective, Multicenter Study to Assess the Safety and Efficacy of Translingual Neurostimulation Plus Physical Therapy for the Treatment of a Chronic Balance Deficit Due to Mild-to-Moderate Traumatic Brain Injury". *Neuromodulation: Technology at the Neural Interface*. The second is from the Long-Term Treatment study in mmTBI Trial: Tyler, ME, Skinner, KL, Prabhakaran, V, Kaczmarek, KA, Danilov, YP (2019). "Translingual neurostimulation for the treatment of chronic symptoms due to mild-to-moderate traumatic brain injury." Archives of Rehabilitation Research and Clinical Translation; 1(304):100026.

PoNS Registrational Clinical Trial in mmTBI

Both studies were double-blind randomized, controlled, aiming to assess the safety and effectiveness of the PoNS Therapy using translingual noninvasive electric stimulation in conjunction with physical therapy performed in clinic for the first two weeks of treatment under supervision of a registered PoNS trainer, and, individually, at home over a short-term period of time (3 or 12 weeks) for a total of 5- or 14-week therapy, respectively for the short- and long-term studies. Both trials enrolled chronic (> 1 year post head trauma event) TBI subjects with a balance deficit established as sensory organizational test (SOTT) composite score of at least 16 points below the normative value for the participant's age, who have reached a plateau in their prior physical rehabilitation regimen outcome. According to published clinical trial data, balance impaired TBI subjects treated with physical therapy alone reached an average improvement of 10-13 points in their SOT composite score over a short-term treatment period, an improvement that trended back towards baseline values upon physical therapy discontinuation. In both PoNS studies, participants entered the trial with an average SOT composite score of 40 (1-100 range), indicative of compromised functional balance, and were randomized to treatment with PoNS devices that delivered either a high-frequency pulse (HFP) (25.7 million pulses per 20 minute treatment) or a low-frequency pulse (LFP) (13,728 pulses per 20-minute treatment).

In both studies, the primary efficacy endpoint was constructed for a between-group (HFP-treated and LFP-treated cohorts) comparison based on a greater than 15-point SOT composite score improvement at endpoint. The statistical plans also provided for a key secondary efficacy endpoint that established the treatment response (> 15 points on SOT composite score) from baseline in the pooled HFP and LFP groups at endpoint(s), should the primary measure failed to establish a significant difference between the HFP and LFP treatment groups.

Summary results of the registrational study (Ptito et al. 2020) in mild to moderate TBI subjects with balance deficit:

- The trial, launched in 2015 in conjunction with the U.S. Army Medical Research and Materiel Command, or the USAMRMC and conducted at seven sites in the U.S. and Canada, evaluated 122 randomized subjects.
- The primary efficacy endpoint, although failing to demonstrate a between-group difference (p<0.081), showed a higher responder rate in the HFP arm with 71.2% of subjects experiencing a greater than 15-point improvement on the SOT composite score as compared to 63.5% in the LFP arm over a 5-week treatment period.
- The key secondary efficacy endpoints demonstrated a statistically significant increase (p<0.0005) in SOT composite scores from baseline for the pooled arms with a mean improvement of 18.3 points at two weeks of treatment and of 24.6 points at five weeks of treatment.
- The primary safety endpoint demonstrated a decrease in the frequency of falls as determined by daily event(s) during the in-clinic phase of the study (week two).

- The secondary safety endpoint demonstrated a decrease in the frequency and severity of headaches (by the Headache Disability Index) from baseline to end of treatment (at week 5).
- No device-related serious adverse events were observed.

Summary of the results of the 26-week long-term treatment study (Tyler et al, 2019) in people with mmTBI:

- The study, performed to evaluate the durability of response to the PoNS Therapy over a 26-week period (14-week therapy followed by 12-week washout period) conducted at the Tactile Communication & Neurorehabilitation Laboratory at the University of Wisconsin-Madison and sponsored by the U.S. Army, enrolled 44 mild-to-moderate subjects with gait deficit.
- The primary efficacy endpoint, although similar to the registrational study, did not show a separation on the composite SOT score improvement between the HFP and LFP groups, confirmed the trend of a higher response rate in the HFP group.
- The secondary endpoint showed a 29.8-point improvement of the composite SOT score from baseline in the HFP-treated group at the end of 14 weeks of treatment.
- At the end of the 12-week washout period, the participants maintained, on average, the same SOT composite score achieved over the 14 weeks of PoNS Therapy.
- The study confirmed the favorable safety profile shown in the registrational study.

These studies demonstrated that the PoNS Therapy could, on average, allow people with mmTBI who had balance deficit reach, over 14 weeks of treatment, and maintain, over 12-week post-treatment, an SOT composite score within or above the normal range. Furthermore, in a subset of nine participants, who underwent sequential magnetic resonance imaging (MRI) scans, showed meaningful structural and functional changes in specific brain areas consistent with PoNS therapeutic effect on the balance function.

PoNS Clinical Evidence and Scientific Support in Stroke

In a clinical study (2017) published by Dr. Mary Galea, PoNS Therapy displayed a statistically significant effect on improving balance deficit after 2 weeks of intense physical therapy rehabilitation with PoNS, as compared to high-intensity physical therapy alone. The study was conducted in an in-patient rehabilitation setting on 10 patients who were in the subacute stroke phase and with therapy intensity higher than in most stroke rehabilitation settings.

The following is a summary of the real-world evidence (“RWE “) database analysis of stroke patients treated with PoNS in Australia:

- The combined intervention with PoNS was significantly more effective than high intensity physiotherapy alone for the rehabilitation of balance in stroke survivors.
- After two weeks of therapy, the median score on the Mini-BEST was 22.0 in the PoNS-treated group, compared to 13 in the control group, providing a clinically significant and meaningful therapeutic outcome, especially when considering that a cut-off score of 17.5 has been shown to discriminate between fallers and non-fallers with chronic stroke (> 6 months).

Gait deficit treatment outcomes for PoNS-treated individuals were analyzed through a RWE retrospective analysis of clinical data from 10 clinical rehabilitation settings in Canada sites. The RWE dataset consisted of 31 consecutive stroke patients that started treatment between March 2019 and November 2022. Patients included in this data set met the criteria for mild to moderate chronic stroke based on the rating of gait (walking) ability. Gait performance was determined using the FGA. FGA at Baseline and at Week 14, as well as changes form Baseline to Week 14 and FGA values at intermediate time points were summarized using means, standard deviations, medians, minimum and maximum values and where appropriate using 95% confidence intervals.

Summary of RWE database analysis in stroke patients treated with PoNS in Canada:

- The adjusted mean improvement in the FGA was 6.74 (95% CI: 4.85 to 8.63) among 30 subjects. The lower bound of this confidence interval exceeds the reported minimum detectable change (MDC) of 4.2 points for improvements in FGA in stroke patients.
- 18 of 26 (69.2%) subjects with complete data at baseline and at Week 14 had improvements larger than the MDC (95% 2-sided binomial exact CI 51.5% to 87.0%).
- Among subjects with evaluable baseline and Week 14 FGA, 25 of 26 (96.2%) subjects were at risk for falling at baseline (FGA<23). Among the 25 subjects with baseline fall risk, 7 (28%) subjects were no longer at risk for falling at Week 14. The one subject not at fall risk at baseline remained not at fall risk at Week 14.
- There was no statistically reliable evidence that effectiveness varies by age, gender, or clinical site.

Safety and Tolerability Profile of PoNS Therapy

PoNS Therapy has an excellent high safety profile. Overall, the therapy is safe and well tolerated. Reported adverse events were mild and typically related to baseline comorbidities and not PoNS treatment. In Dr. Galea's two-week randomized controlled study, no serious device-related adverse events were reported for any subject treated with PoNS. Similarly, in the MS and TBI randomized studies, there were no serious PoNS device-related adverse events in any disease groups. Furthermore, there were reductions from baseline in fall rate and in the Headache Disability Index ("HDI") and improvements in sleep quality were also reported in the TBI studies.

The PoNS device has been used in clinical rehabilitation settings with over 798 patients since March 4, 2019 to treat balance and gait disorders with more than 247,000 patient sessions recorded, no serious device-related events have been recorded along with zero reported adverse events.

Regulatory Status Worldwide

Canadian Regulatory Status: mmTBI, MS and Stroke

On October 17, 2018, we received our Canadian marketing authorization from Health Canada allowing us to commercialize the PoNS device in Canada for use as a short-term treatment (14 weeks) of balance deficit due to mmTBI.

On March 18, 2020, we received marketing authorization from Health Canada allowing us to commercialize the PoNS device in Canada for the treatment of gait deficit in patients with mild and moderate MS symptoms. Our market authorization application comprised objective statistical evidence as well as independently reviewed clinical research analysis. This label expansion expanded our addressable market in Canada to include a patient population seeking treatment options that may resolve or delay the progression of MS gait deficit symptoms.

On March 8, 2023, we received marketing authorization from Health Canada allowing us to commercialize the PoNS device in Canada for use as a short-term treatment of gait deficit due to mild and moderate symptoms from stroke. This expands our addressable market in Canada to include a patient population seeking treatment options that may resolve stroke gait deficit symptoms.

U.S. Regulatory Status: MS

On May 7, 2020, we received Breakthrough Designation for the PoNS device as a potential treatment for gait deficit due to symptoms of MS, to be used as an adjunct to a supervised therapeutic exercise program. The goal of the Breakthrough Devices Program is to provide patients and health care providers with timely access to these medical devices by speeding up their development, assessment, and review, while preserving the statutory standards for premarket approval, 510(k) clearance, and de novo classification and clearance, consistent with FDA's mission to protect and promote public health.

The Breakthrough Devices Program offers manufacturers an opportunity to interact with the FDA to efficiently address topics as they arise during the premarket review phase, which can help manufacturers receive feedback from the FDA and identify areas of agreement in a timely way. Manufacturers can also expect prioritized review of their submission.

Breakthrough Device Designation does not change the requirements for approval of an application for a marketing authorization.

On March 26, 2021, we received marketing authorization from the FDA of the PoNS device for use as a short-term treatment of gait deficit due to mild-to-moderate symptoms of MS and is to be used as an adjunct to a supervised therapeutic exercise program in patients 22 years of age and over by prescription only.

On February 29, 2024, we received Healthcare Common Procedure Coding System (HCPCS) codes for the PoNS controller and for the PONS mouthpiece, which became effective on April 1, 2024.

We also intend to provide broad access and reimbursement for the PoNS Therapy over time through commercial insurers. Prior to the initiation of CMS or broad commercial payer coverage, the primary source of sales has been self-pay patients. We expect to continue to support the cost of the PoNS Therapy by collaborating with third parties to provide self-pay patients with financing options as well as working with advocacy groups and charitable organizations to help self-pay patients access our technology. In general, we anticipate that it will take at least 24 months to obtain broad coverage and reimbursement among government and private payers.

U.S. Regulatory Status: Stroke

In August 2021, we received Breakthrough Designation for the PoNS device as a potential treatment for dynamic gait and balance deficits due to symptoms from stroke, to be used as an adjunct to a supervised therapeutic exercise program in patients 22 years of age and over. With Breakthrough Designation received, we have started a stroke registrational program (SPR) including two company sponsored pivotal studies, a randomized controlled double blinded trial (HMI-RCT) and an open label study (OLS) of PoNS Therapy in people with gait and/or balance deficit due to chronic stroke, at 10 clinical sites across the US and Canada. In addition, the SPR includes an investigator-initiated pilot study, sharing the same study design, patient population, study treatment, endpoints, and statistical analysis of the pivotal studies, conducted at the Medical University of South Carolina and at Brooks Rehabilitation (FL). All studies are fully enrolled and we are targeting a submission to FDA in mid-to-late 2025.

U.S. Regulatory Status: mmTBI

Our U.S. regulatory strategy initially focused on pursuing de novo classification and clearance of the PoNS device from the FDA for the treatment of balance deficit due to mmTBI.

We submitted a request for de novo classification and clearance of the PoNS device to the FDA for this indication in August 2018. This request was supported by data from two of our clinical trials in mmTBI, including our registrational trial, TBI-001.

In April 2019, we announced that the FDA had completed its review and had denied our request for de novo classification and clearance of the PoNS device for the treatment of balance deficit due to mmTBI. In reaching its conclusion, the FDA noted, via a denial letter, that although the safety profile of the PoNS device is acceptable, the FDA did not have sufficient information to discern the relative independent contributions of the PoNS device and physical therapy on the improvements from baseline. The FDA noted that we could generate additional data to address its concerns and resubmit our application.

In October 2019, we had a pre-submission meeting where the FDA provided feedback needed to help complete the design of a new clinical trial intended to address the FDA's request for a trial that demonstrates the benefit of the PoNS Therapy compared to physical therapy alone. In January 2020, we received the FDA's feedback on the minutes from the October 2019 pre-submission meeting. In its feedback, the FDA provided post-meeting notes with specific recommendations regarding the trial design that were not discussed in the October 2019 pre-submission meeting.

Based on the receipt of the FDA's final minutes from the pre-submission meeting, 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.

European Regulatory Status

In December 2018, we submitted an application for CE certification with a notified body in the European Union ("EU"), which, if granted, would allow us to CE mark and market the PoNS device in the EU. During the second quarter of 2019, we engaged with our notified body in Europe to answer questions that we received from them as part of the conformity assessment of our PoNS device for CE certification. In August 2019, we withdrew our application to be CE certified due to uncertainty in Europe caused by the switch from the Medical Device Directive, or MDD, to the Medical Device Regulation, or MDR, Brexit, and the withdrawal of Lloyd's Register Quality Assurance, our notified body, from the EU notified body business. We have engaged G-MED NA (North America) as our ISO registrar and will reconsider submitting to the EU when conditions stabilize.

Australian Regulatory Status

In the third quarter of 2019, we initiated the submission of our application to the Therapeutic Goods Administration, or TGA. We supplemented our submission with additional data based on questions supplied to date and provided responses to additional questions during the third quarter of 2020. In November 2021, we received market authorization from the TGA for the sale of PoNS as a Class IIa medical device. In Australia, PoNS is intended for short term use by healthcare professionals as an adjunct to a therapeutic exercise program to improve balance and gait. PoNS is not intended to be used alone without an exercise program.

HTC Exclusive Distribution Agreement

On March 3, 2023, we entered into an Exclusive Distribution Agreement with Health Tech Connex, Inc. ("HTC") ("HTC Exclusivity Agreement"), whereby, subject to certain terms and conditions, we granted to HTC the exclusive right to provide the PoNS Therapy in the Fraser Valley and Vancouver metro regions of British Columbia, where HTC has operated a PoNS authorized clinic since February 2019. HTC purchases the PoNS devices for use in these regions exclusively from us and on terms no less favorable than the then-current standard terms and conditions. This HTC Exclusivity Agreement replaces the previous Clinical Research and Co-Promotion Agreement ("HTC Co-Promotion Agreement") between the parties dated October 2019.

Product Development, Manufacturing and Logistics Services

The commercial design of the PoNS device was originally manufactured and assembled by Key Tronic Corporation ("Key Tronic"), our contract manufacturing partner since 2017, at its facility located in Oakdale, Minnesota. During the third quarter of 2023, the Company began implementing the transition of the manufacturing of PoNS device controllers and mouthpieces from Key Tronic to Minnetronix, Inc ("Minnetronix") in St. Paul, MN. The Company has completed the transition during the fourth quarter of 2024. Minnetronix now manufactures devices for engineering and design verification testing and for our FDA submissions as well as commercial devices for inventory.

We place an emphasis on protecting our patented technology, trade secrets and know-how and only share confidential information on an as-needed basis. Minnetronix is registered as a medical device manufacturer in good standing with the FDA and along with Cambridge Consultants, our design services supplier, are certified in accordance with International Organization for Standardization, or ISO, 13485, a comprehensive quality management system for the design and manufacture of medical devices. HMI maintains a compliant quality management system certified to ISO 13485:2016 and is compliant with MDSAP requirements for the U.S., Canada and Australia.

During 2021, we contracted with Healthlink International Inc. ("Healthlink") to provide third party logistics for domestic and Canadian shipment and order fulfillment, and to provide warehousing services for finished goods. Healthlink began fulfilling orders in the United States effective with the commencement of commercial sales in the United States in April 2022 and in Canada during the fourth quarter of 2022. Healthlink is a life science solutions company, specializing in

logistics, temperature-controlled warehousing, fulfillment and freight management as well as back-office services, including multilingual customer service, financial services and VAT management.

Commercialization

U.S. Commercialization Activities

On March 26, 2021, we received marketing authorization from the FDA for the PoNS device. The PoNS device is indicated for use as a short-term treatment of gait deficit due to mild-to-moderate symptoms of MS and is to be used as an adjunct to a supervised therapeutic exercise program in patients 22 years of age and over by prescription only.

Throughout the pre-commercial phase during 2021 and early 2022, we developed and refined our commercial strategy including a focus on payer strategy, both government and commercial, securing distribution licenses in various states and beginning to build relationships with key large neurorehabilitation centers, which focus on treatment of MS patients. We continue to generate data on outcomes of the PoNS Therapy generated from treatment of patients in Canada and ensuring that our scientific data is presented at many of the key national and international neurology and neuromodulation meetings. We believe this scientific dissemination may begin to pave the way to establishing the PoNS Therapy as the standard of care for the treatment of MS-related gait deficit.

We began accepting prescriptions for PoNS in the U.S. in the first quarter of 2022, and our first commercial sales began in April 2022.

We have targeted specific Key Opinion Leaders (i.e., neurologists and physiatrists) and their associated neurorehabilitation centers, where selected physical therapists will be trained to deliver the PoNS Therapy. Importantly, this focused strategy will also allow us to measure patient outcomes to determine if they are comparable to those observed in our clinical trials.

In June 2022, we launched the Patient Therapy Access Program ("PTAP") program, which provided qualifying patients access to PoNS Therapy at a significantly reduced price. Through the PTAP program, the Company collected important health information that helped gain insight into the value of PoNS on key therapeutic outcomes that supplemented the data collected through clinical trials and real-world data. The PTAP was not renewed and terminated on June 30, 2023.

In December 2022, we launched an e-commerce site in the US to make it easier for patients to obtain PoNS devices and began processing orders in January 2023. Accessed via ponstherapy.com, the site is powered through a new partnership with UpScriptHealth, a leading telehealth company focused on making medications and devices available direct-to-consumer. UpScriptHealth's platform provides for (1) online health evaluations with qualified medical providers, (2) fulfillment of prescriptions required for PoNS Therapy and (3) shipping of PoNS devices directly to the homes of eligible patients in the United States. The UpScriptHealth platform makes it possible for people with MS to have a PoNS device delivered directly to their doorstep.

During 2021, we contracted with an industry consultant to conduct a health economic study of PoNS. Based upon the results of this study and comparing PoNS to other medical devices utilizing similar patented technologies we established a U.S. list price for the PoNS device of $25,700, comprised of $17,800 for the controller and $7,900 for the mouthpiece. We are pursuing commercial insurance coverage and Medicare reimbursement for PoNS within the Durable Medical Equipment ("DME"), benefit category. Effective in 2025, the list price for the PoNS Device is $28,270, comprised of $19,580 for the controller and $8,690 for the mouthpiece.

We initially applied for unique Healthcare Common Procedure Coding System ("HCPCS") codes during the third quarter of 2021. In order to address CMS's request for additional information to "further understand the PoNS device indication for use", we decided to monitor real-world utilization of PoNS Therapy and collect additional clinical evidence through the PoNSTEP study and our registry program. Based on consistent reports of positive therapeutic benefits experienced by MS patients through our commercial programs, we reapplied for HCPCS codes in the second quarter of 2023 leveraging new information, addressing their questions and providing further support in favor of obtaining unique HCPCS codes for PoNS. In February 2024, CMS assigned HCPCS Level II codes A4593, "Neuromodulation stimulator system, adjunct to rehabilitation therapy regime" to describe the PoNS controller and A4594, "Neuromodulation stimulator system, adjunct to rehabilitation therapy regime, mouthpiece each" to describe the PoNS mouthpiece. The new HCPCS codes became effective April 1, 2024.

On May 2, 2024, CMS published a proposed fee schedule payment rates for the PoNS controller and PoNS mouthpiece to be discussed at CMS' bi-annual Healthcare Common Procedure Coding System ("HCPCS") public meeting to be held on May 29, 2024. For the PoNS Controller (HCPCS Code A4593), CMS preliminarily set pricing by mapping reimbursement to existing code E0745, (Neuromuscular stimulator, electronic shock unit), resulting in a capped fee of $1,206.53. For the PoNS Mouthpiece (HCPCS code A4594), CMS based pricing on the previously offered, temporary, cash pay price of $4,500, resulting in a total capped payment of $3,075.53.

The Company subsequently provided CMS additional information to support reimbursement economics and presented that information at the public meeting with CMS on May 29, 2024 for consideration by CMS for determination of the final reimbursement amount for each of the PoNS controller and mouthpiece.

On October 7, 2024, CMS posted the final payment rate for the PoNS Mouthpiece (HCPCS code A4594) at $2,963.30, which will be effective January 1, 2025 and deferred final national determination of the payment rate for the PoNS Controller (HCPCS Code A4593) to the next payment cycle. At the Company's request, Company management subsequently met with CMS in December 2024 prior to PoNS Mouthpiece pricing taking effect on January 1, 2025 to request that they revisit the starting point for the gap filling process to more appropriately use the market pricing established through negotiation with the VA and an insurance carrier.

On October 8, 2024, CMS published the preliminary rate for the PoNS Controller (HCPCS Code A4593) at the capped total payment of $519.80, based on its view that the product is comparable to devices reported with HCPCS code E0730 (transcutaneous electrical nerve stimulation (TENS) device, four or more leads, for multiple nerve stimulation) to be effective April 1, 2025.

On January 13, 2025, CMS posted final Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies fee schedule payment rates for the PoNS Controller (HCPCS Code A4593) at the capped total payment of $532.27 and no changes to the previous final determination for the PoNS Mouthpiece (HCPCS code A4594) were made.

The Company continues to disagree with CMS' pricing determinations for both the Controller and Mouthpiece and plans to continue to challenge the pricing decisions through avenues available including the individual claims appeal process.

During the first quarter of 2024, the Company partnered with Lovell Government Services ("Lovell"), an SBA-certified Service-Disabled Veteran-Owned Small Business, to make the PoNS device available to federal healthcare systems. In May 2024, PoNS became available on the Veteran Affairs Federal Supply Schedule and General Services Administration Advantage Contracts at $23,843.72 for the PoNS device and $7,344.97 for the PoNS mouthpiece. In July 2024, PoNS became available to the Department of Defense and U.S. Military facilities on the Distribution and Pricing Agreement at $23,724.50 for the PoNS device and $7,308.25 for the PoNS mouthpiece. In December 2024, the first PoNS System sale to the VA Healthcare System through Lovell was delivered at the contracted price of $23,844, comprised of $16,499 for the PoNS Controller and $7,345 for the PoNS Mouthpiece.

Concurrently, we will be approaching various third-party payers to negotiate coverage under these codes. In general, we anticipate that it will take at least 24 months to obtain broad coverage and reimbursement among government and private payers.

Canadian Commercialization Efforts

In March 2019, we commenced the commercialization of our PoNS Therapy in Canada, where PoNS became the first and only device authorized by Health Canada for the treatment of balance deficit due to mmTBI. Throughout 2019, we made important progress in advancing and refining our commercialization strategy in Canada building access, awareness and credibility for the PoNS Therapy, including the acquisition of the Heuro Canada, Inc. ("Heuro") operating entity of HTC. These efforts, which were led by our local Canadian commercial team, included the establishment of our authorized clinic network throughout Canada, launching digital marketing campaigns, and building key opinion leader and advocacy networks.

On March 18, 2020, the Company received notification that its Canadian Class II license amendment application for the treatment of gait deficit in patients with mild and moderate symptoms from MS, when used in conjunction with physical therapy, was successful and received marketing authorization for PoNS from Health Canada.

On March 9, 2023, we announced the authorization from Health Canada to market PoNS Therapy for the treatment of gait deficit due to mild and moderate symptoms from stroke. This indication is instrumental as it is one of the most significant indications impacting balance and gait in Canada, and it provides the opportunity to extend options for coverage through government and third-party payers.

Following in-depth market analysis and field intelligence, our Canadian commercial team began an expansion plan to increase the number of authorized PoNS clinics. In addition to continuing to increase the number of clinic locations, we have shifted our focus to driving patient throughput to these clinics.

The value dossiers for mmTBI, stroke and MS that were created in mid-2020 to fully demonstrate, in both scientific and financial terms, the merits of PoNS Therapy for claimants are now being utilized along with submissions from clinics on behalf of their patients. The dossiers are provided to our clinics across Canada to submit as part of treatment plans with reimbursement applications to the payer community. Our reimbursement strategy for mmTBI is focused on the auto collision insurance and workers' compensation ("WC"), market as well as long-term disability cases. Our reimbursement strategy for MS is focused on commercial insurers/extended health benefits and charitable foundations that support these patient conditions. Our reimbursement strategy for stroke is focused on private payers while also demonstrating to public health organizations the benefits and potential PoNS Therapy could provide within their respective networks.

As part of our overall PoNS Therapy strategy, we are also gathering comprehensive health economic assessments of treatment outcomes. These data will, in-turn, be used to support our applications for WC, auto insurance and commercial insurance reimbursement initiatives in Canada, the U.S. and other markets around the world.

The real-world results from the collective experience of our patients that have completed the 14-week PoNS Therapy in Canada, thus far, have been encouraging. Consistent with what we observed in our two clinical trials, one for 5 weeks and the other for 14 weeks, commercial MS and mmTBI patients demonstrated improvements in balance and gait within the first two weeks followed by continued improvement over the following twelve weeks. The majority of patients had a mean patient adherence to treatment of over 90% and showed significant improvement in their balance and gait with a meaningful clinical difference at the end of their treatment. Similar results were observed in the treatment of patients with symptoms from stroke. The consistency of the patient results from our initial commercial experience supports our plans to expand access PoNS Therapy in Canada.

Commercialization in Other Markets

We submitted an application to be CE certified in December 2018. In preparation for our launch in the United Kingdom ("UK"), and the EU, we entered into a consulting agreement with a UK-based company with expertise in the development of new services in the healthcare industry to leverage local market insights to develop a comprehensive commercialization strategy and tactical plan for launch of the PoNS Therapy in the UK. As previously described, in August 2019, we withdrew our application to be EU certified and will revisit our UK and EU commercialization plans as terms of CE/UKCA certification become clearer under the new regulations.

We submitted an application to the TGA in Australia during the third quarter of 2019. We supplemented our submission with additional data based on questions supplied to date and provided responses to additional questions during the third quarter of 2020. In November 2021, we received market authorization from the TGA for the sale of PoNS as a Class IIa medical device. In Australia, PoNS is authorized as a non-implantable neurostimulator intended for short term used by healthcare professionals as an adjunct to a therapeutic exercise program to improve balance and gait. PoNS is not intended to be used alone without an exercise program. We are working to establish a distribution partner for Australia but have not yet had any commercial sales of PoNS in Australia.

Global Economic Conditions

Generally, worldwide economic conditions remain uncertain, in part due to supply chain disruptions, labor shortages, global conflicts and increased inflation. The general economic and capital market conditions both in the U.S. and worldwide, have been volatile in the recent years and at times have adversely affected our access to capital and have 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 continue to remain volatile or decline, our future cost of equity or debt capital and access to the capital markets could be adversely affected.

Our operating results could be materially impacted by changes in the overall macroeconomic environment and other economic factors. Changes in economic conditions, supply chain constraints, logistics challenges, labor shortages, global conflicts such as the conflicts in Ukraine and in the Middle East, and steps taken by governments and central banks as well as other stimulus and spending programs, have led to higher inflation, which has led to an increase in costs and has caused changes in fiscal and monetary policy, including increased interest rates. Although we may take measures to mitigate these impacts, if these measures are not effective, our business, financial condition, results of operations, and liquidity could be materially adversely affected.

Coverage and Reimbursement

Canadian Reimbursement

We believe that traditional life and health payers may be among the most relevant to provide coverage and reimbursement for the PoNS Therapy, and therefore, we are focusing on gaining coverage for the PoNS Therapy through them. Life and health encompass long- and short-term disability claims. Because these payers are responsible for both medical expenses and lost wages, they have an incentive to seek ways to help injured employees to return to work. As part of our commercial treatment program in Canada, we will collect both outcomes and return to work data, which we plan to utilize with life and health, provincial workers compensation insurance programs, and property and casualty insurers to demonstrate both the clinical and economic value associated with the PoNS Therapy. In addition to private and public payers, we are pursuing in-patient hospital utilization with submissions to hospital formularies to encourage the use of PoNS in acute treatment especially in post-Traumatic Brain Injury and Stroke patients.

U.S. Reimbursement

In the U.S., we plan to engage with select payer segments to obtain coverage and reimbursement for the PoNS Therapy. We intend to combine evidence from our clinical trials and real-world experience from commercial clinics in Canada to demonstrate the value proposition of the PoNS Therapy to payers and support favorable coverage and reimbursement decisions.

Significant uncertainty exists regarding the coverage and reimbursement status of products approved by the FDA and other government authorities. In the United States, sales of our products depend in significant part on the availability and adequacy of coverage and reimbursement from third party payers for our product and for services that use our products. Third-party payers include government authorities such as Medicare and Medicaid, managed care providers, private health insurers, and other organizations. The process for determining whether a payer will provide coverage may be separate from the process for setting the reimbursement rate that the payer will pay for the product or service. Moreover, a payer's decision to provide coverage does not imply that an adequate reimbursement rate will be approved. Adequate third-party

reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Third-party payers are increasingly challenging the prices charged for, examining the medical necessity, safety, and efficacy of, and assessing the cost-effectiveness of medical products. The U.S. government and state legislatures have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price controls and restrictions on reimbursement. Any such downward pressure on the reimbursement for our products could limit our ability to realize an appropriate return on our investment in product development.

CMS has indicated that it is developing a program that would provide a pathway for expedited transitional coverage of emerging technologies under the Medicare program, though that rule has yet to be released. While we continue to monitor this, we will also remain focused on building out our reimbursement strategy for both commercial and government payers. We continue to work with Medicare requirements and policies for coverage, coding, and payment of durable medical equipment and assess how the PoNS device may be treated with respect to coding, coverage, and reimbursement under the Medicare program.

Competition

The neurostimulation market is predominantly comprised of surgically implanted, invasive technologies that are not directly competitive with our technology. Several neurostimulation companies are large, publicly traded companies that have a history in the market, have significantly easier access to capital and other resources and have an established product pipeline. The combined clinical research and product development done by the industry, including by us and all of our competitors, is uncovering the beneficial effects of neurostimulation which now establishes neuromodulation as a valid and scientifically supported approach to the treatment of neurological conditions, and accordingly, we expect for competition in the non-implantable space to grow in the future.

However, we believe that we will have the first-mover advantage in the non-implantable neurostimulation space.

We believe that the PoNS Therapy introduces an innovative target and method of stimulation, because targeting the tongue for neurostimulation provides several advantages that competitively distinguish the PoNS Therapy, which are discussed below.

Advantages of the PoNS Therapy

We believe that the PoNS Therapy offers the following benefits over existing neurostimulation technologies:

- The PoNS device stimulates the trigeminal nerve, which developing science has implicated to be beneficial in some neurological disorder models. Specifically, PoNS stimulates only one branch of the trigeminal nerve, the lingual nerve through its terminals in the tongue, while other technologies stimulate other branches of the trigeminal nerve.
- Translingual stimulation also results in stimulating the facial nerve through its chorda tympani branch, which has its nerve terminals in the tongue. Although it's unclear whether concomitant stimulation of additional nerves is material to the efficacy or safety of PoNS, stimulation of these two cranial nerves triggers selective activation of specific cerebellar, brainstem, and cerebral areas involved in the control of movement and coordination functions. Furthermore, the ability to stimulate more than one nerve at a time differentiates our technology from our competition.
- The tongue has an anatomically unique surface with a high density of receptors, a consistently moist and conductive environment, constant pH, constant temperature and a direct connection to the brain through at least two cranial nerves. This a critical feature of how PoNS therapeutic effect is mediated since, similarly to the way most of the pharmacological agents act, translingual stimulation allows direct activation of neural targets that mediate signal transmission to the spinal cord and resulting therapeutic effect.

- Scientific studies suggest that the trigeminal cranial nerves offer a high-bandwidth pathway for impulses to directly affect the central nervous system. The trigeminal nerves project directly onto several areas of the brain, primarily the brainstem (trigeminal and solitary nuclei), cerebellum, cochlear nuclei and spinal cord. Secondary targets include the cerebral premotor, motor, and prefrontal cortices, as well as deep brain areas such as the limbic system, basal ganglia and thalamus. We believe that this range of projections will allow impulses to reach central and peripheral targets that regulate dozens of functions.
- Unlike deep brain stimulation devices, implantable vagal nerve devices and other invasive forms of electrical stimulation, the tongue allows for neurostimulation to be delivered via a portable, non-implantable device. This allows for the concomitant utilization of portable neurostimulation with a wide range of pharmacological therapies and non-pharmacological interventions previously unexplored for neurological rehabilitation.

Intellectual Property

Licensed Intellectual Property

Pursuant to the Second Amended and Restated Patent Sub-License, or the Sublicense Agreement, dated June 6, 2014 entered into between Advanced NeuroRehabilitation LLC, or ANR, and HMI, ANR has granted HMI a worldwide, exclusive license to make, have made, use, lease and sell devices utilizing certain patent applications, which are collectively referred to as the "Patent Pending Rights." The Patent Pending Rights relate to the PoNS device and include the following patents and patent applications, which cover a device that noninvasively delivers neurostimulation through the skin or intra-orally to the brain stem via various nerves including the trigeminal and facial nerves:

U.S. Patent Application No.	Application Filing Date	Status	U.S. Patent No.	Issue Date	Subject Matter
12/348,301	1/4/2009	Issued	8,849,407	9/30/2014	Non-invasive neurostimulation of the skin combined with simultaneous physical therapy to provide neurorehabilitation of a patient to treat various maladies including, e.g., TBI, stroke and Alzheimer's disease
14/340,144	7/24/2014	Issued	8,909,345	12/9/2014	Non-invasive neurostimulation within a patient's mouth combined with physical therapy to provide neurorehabilitation of a patient to treat various maladies including, e.g., TBI, stroke, and Alzheimer's disease
14/341,141	7/25/2014	Issued	9,020,612	4/28/2015	Non-invasive neurostimulation within a patient's mouth combined with cognitive therapy to provide neurorehabilitation of a patient resulting in improved reading comprehension and increased attention span as well as the treatment various maladies including, but not limited to, TBI, stroke, and Alzheimer's disease
14/615,766	2/6/2015	Issued	9,656,078	5/23/2017	Non-invasive neurostimulation within a patient's mouth combined with stimulation of the patient's vision, hearing, vestibular systems, or somatosensory systems for the treatment of tinnitus
14/689,462	4/17/2015	Issued	9,597,501	3/21/2017	Non-invasive neurostimulation of a patient's skin combined with cognitive therapy to provide neurorehabilitation of a patient resulting in improved reading comprehension and increased attention span as well as the treatment various maladies including, e.g., TBI, stroke, and Alzheimer's disease
14/815,171	7/31/2015	Issued	9,597,504	3/21/2017	Non-invasive neurostimulation of a patient's mouth combined with therapy to provide neurorehabilitation of a patient, with a focus on features of a neurostimulation device
15/207,029	7/11/2016	Issued	9,656,069	5/23/2017	Non-invasive neurostimulation of a subject's oral cavity while the subject engages in an exercise in order to enhance the subject's proficiency in the exercise
15/283,894	10/3/2016	Issued	10,293,163	5/21/2019	Non-invasive neurostimulation of a subject's oral cavity or skin while the subject engages in a physical or cognitive exercise in order to enhance the subject's proficiency in the exercise
15/602,060	5/22/2017	Issued	10,328,263	6/25/2019	Non-invasive neurostimulation within a patient's mouth or on a patient's skin combined with an exercise for treatment of a disorder affecting sleep patterns
16/376,595	4/5/2019	Issued	11,185,696	11/30/2021	Non-invasive neurostimulation of a subject's oral cavity or skin while the subject engages in a physical or cognitive exercise in order to enhance a subject's proficiency in the exercise
16/450,915	6/24/2019	Issued	11,285,325	3/29/2022	Non-invasive neurostimulation of a subject's oral cavity or skin while the subject engages in a physical or cognitive exercise in order to enhance the subject's proficiency in the exercise
17/704,051	3/25/2022	Issued	12,064,629	8/20/2024	Non-invasive neurostimulation of a subject's oral cavity or skin while the subject engages in a physical or cognitive exercise in order to enhance the subject's proficiency in the exercise
18/773,984	7/16/2024	Pending	N/A	N/A	Non-invasive neurostimulation of a subject's oral cavity or skin while the subject engages in a physical or cognitive exercise and while the patient is not engaged in the exercise in order to enhance the subject's proficiency in the exercise
61/019,061 . . . . (Provisional)	1/4/2008	Expired	N/A	N/A	N/A
61/020,265 . . . . (Provisional)	1/10/2008	Expired	N/A	N/A	N/A

U.S. Patent Nos. 8,909,345; 9,020,612; 9,656,078; 9,597,501; 9,597,504; 9,656,069; 10,293,163; 10,328,263; 11,185,696; 11,285,325; and 12,064,629 and U.S. Application No. 18/773,984 claim priority to U.S. Patent No. 8,849,407.

A U.S. provisional patent application provides the means to establish an early effective filing date for a later filed nonprovisional patent application. Therefore, though the two provisional applications have expired, they establish a priority date for U.S. Patent Nos. 8,909,345; 9,020,612; 9,656,078; 9,597,501; 9,597,504; 9,656,069; 10,293,163; 10,328,263; 11,185,696; 11,285,325; and 12,064,629, and U.S. Application No. 18/773,984, and any future filings that claim priority. We intend to file additional continuation applications in the United States Patent and Trademark Office, or USPTO, claiming priority to U.S. Provisional Patent Application Nos. 61/019,061 and 61/020,265 to protect other aspects of the PoNS device and related non-invasive neurostimulation techniques.

ANR holds an interest in the Patent Pending Rights pursuant to an exclusive license from the inventors. U.S. Patent Nos. 8,909,345; 9,020,612; 9,656,078; 9,597,501; 9,597,504; 9,656,069; 10,293,163; 10,328,263; 11,185,696; 11,285,325; and 12,064,629, and U.S. Application No. 18/773,984 are included in the exclusive license as the exclusive license agreement covers (i) U.S. Patent Application No. 12/348,301 (now U.S. Patent No. 8,849,407) and Provisional Application No. 61/019,061, (ii) any patents issuing therefrom and (iii) any patents claiming priority to U.S. Patent Application No. 12/348,301 or Provisional Application No. 61/019,061, which U.S. Patent Nos. 8,909,345; 9,020,612; 9,656,078; 9,597,501; 9,597,504; 9,656,069; 10,293,163; 10,328,263; 11,185,696; 11,285,325; and 12,064,629, and U.S. Application No. 18/773,984 claim priority through such provisional application as well as through Provisional Application 61/020,265.

In addition, ANR has agreed that ownership of any improvements, enhancements or derivative works of the Patent Pending Rights that are developed by HMI or ANR shall be owned by HMI, provided that if HMI decides not to patent such improvements, ANR may choose to pursue patent rights independently. Pursuant to the Sublicense Agreement, HMI has agreed to pay ANR royalties equal to 4% of HMI's revenues collected from the sale of devices covered by the Patent Pending Rights and services related to PoNS Therapy or use of devices covered by the Patent Pending Rights in therapy services. The Sublicense Agreement provides that the sublicense granted by ANR to HMI, if in good standing, shall not be cancelled; limited or impaired in any way should there be a termination of the master license granted by the inventors to ANR, which was acknowledged by the inventors in the Sublicense Agreement. On June 6, 2014, HMI and ANR entered into a second amended and restated sublicense agreement, or the Second Sublicense Agreement, which acknowledges the Reverse Merger (see "Our Corporate History – Acquisition of Helius Medical, Inc and Concurrent Financing" below) and adds us as a party to the agreement.

The license of the Patent Pending Rights is subject to the right of the government of the United States, which funded certain research relating to the development of the PoNS device, to a nonexclusive, non-transferable, irrevocable, paid-up license to use the Patent Pending Rights for governmental purposes. In addition, HMI has granted a perpetual, royalty-free license to the Patent Pending Rights back to ANR for non-profit research and development activities, which do not compete with HMI's business and to produce and derive revenues from devices and services in connection with investigational uses of the PoNS device and related technology.

Company Owned Intellectual Property

As of February 23, 2025, we have been granted 36 U.S. patent applications related to various technical and ornamental aspects of the PoNS device: 15 patents that cover various technical features in the current version device and 21 design patents describing various ornamental designs. We have also filed two U.S. provisional patent applications related to aspects of our next generation neurostimulation technology. We are the sole assignee for these 38 U.S. patent filings.

Our current U.S. patent portfolio consists of the following:

U.S. Patent Application No.	Application Filing Date	Status	U.S. Patent No.	Issue Date	Subject Matter
14/558,768 . . .	12/3/2014	Issued	9072889	7/7/2015	Utility patent covering overall system design, including controller and mouthpiece
14/559,123 . . .	12/3/2014	Issued	9272133	3/1/2016	Utility patent covering strain relief mechanisms for the connection between the mouthpiece and the controller
14/558,787 . . .	12/3/2014	Issued	9227051	1/5/2016	Utility patent covering shape of the mouthpiece
14/558,789 . . .	12/3/2014	Issued	9283377	3/15/2016	Utility patent covering center of gravity of the mouthpiece
14/559,080 . . .	12/3/2014	Issued	9415209	8/16/2016	Utility patent covering structural support of the mouthpiece
14/559,105 . . .	12/3/2014	Issued	9415210	8/16/2016	Utility patent covering glue wells of the mouthpiece
14/727,100 . . .	6/1/2015	Issued	9616222	4/11/2017	Utility patent covering overall system design, including controller and mechanical details of the mouthpiece
14/558,775 . . .	12/3/2014	Issued	9981127	5/29/2018	Utility patent covering aspects of the controller
14/558,784 . . .	12/3/2014	Issued	9789306	10/17/2017	Utility patent covering authentication techniques
14/559,045 . . .	12/3/2014	Issued	9993640	6/12/2018	Utility patent covering the locators of the mouthpiece
14/559,118 . . .	12/3/2014	Issued	9656060	5/23/2017	Utility patent covering methods of manufacturing the mouthpiece
15/484,077 . . .	4/10/2017	Issued	10258790	4/16/2019	Utility application covering overall system design, including controller and mechanical details of the mouthpiece
15/602,055 . . .	5/22/2017	Issued	10463850	11/5/2019	Utility application covering methods of manufacturing the mouthpiece
16/005,624 . . .	6/11/2018	Issued	10709887	7/14/2020	Utility patent application covering methods of placing a mouthpiece in a patient's mouth prior to engaging in NINM
16/384,016 . . .	4/15/2019	Issued	11197994	12/14/2021	Utility patent application covering overall system design, including controller and mechanical details of the mouthpiece, where controller and mouthpiece communicate wirelessly
63/761,434 . . .	2/21/2025	Pending	N/A	N/A	Provisional patent application covering next generation neurostimulation technology
63/761,480 . . .	2/21/2025	Pending	N/A	N/A	Provisional patent application covering next generation neurostimulation technology
29/510,741 . . .	12/3/2014	Issued	D750264	2/23/2016	Design patent covering an alternative version of the current PoNS device - over-ear double boom design
29/510,742 . . .	12/3/2014	Issued	D749746	2/16/2016	Design patent covering an alternative version of the current PoNS device - overhead minimal interference design
29/510,743 . . .	12/3/2014	Issued	D752236	3/22/2016	Design patent covering system design used in the current PoNS device
29/510,745 . . .	12/3/2014	Issued	D750265	2/23/2016	Design patent covering an alternative mouthpiece not used in the current PoNS device
29/510,754 . . .	12/3/2014	Issued	D750794	3/1/2016	Design patent covering the controller used in the PoNS device
29/510,755 . . .	12/3/2014	Issued	D751214	3/8/2016	Design patent covering an alternative controller not used in the current PoNS device
29/510,746 . . .	12/3/2014	Issued	D750266	2/23/2016	Design patent covering an alternative mouthpiece not used in the current PoNS device
29/510,749 . . .	12/3/2014	Issued	D750268	2/23/2016	Design patent covering an alternative mouthpiece not used in the current PoNS device
29/510,747 . . .	12/3/2014	Issued	D751213	3/8/2016	Design patent covering an alternative mouthpiece not used in the current PoNS device
29/510,748 . . .	12/3/2014	Issued	D750267	2/23/2016	Design patent covering an alternative mouthpiece not used in the current PoNS device
29/510,750 . . .	12/3/2014	Issued	D753315	4/5/2016	Design patent covering mouthpiece used in the current PoNS device
29/510,751 . . .	12/3/2014	Issued	D751722	3/15/2016	Design patent covering an alternative controller not used in the current PoNS device
29/510,752 . . .	12/3/2014	Issued	D752766	3/29/2016	Design patent covering an alternative controller not used in the current PoNS device
29/510,753 . . .	12/3/2014	Issued	D753316	4/5/2016	Design patent covering an alternative controller not used in the current PoNS device
29/510,744 . . .	12/3/2014	Issued	D760397	6/28/2016	Design patent covering alternative system design used in the current PoNS device
29/510,756 . . .	12/3/2014	Issued	D759830	6/21/2016	Design patent covering alternative system design used in the current PoNS device
29/681,984 . . .	2/28/2019	Issued	D891084	7/28/2020	Design patent covering mouthpiece retainer case design used in the current PoNS device
29/681,990 . . .	2/28/2019	Issued	D894601	9/1/2020	Design patent covering carry case design used in the current PoNS device
29/682,001 . . .	2/28/2019	Issued	D907221	1/5/2021	Design patent covering alternative system design used in the current PoNS device
29/681,993 . . .	2/28/2019	Issued	D927005	8/3/2021	Design patent covering alternative system design used in the current PoNS device
29/681,997 . . .	2/28/2019	Issued	D916300	4/13/2021	Design patent covering alternative system design used in the current PoNS device

In addition to our U.S. patents, we currently own 17 foreign utility patents (nine in Australia, two in Canada, two in Israel, three in Europe (validated in France, Germany, Italy, the UK and Spain), and one in the UK and 34 foreign design patents (three in Australia, ten in Canada, six in Russia, and fifteen registered community designs in Europe).

Further, we have six foreign utility patent applications that are currently pending: two in Europe, and one in each of Australia, Canada, China and Israel.

Our current owned foreign utility patent portfolio consists of the following:

PCT application	US Priority document(s) (filing date)	Foreign patents/ *patent applications
WO2016/089751A1	14/559,080 (3 December 2014)	AU2015355211B2
(PCT/US2015/062950)	14/559,123 (3 December 2014)	AU2017218934B2
	14/559,118 (3 December 2014)	AU2017276270B2
	14/559,105 (3 December 2014)	AU2018204184B2
Title: Systems and Methods for		AU2018247259B2
Providing Non-Invasive		CA2969729C
Neurorehabilitation of a Patient		EP3226962B1
		EP3662969B1
		IL252648B
WO2016/089752A1	14/557,787 (3 December 2014)	AU2015355212B2
(PCT/US2015/062953)	14/557,789 (3 December 2014)	AU2017228517B2
	14/559,045 (3 December 2014)	AU2019200175B2
		AU2019246836B2
Title: Devices for Delivering Non-		CA2969731C
Invasive Neuromodulation to a		EP3226961B1
Patient.		EP19190373.1A*
		IL252649A0
WO2016/089795A1	14/559,080 (3 December 2014)	N/A
(PCT/US2015/063059)	14/559,123 (3 December 2014)	
	14/559,118 (3 December 2014)	
	14/559,105 (3 December 2014)	
Title: Methods of Manufacturing Devices for the Neurorehabilitation of a Patient		
WO2020/176954	62/812,185 (28 February 2019)	AU2020228618A1*
(PCT/US2020/019853)		CA3131684A1*
		CN113728393A*
Title: Computer Systems and		EP20712806.7A*
Methods for Enhancing		IL285901A*
Neurorehabilitation		UK2596678B

Our current owned Australian design patent portfolio consists of the following:

Australian Design Application No.	Application Filing Date	Status	Australian Patent No.	Issue Date	Subject Matter
201914827	8/26/2019	Issued	201914827	10/8/2019	Design patent covering system design used in the PoNS device
201914900	8/28/2019	Issued	201914900	10/24/2019	Design patent covering the controller design used in the PoNS device
201914906	8/28/2019	Issued	201914906	10/23/2019	Design patent covering the mouthpiece design used in the PoNS device

Our current owned Canadian design patent portfolio consists of the following:

Canadian Design Application No.	Application Filing Date	Status	Canadian Patent No.	Issue Date	Subject Matter
162676 . . .	6/2/2015	Issued	162676	2/29/2016	Design patent covering system design used in the current PoNS device
162672 . . .	6/2/2015	Issued	162672	2/29/2016	Design patent covering an alternative mouthpiece not used in the current PoNS device
162671 . . .	6/2/2015	Issued	162671	2/29/2016	Design patent covering an alternative mouthpiece not used in the current PoNS device
162674 . . .	6/2/2015	Issued	162674	2/29/2016	Design patent covering mouthpiece used in the current PoNS device
162675 . . .	6/2/2015	Issued	162675	2/29/2016	Design patent covering an alternative controller not used in the current PoNS device
162670 . . .	6/2/2015	Issued	162670	2/29/2016	Design patent covering the controller used in the PoNS device
162673 . . .	6/2/2015	Issued	162673	2/29/2016	Design patent covering system design used in the current PoNS device
189953 . . .	8/28/2019	Issued	189953	10/5/2021	Design patent covering alternative system design used in the current PoNS device
189954 . . .	8/28/2019	Issued	189954	8/8/2023	Design patent covering alternative system design used in the current PoNS device
189955 . . .	8/28/2019	Issued	189955	6/18/2021	Design patent covering alternative system design used in the current PoNS device

Our current owned Russian design patent portfolio consists of the following:

Russian Design Application No.	Application Filing Date	Status	Russian Patent No.	Issue Date	Subject Matter
2015501883	6/3/2015	Issued	98981	7/16/2016	Design patent covering the system design currently used in the PoNS device
2015501882	6/3/2015	Issued	99240	8/16/2016	Design patent covering the mouthpiece design currently used in the PoNS device
2015501881	6/3/2015	Issued	98947	7/16/2016	Design patent covering the controller design currently used in the PoNS device
2019503623	8/28/2019	Issued	120540	7/13/2020	Design patent covering alternative system design used in the current PoNS device
2019503624	8/28/2019	Issued	120541	7/13/2020	Design patent covering alternative system design used in the current PoNS device
2019503625	8/28/2019	Issued	120727	7/27/2020	Design patent covering alternative system design used in the current PoNS device

Our current owned EU design patent portfolio consists of the following:

EU Community Design Application No.	Application Filing Date	Status	EU Community Design Reg. No.	Issue Date	Subject Matter
002712026	6/2/2015	Issued	002712026-0001 - 002712026-0007	9/4/2015	Design patents covering several aspects of the system design currently used in the PoNS device
006753877	8/23/2019	Issued	006753877-0001 – 006753877-0008	11/21/2019	Design patents covering the controller design used in the PoNS device

Currently, we own rights in five trademarks: PoNS, PoNS Therapy, Helius, Helius Medical, and Helius Medical Technologies. We own the rights to the PoNS mark by virtue of an assignment agreement having an effective date of October 27, 2014 and entered into with ANR and the inventors of the PoNS technology. We are also the owner of the rights in the PoNS Therapy, Helius, Helius Medical, and Helius Medical Technologies marks.

We are the owner of the trademark registrations for the Helius, Helius Medical, PoNS, and PoNS Therapy marks in the U.S. as well as the trademark registrations for the PoNS mark in Australia, Europe, Israel, New Zealand, and Russia. We have also applied for the Helius trademark in Canada.

Below is a listing of our active trademark registrations or pending trademark applications:

Mark	Country	Registration Number	Application Number
PONS	U.S.	4,998,391	86978547
PONS	U.S.	5,845,725	86440699
PONS THERAPY	U.S.	7,219,613	97124824
HELIUS	U.S.	7,231,015	88443662
HELIUS MEDICAL	U.S.	7,579,897	88443664
PONS	Australia	1923122	1923122
HELIUS	Canada	pending	1996550
PONS	Europe	15004799	15004799
PONS	Israel	306606	306606
PONS	New Zealand	1091833	1091833
PONS	Russia	634298	2015712398
PONS	Russia	674026	2010729117
PONS	Russia	653065	2017727589

Government Regulation

Our products under development and our operations are subject to significant government regulation. In the U.S., our products are regulated as medical devices by the FDA and other federal, state, and local regulatory authorities. The following is a general description of the review and marketing authorization process of the FDA for medical devices.

FDA Regulation of Medical Devices

The FDA and other U.S. and foreign governmental agencies regulate, among other things, the following activities with respect to medical devices:

- design, development and manufacturing;
- testing, labeling, content and language of instructions for use and storage;
- clinical trials;
- product storage and safety;
- marketing, sales and distribution;
- pre-market clearance and approval;
- record keeping procedures;
- advertising and promotion;
- recalls and field safety corrective actions;
- post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;
- post-market approval studies; and
- product import and export.

In the U.S., numerous laws and regulations govern all the processes by which medical devices are brought to market and marketed. These include the Food, Drug, and Cosmetic, or FD&C Act and the FDA's implementation of regulations, among others.

The FDA Review, Clearance and Approval Processes

Unless an exemption applies, each medical device commercially distributed in the U.S. requires either FDA clearance of a 510(k) premarket notification, approval of a premarket approval, or PMA, or approval of a de novo application. Under the FDCA, medical devices are classified into one of three classes—Class I, Class II or Class III— depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to ensure its safety and effectiveness. Classification of a device is important because the class to which a device is assigned determines, among other things, the necessity and type of FDA review required prior to marketing the device.

Class I devices are those for which safety and effectiveness can be assured by adherence to FDA's "general controls" for medical devices, which include compliance with the applicable portions of the FDA's Quality System Regulation, or QSR, facility registration and product listing, reporting of adverse medical events, and appropriate, truthful and non-misleading labeling, advertising, and promotional materials. Some Class I devices also require premarket clearance by the FDA through the 510(k) premarket notification process described below.

Class II devices are subject to FDA's general controls, and any other "special controls" deemed necessary by FDA to ensure the safety and effectiveness of the device, such as performance standards, product-specific guidance documents, special labeling requirements, patient registries or post-market surveillance. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification process, though certain Class II devices are exempt from this premarket review process. When a 510(k) is required, the manufacturer must submit to the FDA a premarket notification submission demonstrating that the device is "substantially equivalent" to a legally marketed device, which in some cases may require submission of clinical data. Unless a specific exemption applies, 510(k) premarket notification submissions are subject to user fees. If the FDA determines that the device, or its intended use, is not substantially equivalent to a legally marketed device, the FDA will place the device, or the particular use of the device, into Class III, and the device sponsor must then fulfill much more rigorous premarketing requirements.

Class III devices, consisting of devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a predicate device. The safety and effectiveness of Class III devices cannot be assured solely by general or special controls. Submission and FDA approval of a premarket approval, or PMA, application is required before marketing of a Class III device can proceed. As with 510(k) submissions, unless subject to an exemption, PMA submissions are subject to user fees. The PMA process is much more demanding than the 510(k) premarket notification process. A PMA application, which is intended to demonstrate that the device is safe and effective, must be supported by extensive data, typically including data from preclinical studies and human clinical trials.

Our PoNS device is currently regulated as a Class II medical device for use in MS. However, if the FDA requires us to go through a lengthier, more rigorous examination for the PoNS device for balance and gait deficit in stroke, introducing the product for stroke could be delayed or canceled. For example, if the FDA decides that the de novo classification procedures are not the appropriate path to obtain marketing authorizations for the PoNS device in stroke, the FDA may require us to submit a PMA application, which is generally more costly and uncertain and can take from one to three years, or longer, from the time the application is submitted to the FDA until an approval is obtained. Further, even with respect to those future products where a PMA may not be required, we cannot be certain that we will be able to obtain 510(k) clearance with respect to our PoNS device.

510(k) Clearance Process

To obtain 510(k) clearance for a medical device, an applicant must submit to the FDA a premarket notification submission demonstrating that the proposed device is "substantially equivalent" to a legally marketed device, known as a "predicate device." A legally marketed predicate device may include a device that was legally marketed prior to May 28, 1976 for which a PMA is not required (known as a "pre-amendments device" based on the date of enactment of the Medical Device Amendments of 1976), a device that has been reclassified from Class III to Class II or Class I, or a device that was found substantially equivalent through the 510(k) process. A device is substantially equivalent if, with respect to the predicate device, it has the same intended use and has either (i) the same technological characteristics, or (ii) different technological characteristics, but the information provided in the 510(k) submission demonstrates that the

device does not raise new questions of safety and effectiveness and is at least as safe and effective as the predicate device. A showing of substantial equivalence sometimes, but not always, requires clinical data.

Before the FDA will accept a 510(k) submission for substantive review, the FDA will first assess whether the submission satisfies a minimum threshold of acceptability through its eSTAR submission form. If the eSTAR does not pass technical screening (i.e., an eSTAR is provided where none of the attachments to a question are relevant to the question, or if an inaccurate response is provided to any question), the submission may be put on an early Technical Screening hold for 180 days, until a complete replacement eSTAR is submitted. An applicant must submit the requested information before the FDA will proceed with additional review of the submission. Once the 510(k) submission is accepted for review, by regulation, the FDA has 90 days to review and issue a determination. As a practical matter, clearance often takes longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence.

If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device. If the FDA determines that the device is "not substantially equivalent" to a previously cleared device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements, or can request a risk-based classification determination for the device in accordance with the "de novo" process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device.

After a device receives 510(k) marketing clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) marketing clearance or, depending on the modification, PMA approval. The determination as to whether or not a modification could significantly affect the device's safety or effectiveness is initially left to the manufacturer using available FDA guidance. Many minor modifications today are accomplished by a "letter to file" in which the manufacture documents the rationale for the change and why a new 510(k) is not required. However, the FDA may review such letters to file to evaluate the regulatory status of the modified product at any time and may require the manufacturer to cease marketing and recall the modified device until 510(k) clearance or PMA approval is obtained. The manufacturer may also be subject to significant regulatory fines or penalties.

De novo Classification Process

If a previously unclassified new medical device does not qualify for the 510(k) pre-market notification process because no predicate device to which it is substantially equivalent can be identified, the device is automatically classified into Class III. The Food and Drug Administration Modernization Act of 1997 established a new route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the *de novo* classification procedure. This procedure allows a manufacturer whose novel device is automatically classified into Class III to request classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA. Prior to the enactment of the Food and Drug Administration Safety and Innovation Act, or FDASIA, in July 2012, a medical device could only be eligible for *de novo* classification if the manufacturer first submitted a 510(k) pre-market notification and received a determination from the FDA that the device was not substantially equivalent. FDASIA streamlined the *de novo* classification pathway by permitting manufacturers to request *de novo* classification directly without first submitting a 510(k) pre-market notification to the FDA and receiving a not substantially equivalent determination. Under FDASIA, the FDA was required to classify the device within 120 days following receipt of the *de novo* application. If the manufacturer sought reclassification into Class II, the manufacturer was to include a draft proposal for special controls necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. The FDA may reject the reclassification petition if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk or that general controls would be inadequate to control the risks and special controls cannot be developed.

FDA granted *de novo* classification for the PoNS device for gait deficit in MS, which resulted in Class II classification. In order to be placed in Class II, the FDA required reasonable assurance of safety and effectiveness of the PoNS device.

Under Class II, general controls (e.g., premarket notification) and special controls (e.g., specific performance testing) are applicable.

Clinical Trials

Clinical trials are typically required to support a PMA and are sometimes required to support a 510(k) or de novo submission. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA's investigational device exemption, or IDE, regulations which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk," as defined by the FDA, to human health, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval. If the device is considered a "non-significant risk," IDE submission to FDA is not required. Instead, only approval from the Institutional Review Board, or IRB, overseeing the investigation at each clinical trial site is required.

The IRB is responsible for the initial and continuing review of the IDE and may pose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements. Acceptance of an IDE application for review does not guarantee that the FDA will allow the IDE to become effective and, if it does become effective, the FDA may or may not determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA's regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and record keeping requirements.

Additionally, after a trial begins, the sponsor, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. Even if a clinical trial is completed, there can be no assurance that the data generated during a clinical study will meet the safety and effectiveness endpoints or otherwise produce results that will lead the FDA to grant marketing clearance or approval.

Pervasive and Continuing U.S. Food and Drug Administration and Healthcare Regulation

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment, registration and device listing with the FDA;

- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of investigational products, or ‘‘off-label’’ uses of cleared or approved products;
- requirements related to promotional activities;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices;
- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- the FDA’s recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Advertising and promotion of medical devices, in addition to being regulated by the FDA, are also regulated by the FTC and by state regulatory and enforcement authorities. Recently, promotional activities for FDA-regulated products of other companies have been the subject of enforcement action brought under healthcare reimbursement laws and consumer protection statutes. In addition, under the federal Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims. If the FDA determines that promotional materials or training constitutes promotion of an unapproved or uncleared use, it could request that modification of promotional materials or subject a company to regulatory or enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider promotional or training materials to constitute promotion of an unapproved or uncleared use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

Healthcare providers, physicians, and third party payers play a primary role in the recommendation and use of our current products and will do so for any future products we commercialize. Arrangements with third party payers, healthcare providers and physicians expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute products. In the United States, we are subject to various federal and state anti-fraud and abuse laws, including, without limitation, the federal health care program Anti-Kickback Statute, the federal civil False Claims Act, and the health care fraud provisions of the federal Health Insurance Portability and Accountability Act.

The Anti-Kickback Statute makes it illegal for any person, including a device manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration, directly or indirectly, in cash or in kind, that is intended to induce or reward referrals, including the purchase, lease, or order , or arranging for or recommending, any good or service, including a device, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. The term “remuneration” expressly includes kickbacks, bribes, or rebates and also has been broadly interpreted to include anything of value. There are a number of statutory exceptions and regulatory safe harbors protecting certain business arrangements from prosecution under the Anti-Kickback Statute, however, those exceptions and safe harbors are drawn narrowly, and there may be no available exception or safe harbor for many common business activities, such as reimbursement support programs, educational and research grants, or charitable donations. Practices that involve remuneration to those who prescribe, purchase, or recommend medical devices, including discounts, providing items or services for free or engaging such individuals as consultants, advisors, or speakers, may be subject to scrutiny if they do not fit squarely within an exception or safe harbor and would be subject to a facts and circumstances analysis to determine compliance with the Anti-Kickback Statute. Violations of this law are

punishable by up to ten years in prison, criminal fines, administrative civil money penalties, damages, disgorgement and exclusion from participation in federal healthcare programs. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it. Various states have adopted laws similar to the Anti-Kickback Statute, and some of these state laws may be broader in scope in that some of these state laws extend to all payers and may not contain safe harbors.

The federal civil False Claims Act imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities (including manufacturers) for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment of government funds or knowingly presenting or causing to be presented a false statement or record material to payment of a false claim or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the federal government. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus significant mandatory civil penalties for each separate false claim and the potential for exclusion from participation in federal healthcare programs. The government may deem manufacturers to have "caused" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. Claims which include items or services resulting from a violation of the federal Anti-Kickback Statute also are deemed false or fraudulent claims for purposes of the False Claims Act. Our marketing and activities relating to the reporting of wholesaler or estimated retail prices for our products and other information affecting federal, state and third-party reimbursement for our products, and the sale and marketing of our product and any future product candidates, are subject to scrutiny under this law. Conduct that violates the False Claims Act also may implicate various federal criminal statutes. Various states have adopted laws similar to the False Claims Act, and many of these state laws are broader in scope and apply to all payers, and therefore, are not limited to only those claims submitted to the federal government.

The federal Health Insurance Portability and Accountability Act ("HIPAA") imposes criminal liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payers, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement 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.

The manufacturing processes associated with medical devices are required to comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, design history file, device history records, and complaint files. As a manufacturer, we are subject to periodic scheduled or unscheduled inspections by the FDA. Any failure to maintain compliance with the QSR requirements could result in the shut-down of, or restrictions on, manufacturing operations and the recall or seizure of products, which would have a material adverse effect on our business. The discovery of previously unknown problems with any of our products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that a company has failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions
- customer notifications for repair, replacement, refunds;
- 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 or PMA approval of new products or modified products;
- operating restrictions;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

U.S. Healthcare Reform

In the United States, there has been significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls and restrictions on reimbursement. Because private payers often follow Medicare and Medicaid coverage policy and payment limitations in setting their own reimbursement rates, any reduction in reimbursement that results from federal legislation or regulation may result in a similar reduction in payments from private payers. We expect to experience pricing pressures in connection with the sale of our due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative and regulatory measures.

Such legislative changes in the United States include the Affordable Care Act (ACA), which intended to broaden access to health insurance, reduced or constrained the growth of healthcare spending, enhanced remedies against healthcare fraud and abuse, added new transparency requirements for healthcare and health insurance industries, and imposed additional health policy reforms. We expect that additional federal, state, and foreign healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal, state, and foreign governments will pay for healthcare products and services, which could result in limited coverage and reimbursement of, reduced demand for, or additional pricing pressures on our products.

Health Canada

After a medical device has been approved for commercial use in Canada, there are a number of Health Canada requirements that must be adhered to including but not limited to the following:

- annual license renewals;
- labeling regulations, which prohibit “misbranded” devices from entering the market, as well as prohibit on the promotion of products for unapproved or “off-label” use and impose other restrictions on labeling including truthfulness and accuracy;
- assessment of product modifications for significant changes that would require license amendments;
- post-market surveillance including medical device reporting, which requires manufacturers report to Health Canada if their device may have caused or contributed to a death or serious injury, or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; and
- other post-approval restrictions or conditions.

European Union

We submitted an application for a CE certification of the PoNS device with our UK based notified body in December 2018. In August 2019, we withdrew our application for the CE certification conformity process procedure due to notified body activities being delayed by Brexit and the upcoming medical devices regulation changes. We have engaged G-MED NA as our notified body and will reconsider submitting to the EU when conditions stabilize. The successful completion of this review would result in CE certification of the PoNS device in the EU, which now excludes the UK. Some EU member states have additional notification requirements that we expect to satisfy before we launch our PoNS Therapy in those member states. Once the PoNS device is placed into the EU market, post market requirements apply including but not limited to:

- ensuring that the labeling promotes only intended use(s) of the device which have been certified;
- assessment of product modifications for significant changes may require license amendments;
- post-market surveillance including vigilance reporting, which requires manufacturers report to authorities if our PoNS device caused or contributed to a death or serious injury, or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; and
- other post-approval restrictions or conditions.

Australia

We submitted our application for marketing authorization to the TGA during the third quarter of 2019. We supplemented our submission with additional data based on questions supplied to date and provided responses to additional questions during the third quarter of 2020. In November 2021, we received market authorization from the TGA for the sale of PoNS as a class IIa medical device. In Australia, PoNS is indicated for short term use by healthcare professionals as an adjunct to a therapeutic exercise program to improve balance and gait. PoNS is not intended to be used alone without an exercise program.

Data Privacy and Security Laws; Breaches

Medical device companies may be subject to U.S. federal and state health information privacy, security and data breach notification laws, which may govern the collection, use, disclosure and protection of health-related and other personal information. The Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon "covered entities" (health plans, health care clearinghouses and certain health care providers), and their respective business associates, individuals or entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HIPAA mandates the reporting of certain breaches of health information to the U.S. Department of Health and Human Services, or HHS, affected individuals and if the breach is large enough, the media. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information, or PHI, a complaint about privacy practices or an audit by HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. Even when HIPAA does not apply, according to the FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Personally identifiable health information is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule. With respect to privacy, the FTC also sets expectations that companies honor the privacy promises made to individuals about how the company handles consumers' personal information; any failure to honor promises, such as the statements made in a privacy policy or on a website, may also constitute unfair or deceptive acts or practices in violation of the FTC Act. The FTC has the power to enforce promises as it interprets them, and events that we cannot fully control, such as data breaches, may be

result in FTC enforcement. Enforcement by the FTC under the FTC Act can result in civil penalties or enforcement actions.

In addition, certain state laws govern the privacy and security of health information in certain circumstances, some of which may be more stringent, broader in scope or offer greater individual rights with respect to PHI, than HIPAA, and many of which differ from each other, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, California enacted the California Consumer Privacy Act, as amended by the California Privacy Rights Act ("CCPA") which gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for certain data breaches that is expected to increase data breach litigation. The amendments introduced by the CPRA went effect on January 1, 2023, and new implementing regulations continue to be introduced by the California Privacy Protection Agency, a dedicated California privacy regulator. Failure to comply with the CCPA may result in, among other things, significant civil penalties and injunctive relief, or statutory or actual damages. In addition to the CCPA, numerous other states' legislatures are considering similar laws that will require ongoing compliance efforts and investment. For example, Virginia, Colorado, Utah, Indiana, Iowa, Tennessee, Montana, Texas, and Connecticut have enacted privacy laws similar to the CCPA that impose new obligations or limitations in areas affecting our business and we continue to assess the impact of these state legislation, on our business as additional information and guidance becomes available.

In the European Union, the General Data Protection Regulation, including as implemented in the UK (collectively "GDPR"), imposes many requirements for controllers and processors of personal data, including, for example, higher standards for obtaining consent from individuals to process their personal data, more robust disclosures to individuals and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention and secondary use of information, increased requirements pertaining to health data and pseudonymized (i.e., key-coded) data and additional obligations when we contract third-party processors in connection with the processing of the personal data. The GDPR allows EU member states to make additional laws and regulations further limiting the processing of genetic, biometric or health data. Failure to comply with the requirements of GDPR and the applicable national data protection laws of the EU member states may result in fines for the most serious breaches of up to €20 million or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties.

With regard to transfer of personal data, the GDPR restricts the ability of companies to transfer personal data from the EU to the U.S. and other countries, which may adversely affect our ability to transfer personal data or otherwise may cause us to incur significant compliance costs for implementing lawful transfer mechanisms, conducting data transfer impact assessments, and implementing additional measures where necessary to ensure that personal data transferred are adequately protected in a manner essentially equivalent to the EU. The GDPR provides different transfer mechanisms we can use to lawfully transfer personal data from the EU to countries outside the EU. An example is relying on adequacy decisions of the European Commission, such as the EU-U.S. Data Privacy Framework. In July 2023, the European Commission adopted its adequacy decision for the EU-U.S. Data Privacy Framework. The adequacy decision concludes that the U.S. ensures an adequate level of protection (compared to that of the EU) for personal data transferred from the EU to U.S. companies participating in the EU-U.S. Data Privacy Framework. The adequacy decisions of the European Commission are subject to periodic reviews and may be amended or withdrawn. Another example of a lawful transfer mechanism is using the EU Standard Contractual Clauses as approved by the European Commission in June 2021. In order to use the EU Standard Contractual Clauses mechanism, the exporter and the importer must ensure that the importer may guarantee a level of personal data protection in the importing country's level of protection must be adequate that is essentially equivalent to that of the EEA. Compliance with EU data transfer obligations involves conducting transfer impact assessments, which includes documenting detailed analyses of data access and protection laws in the countries in which data importers are located, which can be costly and time-consuming. Data importers must also expend resources in analyzing their ability to comply with transfer obligations, including implementing new safeguards and controls to further protect personal data. A lack of valid transfer mechanisms for GDPR-covered data could increase exposure to enforcement actions and may affect our business operations and require commercial cost (including potentially limiting our ability to collaborate/work with certain third parties and/or requiring an increase in our data processing capabilities in the EU/UK). Further, the European/UK data protection laws (including laws on data transfers) may also be updated/revised,

accompanied by new guidance and/or judicial/regulatory interpretations, which could entail further impacts on our compliance efforts and increased cost.

Additionally, other countries outside of Europe/UK have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of delivering our services and operating our business. The type of challenges we face in Europe/UK will likely also arise in other jurisdictions that adopt laws similar in construction to the GDPR or regulatory frameworks of equivalent complexity.

Our Corporate History Highlights

Formation and Reincorporation

We were originally incorporated in British Columbia, Canada on March 13, 2014 under the British Columbia Business Corporations Act, or the BCBCA, as "0996445 B.C. Ltd." On March 25, 2014, and amended on April 8, 2014, we entered into an arrangement agreement with Boomerang Oil, Inc. (formerly known as 0922327 B.C. Ltd.) and 0995162 B.C. Ltd. to reorganize the business structure of such three entities in such a manner which would allow Boomerang Oil, Inc. to spin us out to become an independent entity that is a reporting issuer in Canada and for us to complete a reverse take-over of 0995162 B.C. Ltd.

On May 23, 2014, we changed our name to "Helius Medical Technologies, Inc." and filed articles of continuation with the Wyoming Secretary of State office to reincorporate from being a corporation governed by the BCBCA to a corporation governed by the Wyoming Business Corporation Act. On July 20, 2018, we reincorporated from the state of Wyoming to the state of Delaware.

On March 11, 2025, we obtained a Certificate of Formation for Revelation Neuro with the Secretary of State of Texas.

Acquisitions, Mergers and Dissolutions

On June 13, 2014, we acquired NeuroHabilitation Corporation ("NHC") and on December 21, 2018, NHC changed its name to Helius Medical, Inc. HMI is our operating subsidiary in the United States.

On October 30, 2019, we acquired Heuro, a company incorporated under the federal laws of Canada. Heuro is an indirect wholly owned subsidiary of HMC, a company incorporated under the federal laws of Canada. HMC is our operating subsidiary in Canada.

On September 12, 2024, Helius NeuroRehab, Inc., a wholly owned and dormant subsidiary of HMTI, was merged into HMTI pursuant to a Certificate of Ownership and Merger certified by the State of Delaware.

On September 20, 2024, Heuro was dissolved pursuant to a Certificate of Dissolution issued under the Canada Business Corporations Act.

On September 23, 2024, Helius Canada Acquisition Ltd., a wholly owned Canadian subsidiary of HMC, was dissolved pursuant to a Certificate of Dissolution issued under the Canada Business Corporations Act.

Corporate Information

Our principal executive offices are located at 642 Newtown Yardley Road, Suite 100, Newtown, PA 18940 and our telephone number is 215-944-6100. We maintain a corporate website at www.heliusmedical.com. We make available free of charge through our Internet website our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and any amendments to these reports, as soon as its reasonably practicable after we electronically file such material with, or furnish such material to the SEC. We are not including the information on our website as a part of, nor incorporating it by reference into this Form 10-K. Additionally, the SEC maintains a website that contains annual, quarterly, and current reports, proxy statements, and other information that issuers (including us) file electronically with the SEC. The SEC's website address is http://www.sec.gov.

Human Capital Resources

As a neurotechnology company focused on neurological wellness through the development, licensing or acquisition of non-implantable technologies targeted at reducing symptoms of neurological disease or trauma, our human capital is important to the long-term success of our company.

Our People

We believe our diverse workforce is comprised of engaged individuals with appropriate qualifications and competencies to support our growth. Our senior management team has an average of over 25 years of experience in the health sciences industry with recognized leadership expertise in their functional areas.

As of December 31, 2024, we had 21 full-time employees, of which 19 are located in the United States and 2 are located in Canada. None of our employees were covered by collective bargaining agreements. We have not experienced any interruptions of operations due to disputes with our employees.

Talent Acquisition, Development and Retention

Hiring, developing, and retaining high-performing employees is important to our operations and we are focused on creating experiences that foster growth, performance and retention. Retaining and acquiring the right talent in this competitive environment, particularly at speed and scale, will continue to be a priority. Our workforce reflects talent from diverse perspectives.

Compensation, Benefits, Safety and Wellness

In addition to offering market competitive salaries and wages, we offer comprehensive health benefits to eligible employees.

ITEM 1A. RISK FACTORS

An investment in our securities has a high degree of risk. Before you invest you should carefully consider the risks and uncertainties described below and the other information in this Form 10-K. Any of the risks and uncertainties set forth herein could materially and adversely affect our business, results of operations and financial condition, which in turn could materially and adversely affect the trading price or value of our securities. Additional risks not currently known to us or which we consider immaterial based on information currently available to us may also materially adversely affect us. As a result, you could lose all or part of your investment.

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, we incurred a net loss of $11.7 million and $8.9 million, respectively, and used cash in operating activities of $11.1 million and $10.4 million, respectively. We have an accumulated deficit of $171.7 million as of December 31, 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, 2024, we generated approximately $0.5 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 had $1.1 million of cash as of December 31, 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 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 year ended December 31, 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 into the second quarter of 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, 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 Product

We 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 neuromodulation market, but we cannot begin marketing and selling the device in Europe until we obtain applicable CE

certificate 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

fails 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 Parties

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 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 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.

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 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.

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 Regulation

Before 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 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 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 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.

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.

We 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

regulations. 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

decisions 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

government, 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 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 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.

Even 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

unacceptable 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 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 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 Operations

Worldwide 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, 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 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.

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 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.

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,

cash 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.

Risks Related to Our Common Stock

We 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 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 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 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 ⅔% 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 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 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.

General Risks

We 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 of key employees, these agreements cannot assure the continued services of such employees. Any loss of the services of such individuals could have a material adverse effect on our business, operating results or financial condition.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 1C. CYBERSECURITY

Our corporate information technology, communication networks, enterprise applications, accounting and financial reporting platforms, and related systems are necessary for the operation of our business. We use these systems, among others, to manage our product development, to communicate internally and externally, to operate our accounting and record-keeping functions, to store and access data including sensitive patient data and for many other key aspects of our business. Our business operations rely on the secure collection, storage, transmission, and other processing of proprietary, confidential, and sensitive data.

Risk Management and Strategy

We recognize the importance of assessing, identifying, and managing material risks associated with cybersecurity threats, as such term is defined in Item 106(a) of Regulation S-K. These risks include, among other things: operational risks, intellectual property theft, fraud, extortion, harm to employees, customers or patients, violation of data privacy or security laws, litigation, and legal, financial and reputational risk.

In coordination with third-party consultants, we have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical systems and data. Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards, and/or policies designed to manage and mitigate material risks from cybersecurity threats to our

information systems and data, including risk assessments, incident detection and response, vulnerability management, disaster recovery and business continuity plans, internal controls within our accounting and financial reporting functions, encryption of data, network security controls, access controls, physical security, asset management, systems monitoring, vendor risk management program and employee training. We conduct annual reviews and tests of our information security program to evaluate its effectiveness and improve our security measures and planning.

To operate our business, we utilize certain third-party service providers and vendors to support a variety of functions. We seek to engage reliable, reputable service providers and vendors that maintain cybersecurity programs, and we implement a vetting process to ensure that all third-party service providers and vendors comply with our cybersecurity program requirements. Depending on the nature of the services provided, the sensitivity and quantity of information processed, and the identity of the service provider, our vendor management process may include reviewing the cybersecurity practices of such provider, contractually imposing obligations on the provider, conducting security assessments, and conducting periodic reassessments during their engagement.

We are not aware of any risks from cybersecurity threats, including as a result of any cybersecurity incidents, which have materially affected or are reasonably likely to materially affect our Company, including our business strategy, results of operations, or financial condition.

Governance

Our Board of Directors holds oversight responsibility for the Company's strategy and risk management, including material risks related to cybersecurity threats. Oversight of such cybersecurity risks is executed directly by the Board of Directors. The Board receives reports and engages in regular discussions with management regarding the Company's significant risk exposures resulting from material cybersecurity threats and the measures implemented to monitor and reasonably manage these risks.

Our Director of Information Technology leads our information security organization and reports to our Chief Executive Officer and Chief Financial Officer on matters related to cybersecurity who then in turn report to the Board of Directors any material information regarding such cybersecurity matters. Our Director of Information Technology has over 30 years of IT experience and has developed a focus of experience in the healthcare industry.

ITEM 2. PROPERTIES

The Company leases corporate office space in Newtown, Pennsylvania under an operating lease. In January 2025, the Company entered into an agreement with the landlord to extend the term of such lease to expire in March 2026. The lease does not contain any options to extend. We believe our current facility is adequate for our needs.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we are subject to litigation and claims arising in the ordinary course of business. Although the results of litigation and claims cannot be predicted with certainty, as of the date of this filing, we do not believe we are party to any claim or litigation, the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business or financial condition. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is traded on the Nasdaq Capital Market under the symbol "HSDT".

Holders

As of March 18, 2025, there were approximately 37 holders of record of our common stock. The number of holders of record is based on the actual number of holders registered on the books of our transfer agent and does not reflect holders of shares in "street name" or persons, partnerships, associations, corporations or other entities identified in security position listings maintained by depository trust companies.

Dividend Policy

We have never paid any cash dividends on our common stock and have no current plans to pay any cash dividends. Our current policy is to retain any future earnings for use in our business.

Recent Sales of Unregistered Securities.

None.

ITEM 6. [Reserved]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes included elsewhere in this Form 10-K (collectively referred to as the "consolidated financial statements"). Further, you should read the following discussion and analysis of our financial condition and results of operations together with "Item 1A. Risk Factors" included elsewhere in this Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. See also "Forward-Looking Statements."

Company Overview

We are a neurotechnology company focused on neurological wellness. Our purpose is to develop, license or acquire non-implantable technologies targeted at reducing symptoms of neurological disease or trauma.

Our product, known as the Portable Neuromodulation Stimulator, or PoNS®, is an innovative non-implantable medical device, inclusive of a controller and mouthpiece, which delivers mild electrical stimulation to the surface of the tongue to provide treatment of gait deficit and chronic balance deficit. PoNS Therapy® is integral to the overall PoNS solution and is the physical therapy applied by patients during use of the PoNS neuromodulation stimulator. PoNS has marketing clearance in the U.S. for use in the U.S. as a short-term treatment of gait deficit due to mild-to-moderate symptoms for MS and is to be used as an adjunct to a supervised therapeutic exercise program in patients 22 years of age and over by prescription only. We began accepting prescriptions for PoNS in the U.S. in March 2022, and commercial sales of PoNS commenced in April 2022. PoNS is authorized for sale in Canada for three indications: (i) as a short term treatment (14 weeks) of chronic balance deficit due to mild-to-moderate traumatic brain injury, or mmTBI, and is to be used in conjunction with physical therapy; (ii) as a short term treatment (14 weeks) of gait deficit due to mild and moderate symptoms from MS and it is to be used in conjunction with physical therapy; and (iii) as a short term treatment (14 weeks) of gait deficit due to mild and moderate symptoms from stroke, to be used in conjunction with physical therapy. It has been commercially available in Canada since March 2019. PoNS is authorized for sale as a Class IIa medical device in Australia and we have been seeking a business partner to commercialize and distribute PoNS in Australia.

Recent Developments

Corporate Updates

On August 9, 2024, we received written notice (the "Notification Letter") from The Nasdaq Stock Market LLC ("Nasdaq") notifying us that the Company was not in compliance with the minimum bid price requirements set forth in Nasdaq Listing Rule 5550(a)(2) for continued listing on the Nasdaq Capital Market. Nasdaq Listing Rule 5550(a)(2) requires listed securities maintain a minimum closing bid price of $1.00 per share, and Nasdaq Listing Rule 5810(c)(3)(A) provides that a failure to meet the minimum closing bid price requirement exists if the deficiency continues for a period of 30 consecutive business days. Based on the closing bid price of the Company's Class A common stock ("Common Stock") for the 30 consecutive business days prior to the date of the Notification Letter, the Company did not meet the minimum closing bid price requirement. To regain compliance, the closing bid price of the Company's Common Stock must be at least $1.00 per share for a minimum of 10 consecutive business days at any time prior to February 5, 2025. There can be no assurance that we will be able to regain compliance with the minimum bid price requirement and other Nasdaq listing criteria. If we fail to meet the applicable continued listing requirements for the Nasdaq Capital Market, Nasdaq may delist our Common Stock. If such delisting should occur, it would likely have a negative effect on the price of our Common Stock and would impair an investor's ability to sell or purchase our Common Stock when desired. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our Common Stock to become listed again, stabilize the market price or improve the liquidity of our Common Stock, prevent our Common Stock from dropping below the Nasdaq minimum bid price requirement, or prevent future non-compliance with Nasdaq's listing requirements. Additionally, Nasdaq rules allow an expedited delisting of securities of companies that have had one or more reverse stock splits with a cumulative ratio of one for 250 or more shares over the prior two-year period. Under these rules, if a company falls out of compliance with the $1.00 minimum bid price after completing reverse stock splits over the immediately preceding two years that cumulatively result in a ratio one for 250 shares, the company will not be able to avail itself of any compliance periods and Nasdaq will instead require the issuance of a Staff delisting determination, which is appealable to a hearings panel. Our ability to remain listed on Nasdaq may be negatively impacted by this Nasdaq rule.

On February 7, 2025, we received a determination letter from Nasdaq notifying us that because we did not comply with the $5 million minimum stockholders' equity initial listing requirement for The Nasdaq Capital Market, we were not eligible for a second 180-day period. On February 14, 2025, we requested an appeal of this determination and will submit a plan to regain compliance. 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.

On March 11, 2025, we established Revelation Neuro to pursue the development of a new gold standard of care for personalized neurorehabilitation using a non-implantable AI powered brain computer interface combining our newly developed intellectual property with Helius' existing intellectual property.

On January 21, 2025, the Company entered into warrant exercise inducement offer letters with certain holders of existing Series A warrants and Series B warrants generating gross proceeds of $3.7 million as discussed further in Note 15 in our consolidated financial statements.

Presently, PoNS Therapy is not reimbursed under contract by any third-party payers in the U.S. We are pursuing commercial insurance coverage for PoNS within the Durable Medical Equipment benefit category. On February 29, 2024, CMS assigned HCPCS Level II codes to the PoNS controller and PoNS mouthpiece, effective April 1, 2024. On May 2, 2024, CMS published a proposed fee schedule payment rates for the PoNS controller and PoNS mouthpiece to be discussed at CMS' bi-annual Healthcare Common Procedure Coding System ("HCPCS") public meeting to be held on May 29, 2024. For the PoNS Controller (HCPCS Code A4593), CMS preliminarily set pricing by mapping reimbursement to existing code E0745, (Neuromuscular stimulator, electronic shock unit), resulting in a capped fee of $1,206.53. For the PoNS Mouthpiece (HCPCS code A4594), CMS based pricing on the previously offered, temporary, cash pay price of $4,500, resulting in a total capped payment of $3,075.53.

The Company subsequently provided CMS additional information to support reimbursement economics and presented that information at the public meeting with CMS on May 29, 2024 for consideration by CMS for determination of the final reimbursement amount for each of the PoNS controller and mouthpiece.

On October 7, 2024, CMS posted the final payment rate for the PoNS Mouthpiece (HCPCS code A4594) at $2,963.30, which will be effective January 1, 2025 and deferred final national determination of the payment rate for the PoNS Controller (HCPCS Code A4593) to the next payment cycle. At the Company's request, Company management subsequently met with CMS in December 2024 prior to PoNS Mouthpiece pricing taking effect on January 1, 2025 to request that they revisit the starting point for the gap filling process to more appropriately use the market pricing established through negotiation with the VA and an insurance carrier.

On October 8, 2024, CMS published the preliminary rate for the PoNS Controller (HCPCS Code A4593) at the capped total payment of $519.80, based on its view that the product is comparable to devices reported with HCPCS code E0730 (transcutaneous electrical nerve stimulation (TENS) device, four or more leads, for multiple nerve stimulation) to be effective April 1, 2025.

On January 13, 2025, CMS posted final Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies fee schedule payment rates for the PoNS Controller (HCPCS Code A4593) at the capped total payment of $532.27 and no changes to the previous final determination for the PoNS Mouthpiece (HCPCS code A4594) were made.

During the first quarter of 2024, the Company partnered with Lovell Government Services ("Lovell"), an SBA-certified Service-Disabled Veteran-Owned Small Business, to make the PoNS device available to federal healthcare systems. In May 2024, PoNS became available on the Veteran Affairs Federal Supply Schedule and General Services Administration Advantage Contracts at $23,843.72 for the PoNS device and $7,344.97 for the PoNS mouthpiece. In July 2024, PoNS became available to the Department of Defense and U.S. Military facilities on the Distribution and Pricing Agreement at $23,724.50 for the PoNS device and $7,308.25 for the PoNS mouthpiece. In December 2024, the first PoNS System sale to the VA Healthcare System through Lovell was delivered at the contracted price of $23,844, comprised of $16,499 for the PoNS Controller and $7,345 for the PoNS Mouthpiece.

As discussed further in Note 8 to our consolidated financial statements, in May 2024, the Company closed on a registered public offering of its Common Stock and warrants and received net proceeds of approximately $5.5 million.

On April 4, 2024, the Company received written notice from Nasdaq stating that the Company no longer complied with the minimum stockholders' equity requirement under Nasdaq Listing Rule 5550(b)(1) for continued listing on Nasdaq because the Company's stockholders' equity, as reported in our 2023 10-K, had fallen below $2.5 million. The notice also indicated that the Company did not meet the alternative compliance standards. Under applicable Nasdaq rules, the Company had 45 calendar days from the date of the notice, or until May 20, 2024, to submit a plan to regain compliance. On May 31, 2024, the Company received formal notification from Nasdaq confirming that, following the consummation of a registered public offering on May 9, 2024, the Company regained compliance with the minimum stockholders' equity requirement, and that the Company satisfied all other applicable criteria for continued listing on Nasdaq.

During the second quarter of 2024, the Company received the first third-party reimbursement from a major insurance carrier at a 7% rebate, which resulted in pricing of $23,900 for the PoNS device, comprised of $16,554 for the PoNS controller and $7,347 for the PoNS mouthpiece, exclusive of rounding.

In June 2024, the Company began establishing sales representative agreements with organizations and individuals to sell PoNS devices to Veterans Affairs ("VA") facilities in the U.S. The Company has since established agreements with representatives covering facilities in Texas and east of the Mississippi with plans to expand west.

During the first quarter of 2024, leveraging the Breakthrough Designation, the Company reached alignment with the FDA on the registrational program to evaluate the therapeutic benefit of PoNS on gait and balance deficits in chronic stroke subjects, which originally included two initial studies. The first was an investigator-initiated randomized placebo-controlled trial ("MUSC-RCT") in approximately 60 subjects, led by Dr. Steven Kautz at the Medical University of South Carolina ("MUSC") and Dr. Mark Bowden at Brooks Rehabilitation. The second study was a company-sponsored open-label study ("HMI-OLS"), in approximately 30 subjects. Following guidance from FDA, Helius added, in May 2024, a third company-sponsored randomized placebo-controlled trial ("HMI-RCT") in approximately 60 subjects, as the pivotal study, along with the OLS, for the registrational program. All three studies shared the same design and endpoints, including primary outcomes on gait and balance improvement, as well as key secondary endpoints with Type 1 error of reduced risk of falling and maintenance of effect at 12 weeks post-treatment.

Enrollment of the stroke registrational studies started at MUSC for the MUSC-RCT in August 2023 and, at Brooks Rehabilitation, in August 2024. In June 2024, Helius started enrollment of the HMI-OLS at five U.S. Centers of Excellence for Neurorehabilitation including Shepherd Center, MGH-IHP, REHABOLOGYM, Brooks Rehabilitation and New England Neurological Center. Enrollment continued, with the HMI-RCT, in July 2024 at Neuro-Concept Rehabilitation Center, Neuphysio, Synaptic Health, Bergin Motion in Canada and REHABOLOGYM in the U.S.

The Company has completed and far exceeded the initial 90-subject target enrollment for its stroke registrational program enrolling 128 participants by December 31, 2024. With maximum enrollment of over 150 participants achieved at the end of January 2025, the Company is on track to submit for FDA authorization for stroke in the second quarter of 2025, with the plan to achieve FDA authorization by the end of 2025.

During the fourth quarter of 2024, the Company completed the transition of the manufacturing of PoNS device controllers and mouthpieces to Minnetronix, Inc. from its previous contract manufacturer, Key Tronic Corporation.

We also intend to provide broad access and reimbursement for the PoNS Therapy over time through commercial insurers. Prior to broad commercial payer coverage, we anticipate the primary source of sales will be self-pay and VA patients. We expect to support the cost of the PoNS Therapy by working with advocacy groups and charitable organizations to help self-pay patients access our technology. In general, we anticipate that it will take at least 24 months to obtain broad coverage and reimbursement among government and private payers from the date that the HCPCS codes became effective.

Material Trends and Uncertainties

Global Economic Conditions

Generally, worldwide economic conditions remain uncertain, in part due to supply chain disruptions, labor shortages, global conflicts, increased inflation and unpredictable trade policies, including tariffs, customs regulations and other trade restriction. The general economic and capital market conditions both in the U.S. and worldwide, have been volatile in recent years and at times have adversely affected our access to capital and have 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 continue to remain volatile or decline, our future cost of equity or debt capital and access to the capital markets could be adversely affected.

Our operating results could be materially impacted by changes in the overall macroeconomic environment and other economic factors. Changes in economic conditions, supply chain constraints, logistics challenges, labor shortages, global conflicts such as the conflicts in Ukraine and in the Middle East, and steps taken by governments and central banks as well as other stimulus and spending programs have led to higher inflation, which has led to an increase in costs and has caused changes in fiscal and monetary policy, including increased interest rates. Although we may take measures to

mitigate these impacts, if these measures are not effective, our business, financial condition, results of operations, and liquidity could be materially adversely affected.

Other Trends and Uncertainties

To successfully commercialize, we need to continue to build infrastructure necessary to grow our business including adding headcount and implementing or upgrading business systems. Competition for talent in today's labor market may impact our ability to add headcount and to recruit talent with the expertise we need to develop our commercial infrastructure.

Results of Operations

The following table summarizes our results of operations for the years ended December 31, 2024 and 2023 (in thousands):

	Years Ended December 31,		
	2024	2023	Change
Revenue:			
Product sales, net:			
United States	$ 181	$ 324	$ (143)
Canada	295	281	14
Total product sales, net	476	605	(129)
Other revenue	44	39	5
Total revenue	520	644	(124)
Cost of revenue	582	583	(1)
Gross (loss) profit	(62)	61	(123)
Operating expenses:			
Selling, general and administrative expenses	10,118	9,271	847
Research and development expenses	3,659	2,942	717
Amortization expense	24	117	(93)
Fixed asset impairment	40	159	(119)
Total operating expenses	13,841	12,489	1,352
Loss from operations	(13,903)	(12,428)	(1,475)
Nonoperating income			
Interest (expense) income, net	(17)	257	(274)
Change in fair value of derivative liability	2,981	2,966	15
Foreign exchange (loss) gain	(1,006)	275	(1,281)
Other income, net	203	80	123
Nonoperating income, net	2,161	3,578	(1,417)
Loss before provision for income taxes	(11,742)	(8,850)	(2,892)
Provision for income taxes	—	—	—
Net loss	$ (11,742)	$ (8,850)	$ (2,892)

Year Ended December 31, 2024 Compared to Year Ended December 31, 2023

Revenue

The decrease in total net product sales was primarily attributable to a decrease in unit volumes for U.S. sales of PoNS systems due to the termination of our Patient Therapy Access Program ("PTAP") on June 30, 2023 as well as the termination of the previously offered temporary cash pay pricing in May 2024.

Cost of Revenue

The cost of revenue for 2024 as compared to the same period in the prior year remained relatively flat year to year due to decreased unit volumes sold offset by increases in certain inventory reserve adjustments, warranty and fixed employee costs.

Gross (Loss) Profit

Gross loss for the year ended December 31, 2024 was $62,000 compared to gross profit of $61,000 for the same period in the prior year. Decreased revenues in 2024 with cost of revenues remaining flat from the prior year were the primary reasons for the year-to-year variance.

Selling, General and Administrative Expenses

The increase in selling, general and administrative expenses was primarily from a $0.7 million increase in non-cash stock-based compensation expense, a $0.3 million in increased legal costs partially offset by a $0.2 million decrease in insurance costs and a $0.1 million decrease in franchise taxes. Refer to Note 9 to our consolidated financial statements for detailed information about stock-based compensation.

Research and Development Expenses

The increase in research and development expenses was primarily from increases in clinical trial related costs of $0.4 million, an increase in non-cash employee stock compensation expense of $0.2 million and product development costs of $0.1 million. Refer to Note 9 to our consolidated financial statements for detailed information about stock-based compensation.

Amortization Expense

Amortization expense is primarily comprised of the amortization of acquired finite-lived intangible assets. The decrease in amortization expense is primarily due to the remaining unamortized intangible assets becoming fully amortized during the year ended December 31, 2024. Refer to Note 6 to our consolidated financial statements for additional information about the composition of intangible assets.

Fixed Asset Impairment

During the fourth quarter of 2024, we recorded an impairment of $40,000 for certain software used with our enterprise resource planning system. Refer to Note 3 to our consolidated financial statements for additional information.

Nonoperating Income

Interest (Expense) Income, Net

Net interest expense for the year ended December 31, 2024 was primarily attributable to interest expense related to the Company’s insurance premium financing and lower interest income earned on investments of excess cash in an unrestricted money market savings account year to year due to lower current year cash balances and a shift to excess cash being primarily invested in money market mutual funds earning dividend income in the current year, versus interest bearing securities in the prior year.

Change in Fair Value of Derivative Liability

As discussed in more detail in Note 8 to our consolidated financial statements, the warrants issued in connection with the August 2022 Public Offering are being accounted for as a derivative liability instrument. The change in fair value of derivative liability for the year ended December 31, 2024 of $3.0 million is the result of the decrease in our stock price offset partially by reduced outstanding warrant exposure due to warrant exercises during the year.

Foreign Exchange (Loss) Gain

The foreign exchange loss for the year ended December 31, 2024 was primarily due to higher Canadian to U.S. dollar exchange rates in 2024.

Other Income, Net

Other income was primarily attributable to dividend income earned on investments of excess cash in a money market mutual fund.

Liquidity and Capital Resources

The following table summarizes our cash and cash equivalents and working capital as of December 31, 2024 and 2023 (in thousands):

	December 31, 2024	December 31, 2023
Cash and cash equivalents	$ 1,088	$ 5,182
Working capital	1,261	5,559

Our available capital resources have been primarily used to expand our U.S. commercialization efforts, fund manufacturing activities for the PoNS device, conduct clinical trials and for working capital and general corporate purposes. Our primary sources of cash and cash equivalents have been proceeds from public and private offerings of our common stock which most recently included $5.5 million in net proceeds we received from a public offering of our common stock and warrants completed in May 2024 ("May 2024 Public Offering") as discussed in more detail in Note 8 to our consolidated financial statements.

As discussed in more detail in Note 8 to our consolidated financial statements, the Company entered into a sales agreement related to our at-the-market offering program ("ATM") under which we may offer and sell shares having gross proceeds up to $2.0 million. During the year ended December 31, 2024, the Company issued and sold shares with gross proceeds of $1.3 million under the ATM. In addition, the Company received gross proceeds of $0.2 million from the issuance of shares upon the exercise of warrants for the year ended December 31, 2024. On January 21, 2025, the Company entered into warrant exercise inducement offer letters and new warrant issuance which generated $3.4 million in net proceeds as discussed in more detail in Note 15 to our consolidated financial statements.

Statement of Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2024 and 2023 (in thousands):

	Years Ended December 31,		
	2024	2023	Change
Net cash used in operating activities	$ (11,041)	$ (10,416)	$ (625)
Net cash used in investing activities	(5)	(29)	24
Net cash provided by financing activities	6,954	1,077	5,877
Effect of foreign exchange rate changes on cash	(2)	1	(3)
Net decrease in cash and cash equivalents	$ (4,094)	$ (9,367)	$ 5,273

Net Cash used in Operating Activities

The higher level of cash used in operating activities in 2024 primarily resulted from increases in selling, general and administrative expenses and research and development expenses as compared to 2023.

Net Cash Used in Investing Activities

Our investing activities are primarily related to the purchase of property and equipment.

Net Cash Provided by Financing Activities

During the year ended December 31, 2024, we received net proceeds of $1.3 million from the issuance and sale of shares under the ATM. In addition, we received $0.2 million in net proceeds from the exercise of warrants. During the year ended December 31, 2024, we received net proceeds of $5.5 million from the sale of shares primarily from our May 2024 Public Offering, as described in Note 8 to our consolidated financial statements.

Cash Requirements

Our ability to generate product revenues sufficient to achieve profitability will depend heavily on the successful commercialization of PoNS Therapy in the U.S. Our net loss was $11.7 million and $8.9 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of $171.7 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future. These and other factors indicate substantial doubt about our ability to continue as a going concern. Refer to Note 1 to our consolidated financial statements for additional discussion about our going concern uncertainty.

We intend to use our available capital resources primarily to expand our U.S. commercialization efforts, fund manufacturing activities for the PoNS device, conduct clinical trials and for working capital and general corporate purposes. We believe that our existing capital resources, including the $0.1 million of additional net proceeds from the ATM and $3.4 million in net proceeds from warrant inducements in 2025 through the date of this filing, will be sufficient to fund our operations into the second quarter of 2025, but we will be required to seek additional funding through the sale of equity or debt financing to continue to fund our operations thereafter. We will need additional funding for our ongoing clinical trials for stroke. The amount required to fund operations thereafter will depend on various factors, including timing of approval of clinical trials, duration and result of clinical trials and other factors that affect the cost of the clinical trial, manufacturing costs of product, development of our product for new indications and demand for our authorized products in the market.

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 raise sufficient additional capital, we may be compelled to reduce the scope of our operations and planned capital expenditure 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.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based upon our financial statements that have been prepared in accordance with U.S. GAAP. This preparation requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and the disclosure of contingent assets and liabilities. U.S. GAAP provides the framework from which to make these estimates, assumption and disclosures. We choose accounting policies within U.S. GAAP that management believes are appropriate to accurately and fairly report our operating results and financial position in a consistent manner. Management regularly assesses these policies in light of current and forecasted economic conditions. Actual results could differ from those estimates made by management. While there are a number of significant accounting policies affecting our financial statements, we believe the critical accounting policies involving the most complex, difficult and subjective estimates and judgments are: revenue recognition, stock-based compensation, derivative financial instruments and accounting for warrants.

Revenue Recognition

The Company generates nearly all of its revenue from product sales directly to patients, its e-commerce partner in the United States and to clinics in Canada. Revenue from product sales is recognized at a point in time as the performance obligation is satisfied and when the customer obtains control at the established transaction price. Taxes that the Company collects concurrent with revenue-producing activities are excluded from revenue.

The Company requires some customers in the United States to prepay the full product selling price, net of cash discount, prior to shipment. The Company records a contract liability for any customer prepayment received for which delivery had not yet occurred as of the end of the period.

Accounting and Valuation of Warrants

We have issued and may continue to issue warrants to purchase shares of common stock through our public and private offerings. We account for such warrants in accordance with ASC 480 Distinguishing Liabilities from Equity, which identifies three categories of freestanding financial instruments that are required to be accounted for as a liability. If determined to be classified as a liability, we will remeasure the fair value of the warrants at each balance sheet date. If determined to be classified as equity, the fair value of the warrants will be measured as of the date of issuance and will not be subject to remeasurement at each balance sheet date.

We evaluate our financial instruments and other contracts to determine if those contracts or embedded components of those contracts qualify as derivatives to be separately accounted for in accordance with ASC 815, Derivatives and Hedging. The result of this accounting treatment is that the fair value of the derivative is re-measured at each balance sheet date and recorded as a liability or asset and the change in fair value is recorded in the consolidated statements of operations and comprehensive loss. Upon settlement of a derivative financial instrument, the instrument is re-measured at the settlement date and then that fair value of the underlying instrument is reclassified to equity.

The classification of derivative financial instruments, including whether such instruments should be recorded as liabilities/assets or as equity, is reassessed at the end of each reporting period. Derivative financial instruments that become subject to reclassification are reclassified at the fair value of the instrument on the reclassification date. Derivative financial instrument liabilities are classified in the consolidated balance sheet as current if the right to exercise or settle the derivative financial instrument lies with the holder.

We use the Monte Carlo and Black-Scholes option-pricing models to value derivative financial instrument liabilities. This model uses Level 3 inputs in the fair value hierarchy established by ASC 820 - Fair Value Measurement.

As of December 31, 2024, our derivative financial instruments accounted for in accordance with ASC 815 were comprised of warrants issued in connection with our August 2022 public offering as discussed in more detail in Note 8 to our Consolidated Financial Statements.

Income Taxes

We account for income taxes using the asset and liability method. The asset and liability method provide that deferred tax assets and liabilities are recognized for the expected future tax consequences of temporary differences between the financial reporting and tax bases of assets and liabilities, and for operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using the currently enacted tax rates and laws that will be in effect when the differences are expected to reverse. We record a valuation allowance to reduce deferred tax assets to the amount that is believed more likely than not to be realized.

Going Concern

Because we have generated limited revenues from commercialization, our operations to date have been principally financed through public and private offerings of our common stock 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 successful commercialization of the PoNS device in the U.S.

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. While we had $1.1 million of cash as of December 31, 2024, 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 expect that we will require additional financing to continue to fund our operations. There is no guarantee that such funding will be available at all or in sufficient amounts to satisfy our required expenditures. In reviewing this filing, you should carefully consider this uncertainty, the risks described in the section entitled "Item 1A. Risk Factors" and other risks described throughout this Form 10-K.

Recently Issued Accounting Pronouncements

Information regarding recently issued accounting pronouncements is included in Note 2 to the consolidated financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this item is included in this Form 10-K beginning on page F-1 and is incorporated herein by reference.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(b) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, under the direction of the Chief Executive Officer and the Chief Financial Officer, we have evaluated our disclosure controls and procedures as defined in Rule 13a-15(e) or 15d-15(e) as of the end of the period covered by this Form 10-K. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Form 10-K.

Management's Annual Report on Internal Control over Financial Reporting

We are responsible for establishing and maintaining adequate internal controls over financial reporting. Our management assessed the effectiveness of our internal controls over financial reporting as of December 31, 2024. In making this assessment, our management used the criteria described in Internal Control—Integrated Framework (2013), issued by the Committee of Sponsoring Organizations of the Treadway Commission and assessed the applicability of the principles within each component of internal control and determined whether or not they have been adequately addressed within the current system of internal control and adequately documented. Based on this assessment, management, under the supervision and with the participation of our principal executive officer and our principal financial officer, concluded that, as of December 31, 2024, our internal control over financial reporting was effective.

This Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting as required by Section 404(b) of the Sarbanes Oxley Act of 2002. As a non-

accelerated filer, our management's report was not subject to attestation by our registered public accounting firm pursuant to rules of the SEC that permit us to provide only management's report in this Form 10-K.

Changes in Internal Control over Financial Reporting

We monitor our internal control over financial reporting on a continuous basis. There has not been any change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(f) and 15d-15(f) under the Exchange Act that occurred during the year ended December 31, 2024 which has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by Item 10 is hereby incorporated by reference to the sections of the 2025 Proxy Statement under the captions “Information Regarding the Board of Directors and Corporate Governance,” “Proposal 1 - Election of Directors,” “Executive Officers”, and “Delinquent Section 16(a) Reports”.

ITEM 11. EXECUTIVE COMPENSATION

The information required by Item 11 is hereby incorporated by reference to the sections of the 2025 Proxy Statement under the captions “Executive Compensation” and “Information Regarding the Board of Directors and Corporate Governance– Non-Employee Director Compensation.”

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by Item 12 is hereby incorporated by reference to the sections of the 2025 Proxy Statement under the captions “Security Ownership of Certain Beneficial Owners and Management" and "Executive Compensation.”

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by Item 13 is hereby incorporated by reference to the sections of the 2025 Proxy Statement under the captions “Certain Relationships and Related Transactions” and “Information Regarding the Board of Directors and Corporate Governance - Independence of the Board of Directors.”

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by Item 14 is hereby incorporated by reference to the sections of the 2025 Proxy Statement under the caption “Proposal 2 - Ratification of Appointment of Independent Registered Public Accounting Firm.”

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

The following documents are filed as part of this Form 10-K:

1. Financial Statements—See the Index to Consolidated Financial Statements on Page F-1.

2. Financial Statement Schedules—None. We have omitted financial statement schedules because they are not required or are not applicable, or the required information is shown in the consolidated financial statements or notes to the consolidated financial statements.

3. Exhibits.

Exhibit Number	Exhibit
3.1	Certificate of Conversion filed with the Delaware Secretary of State on July 18, 2018 (incorporated by reference to Exhibit 3.1 to the Form 10-Q filed August 9, 2018)
3.2	Certificate of Incorporation, as corrected (incorporated by reference to Exhibit 3.1 to the Form 8-K filed October 30, 2018)
3.3	Certificate of Amendment to Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Form 8-K filed on December 31, 2020)
3.4	Certificate of Amendment to Certificate of Incorporation, as corrected (incorporated by reference to Exhibit 3.1 to the Form 8-K filed on August 16, 2023)
3.5	Second Amended and Restated Bylaws (incorporated by reference to Exhibit 3.3 to the Form 8-K filed March 15, 2024)
4.1	Form of Warrant (incorporated by reference to Exhibit 4.1 to the Form S-1/A filed January 20, 2021)
4.2	Warrant Agency Agreement (incorporated by reference to Exhibit 4.2 to the Form S-1/A filed January 20, 2021)
4.3	Description of Registrant's Securities (incorporated by reference to Exhibit 4.7 to the Form 10-K filed March 14, 2021)
4.4	Warrant Agency Agreement dated as of February 1, 2021 by and between Helius Medical Technologies, Inc. and American Stock Transfer & Trust Company, LLC (incorporated by reference to Exhibit 4.2 to the Form 8-K filed February 1, 2021)
4.5	Form of Warrant to purchase shares of common stock (incorporated by reference to Exhibit 4.1 to the Form 8-K filed August 9, 2022)
4.6	Warrant Agency Agreement dated as of August 9, 2022 by and between Helius Medical Technologies, Inc. and American Stock Transfer & Trust Company, LLC (incorporated by reference to Exhibit 4.2 to the Form 8-K filed August 9, 2022)
4.7	Form of Series A Warrant to purchase shares of Common Stock (incorporated by reference to Exhibit 4.1 to the Form 8-K filed May 9, 2024)
4.8	Form of Series B Warrant to purchase shares of Common Stock (incorporated by reference to Exhibit 4.2 to the Form 8-K filed May 9, 2024)
4.9	Form of Placement Agent Warrant to purchase shares of Common Stock (incorporated by reference to Exhibit 4.3 to the Form 8-K filed May 9, 2024)
4.10	Form of Pre-Funded Warrant to purchase shares of Common Stock (incorporated by reference to Exhibit 4.4 to the Form 8-K filed May 9, 2024)
4.11	Form of Inducement Warrant to purchase shares of Common Stock (incorporated by reference to Exhibit 4.1 to the Form 8-K filed January 24, 2025)
10.1	License Agreement between Advanced NeuroRehabilitation, LLC and Yuri Danilov, Mitchell Tyler, Kurt Kaczmarek and John Klus, dated June 29, 2011 (incorporated by reference to Exhibit 10.8 to the Amendment to Form S-1 filed with the SEC on September 23, 2014)

Exhibit Number	Exhibit
10.2	Amended and Restated Patent Sub-License Agreement between Advanced NeuroRehabilitation, LLC and Helius Medical, Inc, having an effective date of January 22, 2013 (incorporated by reference to Exhibit 10.1 to the Form S-1 filed with the SEC on July 14, 2014)
10.3	Second Amended and Restated Patent Sub-License Agreement between Advanced NeuroRehabilitation, LLC and Helius Medical, Inc, dated June 6, 2014, but having an effective date of January 22, 2013 (incorporated by reference to Exhibit 10.7 to the Form S-1 filed with the SEC on July 14, 2014)
10.4	Design and Manufacturing Consultant Agreement between Helius Medical, Inc and Clinvue, LLC, dated January 30, 2013 (incorporated by reference to Exhibit 10.3 to the Form S-1 filed with the SEC on July 14, 2014)
10.6‡	Asset Purchase Agreement between the Company and A&B (HK) Company Limited, dated as of October 9, 2015 (incorporated by reference to Exhibit 2.1 to the Form 8-K filed with the SEC on October 16, 2015)
10.6.1	Amendment to Asset Purchase Agreement between the Company and A&B (HK) Company Limited, dated as of October 30, 2017 (incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on November 2, 2017)
10.6.2	Supplemental Agreement to Asset Purchase Agreement dated October 9, 2015, between Helius Medical, Inc. and A&B (HK) Company Limited, dated as of August 15, 2018 (incorporated by reference to Exhibit 10.27 to the Form 10-K filed March 14, 2019)
10.7†	Amended and Restated June 2014 Equity Incentive Plan (incorporated by reference to Exhibit 4.3 to the Form 10-Q filed with the SEC on November 9, 2017)
10.7.1†	2014 Stock Incentive Plan Form of Option Grant Agreement (incorporated by reference to Exhibit 10.23.1 to the Transition Report on Form 10-K filed with the SEC on April 3, 2017)
10.8†	2016 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.25 to the Transition Report on Form 10-K filed with the SEC on April 3, 2017)
10.8.1†	Amendment Number 1 to the 2016 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.25.1 to the Transition Report on Form 10-K filed with the SEC on April 3, 2017)
10.8.2†	Amendment Number 2 to the 2016 Omnibus Incentive Plan (incorporated by reference to Exhibit 4.7 to the Registration Statement on Form S-8 filed with the SEC on May 18, 2017)
10.8.3†	2016 Omnibus Incentive Plan Form of U.S. Option Grant Agreement (incorporated by reference to Exhibit 4.8 to the Registration Statement on Form S-8 filed with the SEC on May 18, 2017)
10.8.4†	2016 Omnibus Incentive Plan Form of Canada Option Grant Agreement (incorporated by reference to Exhibit 4.9 to the Registration Statement on Form S-8 filed with the SEC on May 18, 2017)
10.9*	Commercial Lease Agreement, dated November 29, 2021 between Helius Medical, Inc and 660 Tudor Square, L.P.
10.9.1*	Lease Addendum #1, dated January 16, 2025 between Helius Medical Technologies, Inc. and 660 Tudor Square, L.P.
10.10†	2018 Omnibus Incentive Plan, as amended (incorporated by reference to Exhibit 10.2 to the Form 10-Q filed November 8, 2018)
10.10.1†	2018 Omnibus Incentive Plan Form of Option Grant Agreement (incorporated by reference to Exhibit 10.3 to the Form 10-Q filed November 8, 2018)
10.10.2†	2018 Omnibus Incentive Plan Form of Restricted Stock Unit Grant Agreement (incorporated by reference to Exhibit 10.4 to the Form 10 Q filed November 8, 2018)
10.10.3†	2018 Omnibus Incentive Plan Form of Option Grant Agreement – 2020 Retention Grant (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on October 7, 2020)
10.10.4†	2018 Omnibus Incentive Plan Form of Stock Grant Notice and Award Agreement (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on April 7, 2021)
10.10.5†	Amendment to the Helius Medical Technologies, Inc. 2018 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on May 27, 2021)
10.10.6†	2018 Omnibus Incentive Plan Form of Option Grant Agreement – Initial Grants to Dane C. Andreeff and Jeffrey S. Mathiesen (incorporated by reference to Exhibit 10.3 to the Form 8-K filed on June 15, 2021)
10.11†	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.24 to the Form 10-K filed March 10, 2021)

Exhibit Number	Exhibit
10.12	Non-employee Director Compensation Policy (incorporated by reference to Exhibit 10.7 to the Form 10-Q filed on May 17, 2021)
10.13†	Employment Agreement between Helius Medical Technologies, Inc. and Dane C. Andreeff, dated June 14, 2021 (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on June 15, 2021)
10.14†	Employment Agreement between Helius Medical Technologies, Inc. and Jeffrey S. Mathiesen, dated June 14, 2021 (incorporated by reference to Exhibit 10.2 to the Form 8-K filed on June 15, 2021)
10.15†	Helius Medical Technologies, Inc. 2021 Inducement Plan (incorporated by reference to Exhibit 4.5 to the Form S-8 filed July 7, 2021)
10.16.1	Amendment to the Helius Medical Technologies, Inc. 2021 Inducement Plan (incorporated by reference to Exhibit 4.8 to the Form S-8 filed July 24, 2024)
10.16.2†	Form of Stock Option Grant Notice, Option Agreement and Notice of Exercise under the Helius Medical Technologies, Inc. 2021 Inducement Plan (incorporated by reference to Exhibit 4.6 to the Form S-8 filed July 7, 2021)
10.17†	Employment Agreement between Helius Medical Technologies, Inc. and Antonella Favit-Van Pelt, dated July 7, 2021 (incorporated by reference to Exhibit 10.31 to the Form S-1 filed on September 3, 2021)
10.18†	Helius Medical Technologies, Inc. 2022 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on February 18, 2022)
10.18.1	Amendment to the Helius Medical Technologies, Inc. 2022 Equity Incentive Plan, effective as of June 27, 2024 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on June 28, 2024)
10.18.2†	Helius Medical Technologies, Inc. 2022 Equity Incentive Plan Form of Stock Option Agreement (incorporated by reference to Exhibit 10.3 to the Form 8-K filed on February 18, 2022)
10.18.3†	Sales Agreement between Helius Medical Technologies, Inc. and Roth Capital Partners, LLC, dated June 23, 2023 (incorporated by reference to Exhibit 1.1 to the Form 8-K filed on June 23, 2023)
10.19	Placement Agency Agreement dated as of May 6, 2024 by and between Helius Medical Technologies, Inc. and Craig-Hallum Capital Group LLC (incorporated by reference to Exhibit 10.1 to the Form 8-K filed May 9, 2024)
19.1*	Insider Trading Policy
21.1*	Subsidiaries of Helius Medical Technologies, Inc.
23.1*	Consent of Baker Tilly US, LLP
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes – Oxley Act of 2002
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes – Oxley Act of 2002
32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes – Oxley Act of 2002
97.1	Clawback Policy
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Filed herewith.

† Indicates a management contract or compensatory plan.

‡ Confidential information has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been granted with respect to this omitted information.

ITEM 16. FORM 10-K SUMMARY

None

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and the board of directors of Helius Medical Technologies, Inc.:

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Helius Medical Technologies, Inc. (the "Company") as of December 31, 2024 and 2023, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the years ended December 31, 2024 and 2023, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for the years ended December 31, 2024 and 2023, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 1 of the consolidated financial statements, the Company has recurring losses from operations, an accumulated deficit, expects to incur losses for the foreseeable future and requires additional working capital. These are the reasons that raise substantial doubt about their ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 1. The consolidated financial statements do not contain any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

Critical Audit Matter

Critical audit matter is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

Critical Audit Matter Description

Valuation of warrants

As described in Note 8 to the consolidated financial statements, the Company completed an equity offering during the prior year which included the issuance of warrants. Management concluded the warrants met the criteria for the classification as liabilities. Given the liability treatment, the Company is required to determine the fair value of the warrants at each reporting period.

Due to the complexities in determining the fair value, including use of complex valuation techniques and management judgment and estimation in determining assumptions and inputs into the valuation model, we identified the valuation of the warrants issued as a critical audit matter.

How We Addressed the Matter in Our Audit

The primary procedures we performed to address this critical audit matter included:

- Evaluated the methodologies, with the assistance of a firm valuation specialist, and key assumptions used by management to assess the Company's fair value of the warrant liability, including assessing the reasonableness of the source information underlying the valuation assumptions.
- Performed an independent calculation to test the reasonableness of the fair value of the warrant liability.

/s/ Baker Tilly US, LLP

We have served as the Company's auditor since 2022.

Minneapolis, Minnesota
March 25, 2025

Helius Medical Technologies, Inc.
Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	December 31, 2024	December 31, 2023
ASSETS		
Current assets		
Cash and cash equivalents	$ 1,088	$ 5,182
Accounts receivable, net	70	117
Other receivables	565	520
Inventory, net	1,036	457
Prepaid expenses and other current assets	665	1,162
Total current assets	3,424	7,438
Property and equipment, net	107	178
Intangible assets, net	—	24
Operating lease right-of-use asset, net	11	52
Total assets	$ 3,542	$ 7,692
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 873	$ 531
Accrued and other current liabilities	1,239	1,260
Current portion of operating lease liabilities	12	45
Current portion of deferred revenue	39	43
Total current liabilities	2,163	1,879
Operating lease liabilities, net of current portion	—	12
Deferred revenue, net of current portion	79	128
Derivative liability	241	3,323
Total liabilities	2,483	5,342
Commitments and contingencies (Note 13)		
Stockholders' equity		
Class A common stock, $0.001 par value; 150,000,000 shares authorized; 3,728,172 and 714,590 shares issued and outstanding as of December 31, 2024 and December 31, 2023, respectively	4	1
Additional paid-in capital	172,421	162,979
Accumulated deficit	(171,699)	(159,957)
Accumulated other comprehensive loss	333	(673)
Total stockholders' equity	1,059	2,350
Total liabilities and stockholders' equity	$ 3,542	$ 7,692

The accompanying notes are an integral part of these consolidated financial statements.

Helius Medical Technologies, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	Years Ended December 31,	
	2024	2023
Revenue		
Product sales, net	$ 476	$ 605
Other revenue	44	39
Total revenue	520	644
Cost of revenue	582	583
Gross (loss) profit	(62)	61
Operating expenses		
Selling, general and administrative expenses	10,118	9,271
Research and development expenses	3,659	2,942
Amortization expense	24	117
Fixed asset impairment	40	159
Total operating expenses	13,841	12,489
Loss from operations	(13,903)	(12,428)
Nonoperating income		
Interest (expense) income, net	(17)	257
Change in fair value of derivative liability	2,981	2,966
Foreign exchange (loss) gain	(1,006)	275
Other income, net	203	80
Nonoperating income, net	2,161	3,578
Loss before provision for income taxes	(11,742)	(8,850)
Provision for income taxes	—	—
Net loss	(11,742)	(8,850)
Other comprehensive income (loss)		
Foreign currency translation adjustments	1,006	(285)
Comprehensive loss	$ (10,736)	$ (9,135)
Loss per share		
Basic	$ (4.33)	$ (14.56)
Diluted	$ (4.33)	$ (14.56)
Weighted average number of common shares outstanding		
Basic	2,709,781	607,890
Diluted	2,709,781	607,890

The accompanying notes are an integral part of these consolidated financial statements.

Helius Medical Technologies, Inc.
Consolidated Statements of Stockholders' Equity
(in thousands, except share amounts)

	Class A Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	
	Shares	Amount	Capital	Deficit	Loss	Total
Balance as of January 1, 2023	564,094	$ 1	$ 159,645	$ (151,107)	$ (388)	$ 8,151
Issuance of common stock in public offering	53,010	—	500	—	—	500
Share issuance costs	—	—	(65)	—	—	(65)
Exercise of warrants	92,910	—	1,270	—	—	1,270
Settlement of restricted stock units	4,576	—	—	—	—	—
Stock-based compensation	—	—	1,629	—	—	1,629
Other comprehensive income	—	—	—	—	(285)	(285)
Net loss	—	—	—	(8,850)	—	(8,850)
Balance as of December 31, 2023	714,590	$ 1	$ 162,979	$ (159,957)	$ (673)	$ 2,350

	Class A Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	
	Shares	Amount	Capital	Deficit	Loss	Total
Balance as of January 1, 2024	714,590	$ 1	$ 162,979	$ (159,957)	$ (673)	$ 2,350
Issuance of common stock in public offering	853,200	1	2,960	—	—	2,961
Issuance of warrants in public offering	—	—	4,829	—	—	4,829
Share issuance costs	—	—	(1,132)	—	—	(1,132)
Exercise of warrants	2,158,154	2	263	—	—	265
Settlement of restricted stock units	2,228	—	—	—	—	—
Stock-based compensation	—	—	2,522	—	—	2,522
Other comprehensive loss	—	—	—	—	1,006	1,006
Net loss	—	—	—	(11,742)	—	(11,742)
Balance as of December 31, 2024	3,728,172	$ 4	$ 172,421	$ (171,699)	$ 333	$ 1,059

The accompanying notes are an integral part of these consolidated financial statements.

Helius Medical Technologies, Inc.
Consolidated Statements of Cash Flows
(in thousands)

	Years Ended December 31,	
	2024	2023
Cash flows from operating activities:		
Net loss	$ (11,742)	$ (8,850)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of derivative liability	(2,981)	(2,966)
Stock-based compensation expense	2,522	1,629
Foreign exchange loss (gain)	999	(286)
Depreciation expense	36	45
Amortization expense	24	117
Fixed asset impairment	40	159
Provision for (reversal of) inventory reserve	28	(5)
Non-cash operating lease expense	41	52
Changes in operating assets and liabilities:		
Accounts receivable	41	(44)
Other receivables	(46)	(247)
Inventory	(607)	137
Prepaid expense and other current assets	364	54
Operating lease liabilities	(45)	(53)
Accounts payable	344	(103)
Accrued and other current liabilities	(18)	(20)
Deferred revenue	(41)	(35)
Net cash used in operating activities	(11,041)	(10,416)
Cash flows from investing activities:		
Purchase of property and equipment	(5)	(29)
Net cash used in investing activities	(5)	(29)
Cash flows from financing activities:		
Proceeds from issuance of common stock	2,961	500
Proceeds from issuance of warrants	4,829	—
Proceeds from exercise of warrants	164	642
Share issuance costs	(1,000)	(65)
Net cash provided by financing activities	6,954	1,077
Effect of currency exchange rate changes on cash and cash equivalents	(2)	1
Net decrease in cash and cash equivalents	(4,094)	(9,367)
Cash and cash equivalents at beginning of period	5,182	14,549
Cash and cash equivalents at end of period	$ 1,088	$ 5,182
Supplemental cash flow information		
Non-cash investing and financing transactions:		
Derivative warrant liability reclassified to equity on exercise of warrants	$ 101	$ 628
Deferred offering costs reclassified to equity upon public offering	$ 132	$ —

The accompanying notes are an integral part of these consolidated financial statements.

Helius Medical Technologies, Inc.

Notes to the Consolidated Financial Statements

1. DESCRIPTION OF BUSINESS

Helius Medical Technologies, Inc. (together with its wholly owned subsidiaries the "Company") conducts operations in the United States and Canada. The Company's product, known as the Portable Neuromodulation Stimulator ("PoNS®") has been commercially available in Canada since March 2019. The Company began accepting prescriptions for its PoNS product in the United States in the first quarter of 2022, and the first commercial sales began in April 2022. PoNS is authorized for sale as a Class IIa medical device in Australia. The Company is working to establish a distribution partner for Australia but has not yet had any commercial sales of PoNS in Australia.

Going Concern Uncertainty

As of December 31, 2024, the Company had cash and cash equivalents of $1.1 million. For the year ended December 31, 2024, the Company had an operating loss of $13.9 million, and as of December 31, 2024, its accumulated deficit was $171.7 million. For the year ended December 31, 2024, the Company had $0.5 million of net revenue from the commercial sale of products. The Company expects to continue to incur operating losses and net cash outflows until such time as it generates a level of revenue to support its cost structure. There is no assurance that the Company will achieve profitable operations, and, if achieved, whether it will be sustained on a continued basis. These factors indicate substantial doubt about the Company's ability to continue as a going concern within one year after the date the consolidated financial statements are filed. The Company's consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and satisfaction of liabilities in the ordinary course of business; no adjustments have been made relating to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company not continue as a going concern.

The Company intends to fund ongoing activities by utilizing its current cash and cash equivalents on hand, cash received from the sale of its PoNS device in the U.S. and Canada and by raising additional capital through equity or debt financings. There can be no assurance that the Company will be successful in raising additional capital or that such capital, if available, will be on terms that are acceptable to the Company. If the Company is unable to raise sufficient additional capital, the Company may be compelled to reduce the scope of its operations.

2. SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

The accompanying consolidated financial statements reflect the operations of Helius Medical Technologies, Inc. and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of the consolidated financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and disclosure of contingent assets and liabilities. Significant estimates include the assumptions used in the valuation of the fair value-pricing model for stock-based compensation, liability classified warrants and deferred income tax asset valuation allowance. Financial statements include estimates, which, by their nature, are uncertain. Actual results could differ from those estimates.

Foreign Currency Translation

The local currency, or CAD$, is the functional currency of the Company's foreign operating subsidiary, Helius Medical Technologies (Canada), Inc. All assets and liabilities are translated into United States dollars at the rate of exchange in effect at the balance sheet date. Income and expense items are translated at the weighted-average exchange rate

prevailing during the period. The effects of foreign currency translation adjustments are deferred and reported in stockholders' equity as a component of "Accumulated Other Comprehensive Loss." The effects of foreign currency transactions denominated in a currency other than an entity's functional currency are included in "Foreign Exchange (Loss) Gain" in the Consolidated Statements of Operations and Comprehensive Loss.

Revenue Recognition

The Company generates nearly all revenue from product sales directly to patients, its e-commerce partner in the United States and to clinics in Canada. Revenue from product sales is recognized at a point in time as the performance obligation is satisfied and when the customer obtains control of the product at the established transaction price. Taxes that the Company collects concurrent with revenue-producing activities are excluded from revenue.

The Company requires some customers in the United States to prepay the full product selling price, net of cash discount, prior to shipment. The Company records a contract liability for any customer prepayment received for which delivery had not yet occurred as of the end of the period.

Concentration of Credit Risk

The Company deposits its cash and cash equivalents in demand commercial checking, unrestricted money market savings account, money market mutual funds, treasury bills or certificates of deposit at high-quality credit institutions. At times, such deposits may be in excess of federally insured limits. The Company has not experienced any losses.

Cash Equivalents

The Company considers highly liquid investments with original maturities of three months or less to be cash equivalents. Cash equivalents are valued at cost, which approximates fair value.

Accounts Receivable

Accounts receivable arise primarily from product sales in Canada and generally require payment within 30 days. The Company provides reserves against accounts receivable for estimated credit losses that may result from a customer's inability to pay based on a combination of factors, such as the aging of accounts receivable past the due date, the customer's financial strength and payment history. Amounts determined to be uncollectible are charged or written off against the reserve.

Employee Retention Credit

The employee retention credit ("ERC"), as originally enacted through the Coronavirus Aid, Relief, and Economic Security Act, is a refundable credit against certain employment taxes equal to 50% of the qualified wages an eligible employer pays to employees from March 17, 2020 to December 31, 2020. The Disaster Tax Relief Act extended the ERC for qualified wages paid from January 1, 2021 to June 30, 2021 and the credit was increased to 70% of qualified wages an eligible employer pays to employees during the extended period. The American Rescue Plan Act of 2021, enacted on March 11, 2021, further extended the ERC through December 31, 2021.

The Company qualified for the employee retention credit for the period from March 17, 2020 to September 30, 2021. The Company recognizes government credits for which there is a reasonable assurance of compliance with credit conditions and receipt of credits. The Company accounts for the ERC as government assistance and applies the grant accounting model by analogy to International Accounting Standard 20, Accounting for Government Grants and Disclosure of Government Assistance. Under this approach, the Company recognizes the credit when there is reasonable assurance that it will comply with the conditions of the grant and that the credit will be received.

The Company recorded a credit of $0.5 million against operating expenses on the Consolidated Statement of Operations and Comprehensive Loss during the year ended December 31, 2023 and as a current asset on the consolidated balance

sheets during the year ended December 31, 2024 and December 31, 2023 as an other receivable. The Company expects to receive the credit in the next twelve months.

Inventory

Inventories are stated at the lower of cost (average cost method) or net realizable value. The Company establishes inventory reserves for obsolescence based upon specific identification of expired or unusable units with a corresponding provision included in cost of revenue. The Company calculates provisions for excess inventory based on inventory on hand compared to anticipated sales or usage. Management uses its judgment to forecast sales or usage and to determine what constitutes a reasonable period. There can be no assurance that the amount ultimately realized for inventories will not be materially different than that assumed in the calculation of the reserves.

Property and Equipment

Property and equipment are recorded at cost. Depreciation is calculated for financial reporting purposes on the straight-line method over the estimated useful lives of the related assets, which are seven years for furniture and fixtures, five to fifteen years for equipment and three to five years for computer software and hardware. Depreciation expense is recorded in selling, general and administrative expenses. Expenditures for repairs and maintenance, which do not improve or extend the expected useful life of the assets, are expensed as incurred.

Long-Lived Assets

Management reviews the carrying amounts of definite-lived intangible assets and long-lived assets, including right-of-use (“ROU”) assets, property and equipment whenever events or circumstances indicate that the carrying amounts of an asset may not be recoverable. For purposes of assessing recoverability, definite-lived intangible assets and long-lived tangible assets are each deemed to be one asset group. The carrying amount of the asset group is compared to the estimated undiscounted future cash flows associated with it. If the sum of the expected future net cash flows is less than the carrying value of the asset group being evaluated, an impairment loss is calculated as the amount by which the carrying value of the asset group exceeds its estimated fair value.

Leases

The Company has an operating lease for its corporate office. The Company determines whether a contract is, or contains, a lease at inception. ROU assets represent the Company’s right to use an underlying asset during the lease term, and lease liabilities represent the Company’s obligation to make lease payments arising from the lease. ROU assets and lease liabilities are recognized at lease commencement based upon the estimated present value of unpaid lease payments over the lease term. The Company uses its incremental borrowing rate based on the information available at lease commencement in determining the present value of unpaid lease payments. The Company's incremental borrowing rate is determined based on the estimated rate of interest for collateralized borrowing over a similar term as the associated lease. The Company’s lease arrangement does not have any lease and non-lease components.

Stock-Based Compensation

The Company measures and recognizes compensation expense for all stock-based awards based on estimated fair values. Stock-based awards consist of stock options and restricted stock units. Stock-based compensation expense is measured at the grant date based on the fair value of the award and is recognized as expense over the requisite service period (vesting period) on a straight-line basis. Forfeitures are not estimated, but instead stock-based compensation expense is adjusted upon an actual forfeiture of a stock option. Upon exercise of stock options or vesting of restricted stock units, the Company issues common stock.

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance for deferred income tax assets is recorded when it is more likely than not that some portion or all of the deferred income tax assets will not be realized.

Selling, General and Administrative Expenses

Selling, general and administrative expenses are charged to expense when incurred. Advertising expenses were $651 thousand and $670 thousand for the years ended December 31, 2024 and 2023, respectively.

Research and Development Expenses

Research and development costs are charged to expense when incurred.

Derivatives

The Company does not engage in hedging activities. The Company evaluates its financial instruments and other contracts to determine if those contracts or embedded components of those contracts qualify as derivatives to be separately accounted for. The result of this accounting treatment is that the fair value of the derivative is re-measured at each balance sheet date and recorded as a liability or asset and the change in fair value is recorded in the Consolidated Statements of Operations and Comprehensive Loss. Reclassifications or partial reclassifications to equity are recorded based on the fair value of the derivative on the transaction date. Refer to Note 8 for additional information about the derivative liability.

Basic and Diluted Loss per Share

Basic loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period. Diluted loss per share is based on the weighted-average common shares outstanding during the period plus dilutive potential common shares calculated using the treasury stock method. Such potentially dilutive shares are excluded when the effect would be to reduce a net loss per share.

Recent Accounting Pronouncements

Accounting Standards Adopted

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures. ASU 2023-07 modifies reportable segment disclosure requirements, primarily through enhanced disclosures about segment expenses categorized as significant or regularly provided to the CODM. In addition, the amendments enhance interim disclosure requirements, clarify circumstances in which an entity can disclose multiple segment measures of profit or loss, and contain other disclosure requirements. The purpose of the amendments is to enable investors to better understand an entity's overall performance and assess potential future cash flows. This ASU is effective for annual periods beginning after December 15, 2023, and interim periods within annual periods beginning after December 15, 2024, with early adoption permitted. Refer to Note 14 for additional information regarding implementation of this new standard.

Accounting Standards Not Yet Adopted

In November 2024, the FASB issued ASU 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses. ASU 2024-03 requires

interim and annual tabular disclosure of disaggregated information for certain income statement expense captions. Specific expense categories required to be disclosed quantitatively include inventory purchases, employee compensation, depreciation, and intangible asset amortization, as well as other specified expense categories currently disclosed under existing disclosure requirements. Additionally, any remaining amounts that are not separately disaggregated are required to be described qualitatively. ASU 2024-03 also requires separate disclosure of total selling expenses incurred each reporting period, with annual disclosure of the entity's definition of selling expenses. The annual disclosures required by ASU 2024-03 are effective for the Company beginning in its fiscal year ending December 31, 2027, with interim disclosures effective beginning in its fiscal year ending December 31, 2028. The provisions of ASU 2024-03 are to be applied prospectively, although retrospective application is permitted. Early adoption is also permitted. The Company is currently evaluating the ASU to determine its impact on the Company’s disclosures.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. The guidance requires expanded annual disclosures including the standardization and disaggregation of income tax rate reconciliation categories and the amount of income taxes paid by jurisdiction. The guidance is effective for the Company beginning in its fiscal year ending December 31, 2025. The Company is currently evaluating the ASU to determine its impact on the Company’s disclosures.

In March 2024, the SEC adopted rules under SEC Release No. 33-11275, The Enhancement and Standardization of Climate-Related Disclosures for Investors, which requires the disclosure of material Scope 1 and Scope 2 greenhouse gas emissions and other climate-related topics in annual reports and registration statements. For non-accelerated filers and smaller reporting companies, disclosure requirements will begin phasing in for fiscal years beginning on or after January 1, 2027, subject to legal challenges and the SEC's voluntary stay of the disclosure requirements. The Company is currently evaluating the impact these rules will have on its consolidated financial statements and related disclosures.

3. FIXED ASSETS IMPAIRMENT

In the fourth quarter of 2024, the Company made the decision to no longer utilize certain capitalized software associated with its enterprise resource planning system and as a result, impairment charges of $40 thousand were recorded in the fourth quarter of 2024 on its long-lived tangible assets.

In the third quarter of 2023, the Company identified an impairment indicator associated with its property and equipment and performed interim impairment tests on the long-lived tangible assets as a result of a planned change of the Company’s contract manufacturing partner to be completed in less than one year from September 30, 2023. The interim impairment tests were performed using estimated market prices. The Company had determined that the fair value of certain long-lived tangible assets was lower than the related book values. Additionally, for certain long-lived tangible assets, it is more likely than not that those long-lived assets will be disposed significantly before the end of their previously estimated useful lives. As a result, impairment charges of $159 thousand were recorded in the third quarter of 2023 on its long-lived tangible assets.

4. SUPPLEMENTAL BALANCE SHEET DISCLOSURES

Components of selected captions in the Consolidated Balance Sheets are as follows:

Accounts receivable, net

Accounts receivable is net of allowance for doubtful accounts of $0 as of December 31, 2024 and 2023.

Inventory, net (in thousands)

	December 31, 2024	December 31, 2023
Raw materials	$ 576	$ 351
Work-in-process	402	67
Finished goods	145	96
Inventory, gross	1,123	514
Inventory reserve	(87)	(57)
Inventory, net	$ 1,036	$ 457

During the years ended December 31, 2024 and 2023, existing reserves of $2 thousand and $16 thousand were charged against inventory, respectively.

Prepaid expenses and other current assets (in thousands)

	December 31, 2024	December 31, 2023
Prepaid expenses	$ 603	$ 689
Inventory related	55	333
Deferred offering costs	7	140
Total prepaid expenses and other current assets	$ 665	$ 1,162

Property and equipment, net (in thousands)

	December 31, 2024	December 31, 2023
Furniture and fixtures	$ 59	$ 59
Equipment	247	243
Computer software and hardware	196	235
Property and equipment	502	537
Accumulated depreciation	(395)	(359)
Property and equipment, net	$ 107	$ 178

Accrued and other current liabilities (in thousands)

	December 31, 2024	December 31, 2023
Insurance payable	$ 356	$ 446
Employees benefits	759	509
Professional services	24	52
Franchise tax	—	168
Other	100	85
Total accrued and other current liabilities	$ 1,239	$ 1,260

Deferred revenue

Exclusive Distribution Agreement

Pursuant to an Exclusive Distribution Agreement with Health Tech Connex Inc. (“HTC”) (“Exclusivity Agreement”) entered into on March 3, 2023, subject to certain terms and conditions, the Company granted to HTC the exclusive right to provide PoNS Therapy® in the Fraser Valley and Vancouver metro regions of British Columbia. HTC is to purchase the PoNS devices for use in these regions exclusively from the Company and on terms no less favorable than the then-current standard terms and conditions. This Exclusivity Agreement replaced the previous Clinical Research and Co-Promotion Agreement (“Co-Promotion Agreement”) between the parties entered into in October 2019 that included a similar exclusive right provision. The exclusive right under the Exclusivity Agreement was granted for a fixed value of CAD$273 thousand, which is represented by the unamortized up-front payment under the former Co-Promotion

Agreement. The initial term of the Exclusivity Agreement expires on December 31, 2027, and is renewable by HTC for one additional five-year term upon sixty days' written notice to the Company.

Deferred revenue as of both December 31, 2024 and 2023 is comprised of the remaining unamortized amount under these agreements. Revenue recognized is included in other revenue in the Consolidated Statements of Operations and Comprehensive Loss. Revenue recognized for the years ended December 31, 2024 and 2023 were $41 thousand and $35 thousand, respectively.

5. LEASES

The Company has an operating lease for office space with lease terms that commenced in January 2022 and will expire in March 2025. The lease does not contain any options to extend. Operating lease costs for the years ended December 31, 2024 and 2023 were $41 thousand and $54 thousand, respectively.

On January 16, 2025, the Company entered into an agreement to extend the operating lease for the Newtown, PA office through March 31, 2026, at a rate of $4 thousand per month effective April 1, 2025.

Maturities of operating lease liabilities as of December 31, 2024 were as follows (in thousands):

2025	$ 12
Total lease payments	12
Less: imputed interest	—
Total lease liabilities	$ 12

The following table provides information on the lease term and discount rate for the operating lease as of December 31, 2024:

Remaining lease term (in years)	0.25
Discount rate	4.55 %

6. INTANGIBLE ASSETS

Intangible assets consist of the following (in thousands):

		December 31,					
		2024			2023		
	Useful Life (in years)	Cost	Accumulated Amortization	Net Carrying Value	Cost	Accumulated Amortization	Net Carrying Value
Reacquired rights	3.87	$ 447	$ (447)	$ —	$ 486	$ (486)	$ —
Acquired proprietary software	5.00	134	(134)	—	145	(121)	24
Internally developed software	3.00	84	(84)	—	84	(84)	—
Total intangible assets		$ 665	$ (665)	$ —	$ 715	$ (691)	$ 24

7. FAIR VALUE MEASUREMENTS

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. Fair value of an asset or liability considers assumptions that market participants would use in pricing the asset or liability, including consideration of non-performance risk. The inputs used to determine fair values are categorized in one of the following three levels of the fair value hierarchy:

Level 1 – Quoted market prices in active markets for identical assets or liabilities.

Level 2 – Inputs, other than quoted prices in active markets, that are observable, either directly or indirectly.

Level 3 – Unobservable inputs that are not corroborated by market data.

The Consolidated Financial Statements include financial instruments for which the fair market value of such instruments may differ from amounts reflected on a historical cost basis. Financial instruments of the Company as of December 31, 2024 and 2023 consist of cash equivalents, which were comprised of deposits of excess cash in an unrestricted money market savings account, money market mutual funds, treasury bills and a certificate of deposit. The carrying value of cash equivalents generally approximates fair value due to their short-term nature.

The Company's derivative liability as of December 31, 2024 and 2023 is comprised of warrants issued in connection with the registered public offering completed in August 2022 discussed in Note 8. The derivative liability is classified as Level 3 within the fair value hierarchy and is required to be recorded at fair value on a recurring basis. See Note 8 for further information on the fair value of the derivative liability.

The majority of the Company's non-financial instruments, which include intangible assets, lease assets, inventories and property and equipment, are not required to be carried at fair value on a recurring basis. However, if certain triggering events occur (or at least annually for indefinite-lived intangible assets), a non-financial instrument is required to be evaluated for impairment. If the Company determines that the non-financial instrument is impaired, the Company would be required to write down the non-financial instrument to its fair value. See Note 3 – Fixed Asset Impairment for further detail.

8. COMMON STOCK AND WARRANTS

The Company may issue common stock in connection with underwritten public offerings, registered direct public offerings or other financing transactions. Such issuances of common stock may include the issuance or sale of warrants to purchase common stock. As of December 31, 2024, the Company reserves 146,271,828 shares of Class A Common Stock and 10,000,000 shares of unissued preferred stock for future issuances and future exercises of outstanding warrants and stock-based compensation awards.

Equity Transactions

Public Offering

On May 9, 2024, the Company closed on a registered public offering consisting of 704,999 shares of Common Stock (the "2024 Public Offering"), pre-funded warrants to purchase 2,147,222 shares of Common Stock (the "Pre-funded Warrants") and accompanying Series A Warrants to purchase up to 2,852,221 shares of its Common Stock ("Series A Warrants") and Series B Warrants to purchase up to 2,852,221 shares of its Common Stock ("Series B Warrants", and together with the Series A Warrants, the "2024 Public Warrants"). The 2024 Public Offering price per share of Common Stock and accompanying Series A Warrants and Series B Warrants was $2.25, the public offering price per Pre-funded Warrant and accompanying Series A and Series B warrant was $2.249.

The Pre-funded Warrants have an exercise price of $0.001 per share and 1,076,445 were exercised on the closing date. Net proceeds from the 2024 Public Offering, after deducting placement agent fees and expenses and other offering costs, were approximately $5.5 million.

The 2024 Public Warrants have an exercise price of $2.25 per share and are exercisable upon issuance. The Series A Warrants will expire five years following the date of issuance and the Series B Warrants will expire twelve months following the date of issuance. The Pre-funded Warrants are exercisable upon issuance and may be exercised at any time until the Pre-funded Warrants are exercised in full.

At-The-Market Offering

On June 23, 2023, the Company entered into a Sales Agreement (the "Sales Agreement") with Roth Capital Partners, LLC ("Roth") to create an at-the-market offering program ("ATM") under which the Company may offer and sell shares having an aggregate offering price of up to $2.0 million. Roth is entitled to a commission at a fixed commission rate equal to up to 3% of the gross proceeds pursuant to the Sales Agreement. As of December 31, 2024, 201,211 share issuances of securities have occurred in connection with the ATM generating net proceeds of $1.3 million and $0.4 million inclusive of share issuance costs in 2024 and 2023, respectively. On January 17, 2025, 93,300 shares were issued with the ATM, generating net proceeds of $0.1 million inclusive of share issuance costs.

Series B Preferred Stock

On March 23, 2023, the Board of Directors declared a dividend of one one-thousandth of a share of Series B Preferred Stock ("Series B Preferred Stock") for each outstanding share of Common Stock held of record on April 3, 2023. The value of the Series B Preferred Stock issued in connection with the stock dividend was immaterial.

The outstanding shares of Series B Preferred Stock voted together with the outstanding shares of the Company's Common Stock, as a single class, exclusively with respect to a proposal giving the Board of Directors the authority, as it determines appropriate, to implement a reverse stock split within twelve months following the approval of such proposal by the Company's stockholders as well as any proposal to adjourn any meeting of stockholders called for the purpose of voting on the foregoing matters.

Each share of Series B Preferred Stock entitled the holder to 1,000,000 votes per share and each fraction of a share of Series B Preferred Stock had a ratable number of votes. The holder of Series B Preferred Stock, as such, are not entitled to receive dividends.

At the annual meeting of stockholders of the Company held on May 24, 2023, the Company's stockholders approved an amendment to the Company's Certificate of Incorporation to effect a reverse stock split of its outstanding Common Stock. All shares of Series B Preferred Stock that did not vote in person or by proxy were redeemed in whole by the Company. Shares of Series B Preferred Stock that did vote in person or by proxy will need to request redemption from the Company at a rate of $0.001 per share in cash. As of December 31, 2024, no shareholders of Series B Preferred Stock have requested such redemption.

Reverse Stock Split

At the annual meeting of stockholders on May 24, 2023, our stockholders voted to approve a reverse stock split of our outstanding Class A common stock at a ratio in the range of 1-for-10 to 1-for-80 to be determined at the discretion of the Board of Directors. On August 11, 2023, the Board approved a 1-for-50 reverse stock split of the Company's issued and outstanding Common Stock (the "Reverse Stock Split").

Warrants

August 2022 Warrants

In connection with the Company's registered public offering that closed on August 9, 2022, the Company issued warrants to purchase an aggregate of 720,000 shares of common stock ("2022 Public Warrants"). The Company performed an analysis of the provisions of the Public Warrants and concluded that the Public Warrants did not meet the guidance for being classified as an equity instrument due to a potential price reset prompted by a change in an unrelated instrument's conversion rate or, in the event of a fundamental transaction, settlement rights that differ from those of the underlying common stockholders.

The fair value of the derivative liability as of December 31, 2024 and 2023 was $0.2 million and $3.3 million, respectively. The change in the fair value of the derivative liability was recognized as a component of nonoperating income in the Company's Consolidated Statements of Operations and Comprehensive Loss.

The fair value of the 2022 Public Warrants was determined using both a Monte Carlo simulation model, which uses multiple input variables to determine the probability of the occurrence of a price reset or a fundamental transaction and the Black-Scholes option pricing model. The following table includes the stock price and the inputs used to estimate the fair value of the warrants:

	December 31, 2024	December 31, 2023
Stock price	$ 0.67	$ 8.04
Warrant term (in years)	2.61	3.61
Expected volatility	98.92 %	84.10 %
Risk-free interest rate	4.26 %	3.96 %
Dividend rate	0.00 %	0.00 %

The 603,690 of outstanding liability classified Public Warrants have an exercise price that was reset to $1.6163 per share as a result of the 2024 Public Offering are exercisable upon issuance and will expire five years following the date of issuance. 23,400 Public Warrants were exercised and the Company received gross proceeds of $0.2 million during the year ended December 31, 2024. No warrants were cancelled during the year ended December 31, 2024.

Equity-classified Warrants

The Company has outstanding equity-classified warrants to purchase 5,869,244 shares of common stock at a weighted average exercise price of $3.64, with expiration dates ranging from March 2025 to May 2029. The weighted average exercise price includes 12,222 Pre-funded Warrants with a nominal exercise price of $0.001 outstanding as of December 31, 2024. The weighted average exercise price excluding the outstanding Pre-funded Warrants is $3.65 as of December 31, 2024. During the year ended December 31, 2024, 2,135,000 Pre-funded Warrants were exercised for 2,134,754 common shares as the result of the cashless exercise provision and no warrants were cancelled due to expiration.

9. STOCK-BASED COMPENSATION

The Company may issue stock-based compensation awards under The Helius Medical Technologies, Inc. 2022 Equity Incentive Plan (“2022 Plan”) or the Helius Medical Technologies, Inc. 2021 Inducement Plan (as amended, the “Inducement Plan”). The 2022 Plan provides for the grant of incentive stock options (“ISOs”), nonstatutory stock options (“NSOs”), stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of awards to employees, directors and consultants. Options to purchase shares of the Company’s common stock granted under the 2022 Plan are awarded at a price equal to the fair market value at the date of grant based upon the closing price on that date. Options granted under the 2022 Plan generally vest over periods of between one to three years and expire no later than ten years from the date of grant.

On May 30, 2024, the Board adopted a First Amendment (the “Amendment”) to the 2022 Plan. On June 27, 2024, at the annual meeting of stockholders, the stockholders of the Company approved the Amendment. Pursuant to the terms and conditions of the Amendment, the 2022 Plan was amended to increase the aggregate number of shares of Common Stock that may be issued under the 2022 Plan to 2,089,000 new shares with an automatic increase on January 1st of each year by an amount equal to 5% of the Fully Diluted Shares (as defined in the 2022 Plan) as of the last day of the preceding calendar year. As of January 1, 2025, the number of shares authorized for issuance increased from 2,089,000 to 2,703,678 and there were 637,237 shares of common stock available for issuance under the 2022 Plan.

The Inducement Plan permits the grant of non-statutory stock options, stock appreciation rights, restricted stock, restricted stock units, performance stock and cash awards and other share-based awards The Inducement Plan is used exclusively for grants of awards to individuals who were not previously employees or directors of the Company. Options granted under the Inducement Plan generally vest over four years and expire after ten years. The exercise price of each option is equal to the fair market value of the common stock at the date of grant. On July 2, 2024, the Company approved an amendment to the Inducement Plan pursuant to which, the Inducement Plan was amended to increase the

aggregate number of shares of Common Stock that may be issued under the Inducement Plan to 150,000 new shares. As of December 31, 2024, there were 123,980 shares of common stock available for issuance under the Inducement Plan.

The fair value of each stock option award is estimated on the date of grant using the Black-Scholes option valuation model that uses the assumptions noted in the following tables. The risk-free interest rate is estimated using the United States Treasury yield curve and is based on the expected term of the award. The expected term of stock option awards granted is estimated based on the "simplified" method described in the SEC Staff Accounting Bulletin, Topic 14: Share-Based Payment. Expected volatility is calculated using historical volatility over the expected term.

The Black-Scholes option pricing model was used with the following weighted-average assumptions for options granted during the years ended December 31, 2024 and 2023:

	Years Ended December 31, 2024	
	2024	2023
Risk-free interest rate	4.38 %	3.93 %
Expected volatility	128.73 %	79.43
Expected term (years)	5.27	5.70
Expected dividend yield	0.00 %	0.00 %
Fair value, per share	$ 0.84	$ 10.17

During the year ended December 31, 2024 and 2023, 1,335,623 options with a total grant date fair value of $2.5 million and 86,580 options with a total grant date fair value of $1.6 million vested, respectively.

The fair value of restricted stock units granted during the years ended December 31, 2024 and 2023 was based on the closing price of the Company's common stock on the Nasdaq Capital Market on the day of the grant.

Stock option activity during the year ended December 31, 2024 was as follows:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2023	245,830	$ 76.28	9.03	5.00
Granted	1,856,000	0.96	—	—
Exercised	—	—	—	—
Expired	(5,747)	176.61	—	—
Forfeited	(3,622)	16.27	—	—
Outstanding as of December 31, 2024	2,092,461	9.30	9.33	$ —
Exercisable as of December 31, 2024	1,428,221	12.14	9.31	$ —

The following table summarizes nonvested restricted stock unit activity during the year ended December 31, 2024:

	Shares	Weighted Average Grant Date Fair Value
Nonvested as of December 31, 2023	2,228	$ 7.81
Granted	—	—
Vested	(2,228)	7.81
Forfeited	—	—
Nonvested as of December 31, 2024	—	$ —

Total stock-based compensation expense was as follows (in thousands):

	Years Ended December 31,	
	2024	2023
Cost of sales	$ 28	$ 18
Selling, general and administrative	2,008	1,320
Research and development	486	291
Total stock-based compensation expense	$ 2,522	$ 1,629

As of December 31, 2024, the total remaining unrecognized compensation expense related to nonvested stock options was $1.5 million which will be amortized over weighted-average remaining requisite service period of 0.7 years.

10. BASIC AND DILUTED LOSS PER SHARE

The table below presents the computation of basic and diluted loss per share (in thousands, except share and per share information):

	Years Ended December 31,	
	2024	2023
Basic:		
Net loss available to common stockholders — basic	$ (11,742)	$ (8,850)
Weighted average common shares outstanding — basic [1]	2,709,781	607,890
Loss per share - basic	$ (4.33)	$ (14.56)
Diluted:		
Net loss available to common stockholders — diluted [2]	$ (11,742)	$ (8,850)
Weighted average common shares outstanding — diluted [1]	2,709,781	607,890
Loss per share — diluted	$ (4.33)	$ (14.56)

[1] In May 2024, in connection with the 2024 Public Offering, the Company issued and sold Pre-funded Warrants exercisable for an aggregate of 2,147,222 shares of Common Stock. The total price of the Pre-funded Warrants is $2.25 per share, $2.249 of which was pre-funded and paid to the Company upon issuance of the Pre-funded Warrants. The exercise price of the Pre-funded Warrants is $0.001 per share. The Pre-funded Warrants are immediately exercisable and do not expire. As of December 31, 2024, 2,052,703 Pre-funded Warrants were exercised and 12,222 Pre-funded Warrants remained outstanding. As the remaining shares underlying the Pre-funded Warrants are exercisable for nominal consideration of $0.001 per share, 12,222 in common shares underlying the unexercised Pre-funded Warrants were considered outstanding for purposes of the calculation of loss per share for the year ended December 31, 2024. Refer to Note 8 for additional information about the Pre-funded Warrants.

[2] For the years ended December 31, 2024 and 2023, no adjustment was made to the numerator.

The following outstanding securities, presented based on amounts outstanding as of the end of each period, were not included in the computation of diluted loss per share for the periods indicated, as they would have been anti-dilutive due to the net loss in each period.

	Years Ended December 31,	
	2024	2023
Stock options	2,092,461	245,830
Restricted stock units	—	2,228
Warrants [1]	6,460,712	637,059

11. INCOME TAXES

The Company's loss before provision for income taxes was generated from operations in the United States and outside of the United States as follows (in thousands):

	Years Ended December 31,	
	2024	2023
U.S.	$ (11,303)	$ (8,689)
Non-U.S.	(439)	(161)
	$ (11,742)	$ (8,850)

A reconciliation of the United States federal statutory income tax rate to the Company's effective income tax rate is as follows (in thousands):

	Years Ended December 31,	
	2024	2023
Income tax benefit at United States federal statutory rate	$ (2,466)	$ (1,858)
Derivative liability	(626)	(623)
Share based payments	125	(791)
Tax credits	(189)	(142)
Foreign income taxed at foreign rate	(24)	(9)
Other permanent difference	119	126
Other	7	144
Increase in valuation allowance	3,054	3,153
Income tax expense	$ —	$ —

The components of deferred tax assets and liabilities are as follows (in thousands):

	As of December 31,	
	2024	2023
Deferred tax assets		
Net operating loss carryforwards	$ 32,635	$ 30,642
Stock-based compensation	3,967	3,316
Research and development	2,486	2,164
Tax credit carryforwards	1,419	1,267
Compensation and benefits	195	120
Unrealized foreign currency losses	320	33
Deferred revenue	31	45
Other	36	26
Total deferred tax assets	41,089	37,613
Deferred tax liabilities		
Property and equipment	(4)	(16)
Other	(3)	(19)
Total deferred tax liabilities	(7)	(35)
Valuation allowance	(41,082)	(37,578)
Net deferred tax assets	$ —	$ —

Net operating loss carryforwards and the related carryforward expiration periods as of December 31, 2024 are summarized as follows (in thousands):

	Carryforward Amount	Expiration
United States federal net operating losses	$ 39,561	2032-2037
United States federal net operating losses	83,378	Indefinite
United States state net operating losses	74,624	2033-2044
United States state net operating losses	12,053	Indefinite
Canada federal net operating losses	6,384	2034-2044

The gross tax credit carryforwards and the related carryforward expiration periods as of December 31, 2024 are summarized as follows (in thousands):

	Carryforward Amount	Expiration
United States federal research expenditure tax credits	$ 986	2034-2044
Canada federal research expenditure tax credits	432	2034-2037

Under the provisions of the Internal Revenue Code of 1986, as amended (the "Code"), the net operating loss carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. Net operating loss carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50 percent, as defined under Section 382 of the Code, as well as similar state provisions. This could substantially limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. Although a formal Section 382 analysis has not yet been completed, the Company believes it is possible ownership changes have occurred. The annual limitation may result in the expiration of United States net operating losses and credits before utilization; however, due to the valuation allowance against deferred tax assets as of December 31, 2024, the net effect of any limitation will have no impact on results of operations.

The accounting guidance related to uncertain tax positions prescribes a recognition threshold and measurement attribute for recognition and measurement of a tax position taken or expected to be taken in a tax return. It also provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. As of both December 31, 2024 and 2023, the Company does not have an accrual relating to uncertain tax positions. It is not anticipated that unrecognized tax benefits would significantly increase or decrease within 12 months of the reporting date.

The Company files income tax returns in the United States and Canada. The Company's tax returns are subject to tax examinations by United States federal and state tax authorities, or examinations by foreign tax authorities until the expiration of the respective statutes of limitation. The Company currently has no tax years under examination.

12. DEFINED CONTRIBUTION PLAN

The Company's employees in the United States are eligible to participate in the Helius Medical Inc. Savings Plan, as amended, a safe harbor 401(k) plan ("401(k) Plan"). The 401(k) Plan allows eligible employees to make contributions through payroll deductions up to IRS limits. The Company matches the first 3% of the participant's annual eligible compensation contributed to the plan on a dollar-for-dollar basis and matches the next 2% of the participant's annual eligible compensation to the plan on a 50% basis. Pursuant to the 401(k) safe harbor provisions, the Company's matching contributions are 100% vested. For the years ended December 31, 2024 and 2023, the Company's defined contribution plan expense was $137 thousand and $148 thousand, respectively.

13. COMMITMENTS AND CONTINGENCIES

The Company is obligated under a license agreement with Advanced NeuroRehabilitation, LLC ("ANR") to pay a 4% royalty on net revenue collected from the sale of devices covered by ANR's patent pending technology, claims and knowhow. For the years ended December 31, 2024 and 2023, the Company recorded royalty expense from the sale of devices of approximately $19 thousand and $24 thousand, respectively, in its Consolidated Statements of Operations and Comprehensive Loss.

14. SEGMENT AND GEOGRAPHIC INFORMATION

Segment Information

Operating segments are components of an enterprise for which separate financial information is available and are evaluated regularly by the Company's chief operating decision maker ("CODM") in deciding how to allocate resources and assessing performance. The Company's CODM is its Chief Executive Officer. The Company's Chief Executive Officer views the Company's operations and manages its business in one operating segment, which is the business of development and commercialization of products related to PoNS® devices. The Company has a single reporting segment and the determination of the single segment is consistent with the information provided to the CODM. The CODM evaluates performance and allocates resources based on the Company's consolidated financial results.

Geographic Information

The following table presents the Company's revenue disaggregated by geographic area (in thousands):

	Years Ended	
	2024	2023
Product sales, net:		
United States	$ 181	$ 324
Canada	295	281
Total product sales, net	476	605
Other revenue	44	39
Total revenue	$ 520	$ 644

Two customers accounted for 72% and 65% of net product sales for the years ended December 31, 2024 and 2023, respectively. Two customers accounted for 100% of accounts receivable, net as of December 31, 2024 and a single customer accounted for 83% of accounts receivable, net as of December 31, 2023.

Long-lived assets are held in the United States and Canada with the majority of long-lived assets being held in the United States as of December 31, 2024 and 2023. As of December 31, 2024, the carrying value of long-lived assets held in Canada is $0.

15. SUBSEQUENT EVENTS

Warrant inducement

On January 21, 2025, the Company entered into warrant exercise inducement offer letters (the "Inducement Letters") with certain holders (the "Holders") of its existing 2024 Public Warrants to purchase shares of the Company's Class A common stock (the "Existing Warrants"), pursuant to which the Holders agreed to exercise for cash their Existing Warrants to purchase an aggregate of 4,971,110 shares of the Company's common stock, in the aggregate, at a reduced exercise price of $0.751 per share, in exchange for the Company's agreement to issue new Series C Warrants and Series D Warrants (the "Inducement Warrants") on substantially the same terms as the Existing Warrants described below, to purchase up to 6,213,888 shares of the Company's common stock (the "Inducement Warrant Shares"). The Company received aggregate gross proceeds of approximately $3.7 million from the exercise of the Existing Warrants by the

Holders. The Company engaged Roth to act as its financial advisor with the transactions summarized above and has paid Roth $0.2 million for its services, in addition to reimbursement for certain expenses along with other legal and regulatory expenses resulting in net proceeds of $3.4 million.

The Company has filed a registration statement on Form S-3 covering the resale of the Inducement Warrants Shares issued or issuable upon the exercise of the Inducement Warrants. In the Inducement Letters, the Company agreed not to issue any shares of common stock or common stock equivalents or to file any other registration statement with the SEC (in each case, subject to certain exceptions) for sixty (60) calendar days. The Company also has agreed not to effect or agree to effect any variable rate transaction (as defined in the Inducement Letters) for seventy-five (75) calendar days from the date of the Inducement Letters.

The Company has agreed to hold an annual or special meeting of stockholders on or prior to the date that is ninety (90) calendar days following the date of the Inducement Letters for the purpose of obtaining stockholder approval, with the recommendation of the Company's board of directors that such proposals are approved. If the Company does not obtain stockholder approval at the first meeting, the Company has agreed to call a meeting to seek stockholder approval every ninety (90) calendar days until the date that the Inducement Warrants are no longer outstanding.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

HELIUS MEDICAL TECHNOLOGIES, INC.

Dated: March 25, 2025

By: /s/ Dane C. Andreeff
Dane C. Andreeff
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

By /s/ Dane C. Andreeff — Date: March 25, 2025
Dane C. Andreeff
President, Chief Executive Officer (Principal Executive Officer) and Director

By /s/ Jeffrey S. Mathiesen — Date: March 25, 2025
Jeffrey S. Mathiesen
Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer), Treasurer, Secretary and Director

By /s/ Paul Buckman — Date: March 25, 2025
Paul Buckman
Director

By /s/ Blane Walter — Date: March 25, 2025
Blane Walter
Director

By /s/ Sherrie Perkins — Date: March 25, 2025
Sherrie Perkins
Director

By /s/ Edward M. Straw — Date: March 25, 2025
Edward M. Straw
Director

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S 1 (No. 333 278698, 333 259334 and 333 266107), Form S 3 (333 284633 and 333 270433) and Form S 8 (No. 333 280978, 333 204155, 333 218095, 333 229724, 333 256680, 333 257749, 333 265324 and 333 269305) of Helius Medical Technologies, Inc. of our report dated March 25, 2025, relating to the consolidated financial statements, which includes an explanatory paragraph relating to the Company's ability to continue as a going concern and appearing within this annual report on Form 10 K for the year ended December 31, 2024.

/s/ BAKER TILLY US, LLP

Minneapolis, Minnesota

March 25, 2025

Exhibit 31.1

Certification of Chief Executive Officer
of Periodic Report Pursuant to Rule 13a-14(a) and Rule 15d-14(a)

I, Dane C. Andreeff, certify that:

1. I have reviewed this annual report on Form 10-K of Helius Medical Technologies, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 25, 2025

/s/ Dane C. Andreeff
Dane C. Andreeff
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification of Chief Financial Officer
of Periodic Report Pursuant to Rule 13a-14(a) and Rule 15d-14(a)

I, Jeffrey S. Mathiesen, certify that:

1. I have reviewed this annual report on Form 10-K of Helius Medical Technologies, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 25, 2025

/s/ Jeffrey S. Mathiesen
Jeffrey S. Mathiesen
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

Certification of Chief Executive Officer and Chief Financial Officer
Pursuant to
18 U.S.C Section 1350

In connection with the Annual Report on Form 10-K of Helius Medical Technologies, Inc. (the "Company") for the year ended December 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Dane C. Andreeff, as Chief Executive Officer of the Company, and Jeffrey S. Mathiesen, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of their knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 25, 2025

/s/ Dane C. Andreeff

Dane C. Andreeff
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Jeffrey S. Mathiesen

Jeffrey S. Mathiesen
Chief Financial Officer
(Principal Financial officer and Principal Accounting Officer)

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to Helius Medical Technologies, Inc. and will be retained by Helius Medical Technologies, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.