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, 2020

☐ **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 ☐ No ☒

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, 2020, based on the closing price on that date of $14.945, was approximately $17,405,309. As of March 5, 2021, there were 2,311,099 shares of the registrant's Class A common stock outstanding.

Documents Incorporated by Reference

Portions of the registrant's Definitive Proxy Statement to be filed with the Commission pursuant to Regulation 14A in connection with the registrant's 2021 Annual Meeting of Stockholders, to be filed subsequent to the date hereof, are incorporated by reference into Part III of this report. Such Definitive Proxy Statement will be filed with the Securities and Exchange Commission not later than 120 days after the conclusion of the registrant's fiscal year ended December 31, 2020.

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In this Annual Report on 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, or HMI, Helius NeuroRehab, Inc., or HNR, Helius Medical Technologies (Canada), Inc., or HMC, and Helius Canada Acquisition Ltd., or HCA, unless the context otherwise requires. All financial information is stated in U.S. dollars unless otherwise specified. Our financial statements are prepared in accordance with accounting principles generally accepted in the United States, or U.S. GAAP.

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or the Annual Report, includes certain statements that may constitute "forward-looking statements." All statements contained in this Annual Report, 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 Annual Report include but are not limited to statements relating to: clinical development plans, product development activities, our product candidate success, plans for U.S. Food and Drug Administration, or FDA, filings and their subsequent approvals, other foreign or domestic regulatory filings by us or our collaboration partners, including filings with CE Mark and the Therapeutic Goods Administration, our ability to commercialize the product(s), either independently or with collaboration partners, the safety and effectiveness of our product candidate, the timeline for our improvement plans, our market awareness, our ability to compete effectively, the ability and limitation of our manufacturing source(s), 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, our ability to build the necessary commercial infrastructure and to use existing reimbursement codes or receive reimbursement codes from the American Medical Association and the U.S. Department of Health and Human Services, and our ability to receive reimbursement coverage under Medicare, Medicaid or under other insurance plans.

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, obtaining positive results of clinical trials, obtaining regulatory clearances, general business and economic conditions, the availability of financing on reasonable terms, the Company's ability to attract and retain skilled staff, market competition, the assumption that our relationships with our manufacturer and other third parties will be maintained, the products and technology offered by the Company's competitors and the Company's ability to protect patents and proprietary rights.

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 Annual Report 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 Annual Report 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 Annual Report. 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 Annual Report.

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 will require additional financing to carry out our plan of operations, and failure to obtain such financing may cause our business to fail;
- We currently only have one product candidate, the PoNS device, which is authorized for commercial distribution in Canada, and we have not obtained authorization to distribute the PoNS device commercially in the United States, Europe or Australia and may never obtain such authorization;
- 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 to the satisfaction of regulatory authorities;
- Generation of revenue related to the PoNS technology is dependent on the PoNS Treatment being prescribed by physicians in the United States and our ability to train physical therapists in the supervision of the use of the PoNS Treatment;
- Market awareness of the PoNS device is limited, and the neuromodulation market is new and uncertain;
- 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;
- The COVID-19 pandemic and outbreaks of communicable diseases may continue to materially and adversely affect our business, financial condition and results of operations;
- 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 is dependent on obtaining market authorization from the FDA and foreign regulatory authorities, which will require significant time, research, development, and clinical study expenditures and ultimately may not be successful;
- Failure to secure contracts with workers' compensation and third-party administrators or rehabilitation clinics could have a negative impact on our sales and would have a material adverse effect on our business, financial condition and operating results;
- Failure to obtain a reimbursement code from the U.S. Department of Health and Human Services so that the PoNS device is covered by Medicare and Medicaid could have a negative impact on our intended sales and would have a material adverse effect on our business, financial condition and operating results;
- 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;
- After commercialization, a product recall or the discovery of serious safety issues with our products could have a significant adverse impact on us; and
- We have been the victim of a cyber-related crime, and our controls may not be successful in avoiding future cyber-related crimes.

INDUSTRY AND MARKET DATA

In this Annual Report, 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 Annual Report 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-invasive technologies targeted at reducing symptoms of neurological disease or trauma.

Our first product, known as the Portable Neuromodulation Stimulator, or PoNS™, is authorized for sale in Canada as a class II, non-implantable medical device intended for use as a short term treatment (14 weeks) of gait deficit due to symptoms from multiple sclerosis, or MS, and balance deficit due to mild-to-moderate traumatic brain injury, or mmTBI, and is to be used in conjunction with supervised therapeutic exercise, or PoNS Treatment™. It is an investigational medical device in the United States, the European Union, or EU, and Australia, or AUS. The device is currently under review for de novo classification and clearance by the U.S. Food and Drug Administration, or the FDA, as a potential treatment for gait deficit due to symptoms of MS. It is also under premarket review by the AUS Therapeutic Goods Administration. PoNS Treatment™ is not currently commercially available in the United States, the European Union or Australia.

PoNS Device

The PoNS device is a non-implantable investigational 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 Treatment, or the "Treatment", utilizes the PoNS device in conjunction with supervised therapeutic exercise and / or cognitive therapy. The Treatment consists of condition specific exercises for movement control, balance and gait training, and breathing and awareness training that are designed to focus on the individual patient's functional deficits. The Treatment is 14 weeks and is delivered through authorized PoNS treatment clinics by certified PoNS trainers, with the first 2 weeks in a clinic. The remaining 12 weeks are completed at home with weekly clinic visits to monitor progress, assess improvements and ensure the therapy level is still 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 may enhance the neuroplastic effect, potentially resulting in functional improvements in balance and gait. During each clinic visit and at the end of the 14-week Treatment, the clinic downloads the PoNS usage data from the device and reviews it with the patient. This usage data in combination with the detail of the completed treatment assessments gives the clinician and the patient a unique and powerful method to assess treatment progress. The patient initiates their Treatment sessions under the supervision of the clinicians 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 neurons and structures involved in human function. Researchers believe that supervised therapeutic exercise with neurostimulation can initiate changes in the brain, supporting the rebuilding and reorganizing (neuroplasticity) of multiple 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 Multiple Sclerosis and Current Available Treatments

Multiple Sclerosis, or 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 National MS Society study estimate that nearly 1 million people in the United States are living with MS of which approximately 25-30% are on Medicare and 93,000 people in Canada are living with MS. The National MS Society estimates that 2.3 million people live with MS globally. The United States and Canada have the highest rates of MS, with 309 cases per 100,000 in the United States, and 291 cases per 100,000 in Canada, respectively. 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 85% of individuals diagnosed with MS reporting gait impairment as a major limitation in their daily lives. 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 predicators of patient 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. Additionally, 50-80% of MS patients suffer from balance and gait dysfunction and over 50% fall at least once a year. It has also been reported that unemployment rates in MS patients range from 24-80% with higher rates associated with decreased ambulation and mobility. 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, with average yearly healthcare costs ranging from $30 thousand to $100 thousand based on the severity of the disease. Since the exact cause of MS is still unknown, there is no known prevention. Although there is no cure for MS yet, treatments can manage symptoms. MS medications are designed to lessen the frequency of relapses and slow the progression of the disease, but none have proven to halt progression of the disease.

While there are several disease-modifying medications approved by the U.S. Food and Drug Administration to treat MS, only one drug approved by FDA and Heath Canada, Ampyra® (dalfampridine), is indicated for the improvement of gait speed in patients with MS, which offers the closest comparison to the effects of PoNS Treatment on improvement in gait.

Overview of mmTBI and Current Available Treatments

There are an estimated 14.5 million people globally, with over 1.5 million in the United States and 350,000 in Canada, living with balance deficit due to mmTBI. Every year in Canada and the United States there are approximately 20,000 and 420,000 newly diagnosed mmTBIs, respectively, resulting in balance deficit. 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 mmTBI for resulting motor, cognitive and behavioral impairments. The current standard of care to address balance issues following a mmTBI 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. However, to our knowledge, no mid-to-late stage clinical studies have reported improvements in function of the magnitude that would be considered evidence of systematic recovery of normal function, nor have any studies demonstrated that supervised therapeutic exercise alone has a lasting effect on balance and gait. 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 Treatment in the treatment of balance deficit due to mmTBI. Our goal is to establish the PoNS Treatment as the standard of care for this condition all over the world.

PoNS Clinical Trials and Scientific Support in MS

There are two peer reviewed published clinical trials reporting on the results of clinical trials comparing active PoNS + PT vs Placebo PoNS + PT in subjects with mild and moderate MS. (*Tyler et al. Journal of NeuroEngineering 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 patients with mild and moderate MS:

- In a comparison of the Dynamic Gait Index (DGI), a measure of the ability to walk, after 14 weeks of treatment of 10 subjects treated with active PoNS + PT Vs 10 subjects treated with placebo PoNS + PT
- Results showed a statistically significant change ($p<0.005$) in favor of the Active PoNS group.

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

- At week 14 there was a statistically significant improvement $p=0.001$ in the Sensory Organization Test (SOT), a test of subject's ability to balance, versus baseline for the 7 subjects in the active PoNS treated group and non-significant change in the 7 subjects in placebo PoNS treated group vs baseline.

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

- Treatment outcomes for patients treated in Canada are captured in the company developed validated data capture system. 43 patients with MS were treated with PoNS in Canada between March 2019 and December 2019.
- Using all available data from the treated MS patients, the mean improvement from baseline to Week 14 in the FGA (functional gait assessment) was 4.53 (95% CI 3.35 to 5.72). Based on observed data, the median improvement was 5 points.
- 56.7% had an improvement at Week 14 greater than or equal to 4 points, the minimum detectable change. This finding is remarkable given that the RWE data set consisted of patients with chronic MS with long durations of disease.
- Given the excellent safety profile, these data support a positive benefit risk ratio in the real-world setting.

PoNS Clinical Trials and Scientific Support in mmTBI

There are two peer reviewed published clinical trials reporting on the results of the PoNS Treatment for persons with mmTBI: 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 which are detailed below.

PoNS Registrational Clinical Trial in mmTBI

We completed our registrational clinical trial of the PoNS Treatment for persons with mmTBI in 2017. It was a double-blind randomized, controlled study of the safety and effectiveness of the PoNS Treatment using translingual noninvasive stimulation in participants with balance deficit due to mmTBI.

The trial was launched in 2015 in conjunction with the U.S. Army Medical Research and Materiel Command, or the USAMRMC, and was conducted at seven sites in the United States and Canada. The trial evaluated 122 randomized participants between the ages of 18 and 65 years. Each participant received five weeks of treatment, two weeks in clinic and three weeks at home. The treatment consisted of physical therapy geared toward the functional capability of each individual participant. Enrolled participants worked with a certified PoNS trainer and were randomized to receive either a high-frequency pulse, or HFP, (25.7 million pulses per 20-minute treatment) or a low-frequency pulse, or LFP, (13,728 pulses per 20-minute treatment) PoNS device. While the HFP and the LFP devices were identical, the frequency of the pulses was different.

Trial Design

All participants provided a prior neuroradiologic report (obtained at least one year after the most recent mmTBI), if available, and completed demographic and quality of life surveys and a medical history during an initial screening visit. Participants who met the initial screening entrance criteria were scheduled for an MRI of the head, a neuropsychiatric evaluation, the NeuroCom Sensory Organization Test, or SOT, to evaluate balance, and a 20-minute walk on the treadmill to evaluate fitness. Key eligibility criteria to participate in the study included the following:

- Male or female, 18 to 65 years of age.
- At least 1-year post most recent mmTBI at the time of screening.
- Had participated in a focused physical rehabilitation program for mmTBI and had been deemed by the treating clinician to have reached a plateau.
- Had a balance disorder SOT composite score of at least 16 points below the normative value for the participant's age.
- Stable neurologic status, as determined from the participant's medical records and the trial physician's opinion based on no new or changing symptoms.

Participants meeting all the eligibility criteria, and who were not disqualified by exclusion criteria applicable to the trial, were enrolled and randomly assigned in blocks of four to receive an HFP or LFP device. Randomization occurred at each site, according to the randomization plan developed by the clinical research organization. An objective balance assessment was performed using the composite score from the SOT, which measures balance using computerized sensors that objectively measure participants' ability to maintain balance under six different conditions. The SOT is a widely used measurement tool for balance disorder associated with TBI and was used as the primary efficacy endpoint for the trial. According to published clinical trial data, patients that received physical therapy alone to treat balance deficit related to mmTBI improved by an average of ten to 13 points on the SOT scale, a 0 to 100 scale, and clinical experience shows those patients tend to drift back to baseline levels when physical therapy is discontinued. On average, participants entered the trial with an SOT composite score of approximately 40, which is a score that indicates substantially compromised functional balance. In the trial, an SOT responder was defined as a participant with an improvement of at least 15 points in his/her SOT composite score from baseline to the end of five weeks of PoNS Treatment, a level of change that to our knowledge, has not been achieved in clinical trials of patients with mmTBI-related balance disorder undergoing standard of care physical therapy.

Trial Results

The trial's statistical analysis plan stated that, if the outcome of the primary effectiveness endpoint showed that PoNS Treatment in the HFP and LFP arms both produced responses of greater than 15 points on the SOT composite score that were not significantly different from one another, the secondary endpoint would be calculated by combining the two groups and comparing the response to baseline at week two and week five. This would imply that both devices had a clinical effect.

The primary effectiveness endpoint demonstrated a trend toward 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) than in the LFP arm (with 63.5% of subjects experiencing a greater than 15 point improvement on the SOT composite score), p<0.081. The primary effectiveness endpoint was not reached because of the significant therapeutic effect observed in the LFP arm. Because both arms produced responses of greater than 15 points on the SOT composite score that were not significantly different from one another, the secondary effectiveness endpoint was calculated per the statistical analysis plan, as described above. The secondary effectiveness endpoints demonstrated statistically and clinically significant increases in SOT composite scores:

- The mean improvement at two weeks for the pooled arms was 18.3 points, P<0.0005.
- The mean improvement at five weeks for the pooled arms was 24.6 points, P<0.0005.

Since the majority of patients who have a balance disorder associated with mmTBI are subjected to a higher risk of falls and headaches, the primary safety endpoint was an improvement in the frequency of falls as determined by daily event recording on the participant data case report form during the in-clinic phase of the study (week two). The secondary safety endpoint was the frequency and severity of headaches, as measured by the Headache Disability Index at baseline and at the end of treatment, which was at week five.

- We successfully met the primary and secondary safety endpoints as measured by a decrease in falls at week two a decrease in headaches at week five, respectively, in both treatment groups.
- There were no serious device related adverse events.

PoNS Long-Term Treatment Trial in mmTBI: A 26-Week Study

This study was performed to understand the durability of response to the PoNS Treatment. This double-blind randomized controlled study in patients with mmTBI was completed in 2017 at the Tactile Communication Neurorehabilitation Laboratory at the University of Wisconsin-Madison and was sponsored by the U.S. Army. The study was conducted with 22 and 21 participants randomized to the HFP and LFP PoNS Treatment arms, respectively. Participants underwent 14 weeks of active treatment identical in format to the treatment regime in our registrational clinical trial described above, followed by a 12-week washout period when participants discontinued the PoNS Treatment and were told to resume normal daily lifestyles with no specified physical therapy regime. SOT composite scores were captured at specific time points throughout the study, including at 14 weeks and after the 12-week washout (26 weeks).

Highlights of the study results were as follows:

- There was no statistical difference between the HFP and LFP PoNS Treatment arms mirroring the results of the registrational clinical trial.
- On average, participants entered the study with an SOT composite score of approximately 40, which is a score that indicates substantially compromised functional balance.
- At the end of 14 weeks of active treatment with the HFP PoNS arm, patients showed improvements on average of 29.8 points on the SOT composite score.
- After the 12-week washout period, the participants, on average, maintained the same SOT composite score as after 14 weeks of PoNS treatment.

Conclusion:

- The study demonstrated that the PoNS Treatment could, on average, allow patients with mmTBI who had balance deficit and other injury-related functional disabilities, achieve an SOT composite score in the normal range in 14 weeks and maintain that benefit after a 12-week washout period. We believe that this data supports the durability of the response to the treatment and the potential restoration of the balance system. Furthermore, in a subset of nine participants, sequential magnetic resonance imaging, or MRI, scans were performed that showed increased grey matter volume in the cerebellum and elsewhere, commensurate with improved balance.

Overall Conclusion From the Two mmTBI Trials.

We believe the most significant observations from the two mmTBI trials are:

- Our registrational and long-term treatment trials combined were the largest non-implantable neuromodulation trials in balance and gait deficit due to mmTBI ever performed.

- Participants who had a chronic balance disorder resistant to conventional physical therapy were, on average, in the normal range of balance following the 14 weeks of treatment.
- The PoNS Treatment in one data set also resulted, on average, in patients maintaining the improvement for at least a 12-week period suggesting a permanent improvement in participants' balance issues.
- There were no differences in clinical outcomes across the clinical trial sites performing both trials.
- There were no differences at baseline in age, sex, time from injury, amount of previous physical therapy, level of disability or adherence to therapy in each of the treatment groups.
- The difference in therapeutic effect noted between high and low frequency pulse groups may suggest that there was an independent device effect.

Regulatory Status Worldwide

Canadian Regulatory Status: mmTBI and MS

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 our Canadian marketing authorization from Health Canada allowing us to commercialize the PoNS device for the treatment of gait deficit in patients with mild and moderate MS symptoms. Our market MS authorization application comprised objective statistical evidence as well as independently reviewed clinical research analysis. We believe this label expansion will significantly expand our addressable market opportunity in Canada to include a patient population that is motivated to pursue treatment options which may resolve or delay the progression of MS gait deficit symptoms.

US Regulatory Status: MS

In March 2020, we announced that based on the quality of the data included in our MS submission package to Health Canada and the significant unmet needs of those afflicted with MS, we are prioritizing the MS indication as the pathway to pursue our first U.S. clearance of the PoNS device. We believe the existing published data and real-world evidence with use of the PoNS for the treatment of gait disorder in patients with MS are sufficient to demonstrate a favorable risk/benefit profile, as required for de novo classification and clearance to enable US marketability. Novel treatments for MS are highlighted as a specific target of the FDA as a high unmet medical need disease.

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 replaces the Expedited Access Pathway and Priority Review for medical devices. The FDA considers devices granted designation under the Expedited Access Pathway to be part of the Breakthrough Devices Program.

The Breakthrough Devices Program offers manufacturers an opportunity to interact with the FDA's experts through several different program options 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 under section 510(k) of the Food, Drug, and Cosmetic Act.

On August 4, 2020, we submitted our request to the FDA for de novo classification and clearance of the PoNS device for the treatment of gait deficit due to symptoms from MS, to be used as an adjunct to a supervised therapeutic exercise program in patients over 18 years of age.

On October 19, 2020, we announced that we received a request for additional information from the FDA related to the Company's request for de novo classification and clearance of the PoNS device. During the substantive review phase of a request for de novo classification and clearance, FDA may request additional information in order to obtain information necessary for the FDA to continue or complete its review and, in such instances, places its review on hold until the requested information is submitted. The FDA's request for additional information was received approximately 75 days from the submission date, which is consistent with FDA's expected timing for review of a Breakthrough Designated product in the de novo pathway, such as the PoNS device. The FDA's

request for additional information included requests for additional analysis of clinical data and proposed certain labeling modifications. On January 11, 2021, we announced that we submitted our formal response to the FDA's request for additional information.

On January 14, 2021, the Centers for Medicare & Medicaid Services, or CMS, issued the final rule (CMS-3372-F), 42 C.F.R. § 405.603 on the new Medicare coverage pathway referred to as Medicare Coverage of Innovative Technology, or MCIT, for FDA-designated breakthrough medical devices. The MCIT rule will provide national Medicare coverage as early as the same day as FDA market authorization for breakthrough devices and coverage would last for four years. To be eligible for coverage through MCIT, the breakthrough device must be used for the FDA approved or cleared indication(s) for use and receive FDA clearance. Manufacturers will be able to opt in to MCIT and choose a start date for coverage anytime within two years from the date of FDA market authorization, but coverage will only be valid for four years from market authorization regardless of opt in date. At the end of the four year period, manufacturers are expected to have obtained coding for the specific product which can then be used as the reimbursement pathway for commercial payers. We are working to understand current 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.

US 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 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 Treatment 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 finalized our clinical protocol for a new trial, TBI-002, intended to support a request for de novo classification and clearance of the PoNS device. TBI-002 will be a multi-center, randomized trial in the U.S. and Canada consisting of 103 subjects with balance deficit due to mmTBI. Although TBI-002 will take longer and be more costly than the design that we had discussed at our October 2019 pre-submission meeting, we believe that the chances of obtaining FDA de novo classification and clearance will be significantly increased if we incorporate the FDA's pre-submission feedback into this next trial design.

TBI-002 will proceed in two phases: a run-in phase, followed by a treatment phase. During the run-in phase, all subjects will receive 5 weeks of physical therapy alone. Subjects will then be randomized and assigned to one of two groups in the treatment phase where subjects will either receive up to 10 weeks of physical therapy with the PoNS device or 10 weeks of physical therapy without the PoNS device. The primary effectiveness endpoint of TBI-002 will be a responder analysis.

Prior to the COVID-19 pandemic, our expectation was that we would move forward with the revised protocol and estimated that enrollment would begin in April 2020 with the completion of the trial and submission to the FDA in the second quarter of 2021. However, the launch of the TBI-002 trial has been temporarily suspended, and we are evaluating our options for funding and timing to commence the trial or potentially looking at other indications, including stroke, cerebral palsy, Parkinson's disease, baby boomers balance, and neurological wellness.

European Regulatory Status

In December 2018, we submitted an application for a CE Mark, which, if approved, would allow us to market the PoNS device in the EU. During the second quarter of 2019, we engaged with regulators in Europe to answer questions that we received from them as part of their review of our PoNS device for CE marking. In August 2019, we withdrew our application from the EU marketing process 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 new ISO registrar and new notified body 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 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. We are currently awaiting additional feedback from the TGA on our application.

Partnerships and Agreements

U.S. Army Partnership

Between 2013 and 2015, we entered into a series of agreements with the U.S. Army to determine if the PoNS Treatment could be developed for commercial use in the treatment of service members with balance deficit related to mmTBI, or the U.S. Army Agreement. Under the U.S. Army Agreement, we were the sole regulatory sponsor and oversaw and executed all required clinical studies. The U.S. Army reimbursed us for the initially budgeted costs related to the registrational clinical trial of the safety and effectiveness of the PoNS Treatment for balance deficits related to mmTBI, up to a maximum amount of $3.0 million.

In November 2018, the U.S. Army Combat Capabilities Development Command Army Research Laboratories, or Army Laboratories, notified us of their intention to terminate the Master Cooperative Research and Development Agreement, or the CRADA, effective December 31, 2018. In December 2018, the U.S. Army notified us that it was amending the U.S. Army Agreement to provide that our obligations under the contract were satisfied upon our submission of an application for marketing authorization of the PoNS device to the FDA.

Our satisfaction of the U.S. Army Agreement and the termination of the CRADA concluded our formal contractual relationships with the U.S. Army. We are currently focusing on partnering with the relevant departments in the U.S. Department of Defense, or DOD, and U.S. Department of Veterans Affairs, or Veterans Affairs and other independent advocacy groups, to obtain reimbursement, upon FDA marketing authorization, for U.S. military personnel using our PoNS Treatment.

As of December 31, 2018, we received a total of approximately $3.0 million with respect to reimbursements for expenses owed to us for completion of development milestones. All reimbursement amounts received were credited directly to research and development expenses.

Canadian Strategic Alliance

In September 2018, we entered into an exclusive strategic alliance agreement with Health Tech Connex, Inc., or HTC, and Heuro Canada Inc., or Heuro, a newly formed wholly owned subsidiary of HTC, to establish three founding clinics to treat patients and create a replicable model for future clinic expansion. Under the terms of the agreement, the parties developed a clinic system to facilitate the commercialization of the PoNS Treatment in Canada. Under the terms of the agreement, the parties contracted with the clinics and developed a model for the clinics to deliver clinical services, featuring the PoNS Treatment, to manage neurological conditions.

During the second quarter of 2019, we entered into the clinic expansion phase of the alliance with the addition of up to three new PoNS authorized clinics, bringing the total number of clinics authorized to treat patients with the PoNS device to five in Canada.

Prior to October 30, 2019, the exclusive strategic alliance agreement provided for HTC to pay us CAD$750 thousand in three annual payments of CAD$250 thousand beginning December 31, 2019, in consideration for the exclusivity right we granted to Heuro. We and HTC governed the agreement through a joint steering committee, and each funded up to 50% of Heuro's operating budget as agreed to by the joint steering committee and shared in the net profits and losses of Heuro on a 50/50 basis.

During the third quarter of 2019, we engaged with HTC through the joint steering committee in discussions regarding the future development of the commercialization of the PoNS device and PoNS Treatment in Canada. As we worked with Heuro to expand the commercial infrastructure, the complexity and feasibility of using a franchise model to build a market for PoNS including the physical therapy component became challenging. By acquiring Heuro, as noted below, we were able to streamline the decision-making process and increase our ability to react to evolving market factors as the market for the PoNS Treatment is being developed.

On October 30, 2019, we and HTC entered into a Share Purchase Agreement, or the SPA, whereby we, through our wholly owned subsidiary, acquired Heuro from HTC. Under the terms of the SPA, total consideration of approximately $1.6 million was paid to HTC, which included (1) the repayment to HTC for their investment in the set-up of Heuro's initial commercial infrastructure including the establishment of five authorized PoNS clinics across Canada, (2) the current market value of 55 PoNS devices which we also are to provide to HTC under the SPA, (3) the CAD$750 thousand receivable from the September 2018 strategic alliance agreement and (4) the sale of exclusivity rights granted to HTC in the Co-Promotion Agreement, as defined below, to provide PoNS Treatment in the Fraser Valley and Vancouver metro regions of British Columbia.

In connection with the Share Purchase Agreement, on October 30, 2019, we entered into a Clinical Research and Co-Promotion Agreement with HTC, or the Co-Promotion Agreement, whereby each company will promote the sales of the PoNS Treatment and the NeuroCatch™ device throughout Canada. This co-promotion arrangement terminates upon the earlier of the collection of data from 200 patients in Canada and December 31, 2020. The co-promotion arrangement terminated on December 31, 2020. Also, subject to certain terms and conditions, we granted to HTC the exclusive right to provide the PoNS Treatment in the Fraser Valley and Vancouver metro regions of British Columbia, where HTC has operated a PoNS authorized clinic since February 2019. HTC will purchase 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 exclusivity right has an initial term of ten years, renewable by HTC for one additional ten year term upon sixty days' written notice to us.

A&B Asset Purchase Agreement

In October 2015, we entered into a strategic agreement with A&B (HK) Company Ltd., or A&B, an investment and development company based in Hong Kong for the development and commercialization of the PoNS Treatment in China, Hong Kong, Macau, Taiwan and Singapore, collectively referred to as the Territories. The agreement 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 the Territories. Pursuant to the agreement, A&B has assumed all development, patent (both application and defense), future manufacturing, clinical trial, and regulatory clearance costs for the Territories. A&B and us will share and transfer ownership of any intellectual property or support material (developed by either party) for each of our respective geographies.

In connection with the agreement, A&B agreed to provide us with a $7.0 million funding commitment, consisting of an initial $2.0 million convertible promissory note and a $5.0 million funding commitment. On October 9, 2015, we received the conversion notice on the promissory note and, on November 10, 2015, we issued 11,904 shares of common stock at a price of $168.00 per share and 5,952 warrants exercisable at $252.00 per share for a period of three years from the date of issuance. On December 29, 2015, we drew down the $5.0 million funding commitment through the January 7, 2016 issuance of 31,746 shares of common stock at a price of $157.50 per share and 15,873 warrants exercisable at $236.25 per share for a period of three years from the date of issuance. In November 2017, A&B exercised 5,952 warrants at a price of $252.00 per share and we received gross proceeds of $1.5 million. During the first quarter of 2018, A&B exercised its remaining 15,873 warrants at a price of $236.25 per share and we received gross proceeds of $3.8 million.

In August 2018, A&B executed a transfer agreement whereby A&B transferred all the assets under the A&B asset purchase agreement with us to China Medical Systems Medical Limited, or CMS, a Malaysian based Hong Kong listed company and an affiliate of A&B. In February 2019, we executed a novation deed whereby CMS irrevocably assigned and transferred all of its rights, obligations and assets under the transfer agreement to CMS Medical Hong Kong Limited, a Hong Kong-based investment holding company principally engaged in the manufacture, marketing, promotion and sales of pharmaceutical products. We are currently working with CMS in providing regulatory support of its application to the National Medical Products Administration for marketing authorization in China.

Product Development, Manufacturing and Logistics Services

In January 2017, we entered into an agreement with Cambridge Consultants LLC, or Cambridge, pursuant to which Cambridge assumed responsibilities for key aspects of the design and development of the PoNS device. As part of the agreement, Cambridge will validate the performance of the engineering, design verification testing and product documentation to support our FDA submission. Cambridge will also assist us in the identification of, and transition to, our commercial-scale manufacturer.

On December 29, 2017, we selected Key Tronic Corporation, or Key Tronic, as our contract-manufacturing partner for the PoNS device after a competitive selection process. The commercial design of the PoNS device is manufactured and assembled at Key Tronic's facilities located in Oakdale, Minnesota. Key Tronic manufactured devices for engineering and design verification testing and for our FDA submission as well as commercial devices for launch inventory. Key Tronic has multiple locations across the United States, Mexico and China with back-up manufacturing capabilities to help mitigate the risk of a single source provider. We remain ultimately responsible for the compliance of our submissions and products, and activities performed on our behalf.

We place an emphasis on protecting our patented technology, trade secrets and know-how and only share confidential information on an as needed basis. Key Tronic is registered as a medical device manufacturer in good standing with the FDA and along with Cambridge 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.

On November 30, 2016, HMI received our ISO 13485:2003 certification, which was updated to the 2016 version of the standard during the fourth quarter of 2018 along with receiving our Medical Device Single Audit Plan, or MDSAP, for the United States and Canada, with the scope of the MDSAP certification expanded to include Australia during the third quarter of 2019.

In February 2019, we entered into an agreement with McKesson Specialty Care Distribution LLC, or McKesson, pursuant to which McKesson will provide a comprehensive array of logistical, account management and related distribution services for the commercialization of the PoNS device in the United States. This agreement was terminated in the second quarter of 2019 following the FDA's denial of our request for de novo classification and clearance of the PoNS device for mmTBI.

Commercialization

Canadian Commercialization Efforts

From a real-world results perspective, in Canada thus far, the collective experience of our patients that have completed the 14-week PoNS Treatment have been encouraging. Consistent with what we saw in our two clinical trials, one for 5 weeks and the other for 14 weeks, commercial MS and TBI patients are demonstrating improvements in balance and gait within the first two weeks followed by continued improvement over the following twelve weeks. The majority of patients have 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. The consistency of the patient results from our initial commercial experience supports our plans to expand access PoNS Treatment in Canada.

March 2019 marked the commercialization of our PoNS Treatment 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 Treatment. 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.

During the third quarter of 2019, we made the strategic decision to change our business model in Canada in order to accelerate the adoption of our novel technology. On October 30, 2019, we acquired the Heuro Canada operating entity from HTC which allowed us to streamline the decision-making process and increase our ability to react to evolving market factors as the market for the PoNS Treatment is being developed.

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.

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 the first two months of 2020, we authorized 7 new clinic locations for a total of 14 clinic locations to provide PoNS Treatment across Canada. As of June 30, 2020, we had 20 clinic locations which we increased to 22 clinic locations as of September 30, 2020 and to 31 clinic locations as of December 31, 2020. Beginning in 2021, in addition to continuing to increase the number of clinic locations, we have shifted our focus to driving patient throughput to these 31 clinics. Sales performance in Canada continues to be impacted by the COVID-19 pandemic due to the space restrictions that the provincial governments have imposed as well as the risk tolerance of patients and therapists.

In collaboration with Toronto Rehabilitation Institute (part of University Health Network) we are continuing our clinical experience program, the results of which we will look to publish in 2021.

We continue to refine our go-to-market pricing model based on direct market feedback. Our modified pricing approach is focused on reducing the need for clinics and patients to pay large, upfront costs at the start of treatment. We have also experimented with various promotional pricing programs resulting in lower unit prices for both PoNS system purchases and mouthpieces in order to increase access to the PoNS treatment and drive market awareness which we expect to result in an increase in the volume of units sold, which was seen in the second half of 2020 when compared to the second half of 2019. We intend to keep the promotional pricing in place at least through the first half of 2021.

The value dossiers for mmTBI and MS that were created in mid-2020 to fully demonstrate in both scientific and financial terms, the merits of PoNS Treatment for claimants are now being implemented along with submissions from clinics on behalf of their patients. The dossier is 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 continues to focus on the auto collision insurance and workers' compensation, or WC, market as well as long-term disability cases. Our reimbursement strategy for MS is focused on commercial insurers/extended health benefits.

As part of our overall PoNS Treatment strategy, we are also gathering comprehensive health economic assessments of treatment outcomes. These data will, in-turn, be used to support our applications for workers compensation, auto insurance and commercial insurance reimbursement initiatives in Canada, the United States and other markets around the world. The Canadian commercial experience will be extremely valuable to prepare us for our launches in the United States and internationally.

U.S. Pre-Commercialization Activities

In the United States, the PoNS device is an investigational device pending our request to the FDA for de novo classification and clearance of the PoNS device for the treatment of gait deficit due to symptoms from MS, to be used as an adjunct to a supervised therapeutic exercise program which was submitted on August 4, 2020.

In this pre-commercial phase, we are working on the development of our commercial strategy focused on working with CMS on attaining four years of Medicare coverage under the MCIT pathway for PoNS as a breakthrough designated device, attaining distribution licenses and beginning to build relationships with key large neurorehabilitation centers, which focus on treatment of MS patients. We continue to generate important data on outcomes of the PoNS Treatment gathered from Real World Evidence 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 will begin to pave the way to establishing the PoNS Treatment as the standard of care for the treatment of MS-related gait deficit following FDA marketing authorization, if received.

U.S. Clinical Experience Programs

In 2018, we initiated a series of clinical experience programs, or CEPs, to prepare for a potential U.S. commercial launch. Originally, our CEPs were designed learn from and build relationships with large key neurorehabilitation clinics, train and certify physical therapists and generate health economic, return-to-work and clinical data to inform our payer strategy.

Overall, we enrolled five clinic centers in the U.S. to carry out the CEPs: the Ohio State University Wexner Medical Center, a leading neurorehabilitation center located in Columbus, OH; Northwell Health's Feinstein Institute for Medical Research in Manhasset, NY; Oregon Health & Science University in Portland, OR; Kessler Institute for Rehabilitation and Kessler Foundation in Hanover, NJ; and the Baylor Research Institute in Dallas, TX.

Based on receipt of Canadian marketing authorization of our PoNS device earlier than anticipated, we were able rely on our early Canadian commercialization activities to provide us with the health economic, return-to-work and clinical data that we had planned to generate in the CEPs.

While we cancelled the CEP programs during 2019 after the denial by FDA for the mmTBI indication, we have maintained solid relationships with the U.S. sites and expect several to become clinical trial sites for TBI-002, if pursued based on the availability of funding.

U.S. Commercialization

To commercialize the PoNS Treatment in the United States following FDA marketing authorization, if received, we plan to target a subset of neurorehabilitation centers that have been profiled as early adopters to develop a network of PoNS certified neurorehabilitation centers that will be trained to deliver the PoNS Treatment. Care of patients with MS is concentrated in major neurorehabilitation centers that often have a network of outpatient rehabilitation clinics, where most of the PoNS Treatment will take place. We believe that a small, specialty sales force, calling on new technology review boards for trial and in-house physicians, neurologists, physiatrists and physical therapists, will be sufficient to drive trial and adoption of the PoNS Treatment in certified neurorehabilitation centers. Importantly, this focused strategy will also allow us to inspect whether we are generating patient outcomes similar to those seen in our clinical trials.

We are planning to pursue Medicare coverage for PoNS under the CMS voluntary MCIT program within the Durable Medical Equipment, or DME, benefit category. While there are no currently applicable Healthcare Common Procedure Coding System, or HCPCS, codes to describe the PoNS system or Mouthpiece, our expectation is that we will use miscellaneous codes – E1399

(Miscellaneous durable medical equipment) and A9999 (Miscellaneous DME supply or accessory, not otherwise specified) until specific HCPCS codes are created. We intend to apply for a unique HCPCS code upon FDA authorization, if received, based on timing of our anticipated clearance. We also intend to provide broad access and reimbursement for the PoNS Treatment over time through Commercial insurers. At launch, prior to the initiation of CMS or broad payer coverage, we anticipate the primary source of sales will be self-pay patients. We will support the cost of the PoNS Treatment 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 at least a 24-month window to obtain broad coverage and reimbursement among government and private payers. We plan to work in parallel with non-traditional payers, such as WC, auto insurance and the military, by engaging with them and providing them with relevant health economic and return-to-work data obtained through our Canadian commercial experience.

With the satisfaction of our clinical development contract with the U.S. Army, we are focusing on partnering with relevant departments in the DOD and Veterans Affairs to obtain reimbursement, upon FDA marketing authorization, for U.S. military personnel using our PoNS Treatment. These two initiatives, among others, offer the potential to expand access more expeditiously to these high-unmet need patient populations.

Commercialization in Other Markets

We submitted an application for a CE Mark in December 2018. In preparation for our launch in the United Kingdom, or 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 Treatment in the UK. As previously described, in August 2019, we withdrew our application from the EU marketing and will revisit our UK and EU commercialization upon receipt of marketing clearance.

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. We are currently awaiting additional feedback from the TGA on our application. We are working with consultants in Australia with expertise in market development to build our go-to-market strategy.

We also have marketing authorization to commercialize the PoNS Treatment in Russia and Uzbekistan. To date, we have not delivered any commercial devices in any of these territories and we will re-evaluate our strategic opportunities again at a later point in time.

COVID-19 Pandemic

On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 as a global pandemic, which continues to spread throughout the United States and around the world. The Company's business, results of operations and financial condition have been adversely impacted by the COVID-19 pandemic and global economic conditions. The outbreak and spread of COVID-19 has significantly increased economic uncertainty. Authorities implemented numerous measures to try to contain the virus, such as travel bans and restrictions, quarantines, shelter in place orders, and business shutdowns. The COVID-19 pandemic initially led to the closure of PoNS authorized clinic locations across Canada from March until June 2020. Patients who completed their initial training in the clinics prior to the closures have been able to continue working independently in the at-home portion of the treatment, with remote check-ins with their certified therapists. While all clinics have re-opened, they are all currently operating at reduced capacity within provincial guidelines, which limited operations to 50% capacity during the second half of 2020. Some patients have begun to return to these clinics for treatment, but patients have been and may continue to be less willing to return to the clinics due to COVID-19, impacting our commercial activities and our customer engagement efforts. We have expanded our services to include remote training and treatment, but the long-term viability of these remote programs is still being assessed. In addition, the resurgence of COVID-19 cases across Canada in the fourth quarter of 2020 has led to further restrictions on clinic activities.

Additionally, while we do not currently have any clinical trials underway, we are running clinical experience programs in Canada and have experienced delays in the programs as trial participant attendance has generally decreased as a result of the pandemic, and clinics and clinical research sites have experienced delays and difficulties in recruiting and re-hiring clinical site staff, leading to further delays in the development and approval of the Company's product candidate. As noted above, prior to the COVID-19 pandemic, our expectation was that we would move forward with the launch of our TBI-002 trial and we had estimated that enrollment would begin in April 2020 with the completion of the trial and submission to the FDA in the second quarter of 2021. The launch of the TBI-002 trial has been temporarily suspended and we are evaluating our options for funding and timing to commence the trial, while also evaluating the potential pursuit of other indications.

The COVID-19 pandemic and other outbreaks may cause delays in or the suspension of our business partners manufacturing operations, our research and product development activities, our regulatory workstreams, our research and development activities and

other important commercial functions. We are also dependent upon our suppliers for the manufacture of our PoNS device, and in the second quarter of 2020, two of our business partners diverted resources towards other activities related to COVID-19, resulting in delays in the development and manufacturing of our product. Such diversion of suppliers' resources may occur again in the future, and the pandemic could limit our suppliers' ability to travel or ship materials or force temporary closure of facilities that we rely upon. Disruptions in business operations or governmental operations due to COVID-19 may delay the timing for the submission and approval of the Company's marketing applications with regulatory agencies. Further, the economic impact of the COVID-19 pandemic could affect our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

The extent to which the COVID-19 pandemic will continue to impact our business, results of operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted. We do not know yet the full extent of the impact of COVID-19 on its business, operations or the global economy as a whole.

Coverage and Reimbursement

Canadian Reimbursement

We believe that non-traditional payers may be among the earliest to provide coverage and reimbursement for the PoNS Treatment. Therefore, we are considering focusing initially on gaining coverage for the PoNS Treatment through WC payers. WC is an entitlement for injured workers, and payers are responsible for both medical and indemnity claims. Because these payers are responsible for both medical expenses and lost wages, they have an incentive to seek ways to help injured workers 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 WC payers to demonstrate both the clinical and economic value associated with the PoNS Treatment.

U.S. Reimbursement

With the clearance of the PoNS device for FDA marketing authorization, if received, we plan to engage with select payer segments to obtain coverage and reimbursement for the PoNS Treatment. 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 Treatment to payers and support favorable coverage and reimbursement decisions.

We believe that the CMS Medicare coverage pathway, MCIT, for FDA-designated breakthrough medical devices will be our primary initial pathway for MS. The MCIT rule will provide national Medicare coverage as early as the same day as FDA market authorization for breakthrough devices and coverage would last for four years. Once we are able to secure reimbursement through the MCIT pathway, we expect this will increase engagement with commercial payers to accelerate coverage.

Similarly, military payers have an interest in reducing both medical costs and shortening the time to return to work for people who were injured while serving our country. We are working toward establishing relationships with thought leaders affiliated with the Department of Defense and Veterans Affairs, and will focus on obtaining reimbursement through this payer segment upon clearance for mmTBI, if received. We anticipate that the same clinical and economic evidence that we will use with WC payers will also help to support gaining coverage and reimbursement for the PoNS Treatment military payers.

Competition

The neurostimulation market is predominantly comprised of invasive technologies that are not directly competitive with our technology. Our competitors in the industry are predominantly 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-invasive space to grow in the future.

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

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

Advantages of the PoNS Treatment

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

- The PoNS Treatment stimulates the trigeminal nerve which developing science has implicated to be beneficial in some neurological disorder models. The PoNS Treatment stimulates the lingual part of the nerve through the tongue, while other technologies stimulate other branches of the trigeminal nerve. It is the largest branch, having the highest amount of nerve fibers of the three branches. We believe this will be an advantage in our therapy.

- Stimulating the tongue also allows for the simultaneous stimulation of a second cranial nerve found in the tongue, the facial nerve. The ability to stimulate more than one nerve alone differentiates us from our competition. However, it has not been scientifically proven that stimulating additional nerves adds to the efficacy or safety of the PoNS Treatment.

- 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.

- 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 limbic system, basal ganglia and thalamus. We believe that this range of projections will allow impulses to be sent through sites regulating 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 non-invasively and portably. This opens the door for the integration of neurostimulation with a wide range of therapies 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 a subject's proficiency in the exercise
15/283,894	10/3/2016	Issued	10,258,790	4/16/2019	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 a 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
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; 10,258,790; and 10,328,263 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. 8,849,407; 8,909,345; 9,020,612; 9,656,078; 9,597,501; 9,597,504; 9,656,069; 10,258,790; and 10,328,263, 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; 10,258,790; and 10,328,263 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; 10,258,790; and 10,328,263 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 the 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.

The license of the Patent Pending Rights is also subject to the terms of the CRADA. In the event that we are not willing or unable to commercialize the PoNS technology within four years from the expiration of the CRADA, the Company is required to transfer possession, ownership and sponsorship/holdership of the regulation application, regulatory correspondence and supporting regulatory information related technology to USAMRMC and grant the U.S. Government a non-exclusive, irrevocable license to any patent, copyright, data rights, proprietary information or regulatory information for the U.S. Government to commercialize the technology.

Company Owned Intellectual Property

As of March 9, 2021, we have filed 36 U.S. patent applications related to various technical and ornamental aspects of the PoNS device: 17 non-provisional patent applications that describe various technical features in the current version device and 19 design patent applications describing various ornamental designs. We are the sole assignee for these 36 U.S. patent filings. In addition to the first issued patent (U.S. Patent No. 9,072,889), the USPTO has issued 13 utility patents and 20 design patents as summarized in the table below:

U.S. Patent Application No.	Application Filing Date	Status	U.S. Patent No.	Issue Date	Subject Matter
14/558,768	12/3/2014	Issued	9,072,889	7/7/2015	Utility patent covering overall system design, including controller and mouthpiece
14/559,123	12/3/2014	Issued	9,272,133	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	9,227,051	1/5/2016	Utility patent covering shape of the mouthpiece
14/558,789	12/3/2014	Issued	9,283,377	3/15/2016	Utility patent covering center of gravity of the mouthpiece
14/559,080	12/3/2014	Issued	9,415,209	8/16/2016	Utility patent covering structural support of the mouthpiece
14/559,105	12/3/2014	Issued	9,415,210	8/16/2016	Utility patent covering glue wells of the mouthpiece
14/727,100	6/1/2015	Issued	9,616,222	4/11/2017	Utility patent covering overall system design, including controller and mechanical details of the mouthpiece
14/558,775	12/3/2014	Issued	9,981,127	5/29/2018	Utility patent covering aspects of the controller
14/558,784	12/3/2014	Issued	9,789,306	10/17/2017	Utility patent covering authentication techniques
14/559,045	12/3/2014	Issued	9,993,640	6/12/2018	Utility patent covering the locators of the mouthpiece
14/559,118	12/3/2014	Issued	9,656,060	5/23/2017	Utility patent covering methods of manufacturing the mouthpiece
15/484,077	4/21/2017	Issued	10,258,790	4/16/2019	Utility application covering overall system design, including controller and mechanical details of the mouthpiece
15/602,055	9/5/2017	Issued	10,463,850	11/5/2019	Utility application covering methods of manufacturing the mouthpiece
16/005,624	6/11/2018	Issued	10,709,887	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	Pending	N/A	N/A	Utility patent application covering overall system design, including controller and mechanical details of the mouthpiece, where controller and mouthpiece communicate wirelessly
16/376,595	4/5/2019	Pending	N/A	N/A	Utility patent application covering 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
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

U.S. Patent Application No.	Application Filing Date	Status	U.S. Patent No.	Issue Date	Subject Matter
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	D751215	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	D907,221	1/5/2021	Design patent covering alternative system design used in the current PoNS device

In addition to our U.S. patents, we have been granted 18 foreign utility patents (eight in Australia, five in Russia, two in Israel, two in Europe (validated in France, Germany, Italy, UK and Spain) and one in Eurasia, or EA, (validated in all eight Eurasian member-states), and 28 foreign design patents (three in Australia, seven in Canada, three in Russia, and fifteen registered community designs in Europe), as detailed in the tables below.

Foreign Utility Patents

Australian Application No.	Application Filing Date	Status	Australian Patent No.	Issue Date	Subject Matter
2015355211	6/4/2017	Issued	2015355211	11/16/2017	Utility patent covering overall system design, including controller and mechanical details of the mouthpiece
2015355212	6/4/2017	Issued	2015355212	12/21/2017	Utility patent covering center of gravity of the mouthpiece
2017218934	8/19/2017	Issued	2017218934	1/3/2018	Utility patent covering overall system design, including controller and mechanical details of the mouthpiece
2017276270	12/13/2017	Issued	2017276270	6/28/2018	Utility patent covering authentication techniques
2018204184	6/11/2018	Issued	2018204184	10/25/2018	Utility patent covering aspects of the controller
2017228517	9/11/2017	Issued	2017228517	1/24/2019	Utility application covering the shape of the mouthpiece
2018247259	10/11/2018	Issued	2018247259	11/28/2019	Utility patent covering overall system design, including controller and mouthpiece, and authentication techniques
2019200175	1/7/2019	Issued	2019200175	10/24/2019	Utility patent covering the locators of the mouthpiece

Eurasian Application No.	Application Filing Date	Status	Eurasian Patent No.	Issue Date	Subject Matter
201790009	1/10/2017	Issued	28551 (validated in 8 EA states)	11/30/2017	Utility patent covering methods for non-invasively aiding neurorehabilitation using intraoral stimulation in combination with an exercise regimen

European Application No.	Application Filing Date	Status	European Patent No.	Issue Date	Subject Matter
15813638.2	7/1/2019	Issued	3226962	7/3/2019	Utility application covering overall system design, including controller and mouthpiece
15812899.1	8/6/2019	Issued	3226961	8/7/2019	Utility application covering shape of the mouthpiece

Russian Application No.	Application Filing Date	Status	Russian Patent No.	Issue Date	Subject Matter
2017123125	6/1/2017	Issued	2649512	4/3/2018	Utility patent covering overall system design, including controller and mouthpiece
2017123041	6/1/2017	Issued	2652571	4/26/2016	Design patent covering the controller design currently used in the PoNS device
2018108570	3/12/2018	Issued	2665385	8/29/2018	Utility patent covering center of gravity of the mouthpiece
2018129619	8/14/2019	Issued	2686950	5/6/2019	Utility patent covering authentication techniques
2018112065	3/28/2018	Issued	2686044	4/23/2019	Utility patent covering center of gravity of the mouthpiece

Israeli Application No.	Application Filing Date	Status	Israeli Patent No.	Issue Date	Subject Matter
252649	6/4/2017	Issued	252649	12/21/2018	Utility patent covering center of gravity of the mouthpiece
252648	6/1/2017	Issued	252648	8/31/2019	Utility patent covering overall system design, including controller and mouthpiece

Foreign Design Patents

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	42598	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

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

EU Community Design Application No.	Application Filing Date	Status	EU Community Design Reg. No.	Issue Date	Subject Matter
002712026	6/3/2015	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	10/24/2019	Design patents covering the controller design used in the PoNS device

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

Further, we have seven foreign utility patent applications that are currently pending: one application in Australia, and two applications in each of Canada, Europe, and Russia and three design patent applications that are currently pending in Russia:

Australian Application No.	Application Filing Date	Status	Australian Patent No.	Issue Date	Subject Matter
2019246836	10/9/2019	Pending	N/A	N/A	Utility patent application covering methods of placing a mouthpiece in a patient's mouth prior to engaging in NINM

Canadian Application No.	Application Filing Date	Status	Canadian Patent No.	Issue Date	Subject Matter
2969729	6/2/2017	Pending	N/A	N/A	Utility application covering overall system design, including controller and mouthpiece, and authentication techniques
2969731	6/2/2017	Pending	N/A	N/A	Utility application covering various aspects of the mouthpiece such as shape, center of gravity, and the locators

European Application No.	Application Filing Date	Status	European Patent No.	Issue Date	Subject Matter
19183730.1	7/1/2019	Pending	N/A	N/A	Utility application covering overall system design, including controller and mouthpiece
19190373.1	8/6/2019	Pending	N/A	N/A	Utility patent application covering methods of placing a mouthpiece in a patient's mouth prior to engaging in NINM

Russian Application No.	Application Filing Date	Status	Russian Patent No.	Issue Date	Subject Matter
2019112637	4/25/2019	Pending	N/A	N/A	Utility patent application covering aspects of the controller
2019109970	4/4/2019	Pending	N/A	N/A	Utility patent application covering the locators of the mouthpiece
2019503625	8/28/2019	Pending	N/A	N/A	Design patent application covering the mouthpiece design used in the PoNS device
2019503624	8/28/2019	Pending	N/A	N/A	Design patent application covering the controller design used in the PoNS device
2019503623	8/28/2019	Pending	N/A	N/A	Design patent application covering the system design used in the PoNS device

Currently, we own rights in four trademarks: PoNS, 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 Helius, Helius Medical, and Helius Medical Technologies marks.

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

Government Regulation

Our products under development and our operations are subject to significant government regulation. In the United States, 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 United States, 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 United States 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 likely to be regulated as a Class II medical device. We therefore utilized the *de novo* classification process to seek classification and U.S. marketing authorization for the PoNS device for gait deficit in MS, because there is no predicate cleared or approved by the FDA for commercial distribution and no existing classification decision by the FDA for such a device.

If the FDA requires us to go through a lengthier, more rigorous examination for the PoNS device for gait deficit in MS, introducing the product could be delayed or canceled, which could cause our commercial launch for the PoNS device for gait deficit in MS in the United States to be delayed or to not occur. In addition, the FDA may determine that the PoNS device requires the more costly, lengthy and uncertain PMA process. For example, if the FDA disagrees with our determination that the de novo classification procedures are the appropriate path to obtain marketing authorizations for the PoNS device in MS, 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) clearances 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. If the FDA determines that the 510(k) submission is incomplete, the FDA will issue a "Refuse to Accept" letter which generally outlines the information the FDA believes is necessary to permit a substantive review and to reach a determination regarding substantial equivalence. 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.

We utilized the *de novo* classification process to request our marketing authorization for the PoNS device for gait deficit in MS, and we plan to seek Class II classification. In order to be placed in Class II, the FDA would need 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) would be applicable.

Obtaining FDA marketing authorization, de novo classification and clearance, or approval for medical devices 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.

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.

In addition, the study must be approved by, and conducted under the oversight of, an Institutional Review Board, or IRB, for each clinical site. 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 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 will play a primary role in the recommendation and use of any products for which we obtain marketing approval. Our future arrangements with third party payers, healthcare providers and physicians may 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 any device for which we obtain marketing approval. In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the CMS, other divisions of the United States Department of Health and Human Services (e.g., the Office of Inspector General), the United States Department of Justice and individual United States Attorney offices within the Department of Justice, and state and local governments. The applicable laws and regulations include the federal health care programs Anti-Kickback Statute, or AKS, and the federal Civil False Claims Act.

The AKS 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, recommendation, or order of a particular device, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by up to ten years in prison, criminal fines, administrative civil money penalties 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.

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 making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties of between $11,463 and $22,927 (adjusted annually for inflation) for each separate false claim and the potential for exclusion from participation in federal healthcare programs. Conduct that violates the False Claims Act also may implicate various federal criminal statutes. 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 AKS also are deemed false or fraudulent claims for purposes of the False Claims Act. Our future 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.

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.

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 Mark of the PoNS device with our UK based notified body in December 2018. In August 2019 we withdrew our application from the EU marketing process 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 marketing authorization for the sale of the PoNS device in the EU. Some EU member states have additional notification requirements that we expect to satisfy before we launch our PoNS Treatment 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 approved use(s) of the device;
- 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. We are currently awaiting additional feedback from the TGA on our application.

Third-Party Payer Coverage and Reimbursement

Significant uncertainty exists as to whether coverage and reimbursement of the PoNS Treatment will develop; but we intend to seek reimbursement through private or governmental third-party payers in the future. In both the United States and foreign markets, our ability to commercialize the PoNS device successfully, and to attract commercialization partners for the PoNS device, depends in part on the availability of adequate financial coverage and reimbursement from third-party payers, including, in the United States, governmental payers such as the Medicare and Medicaid programs, managed care organizations, and private health insurers. Medicare is a federally funded program managed by the CMS, through local contractors that administer coverage and reimbursement for certain healthcare items and services furnished to the elderly and disabled. Medicaid is an insurance program for certain categories of patients whose income and assets fall below state defined levels and who are otherwise uninsured, and it is both federally and state funded and managed by each state. The federal government sets general guidelines for Medicaid and each state creates specific regulations or other guidelines that govern its individual program. Each payer, whether governmental or private, has its own process and standards for determining whether it will cover and reimburse a procedure or particular product. Private payers often rely on the lead of the governmental payers in rendering coverage and reimbursement determinations. Therefore, achieving favorable CMS coverage and reimbursement is usually a significant gating issue for successful introduction of a new product. On January 12, 2021, the CMS stated that it is finalizing a new Medicare coverage pathway, MCIT, for FDA-designated breakthrough medical devices. The MCIT rule will provide national Medicare coverage as early as the same day as FDA market authorization for breakthrough devices and coverage would last for four years. The competitive position of the PoNS device will depend, in part, upon the extent of coverage and adequate reimbursement for such product and for the procedures in which such product is used. Prices at which we or our customers seek reimbursement for the PoNS device can be subject to challenge, reduction or denial by the government and other payers.

In the event we do receive approval for third-party or government reimbursement for our product, the marketability of such product may suffer if the government and commercial third-party payers fail to provide adequate coverage and reimbursement. An emphasis on cost containment measures in the United States has increased and we expect it will continue. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained if and when we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

State and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for our product candidate for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

In addition, in some foreign countries, the proposed pricing for a medical device must be approved before it may be lawfully marketed. The requirements governing medical device pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medical devices for which their national health insurance systems provide reimbursement and to control the prices of medical devices. In some countries, we may be required to conduct a clinical study or other studies that compare the cost-effectiveness of our medical device to other available therapies in order to obtain or maintain reimbursement or pricing approval. Historically, products launched in the European Union do not follow price structures of the United States and generally tend to be priced significantly lower. Publication of discounts by third-party payers or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our medical device is unavailable or limited in scope or amount, our revenues from sales by us or our strategic partners and the potential profitability of any of our medical devices in those countries would be negatively affected.

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, received, 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.

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, or the CCPA, on June 28, 2018, which took effect on January 1, 2020. The CCPA 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 data breaches that is expected to increase data breach litigation. Additionally, many of the more ambiguous provisions of the CCPA have yet to be fully interpreted and applied, and numerous amendments have been proposed and are working their way through legislature. Consequently, the CCPA currently presents many compliance questions that remain unresolved. The CCPA may increase our compliance costs and potential liability. In addition to the CCPA, numerous other states' legislatures are considering similar laws that will require ongoing compliance efforts and investment.

In the European Union, as of May 25, 2018, Regulation 2016/676, known as the General Data Protection Regulation, or GDPR, replaced the Data Protection Directive with respect to the processing of personal data in the European Union. The 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 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.

Our Corporate History Highlights

Formation and Arrangement with Boomerang Oil, Inc.

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. As a result of the arrangement agreement, we became a reporting issuer in the provinces of British Columbia and Alberta. In addition, the arrangement resulted in 0995162 B.C. Ltd. becoming our wholly owned subsidiary. The assets of 0995162 B.C. Ltd. consisted of cash and 0995162 B.C. Ltd.'s interest in a letter agreement pursuant to which it had agreed to acquire all of the outstanding shares of HMI, a Delaware corporation, and to seek a listing on a recognized stock exchange.

Reincorporation in Wyoming

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.

Acquisition of NeuroHabilitation Corporation and Concurrent Financing

On June 13, 2014, we completed the acquisition of NeuroHabilitation Corporation, or NHC, by way of an agreement and plan of merger. We refer to this transaction as the Reverse Merger. Pursuant to the agreement and plan of merger, HMT Mergersub, Inc., our wholly owned subsidiary, merged with and into NHC with NHC as the surviving corporation. In connection with the Reverse Merger, we issued an aggregate of 201,714 shares of our common stock to the former shareholders of HMI. The Reverse Merger was deemed to be a capital transaction in substance and recorded as a reverse recapitalization of NHC whereby NHC is deemed to be the continuing, surviving entity for accounting purposes, but through reorganization, has deemed to have adopted the capital structure of Helius. On December 21, 2018, NHC changed its name to Helius Medical, Inc.

In connection with the Reverse Merger, we completed a non-brokered private placement financing of $7.02 million (CAD$7.62 million) by issuing 87,085 subscription receipts. Pursuant to its terms, each subscription receipt automatically converted into one unit upon satisfaction of certain escrow release conditions, which had been satisfied. Each unit consisted of one share of our common stock and one-half of one share purchase warrant with each whole warrant being exercisable at CAD$175.00 per share for a period of two years.

Change in Functional Currency

Prior to April 1, 2018, our functional currency was the Canadian dollar, or CAD$. We re-assessed our functional currency and as of April 1, 2018, our functional currency changed from the CAD$ to the U.S. dollar based on management's analysis of changes in the primary economic environment in which we operate. The change in functional currency was accounted for prospectively from April 1, 2018 and financial statements prior to and including the period ended March 31, 2018 were not restated for the change in functional currency.

Reincorporation in Delaware

On June 28, 2018, at our 2018 Annual Meeting of Shareholders, our shareholders approved our reincorporation from the state of Wyoming to the state of Delaware. On July 20, 2018, we completed the reincorporation to the state of Delaware.

Formation of Helius NeuroRehab Inc.

In January 2019, we formed Helius NeuroRehab, Inc., or HNR, a Delaware corporation, which is a wholly owned subsidiary of Helius Medical Technologies, Inc. to operate a clinic focusing on the delivery of PoNS Treatment to patients with balance and gait disorders if and when FDA clearance is received.

Formation of Helius Canada Acquisition Ltd. and Acquisition of Heuro Canada Inc.

On October 10, 2019, we formed HCA, a company incorporated under the federal laws of Canada, which is a wholly owned subsidiary of HMC, a company incorporated under the federal laws of Canada. On October 30, 2019, we acquired Heuro, a company incorporated under the federal laws of Canada, as a wholly owned subsidiary of HCA, from HTC.

Listing of our Common Stock

Following our Reverse Merger, we obtained approval of the listing of our common stock on the Canadian Securities Exchange, or CSE, on June 23, 2014. On April 18, 2016, our common stock was listed on the TSX under the symbol "HSM." At the same time, we delisted our common stock from the CSE. The Company's common stock also began trading on the OTC Markets, or OTCQB, under the ticker symbol "HSDT" on February 10, 2015. On April 11, 2018, our common stock began trading on the Nasdaq Capital Market under the ticker symbol "HSDT" and ceased to trade on the OTCBQ.

On March 23, 2020, we received notice from the Staff of Nasdaq (the "Staff") that the bid price for our common stock had closed below $1.00 per share for the prior 30-consecutive business day period and that we had been granted a 180-day grace period, through September 21, 2020, to regain compliance with Nasdaq Marketplace Rule 5550(a)(2) (the "Minimum Bid Price Rule"). Thereafter, on April 17, 2020, we received an additional notice from the Staff indicating that Nasdaq had temporarily stayed enforcement of the

Minimum Bid Price Rule through June 30, 2020 and, accordingly, the 180-day grace period applicable to the Company would not expire until December 3, 2020.

On December 4, 2020, we received notice from the Staff indicating that we were not eligible for an additional 180 day extension to meet the Minimum Bid Price Rule. As a result, the Staff determined that our securities would be subject to delisting unless we timely requested a hearing before the Panel. We timely submitted a request for a hearing before the Panel, which request stayed any suspension or delisting action by Nasdaq at least until the hearing process concludes and any extension granted by the Panel expires. On January 15, 2021, we received notice from the Staff that our bid price deficiency had been cured, and that we were in compliance with all applicable listing standards, and so the scheduled hearing before the Panel was cancelled.

Reverse Stock Splits

Effective after the close of business on January 22, 2018, we completed a 1-for-5 reverse stock split of our common stock. All share and per share amounts in this Annual Report have been reflected on a post-split basis.

At a special meeting of our stockholders on December 28, 2020, our stockholders approved a reverse split of our outstanding common stock at a ratio in the range of 1-for-5 to 1-for-35 to be determined at the discretion of our board of directors, whereby each outstanding 5 to 35 shares would be combined, converted and changed into 1 share of our common stock, to enable us to comply with Nasdaq's continued listing requirements.

Following such meeting, our board of directors approved a final reverse stock split ratio of 1-for-35, and we filed with the Secretary of State of the State of Delaware a Certificate of Amendment to our Certificate of Incorporation to effect the reverse stock split. The reverse stock split was effective as of 5:00 pm Eastern Time on December 31, 2020, and our common stock began trading on a split-adjusted basis on The Nasdaq Capital Market and Toronto Stock Exchange on January 4, 2021. The reverse stock split did not change the par value of our stock or the authorized number of common or preferred shares. All share and per share amounts for all periods presented in this Annual Report have been retroactively adjusted for the reverse stock split effected on December 31, 2020.

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 Annual Report. 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-invasive 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.

Given the change in our United States regulatory timeline in 2019, we prioritized our resources to support our resubmission to the FDA and commercialization efforts in Canada. As a result, in April 2019, we reduced our workforce by over 30% to scale back the staff that was hired to prepare for our commercial launch in the United States while maintaining the necessary distribution, regulatory and quality system infrastructure to support our commercial launch in Canada. As of December 31, 2019, we had 19 full time employees and four consultants. During 2020, we maintained a similarly sized workforce, and as such, as of December 31, 2020, we had 19 full time employees, no part time employees, two full time consultants and five part time consultants.

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 if we obtain FDA de novo classification and clearance of the PoNS device. 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

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 Annual Report. 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, 2020 and 2019, we incurred a net loss of $14.1 million and $9.8 million, respectively, and used cash in operations of $11.7 million and $21.0 million, respectively. We have an accumulated deficit of $118.9 million as of December 31, 2020. 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. While we have received a medical device license from Health Canada to market the PoNS device in Canada, and even if we are successful in obtaining marketing authorization from the FDA in order to launch our PoNS device in the United States or additional foreign regulatory authorities to launch outside of the United States, we expect to continue to incur substantial losses for the foreseeable future as we continue to research and develop and seek regulatory marketing authorization for our product candidate.

We are subject to all of the business risks and uncertainties associated with any new business enterprise, including under-capitalization, cash shortages, limitations with respect to personnel, financial and other resources, lack of significant revenue and the risk that we will not achieve our growth objective. If sales revenue from any product candidate that receives marketing authorization from the FDA or other regulatory body is insufficient, if we are unable to develop and commercialize any of our potential product candidates, or if our product development is delayed, we may never achieve or sustain profitability.

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.

From our inception through December 31, 2020, we have generated over $2.0 million in revenue from the commercial sales of products or services. 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 recruitment of patients for treatment in Canada, manufacturing of a commercially viable version of the PoNS device and demonstration of effectiveness sufficient to generate commercial orders by customers for our product. Moreover, because we expect that the revenue opportunity in the United States is significantly greater than in Canada, we believe our ability to generate significant revenue in the future will be dependent upon the receipt of FDA marketing authorization of the PoNS device.

These factors raise substantial doubt about our ability to continue as a going concern through at least 12 months from the date of this Annual Report. While we had $3.3 million of cash as of December 31, 2020 and received net proceeds of $10.9 million in the aggregate from the exercise of outstanding warrants and the issuance and sale of common stock and warrants in a public offering subsequent to December 31, 2020, 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 beginning of the first quarter of 2022. 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 dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidate on terms unfavorable to us.

Our operations to date have principally been financed by public and private offerings of our common stock and convertible debt and exercises of options and warrants and, since inception, we have raised $118.9 million in gross proceeds from equity financings. 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 candidate, future revenue streams, research programs or product candidate, 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 for our product candidate or our preclinical product candidates, or grant rights to develop and market potential future product candidates that we would otherwise prefer to develop and market ourselves. Any of these events could adversely affect our ability to achieve our product development and commercialization goals and have a material adverse effect on our business, financial condition and results of operations.

Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements. We may be unable to continue to operate without the threat of liquidation for the foreseeable future.

In connection with our management's assessment, our report from our independent registered public accounting firm for the fiscal year ended December 31, 2020 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 first quarter of 2022. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. We expect our expenses to increase over time in connection with our ongoing activities, particularly if and as we: invest in marketing and distribution capabilities in support of potentially commercializing our PoNS device in the U.S., if approved; make improvements to our manufacturing process and product design; launch the TBI-002 trial or conduct other trials of the PoNS device; pursue further regulatory approvals; maintain, expand and protect our intellectual property portfolio; and add additional personnel. 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.

Risks Related to the Development and Commercialization of our Product Candidate

We currently only have one product candidate, which is still in development, and we have not obtained authorization from the FDA to commercially distribute the device in the United States, a CE Mark for commercial distribution in Europe or from the TGA for commercial distribution in Australia, and we may never obtain such authorizations.

We currently have no products authorized for commercial distribution in either the United States, Europe or Australia, or in any other country outside of Canada. We are developing the PoNS device for use in the neuromodulation market, but we cannot begin marketing and selling the device in the United States, Europe or Australia until we obtain applicable authorizations from the FDA, European Union (Notified Body) or Therapeutic Goods Administration in Australia, respectively. While we have submitted applications for regulatory marketing authorization in the United States and Australia, the process of obtaining regulatory authorization 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 of a product candidate or rejection of a regulatory application altogether.

In April 2019, the FDA declined our request for de novo classification of the PoNS device for use to improve balance in patients with mmTBI. In reaching its conclusion, the FDA noted that it did not have sufficient information to discern the relative independent

contributions of the PoNS device and physical therapy to establish sufficient evidence of effectiveness based on our clinical trials. 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 Treatment 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 finalized our clinical protocol for a new trial, TBI-002, intended to support a request for de novo classification and clearance of the PoNS device. The launch of the TBI-002 trial has been temporarily suspended, and we are evaluating our options for funding and timing to commence the trial or potentially look at other indications.

In March 2020, we announced that based on the quality of the data included in our MS submission package to Health Canada and the significant unmet needs of those afflicted with MS, we are prioritizing the MS indication as the pathway to pursue our first U.S. clearance of the PoNS device. 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. On August 4, 2020, we submitted our request to the FDA for de novo classification and clearance of the PoNS device for the treatment of gait deficit due to symptoms from MS, to be used as an adjunct to a supervised therapeutic exercise program in patients over 18 years of age.

On October 19, 2020, we announced that we received a request for additional information from the FDA related to our request for de novo classification and clearance of the PoNS device, which includes requests for additional analysis of clinical data and proposes certain labeling modifications. On January 11, 2021, we announced that we submitted our formal response to the FDA's request for additional information.

The FDA has substantial discretion in the de novo review process and may refuse to accept our application 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 from the FDA or other regulatory authorities. Any marketing authorization from the FDA we ultimately obtain may be limited or subject to restrictions or post-market commitments that render the product candidate not commercially viable. If our attempts to obtain marketing authorization are unsuccessful, we may be unable to generate sufficient revenue to sustain and grow our business, and our business, financial condition, and results of operations will be materially adversely affected.

If we are able to complete development of the PoNS device and obtain marketing authorization of the PoNS device for the treatment of gait deficit in patients with MS in the United States, Europe or Australia, we plan to develop the PoNS device for other indications, or symptoms caused by neurological disorders. We would be required to commit our own resources to fund development of any other indications and each would require separate FDA clearance or other marketing authorization. The costs of such development efforts and FDA clearance 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.

The COVID-19 pandemic has adversely impacted, and may continue to materially and adversely impact, our business, financial condition and results of operations.

On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 as a global pandemic, which continues to spread throughout the United States and around the world. The Company's business, results of operations and financial condition have been adversely impacted by the COVID-19 pandemic and global economic conditions. The outbreak and spread of COVID-19 has significantly increased economic uncertainty. Authorities implemented numerous measures to try to contain the virus, such as travel bans and restrictions, quarantines, shelter in place orders, and business shutdowns. The COVID-19 pandemic initially led to the closure of PoNS authorized clinic locations across Canada from March until June 2020. Patients who completed their initial training in the clinics prior to the closures have been able to continue working independently in the at-home portion of the treatment, with remote check-ins with their certified therapists. While all clinics have re-opened, they are all currently operating at reduced capacity within provincial guidelines, which limited operations to 50% capacity during the second half of 2020. Some patients have begun to return to these clinics for treatment, but patients have been and may continue to be less willing to return to the clinics due to COVID-19, impacting our commercial activities and our customer engagement efforts. We have expanded our services to include remote training and treatment, but the long-term viability of these remote programs is still being assessed. In addition, the resurgence of COVID-19 cases across Canada in the fourth quarter of 2020 has led to further restrictions on clinic activities. Additionally, while we do not currently have any clinical trials underway, we are running clinical experience programs in Canada and have experienced delays in the programs as trial participant attendance has generally decreased as a result of the pandemic, and clinics and clinical research sites have experienced delays and difficulties in recruiting and re-hiring clinical site staff, leading to further delays in the development and approval of the Company's product candidate. As noted above, prior to the COVID-19 pandemic, our expectation was that we would move forward with the launch of our TBI-002 trial and we had estimated that enrollment would begin in April 2020 with the completion of the trial and submission to the FDA in the second quarter of 2021. However, the launch of the TBI-002 trial has been

temporarily suspended and we are evaluating our options for funding and timing to commence the trial or potentially looking at other indications.

The COVID-19 pandemic and other outbreaks may cause delays in or the suspension of our business partners manufacturing operations, our research and product development activities, our regulatory workstreams, our research and development activities and other important commercial functions. We are also dependent upon our suppliers for the manufacture of our PoNS device, and in the second quarter of 2020, two of our business partners diverted resources towards other activities related to COVID-19, resulting in delays in the development and manufacturing of our product. Such diversion of suppliers' resources may occur again in the future, and the pandemic could limit our suppliers' ability to travel or ship materials or force temporary closure of facilities that we rely upon. Disruptions in business operations or governmental operations due to COVID-19 may delay the timing for the submission and approval of the Company's marketing applications with regulatory agencies. Further, the economic impact of the COVID-19 pandemic could affect our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

As the COVID-19 pandemic continues, we may experience additional disruptions that could severely impact our business and planned clinical trials including:

- Diversion of healthcare resources away from the conduct on clinical trials, including the diversion of hospitals serving as clinical trial sites and hospital staff supporting the conduct of clinical trials;
- Interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitation on travel imposed or recommended by federal or state governments, employers and others;
- Delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- Changes in local regulations as part of a response to the COVID-19 pandemic which may require us to change the way in which clinical trials are conducted and may result in unexpected costs;
- Delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and
- Delay in the timing of our interactions with the FDA due to absenteeism by federal employees or the diversion of their efforts and attention to approval of other therapeutics or other activities related to COVID-19.

In addition to the risks specifically described above, the COVID-19 pandemic has exacerbated and precipitated the other risks described herein, and may continue to do so. The extent to which the COVID-19 pandemic will continue to impact the Company's business, results of operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted. The Company does not know yet the full extent of the impact of COVID-19 on its business, operations or the global economy as a whole.

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 Treatment, or if we cannot train physical therapists in the supervision of the use of the PoNS Treatment, we will be unable to generate significant revenue, if any.

Our deployment strategy in the United States depends on physicians prescribing the PoNS Treatment 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 the therapy;
- our ability to develop our commercial infrastructure to successfully launch;
- 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, if any, 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 Treatment and implement a 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, if any. 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 candidate is. Competitors also may obtain FDA or other regulatory marketing authorization for their products more rapidly or earlier than we may obtain marketing authorization for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, technologies developed by our competitors may render the PoNS device uneconomical or obsolete.

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 candidate.

We currently have a limited number of employees and resources available to perform the research and development necessary to commercialize our PoNS Treatment and potential future product candidates. We therefore rely, and will continue to rely, on third-party research institutions, collaborators and consultants for this capability.

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, and this contract manufacturer manufactured the units for our engineering and device verification testing and is building the launch quantities for commercialization. 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 could encounter difficulties, including, but not limited to, those caused by the COVID-19 pandemic, in securing long-lead time components, achieving volume production, quality control and quality assurance or suffer shortages of qualified personnel, which could result in their inability to manufacture sufficient quantities of our commercially available product to meet market demand. Our third-party manufacturer or distributor may also 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 QSRs, either of which could lead to significant delays in the availability of materials for our product and/or FDA enforcement actions against them and/or us.

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 such 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.

In order to be successful, we must expand our product lines beyond our PoNS Treatment for gait deficit due to symptoms from MS or balance deficit due to mmTBI, but we may not be able to do so in a timely fashion and at expected costs, or at all.

In order to be successful, we will need to expand our product lines beyond our PoNS Treatment for gait deficit due to symptoms from MS or balance deficit due to mmTBI. To succeed in our commercialization efforts, we must effectively continue product development and testing, obtain regulatory authorizations, and enhance our sales, marketing and market access and reimbursement capabilities. There is no assurance that we will succeed in developing a future product candidate or in bringing any of our current or potential future product candidates to market outside of Canada. If we fail in bringing our product candidates to market, or experience delays in doing so, we will not generate revenues as planned and will need to curtail operations or seek additional financing earlier than otherwise anticipated.

The development of additional products is subject to the risks of failure inherent in the development of new, state of the art products, and products based on new technologies. These risks include: (a) delays in product development or manufacturing; (b) unplanned expenditures for product development or manufacturing; (c) failure of new products to have the desired effect or an acceptable accuracy and/or safety profile; (d) emergence of superior or equivalent products; (e) failure by any potential collaborative partners to successfully develop products; and (f) the dependence on third parties for the manufacture, development and sale of our products. Because of these risks, our research and development efforts or those of potential collaborative partners may not result in any commercially viable products. If a significant portion of these development efforts is not successfully completed, or any products are not commercially successful, we are less likely to generate significant revenues, or become profitable. The failure to perform such activities could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Intellectual Property

If our intellectual property protection is inadequate, competitors may gain access to our technology and undermine our competitive position.

We regard our intended and future intellectual property as important to our success, and we intend to rely on patent law to protect our proprietary rights. Despite our precautions, unauthorized third parties may copy certain portions of our devices or products or reverse engineer or obtain and use information that we regard as proprietary. We may seek additional patents in the future. We do not know if any future patent application will be issued with the scope of the claims, we seek, if at all or whether any patents we receive will be challenged or invalidated. Thus, we cannot assure you that any intellectual property rights that we may receive can be successfully asserted in the future or that they will not be invalidated, circumvented or challenged. In addition, the laws of some foreign countries do not protect proprietary rights to the same extent, as do the laws of the United States. Our means of protecting any proprietary rights we may receive in the United States 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 United States, 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, we will be required to obtain marketing authorization from the FDA and foreign regulatory authorities. These authorizations 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 Treatment for use in the United States, 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. We will also be required to comply with costly and more often time-consuming regulatory requirements by foreign regulatory authorities, including Europe and Australia, if we want to sell our products outside of the United States, other than Canada, where the PoNS Treatment is authorized for sale as a class II, non-implantable, medical device for treatment of gait deficit due to symptoms from MS and balance deficit due to mmTBI in conjunction with supervised therapeutic exercise. 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 of the PoNS device for use to improve balance in patients with mmTBI. In reaching its conclusion, the FDA noted that it did not have sufficient information to discern the relative independent contributions of the PoNS device and physical therapy to establish sufficient evidence of effectiveness based on our clinical trials. 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 Treatment 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 finalized our clinical protocol for a new trial, TBI-002, intended to support a request for de novo classification and clearance of the PoNS device. The launch of the TBI-002 trial has been temporarily suspended, and we are evaluating our options for funding and timing to commence the trial or potentially look at other indications.

In March 2020, we announced that based on the quality of the data included in our MS submission package to Health Canada and the significant unmet needs of those afflicted with MS, we are prioritizing the MS indication as the pathway to pursue our first U.S. clearance of the PoNS device. 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. On August 4, 2020, we submitted our request to the FDA for de novo classification and clearance of the PoNS device for the treatment of gait deficit due to symptoms from MS, to be used as an adjunct to a supervised therapeutic exercise program in patients over 18 years of age.

On October 19, 2020, we announced that we received a request for additional information from the FDA related to our request for de novo classification and clearance of the PoNS device, which includes requests for additional analysis of clinical data and proposes certain labeling modifications. On January 11, 2021, we announced that we submitted our formal response to the FDA's request for additional information.

The FDA has substantial discretion in the de novo review process and may refuse to accept our application 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 from the FDA or other regulatory authorities.

If the FDA requires us to go through a lengthier, more rigorous examination for the PoNS device for MS or any other indication we may pursue, 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.

Moreover, in addition to continuing our pursuit of an indication for mmTBI with the FDA, we are currently considering the development of the PoNS device for other potential indications, including stroke, cerebral palsy, Parkinson's disease, baby boomers balance, and neurological wellness, as well as expanding the label of our current indications. At this time, we do not know what pathways the FDA or other regulatory authorities will require us to utilize for these additional indications. We may be required to pursue marketing authorization via more rigorous pathways, such as a PMA application in the United States, which may require more development work than we are currently planning. This would delay the potential marketing authorization for such indications, potentially make marketing authorization more difficult to obtain, and increase our costs.

Obtaining 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.

Obtaining FDA marketing authorization, *de novo* classification and clearance, or PMA approval for medical devices 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. 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.

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.

Even if granted, a 510(k) clearance, *de novo* classification and clearance, or pre-market approval for any future product would likely place substantial restrictions on how our device is marketed or sold, and FDA will continue to place considerable restrictions on our products and operations. For example, the manufacture of medical devices must comply with FDA's QSR. In addition, manufacturers must register their manufacturing facilities, list the products with 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. 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.

Additionally, the FDA and other regulatory authorities have broad enforcement powers. 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.

We may be required to conduct clinical trials to support a future de novo submission or PMA application for the PoNS device 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 United States, 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. In April 2019, the FDA declined our request for *de novo* classification and clearance for mmTBI. Following a pre-submission meeting with the FDA, we finalized our clinical protocol for a new trial, TBI-002, intended to support a request for de novo classification and clearance of the PoNS device. The launch of the TBI-002 trial has been temporarily suspended, and we are evaluating our options for funding and timing to commence the trial or potentially look at other indications.

In March 2020, we announced that based on the quality of the data included in our MS submission package to Health Canada and the significant unmet needs of those afflicted with MS, we are prioritizing the MS indication as the pathway to pursue our first U.S. clearance of the PoNS device. 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. On August 4, 2020, we submitted our request to the FDA for de novo classification and clearance of the PoNS device for the treatment of gait deficit due to symptoms from MS, to be used as an adjunct to a supervised therapeutic exercise program in patients over 18 years of age.

On October 19, 2020, we announced that we received a request for additional information from the FDA related to our request for de novo classification and clearance of the PoNS device, which includes requests for additional analysis of clinical data and proposes certain labeling modifications. On January 11, 2021, we announced that we submitted our formal response to the FDA's request for additional information.

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.

As described above, following the FDA's denial of our request for de novo classification and clearance for mmTBI in April 2019, in January 2020 we finalized our clinical protocol for TBI-002 intended to support a request for de novo classification and clearance of the PoNS device for mmTBI. Prior to the COVID-19 pandemic, our expectation was that we would move forward with the revised protocol and estimated that enrollment would begin in April 2020 with the completion of the trial and submission to the FDA in the second quarter of 2021. However, the launch of the TBI-002 trial has been temporarily suspended, and we are evaluating our options for funding and timing to commence the trial or potentially look at other indications.

While we currently have no ongoing clinical trials, we expect that we will need to conduct further clinical trials, including the TBI-002 trial if we continue to pursue de novo classification and clearance for mmTBI in the United States. 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 trial can occur at any stage of testing. Delays, including, but not limited to those caused by the COVID-19 pandemic, 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 commercialization, which would harm our business, financial condition, and results of operations.

We may be substantially dependent on third parties to conduct our clinical trials.

Since we may conduct clinical trials to obtain FDA marketing authorization, we will need to 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 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 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 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 secure contracts with WC and third-party administrators or rehabilitation clinics who treat patients with gait deficit due to symptoms from MS or balance issues associated with mmTBI, this could have a negative impact on our intended sales and would have a material adverse effect on our business, financial condition and operating results.

One of our commercialization strategies includes leveraging WC payers to drive early reimbursements and entice Medicaid and commercial payers through third party administrators and rehabilitation clinics. Should we fail in securing such contracts it could have a material adverse effect on our intended sales projections, which would affect our financial conditions and operating results. In addition, until we are successful in engaging WC payers, Medicaid and other third party commercial payers to cover the cost of the PoNS device for their insured customers, we expect our initial sales of the PoNS device will be via cash paid by patients. As a result, we may not be able to sell our PoNS device in commercially reasonable quantities depending on the cost of the device to cash payers.

If we are unable to obtain a reimbursement code from the U.S. Department of Health and Human Services so that the PoNS device is covered under Medicare and Medicaid, this 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 plan to submit an application to the U.S. Department of Health and Human Services for a reimbursement code so that the PoNS device is covered under Medicare and Medicaid. However, there can be no assurance that our application will be successful, or that we will be able to obtain a reimbursement code in a timely manner. In the event that we do not obtain a reimbursement code for the PoNS device, our customers may be unable to obtain reimbursement for their purchases under private or government-sponsored insurance plans, which could have a negative impact on our sales and have a material adverse effect on our business, financial condition and operating results. In addition, Medicare and its administrative contractors as well as other insurers must find that the PoNS device meets their medical necessity requirements for the treatment of patients with mmTBI or they will not pay for the treatment. In addition, there is a risk that the payment amount for the PoNS device is either too low or too high to incentivize customer adoption.

If hospitals and other healthcare providers are unable to obtain coverage or adequate reimbursement for procedures performed with our products, our product will not likely be widely used.

In the United States, 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 procedures utilizing our products. On January 12, 2021, the CMS stated that it is finalizing a new Medicare coverage pathway, Medicare Coverage of Innovative Technology, or "MCIT," for FDA-designated breakthrough medical devices. The MCIT rule will provide national Medicare coverage as early as the same day as FDA market authorization for breakthrough devices and coverage would last for four years. Manufacturers will be able to opt-in to MCIT and choose a start date for coverage anytime within two years from the date of FDA market authorization. Hospitals and other healthcare providers that purchase our product for treatment of their patients generally rely on third-party payers to pay for all or part of the costs and fees associated with our products as part of a "bundled" rate for the associated procedures. The existence of coverage and adequate reimbursement for our products and the procedures performed with them by government and private payers is critical to market acceptance of our existing and future products. Neither hospitals nor physicians are likely to use our product and any future products if they do not receive adequate reimbursement for the procedures utilizing our products.

Many private payers currently base their reimbursement policies on the coverage decisions and payment amounts determined by the CMS, which administers the Medicare program. Others may adopt different coverage or reimbursement policies for procedures performed with 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 the procedures performed with 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 used in a procedure 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 product face in the market and could have a material adverse effect on our business.

Many hospitals and clinics in the United States belong to group purchasing organizations, which typically incentivize their hospital members to make a relatively large proportion of purchases from a limited number of vendors of similar products that have contracted to offer discounted prices. Accordingly, the commercial success of our products may also depend to some extent on our ability to either negotiate favorable purchase contracts with key group purchasing organizations and/or persuade hospitals and clinics to purchase our product "off contract."

The healthcare industry in the United States 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 hospitals will be able to obtain coverage for procedures using our products, the level of payment available to them for such procedures may change over time. State and federal

healthcare programs, such as Medicare and Medicaid, closely regulate provider 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 healthcare providers 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, hospitals and other providers 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 hospitals 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 do not have a product available for sale in the United States. If, however, we achieve this goal, the availability of payments from Medicare, Medicaid or other third-party payers would mean that many healthcare laws would 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: (i) the federal healthcare programs Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as Medicare or Medicaid, (ii) federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent, and which may apply to entities like us if we provide coding and billing advice to customers, or under theories of "implied certification" where the government and *qui tam* relators may allege that device companies are liable where a product that was paid for by the government in whole or in part was promoted "off-label," lacked necessary marketing authorization, or failed to comply with good manufacturing practices or other laws; (iii) transparency laws and related reporting and/or disclosures such as the Sunshine Act; and/or (iv) state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, many of which differ from their federal counterparts in significant ways, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any other 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 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 United States, 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 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 United States.

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, a recall of our products, either voluntarily or at the direction of a governmental authority, or a foreign competent authority, or the discovery of serious safety issues with our products, could have a significant adverse 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.

The FDA requires that certain classifications of voluntary recalls of devices be reported to the FDA within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. Any recalls of any of our products would divert managerial and financial resources and could have an adverse effect on our reputation, results of operations and financial condition, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. We may also be required to bear other costs or take other actions that may have a negative impact on our future sales and our ability to generate profits.

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. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of future products. For example, the recent change in administration may impact our business and industry. Namely, the Trump administration took several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict whether or how these executive actions will be implemented, or whether they will be rescinded or replaced under the current Biden administration. The policies and priorities of a new administration are unknown and could materially impact the regulation governing our products. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency 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 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.

Risks Related to our Business Operations

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: invest in marketing and distribution capabilities in support of potentially commercializing our PoNS device in the U.S., if approved; make improvements to our manufacturing process and product design; launch the TBI-002 trial or conduct other trials of the PoNS device; 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.

We may not be able to build an effective distribution network for our product.

We currently have very few employees and we may either build internal capabilities or rely on distributors to sell our product. We cannot assure you that we will succeed in building an internal team or entering into and maintaining productive arrangements with an adequate number of distributors that are sufficiently committed to selling our products. The establishment of a distribution network is expensive and time consuming. As we launch new products and increase our marketing effort with respect to existing products, we will need to continue to hire, train, retain and motivate skilled resources with significant technical knowledge. In addition, the commissions we pay for product sales could increase over time, which would result in higher sales and marketing expenses. Furthermore, if we were to rely on distributors, the current and potential distributors may market and sell the products of our competitors. Even if the distributors market and sell our product, our competitors may be able, by offering higher commission payments or other incentives, to persuade these distributors to reduce or terminate their sales and marketing efforts related to our product. The distributors may also help competitors solicit business from our existing customers. Some of our independent distributors may likely account for a significant portion of our sales volume, and, if we were to lose them, our sales could be adversely affected. Even if we engage and maintain suitable relationships with an adequate number of distributors, they may not generate revenue as quickly as we expect them to, commit the necessary resources to effectively market and sell our products, or ultimately succeed in selling our product.

Exposure to United Kingdom political developments, including the outcome of the referendum on membership in the European Union, could be costly and difficult to comply with and could seriously harm our business.

In January 2020, the United Kingdom formally withdrew from the European Union, commonly referred to as "Brexit." Brexit has created an uncertain political and economic environment in the United Kingdom and other European Union countries. The political and economic instability created by Brexit has caused and may continue to cause significant volatility in global financial markets and uncertainty regarding the regulation of data protection in the United Kingdom.

Brexit may have a significant negative impact on medical device manufacturers such as us. A Notified Body, or NB, that we contracted with as our EU regulatory service provider is located in the UK. CE Mark issued by a UK NB is at risk due to Brexit. Medical device manufacturers such as us with products CE Marked by a UK NB may not be able to place those products on the market until Brexit issues are resolved by the European Commission and local governments. In addition, the acceptance of medical device market authorization from UK NBs by countries outside of the EU, which have traditionally accepted UK NB CE marked products, is at risk of interruption due to Brexit. The complexity of Brexit places a significant burden on UK NBs which may negatively impact their ability to provide market clearance (i.e., CE Marking) reviews and certifications in a timely manner. Delays in CE Marking and delays in the issuance of certificates could delay us from placing our PoNS device on the market outside of the UK including outside of the EU (for those countries that require quality management system certificates and CE approval prior to marketing).

In December 2018, we submitted an application for a CE Mark, which, if approved, would allow us to market the PoNS device in the European Union. During the second quarter of 2019, we engaged with regulators in Europe to answer questions that we received from them as part of their review of our PoNS device for CE marking. In August 2019, we withdrew our application from the EU marketing process 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 new ISO registrar and new notified body and will reconsider submitting to the EU when conditions stabilize.

As a result of the use of our product candidates 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 will remain a smaller reporting company so long as our public float remains less than $250 million as of the last business day of our most recently-completed second fiscal quarter. 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, such as the material weakness we identified in October 2019, 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.

We have been the victim of a cyber-related crime and our controls may not be successful in avoiding further cyber-related crimes in the future.

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. We are working with law enforcement authorities and the banks involved in the wire transfer to pursue recovery of the $0.1 million, but at this time while law enforcement officials have identified the source of the scam, we do not know whether we will be able to recover any of the funds, and we have been advised that it may take several months before we are better able to evaluate our recovery prospects.

Enhancements have been made to our controls relating to electronic payments by or for us that we believe will reduce our risk of becoming a victim of future frauds related to our payments, including by wire transfers. However, cyber-related criminal activities continue to evolve and increase in sophistication, frequency and severity. As a result, the control enhancements that have been made, and any additional enhancements that may be made in the future, to our controls may not be successful in avoiding our becoming a victim to further cyber-related crimes.

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 internal computer systems, and those of third parties on which we rely, are vulnerable to damage 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. If such an 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

security breach 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 security breach 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 breaches or attacks. 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.

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 United States 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.

In particular, on December 22, 2017, the Tax Cuts & Jobs Act, or TCJA, was signed into law. The legislation significantly changed U.S. tax law by, among other things, lowering the U.S. federal corporate income tax rate from 35% to 21%, implementing a modified territorial tax system and imposing a transition tax on deemed repatriated earnings of foreign subsidiaries, or the Section 965 Transition Tax. Certain changes established by the TCJA increased our effective tax rate in prior years, including a new income inclusion item for global intangible low-taxed income, or GILTI, and the Section 965 Transition Tax on our accumulated offshore earnings held in cash and illiquid assets. Additional changes have impacted the timing of our recognition of certain items of loss and deduction, including a new limitation on the company's deduction for business interest expense, a new limitation of the deduction for NOLs to 80% of current year taxable income, elimination of NOL carrybacks for NOLs arising after December 31, 2017 and the allowance of the indefinite carryforward of such NOLs, and increased bonus depreciation from 50% to 100% for certain qualified property.

Furthermore, the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, was enacted on March 27, 2020 in response to the outbreak of COVID-19 and its consequences. The CARES Act introduced substantial changes to the U.S. tax code, the overall impact of which on our business is uncertain. For example, among other changes, the CARES Act increased the interest expense deductibility limitations and waived certain limitations on the use of NOLs, in each case, temporarily.

On July 23, 2020, final regulations were published that exempt certain income subject to a high rate of foreign tax from inclusion under GILTI for tax years beginning after December 31, 2017.

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

The reverse split of our common stock effected on December 31, 2020 could decrease our total market capitalization and has increased, and may continue to increase, the volatility of our stock price.

At a special meeting of our stockholders on December 28, 2020, our stockholders approved a reverse split of our outstanding common stock at a ratio in the range of 1-for-5 to 1-for-35. Following such special meeting, our board of directors approved a 1-for-35 reverse split of our issued and outstanding shares of common stock. We filed with the Secretary of State of the State of Delaware a Certificate of Amendment to our Certificate of Incorporation to effect the reverse stock split. The reverse stock split was effective as of 5:00 pm

Eastern Time on December 31, 2020, and our common stock began trading on a split-adjusted basis on The Nasdaq Capital Market on January 4, 2021.

There can be no assurance that the total market capitalization of our common stock after the reverse stock split will be equal to or greater than the total market capitalization before the reverse stock split or that the per share market price of our common stock following the reverse stock split will increase in proportion to the reduction in the number of shares of common stock outstanding before the reverse stock split. Furthermore, a decline in the market price of our common stock after the reverse stock split may result in a greater percentage decline than would occur in the absence of a reverse stock split, and the liquidity of our common stock could be adversely affected following such a reverse stock split.

The reverse stock split increased the Company's authorized but unissued shares of common stock, which could negatively impact a potential investor.

Because the number of authorized shares of the Company's common stock was not reduced proportionately, the reverse stock split increased the Board's ability to issue authorized and unissued shares without further stockholder action. The issuance of additional shares of common stock or securities convertible into common stock may have a dilutive effect on earnings per share and relative voting power and may cause a decline in the trading price of the common stock. The Company could use the shares that are available for future issuance in dilutive equity financing transactions, or to oppose a hostile takeover attempt or delay or prevent changes in control or changes in or removal of management, including transactions that are favored by a majority of the stockholders or in which the stockholders might otherwise receive a premium for their shares over then-current market prices or benefit in some other manner.

We could be delisted from The Nasdaq Capital Market, which could seriously harm the liquidity of our stock and our ability to raise capital.

Our common stock is currently listed on The Nasdaq Capital Market. In order to maintain that listing, we must satisfy minimum financial and other continued listing requirements and standards, including those regarding maintaining a minimum share price, director independence and independent committee requirements, minimum stockholders' equity, and certain corporate governance requirements. There can be no assurances that we will be able to comply with the applicable listing standards.

On March 23, 2020, we received a Notice from the Staff of Nasdaq indicating that, based on the closing bid price of the common stock for the 30 consecutive business days preceding the Notice, we no longer meet Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement"). The Notice does not result in the immediate delisting of our common stock from The Nasdaq Capital Market. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were provided a period of 180 calendar days in which to regain compliance. In order to regain compliance with the Minimum Bid Price Requirement, the closing bid price of our common stock must be at least $1.00 for a minimum of ten consecutive business days.

On April 17, 2020, we received the Second Notice for the Staff of Nasdaq stating that the 180-day period to regain compliance with the Minimum Bid Price Requirement has been extended due to the global market impact caused by COVID-19. More specifically, Nasdaq has stated that compliance periods were suspended from April 16, 2020 until June 30, 2020. On July 1, 2020, companies received the balance of any pending compliance period to regain compliance with the Minimum Bid Price Requirement. As a result of this extension, we were given to until December 3, 2020 to regain compliance with the Minimum Bid Price Requirement.

On December 4, 2020, we received notice from the Staff indicating that we were not eligible for an additional 180 day extension to meet the Minimum Bid Price Rule. As a result, the Staff determined that our securities would be subject to delisting unless we timely requested a hearing before the Panel. We timely submitted a request for a hearing before the Panel, which request stayed any suspension or delisting action by Nasdaq at least until the hearing process concluded and any extension granted by the Panel expired. On January 15, 2021, we received a notice from the Staff that our bid price deficiency had been cured, and that we were in compliance with all applicable listing standards, and so the scheduled hearing before the Panel was cancelled.

However, there is no guarantee that we will remain compliant with the requirements of the Nasdaq Capital Market.

If we cease to be eligible to trade on The Nasdaq Capital Market:

- We may have to pursue trading in the United States on a less recognized or accepted market, such as the OTC Bulletin Board or the "pink sheets";
- Shares of our common stock could be less liquid and marketable, thereby reducing the ability of stockholders to purchase or sell our shares as quickly and as inexpensively as they have done historically;

- Our common stock may be deemed a “penny stock,” and transactions in our common stock would be more difficult and cumbersome;
- We may be unable to access capital on favorable terms or at all, as companies trading on alternative markets may be viewed as less attractive investments with higher associated risks, such that existing or prospective institutional investors may be less interested in, or prohibited from, investing in our common stock; and
- The market price of the common stock may further decline.

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 TSX since April 18, 2016 and 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 shares 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.

The United States Tax Cuts and Jobs Act of 2017 could adversely affect our business and financial condition.

The U.S. Tax Cuts and Jobs Act, or the TCJA, significantly reforms the Code. The TCJA, among other things, contains significant changes to U.S. federal corporate income taxation, including reduction of the U.S. federal corporate income tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks for net operating losses arising after December 31, 2017, immediate deductions for certain new investments instead of deductions for depreciation expense over time, and creating, modifying or repealing many business deductions and credits. Federal net operating losses arising in taxable year ending after December 31, 2017 will be carried forward indefinitely pursuant to the TCJA. We continue to examine the impact this tax reform legislation may have on our business. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the TCJA is uncertain and our business and financial condition could be adversely affected. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse.

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 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 2. PROPERTIES

Our head office is located at 642 Newtown-Yardley Road, Suite 100, Newtown, PA 18940, with 2,500 square feet of lease office space. In May 2020, we terminated our lease and entered into a new lease (the “Lease Amendment”) for a smaller footprint of the current office space in Newtown, Pennsylvania. Lease payments under the original contract were made through December 31, 2020. In January 2021, we signed a Lease Amendment extending our current lease term from July 1, 2021 through September 30, 2021, which may be extended on a month-to-month basis thereafter. Monthly rent plus utilities is approximately $5 thousand per month, with a 3% annual increase. We believe our current facilities are 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 shares of common stock trade on the TSX under the symbol "HSM".

On April 11, 2018, our shares of common stock began trading on the Nasdaq under the symbol "HSDT".

Holders

As of March 5, 2021, there were approximately 31 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 not paid any cash dividends on our common stock since our inception and do not anticipate paying any cash dividends in the foreseeable future. We plan to retain our earnings, if any, to provide funds for the expansion of our business.

Recent Sales of Unregistered Securities.

None.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

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 appearing elsewhere in this Annual Report. Further, you should read the following discussion and analysis of our financial condition and results of operations together with the "Item 1A. Risk Factors" included elsewhere in this Annual Report 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". All information is stated in U.S. dollars unless otherwise specified.

Overview

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

Our first product, known as the PoNS™ device, is authorized for sale in Canada as a class II, non-implantable medical device intended for use as a short term treatment (14 weeks) of gait deficit due to symptoms from MS and balance deficit due to mmTBI and is to be used in conjunction with supervised therapeutic exercise. It is an investigational medical device in the United States, the European Union, and Australia. The device is currently under review for de novo classification and clearance by the FDA as a potential treatment for gait deficit due to symptoms of MS. It is also under premarket review by the AUS Therapeutic Goods Administration. PoNS Treatment™ is not currently commercially available in the United States, the European Union or Australia.

Since our inception, we have incurred significant operating losses. Our net loss was $14.1 million and $9.8 million for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, we had an accumulated deficit of $118.9 million. We expect to incur significant expenses and operating losses for the foreseeable future as we continue to advance the PoNS Treatment and seek regulatory clearance and pursue its commercialization. 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 in Canada, manufacturing of a commercially viable version of the PoNS device and demonstration of effectiveness sufficient to generate commercial orders by customers for our product. Moreover, because we expect that the revenue opportunity in the United States is significantly greater than in Canada, we believe our ability to generate significant revenue in the future will be dependent upon the receipt of FDA marketing authorization of the PoNS device. Further, we may incur expenses in connection with the in-license or acquisition of other potential products. See "—Liquidity and Capital Resources" below for additional information.

Business Update

Canadian Regulatory Status: mmTBI and MS

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 our Canadian marketing authorization from Health Canada allowing us to commercialize the PoNS device for the treatment of gait deficit in patients with MS symptoms, when used in conjunction with physical therapy. Our MS market authorization application comprised objective statistical evidence as well as independently reviewed clinical research analysis. We believe this label expansion will significantly expand our addressable market opportunity in Canada to include a patient population that is motivated to pursue treatment options which may resolve or delay the progression of MS gait deficit symptoms.

US Regulatory Status: MS

In March 2020, we announced that based on the quality of the data included in our MS submission package to Health Canada and the significant unmet needs of those afflicted with MS, we are prioritizing the MS indication as the pathway to pursue our first U.S. clearance of the PoNS device. We believe the existing published data and real-world evidence with use of the PoNS for the treatment of gait disorder in patients with MS are sufficient to demonstrate a favorable risk/benefit profile, as required for de novo classification and clearance to enable US marketability. Novel treatments for MS are highlighted as a specific target of the FDA as a high unmet medical need disease.

On May 7, 2020 we received Breakthrough Designation for the PoNS™ device as a potential treatment for gait deficit due to symptoms of Multiple Sclerosis ("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 replaces the Expedited Access Pathway and Priority Review for medical devices. The FDA considers devices granted designation under the Expedited Access Pathway to be part of the Breakthrough Devices Program.

The Breakthrough Devices Program offers manufacturers an opportunity to interact with the FDA's experts through several different program options 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 under section 510(k) of the Food, Drug, and Cosmetic Act.

On August 4, 2020, we submitted our request to the FDA for de novo classification and clearance of the PoNS device for the treatment of gait deficit due to symptoms from MS, to be used as an adjunct to a supervised therapeutic exercise program in patients over 18 years of age.

On October 19, 2020, we announced that we received a request for additional information from the FDA related to the Company’s request for de novo classification and clearance of the PoNS device. During the substantive review phase of a request for de novo classification and clearance, FDA may request additional information in order to obtain information necessary for the FDA to continue or complete its review and, in such instances, places its review on hold until the requested information is submitted. The FDA’s request for additional information was received approximately 75 days from the submission date, which is consistent with FDA’s expected timing for review of a Breakthrough Designated product in the de novo pathway, such as the PoNS device. The FDA’s request for additional information included requests for additional analysis of clinical data and proposed certain labeling modifications. On January 11, 2021, we announced that we submitted our formal response to the FDA’s request for additional information.

On January 14, 2021, the Centers for Medicare & Medicaid Services, or CMS, issued the final rule (CMS-3372-F), 42 C.F.R. § 405.603 on the new Medicare coverage pathway referred to as Medicare Coverage of Innovative Technology, or MCIT, for FDA-designated breakthrough medical devices. The MCIT rule will provide national Medicare coverage as early as the same day as FDA market authorization for breakthrough devices and coverage would last for four years. To be eligible for coverage through MCIT, the breakthrough device must be used for the FDA approved or cleared indication(s) for use. Manufacturers will be able to opt in to MCIT and choose a start date for coverage anytime within two years from the date of FDA market authorization, but coverage will only be valid for four years from market authorization regardless of opt in date. At the end of the four year period, manufacturers are expected to have obtained coding for the specific product which can then be used as the reimbursement pathway for commercial payers. We are working to understand current Medicare requirements and policies for coverage, coding, and payment of durable medical equipment and assesses how the PoNS device may be treated with respect to coding, coverage, and reimbursement under the Medicare program.

US 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 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 Treatment 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 finalized our clinical protocol for a new trial, TBI-002, intended to support a request for de novo classification and clearance of the PoNS device. TBI-002 will be a multi-center, randomized trial in the U.S. and Canada consisting of 103 subjects with balance deficit due to mmTBI. Although TBI-002 will take longer and be more costly than the design that we had discussed at our October 2019 pre-submission meeting, we believe that the

chances of obtaining FDA de novo classification and clearance will be significantly increased if we incorporate the FDA's pre-submission feedback into this next trial design.

TBI-002 will proceed in two phases: a run-in phase, followed by a treatment phase. During the run-in phase, all subjects will receive 5 weeks of physical therapy alone. Subjects will then be randomized and assigned to one of two groups in the treatment phase where subjects will either receive up to 10 weeks of physical therapy with the PoNS device or 10 weeks of physical therapy without the PoNS device. The primary effectiveness endpoint of TBI-002 will be a responder analysis.

Prior to the COVID-19 pandemic, our expectation was that we would move forward with the revised protocol and estimated that enrollment would begin in April 2020 with the completion of the trial and submission to the FDA in the second quarter of 2021. However, the launch of the TBI-002 trial has been temporarily suspended, and we are evaluating our options for funding and timing to commence the trial or potentially look at other indications.

European Regulatory Status

In December 2018, we submitted an application for a CE Mark, which, if approved, would allow us to market the PoNS device in the EU. During the second quarter of 2019, we engaged with regulators in Europe to answer questions that we received from them as part of their review of our PoNS device for CE marking. In August 2019 we withdrew our application from the EU marketing process 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 new ISO registrar and new notified body 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. We are currently awaiting additional feedback from TGA on our application.

Share Purchase Agreement and Co-Promotion Agreement

During the third quarter of 2019, we engaged with HTC through the joint steering committee in discussions regarding the future development of the commercialization of the PoNS device and PoNS Treatment in Canada. As we worked with Heuro to expand the commercial infrastructure, the complexity and feasibility of using a franchise model to build a market for PoNS including the physical therapy component became challenging. By acquiring Heuro, as noted below, we were able to streamline the decision-making process and increase our ability to react to evolving market factors as the market for the PoNS Treatment is being developed.

On October 30, 2019, we and HTC entered into a Share Purchase Agreement, or the SPA, whereby we, through our wholly owned subsidiary, acquired Heuro from HTC. Under the terms of the SPA, total consideration of approximately $1.6 million was transferred to HTC, which included (1) the repayment to HTC for their investment in the set-up of Heuro's initial commercial infrastructure including, the establishment of five authorized PoNS clinics across Canada, (2) the current market value of 55 PoNS devices which we also provided to HTC under the SPA, (3) the forgiveness of the CAD$750 thousand receivable from the September 2018 strategic alliance agreement and (4) the exclusivity rights granted to HTC in the Co-Promotion Agreement, as defined below, to provide PoNS Treatment in the Fraser Valley and Vancouver metro regions of British Columbia.

In connection with the Share Purchase Agreement, on October 30, 2019, we entered into a Clinical Research and Co-Promotion Agreement with HTC, or the Co-Promotion Agreement, whereby each company will promote the sales of the PoNS Treatment and the NeuroCatch™ device throughout Canada. The co-promotion arrangement terminated on December 31, 2020. Also, subject to certain terms and conditions, we granted to HTC the exclusive right to provide the PoNS Treatment in the Fraser Valley and Vancouver metro regions of British Columbia, where HTC has operated a PoNS authorized clinic since February 2019. HTC will purchase 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 exclusivity right has an initial term of ten years, renewable by HTC for one additional ten year term upon sixty days' written notice to us.

Canadian Commercialization Efforts

From a real-world results perspective, in Canada thus far, the collective experience of our patients that have completed the 14-week PoNS Treatment have been encouraging. Consistent with what we saw in our two clinical trials, one for 5 weeks and the other for 14 weeks, commercial MS and TBI patients are demonstrating improvements in balance and gait within the first two weeks followed by

continued improvement over the following twelve weeks. The majority of patients have 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. The consistency of the patient results from our initial commercial experience supports our plans to expand access PoNS Treatment in Canada.

March 2019 marked the commercialization of our PoNS Treatment 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 Treatment. 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.

During the third quarter of 2019, we made the strategic decision to change our business model in Canada in order to accelerate the adoption of our novel technology. On October 30, 2019, we acquired the Heuro Canada operating entity from HTC which allowed us to streamline the decision-making process and increase our ability to react to evolving market factors as the market for the PoNS Treatment is being developed.

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 symptoms from MS, when used in conjunction with physical therapy, was successful and received marketing authorization for PoNS from Health Canada.

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 the first two months of 2020, we authorized 7 new clinic locations for a total of 14 clinic locations to provide PoNS Treatment across Canada. As of June 30, 2020, we had 20 clinic locations which we increased to 22 clinic locations as of September 30, 2020 and to 31 clinic locations as of December 31, 2020. Beginning in 2021, in addition to continuing to increase the number of clinic locations, we have shifted our focus to driving patient throughput to these 31 clinics. Sales performance in Canada continues to be impacted by the COVID-19 pandemic due to space restrictions that the provincial governments have imposed as well as the risk tolerance of patients and therapists.

In collaboration with the Toronto Rehabilitation Institute (part of University Health Network), we are continuing our clinical experience program, the results of which we look to publish in 2021.

We continue to refine our go-to-market pricing model based on market feedback. Our modified pricing approach is focused on reducing the need for clinics and patients to pay large, upfront costs at the start of treatment. We have also experimented with various promotional pricing programs resulting in lower unit prices for both PoNS system purchases and mouthpieces in order to increase access to the PoNS treatment and drive market awareness which we expect to result in an increase in the volume of units sold, which was seen in the second half of 2020 when compared to the second half of 2019. We intend to keep the promotional pricing in place at least through the first half of 2021.

The value dossiers for mmTBI and MS that were created in mid-2020 to fully demonstrate in both scientific and financial terms, the merits of PoNS Treatment for claimants are now being implemented 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 continues to focus on the auto collision insurance and workers' compensation market as well as long-term disability cases. Our reimbursement strategy for MS is focused on commercial insurers/extended health benefits. Moreover, we are currently considering the development of the PoNS device for other potential indications, including stroke, as well as label expansion for our existing indications.

As part of our overall PoNS Treatment strategy, we are also gathering comprehensive health economic assessments of treatment outcomes. These data will, in-turn, be used to support our applications for workers compensation, auto insurance and commercial insurance reimbursement initiatives in Canada, the United States and other markets around the world. The Canadian commercial experience will be extremely valuable to prepare us for our launches in the United States and internationally.

COVID-19 Pandemic

On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 as a global pandemic, which continues to spread throughout the United States and around the world. The Company's business, results of operations and financial condition have been adversely impacted by the COVID-19 pandemic and global economic conditions. The outbreak and spread of COVID-19 has significantly increased economic uncertainty. Authorities implemented numerous measures to try to contain the virus, such as travel bans and restrictions, quarantines, shelter in place orders, and business shutdowns. The COVID-19 pandemic initially led to the closure of PoNS authorized clinic locations across Canada from March until June 2020. Patients who completed their initial training in the clinics prior to the closures have been able to continue working independently in the at-home portion of the treatment, with

remote check-ins with their certified therapists. While all clinics have re-opened, they are all currently operating at reduced capacity within provincial guidelines, which limited operations to 50% capacity during the second half of 2020. Some patients have begun to return to these clinics for treatment, but patients have been and may continue to be less willing to return to the clinics due to COVID-19, impacting our commercial activities and our customer engagement efforts. We have expanded our services to include remote training and treatment, but the long-term viability of these remote programs is still being assessed. In addition, the resurgence of COVID-19 cases across Canada in the fourth quarter of 2020 has led to further restrictions on clinic activities.

Additionally, while we do not currently have any clinical trials underway, we are running clinical experience programs in Canada and have experienced delays in the programs as trial participant attendance has generally decreased as a result of the pandemic, and clinics and clinical research sites have experienced delays and difficulties in recruiting and re-hiring clinical site staff, leading to further delays in the development and approval of the Company's product candidate. As noted above, prior to the COVID-19 pandemic, our expectation was that we would move forward with the launch of our TBI-002 trial and we had estimated that enrollment would begin in April 2020 with the completion of the trial and submission to the FDA in the second quarter of 2021. However, the launch of the TBI-002 trial has been temporarily suspended and we are evaluating our options for funding and timing to commence the trial or potentially look at other indications.

The COVID-19 pandemic and other outbreaks may cause delays in or the suspension of our business partners manufacturing operations, our research and product development activities, our regulatory workstreams, our research and development activities and other important commercial functions. We are also dependent upon our suppliers for the manufacture of our PoNS device, and in the second quarter of 2020, two of our business partners diverted resources towards other activities related to COVID-19, resulting in delays in the development and manufacturing of our product. Such diversion of suppliers' resources may occur again in the future, and the pandemic could limit our suppliers' ability to travel or ship materials or force temporary closure of facilities that we rely upon. Disruptions in business operations or governmental operations due to COVID-19 may delay the timing for the submission and approval of the Company's marketing applications with regulatory agencies. Further, the economic impact of the COVID-19 pandemic could affect our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

The extent to which the COVID-19 pandemic will continue to impact our business, results of operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted. We do not know yet the full extent of the impact of COVID-19 on its business, operations or the global economy as a whole.

Nasdaq Delisting

On March 23, 2020, we received a Notice from the Staff of Nasdaq indicating that, based on the closing bid price of our common stock for the 30 consecutive business days preceding the Notice, we no longer meet the Minimum Bid Price Requirement. The Notice does not result in the immediate delisting of our common stock from Nasdaq. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were provided a period of 180 calendar days in which to regain compliance. In order to regain compliance with the Minimum Bid Price Requirement, the closing bid price of our common stock must be at least $1.00 for a minimum of ten consecutive business days.

On April 17, 2020, we received the Second Notice from Staff of Nasdaq stating that the 180-day period to regain compliance with the Minimum Bid Price Requirement has been extended due to the global market impact caused by COVID-19. More specifically, Nasdaq stated that compliance periods were suspended from April 16, 2020 until June 30, 2020. On July 1, 2020, companies received the balance of any pending compliance period to regain compliance with the Minimum Bid Price Requirement. As a result of this extension, we were given to until December 3, 2020 to regain compliance with the Minimum Bid Price Requirement.

On December 4, 2020, we received notice from the Staff indicating that we were not eligible for an additional 180 day extension to meet the Minimum Bid Price Rule. As a result, the Staff determined that our securities would be subject to delisting unless we timely requested a hearing before the Panel. We timely submitted a request for a hearing before the Panel, which request stayed any suspension or delisting action by Nasdaq at least until the hearing process concluded and any extension granted by the Panel expired. On January 15, 2021, we received notice from the Staff that our bid price deficiency had been cured, and that we were in compliance with all applicable listing standards, and so the scheduled hearing before the Panel was cancelled.

Reverse Stock Split

At a special meeting of our stockholders on December 28, 2020, our stockholders approved a reverse split of our outstanding common stock at a ratio in the range of 1-for-5 to 1-for-35 to be determined at the discretion of our board of directors, whereby each outstanding 5 to 35 shares would be combined, converted and changed into 1 share of our common stock, to enable us to comply with Nasdaq's continued listing requirements.

Following such meeting, our board of directors approved a final reverse stock split ratio of 1-for-35, and we filed with the Secretary of State of the State of Delaware a Certificate of Amendment to our Certificate of Incorporation to effect the reverse stock split. The reverse stock split was effective as of 5:00 pm Eastern Time on December 31, 2020, and our common stock began trading on a split-adjusted basis on The Nasdaq Capital Market on January 4, 2021. The reverse stock split did not change the par value of our stock or the authorized number of common or preferred shares. All share and per share amounts for all periods presented in this Annual Report have been retroactively adjusted for the reverse stock split effected on December 31, 2020.

Financings

See "—Liquidity and Capital Resources" below for information regarding our financing activities in 2020 and subsequent to year-end.

Components of Our Results of Operations

Revenue

We have three categories of revenue: Product Sales, net; Fee Revenue and License Revenue. Product Sales, net is derived from the sale of the PoNS device. Prior to October 30, 2019, it also contained certain support services as explained further below. Fee Revenue was derived from franchise fees from new neuroplasticity clinics engaged in providing the PoNS Treatment. This practice ended during the first quarter of 2020. License Revenue is recognized ratably over the ten-year term as the performance obligation is met in connection with the Co-Promotion Agreement as a result of the Heuro acquisition.

Cost of Sales

Cost of product sales includes the cost to manufacture the PoNS device, royalty expense, freight charges, customs duties as well as wages and salaries of employees involved in the management of the supply chain and logistics of fulfilling sales orders. Prior to the completion of the Heuro acquisition on October 30, 2019, it also included certain support services provided by Heuro on our behalf.

Research and Development Expenses

Research and development, or R&D, expenses consists of expenses incurred in connection with the discovery and development of our product candidates. We expense R&D costs as incurred. These expenses include:

- expenses incurred under agreements with consultants that conduct our clinical trials;
- outsourced professional scientific development services;
- employee-related expenses, which include salaries, benefits and stock-based compensation;
- expenses relating to product development and manufacturing of clinical trial devices;
- expenses relating to regulatory activities, including filing fees paid to regulatory agencies; and
- laboratory materials and supplies used to support our research activities.

R&D activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage registrational clinical trials. We expect our R&D expenses to increase over the next several years as we increase personnel costs, conduct feasibility and pilot studies and registrational clinical trials for additional indications, invest in our product development and manufacturing capabilities and prepare regulatory filings for our product candidate. Our expenditures are subject to certain uncertainties, including those described in Item 1A. "Risk Factors" in this Annual Report.

Selling, General and Administrative Expenses

Selling, general and administrative, or SG&A, expenses consist principally of salaries and related costs for personnel in executive, commercial operations, finance and legal functions, including stock-based compensation, and travel expenses. Other G&A expenses include facility related costs, professional fees for legal, auditing and tax services, consulting, professional services and insurance costs.

We anticipate that our SG&A expenses will increase as a result of increased personnel costs, including stock-based compensation, expanded infrastructure and higher consulting services related to our commercial operations, legal and tax-related services associated with maintaining compliance with Nasdaq and TSX listing and SEC requirements, accounting and investor relations costs, and director and officer insurance premiums associated with being a public company.

Amortization Expense

Amortization expense consists of the periodic amortization of intangible assets, including customer relationships and proprietary software recognized in connection with the acquisition of Heuro on October 30, 2019 and internally developed software. The customer relationships, proprietary software and reacquired rights recognized in connection with the acquisition of Heuro had remaining useful lives at acquisition of 1.25 years, 5 years and 3.87 years, respectively. They are amortized using the straight-line method. The internally developed software has a useful life of 3 years and is amortized using the straight-line method.

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, accounting for warrants and goodwill and other intangible assets.

Revenue Recognition

In accordance with FASB's ASC 606, *Revenue from Contracts with Customers*, ("ASC 606"), we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to be entitled in exchange for those goods or services, in an amount that reflects the consideration which we expect to be entitled in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of ASC 606, we perform the following five steps:

(i) identify the contract(s) with a customer;
(ii) identify the performance obligations in the contract;
(iii) determine the transaction price;
(iv) allocate the transaction price to the performance obligations in the contract; and
(v) recognize revenue when (or as) the entity satisfies a performance obligation.

We apply the five-step model to contracts when we determine that it is probable we will collect substantially all of the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and determine those that are performance obligations and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price, after consideration of variability and constraints, if any, that is allocated to the respective performance obligation when the performance obligation is satisfied.

Product Sales, net

During the first half of 2019, product sales were derived from the sale of the PoNS device and certain support services including services from the use of the NeuroCatch™ device, which is owned by HTC and assesses electroencephalogram brain waves related to cognition of patients participating in the PoNS Treatment at neuroplasticity clinics in Canada. We acted in an agency capacity for services performed using the NeuroCatch device and remitted CAD$600 for each patient assessed with the NeuroCatch device. According to the supply agreement with each of these clinics, our performance obligation was met when we delivered the PoNS device to the clinic's facility and the clinic assumed title of the PoNS device upon acceptance. As such, revenue is recognized at a point in time. Shipping and handling costs associated with outbound freight before control of a product has been transferred to a customer are accounted for as a fulfillment cost and are included in cost of sales. Further, according to our arrangement with HTC and Heuro, we shared 50/50 with Heuro in fees from support services excluding the CAD$600 payment for an assessment using the NeuroCatch device. Subsequent to July 1, 2019, product sales were derived from the sale of the PoNS device alone as the NeuroCatch is sold directly to the neuroplasticity clinics in Canada by HTC. For the year ended December 31, 2019, we recorded $1.45 million in product sales net of $11 thousand for HTC's portion related to assessments using the NeuroCatch device. For the year ended December 31, 2020, we recorded $0.63 million in product sales. As of December 31, 2020, the control of 21 of the 55 PoNS devices included as consideration in the Heuro acquisition had been transferred resulting in revenue of $0.1 million being recognized which is included in the aforementioned $0.63 million in product sales for the year ended December 31, 2020. The fair value of the remaining 34 devices is recorded as deferred revenue of $0.3 million on the consolidated balance sheet. Revenue will be recognized for these

devices as control is transferred. The only returns during 2020 were the result of warranty returns for defective products. These returns were insignificant during the year and any future replacements are expected to be insignificant.

Fee Revenue

During the first half of 2019, our agreement with HTC and Heuro also entitled us to 50% of the franchise fees collected by Heuro from each franchise agreement Heuro executed with neuroplasticity clinics engaged in providing the PoNS Treatment. There were 3 franchise agreements entered into for the year ended December 31, 2019, all of which occurred in the first half of the year. This arrangement ended upon the acquisition of Heuro in October 2019. During the first half of 2020, we earned fee revenue for engaging new neuroplasticity clinics to provide the PoNS Treatment, before terminating these agreements in the second quarter of 2020.

License Revenue

As described above, we modified our arrangement with HTC on October 30, 2019. License revenue will be recognized ratably over the ten year term as the performance obligation is met in connection with the Co-Promotion Agreement.

Stock-Based Compensation

We account for all stock-based payments and awards under the fair value-based method. We recognize our stock-based compensation expense using the straight-line method.

We account for the granting of stock options to employees and non-employees using the fair value method whereby all awards are measured at fair value on the date of the grant. The fair value of all employee-related stock options is expensed over the requisite service period with a corresponding increase to additional paid-in capital. Upon exercise of stock options, the consideration paid by the option holder, together with the amount previously recognized in additional paid-in capital is recorded as an increase to common stock. Stock options granted to employees are accounted for as liabilities when they contain conditions or other features that are indexed to other than a market, performance or service conditions.

Stock-based payments to non-employees are measured based on the fair value of the equity instrument issued. Compensation expense for non-employee stock awards are recognized over the requisite service period following the measurement of the fair value on the grant date over the vesting period of the award.

We use the Black-Scholes option-pricing model to calculate the fair value of stock options. The use of the Black-Scholes option-pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the common stock consistent with the expected term of the option, risk-free interest rates, the value of the common stock and expected dividend yield of the common stock. Changes in these assumptions can materially affect the fair value estimate.

Derivative Financial Instruments

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 embedded derivative is marked-to-market at each balance sheet date and recorded as a liability and the change in fair value is recorded in the consolidated statements of operations and comprehensive loss. Upon conversion or exercise of a derivative financial instrument, the instrument is marked to fair value at the conversion date and then that fair value is reclassified to equity.

The classification of derivative financial instruments, including whether such instruments should be recorded as a liability or as equity, is re-assessed 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 or non-current based on whether or not the right to exercise or settle the derivative financial instrument lies with the holder.

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

Accounting for 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.

The fair value of the warrants is estimated using the Black-Scholes option pricing model, based on the market value of the underlying common stock at the measurement dates, the contractual terms of the warrants, risk-free interest rates and expected volatility of the price of the underlying common stock. There are no expected dividends.

Goodwill and Other Intangible Assets

Goodwill represents the excess of purchase price over the fair values underlying net assets acquired in an acquisition. All of our goodwill as of December 31, 2019 and December 31, 2020 is the result of the Heuro acquisition. Goodwill is not amortized, but rather will be tested annually for impairment or more frequently if events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. We will test goodwill for impairment annually in the fourth quarter of each year using data as of October 1 of that year.

Goodwill is allocated to, and evaluated for impairment at our one identified reporting unit. Goodwill is tested for impairment by either performing a qualitative evaluation or a quantitative test. The qualitative evaluation is an assessment of factors to determine whether it is more likely than not that a reporting unit's fair value is less than its carrying amount. We may elect not to perform the qualitative assessment for our reporting unit and perform the quantitative impairment test. The quantitative goodwill impairment test requires us to compare the carrying value of the reporting unit's net assets to the estimated fair value of the reporting unit.

If the estimated fair value exceeds the carrying value, no further evaluation is required, and no impairment loss is recognized. If the carrying amount of a reporting unit, including goodwill, exceeds the estimated fair value, the excess of the carrying value over the estimated fair value is recorded as an impairment loss, the amount of which is not to exceed the total amount of goodwill allocated to the reporting unit.

Our methodology for estimating the fair value of our reporting unit utilizes the income approach. The income approach is based on the Discounted Cash Flow, or DCF, method, which is based on the present value of future cash flows. The principal assumptions utilized in the DCF methodology include long-term growth rates, operating margins, discount rates and future economic and market conditions. There can be no assurance that our estimates and assumptions regarding forecasted cash flow, long-term growth rates and operating margins made for purposes of the annual goodwill impairment test will prove to be accurate predictions of the future. We believe the current assumptions and estimates utilized are both reasonable and appropriate.

Definite-lived intangibles consist principally of acquired customer relationships, reacquired rights and proprietary software as well as internally developed software. All are amortized straight-line over their estimated useful lives.

Going Concern

From our inception through December 31, 2020, we have generated over $2.0 million in revenue from the commercial sale of products or services. 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 recruitment of patients for treatment in Canada, manufacturing of a commercially viable version of the PoNS device and demonstration of effectiveness sufficient to generate commercial orders by customers for our product. Moreover, because we expect that the revenue opportunity in the United States is significantly greater than in Canada, we believe our ability to generate significant revenue in the future will be dependent upon the receipt of FDA marketing authorization of the PoNS device.

These factors raise substantial doubt about our ability to continue as a going concern through at least 12 months from the date of this Annual Report. While we had $3.3 million of cash as of December 31, 2020 and received net proceeds of $10.9 million in the aggregate from the exercise of outstanding warrants and the issuance and sale of common stock and warrants in a public offering subsequent to December 31, 2020, 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 beginning of the first quarter of 2022. 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 Annual Report.

Results of Operations

The following table summarizes our results of operations for the years ended December 31, 2020 and 2019 (amounts in thousands):

	Year Ended December 31,		
	2020	2019	Change
Revenue:			
Product sales, net	$ 625	$ 1,454	$ (829)
Fee revenue	9	37	(28)
License revenue	27	5	22
Total operating revenue	**661**	**1,496**	**(835)**
Cost of sales:			
Cost of product sales	388	846	(458)
Gross profit	**273**	**650**	**(377)**
Operating expenses:			
Research and development	4,582	8,061	(3,479)
Selling, general and administrative	9,714	16,521	(6,807)
Amortization expense	363	64	299
Total operating expenses	**14,659**	**24,646**	**(9,987)**
Operating loss	(14,386)	(23,996)	9,610
Other income:			
Other income	63	95	(32)
Change in fair value of derivative financial instruments	4	14,113	(14,109)
Foreign exchange gain	189	7	182
Total other income	256	14,215	(13,959)
Net loss	**$ (14,130)**	**$ (9,781)**	**$ (4,349)**

Year Ended December 31, 2020 Compared to Year Ended December 31, 2019

Revenue

For the year ended December 31, 2020, we recognized revenue of $0.7 million, of which $0.63 million was generated through product sales of our PoNS device in Canada pursuant to our executed supply agreements with neuroplasticity clinics in Canada, $9 thousand was generated from fee revenue related to engaging new PoNS authorized clinics, and $27 thousand was generated from license fee revenue related to our co-promotion agreement with HTC. For the year ended December 31, 2019, we recognized revenue of $1.5 million, of which $1.45 million was generated through product sales of our PoNS device in Canada pursuant to our executed supply agreements with neuroplasticity clinics in Canada, $37 thousand was generated in fee revenue from franchise agreements Heuro executed with neuroplasticity clinics engaging in providing the PoNS Treatment and $5 thousand was generated from license fee revenue related to or co-promotion agreement with HTC. The decrease year-over-year in revenue generated through product sales of our PoNS device in Canada is primarily due to pent up demand positively impacting our product sales for the first six months of 2019, the COVID-19 pandemic negatively impacting our product sales beginning in March 2020 and, to a lesser extent, the impact of price changes, focused on reducing the need for clinics and patients to pay large, upfront costs at the start of treatment, that we began implementing in September 2019.

Cost of Sales

For the year ended December 31, 2020, we incurred $0.4 million in our costs of sales, compared to $0.8 million for the year ended December 31, 2019, a decrease of approximately $0.5 million. The decrease is primarily attributable to a decrease in sales during 2020 compared to 2019, offset partially by an increase in inventory reserve of $0.2 million. Cost of sales included the costs to manufacture the PoNS device, royalty expense, freight charges, customs duties as well as wages and salaries of employees involved in the management of the supply chain and logistics of fulfilling our sales orders. Prior to the completion of the Heuro acquisition on October 30, 2019, it also included certain support services provided by Heuro on our behalf.

Research and Development Expenses

Research and development, or R&D, expenses were $4.6 million for the year ended December 31, 2020, compared to $8.1 million for the year ended December 31, 2019, a decrease of approximately $3.5 million. The decrease was primarily driven by a $1.1 million reduction in product development costs due to the completion of the PoNS device development in 2019 and a $0.6 million reduction in

wages and salaries. Medical affairs expenses also decreased $1.0 million due to the effort in 2019 to create awareness of the PoNS device by delivery of clinical and scientific data to key opinion leaders, professional societies and practitioners which was significantly decreased during 2020. Further, professional services fees decreased by $0.6 million.

Selling, General and Administrative Expenses

Selling, general and administrative, or SG&A, expenses were $9.7 million for the year ended December 31, 2020, compared to $16.5 million for the year ended December 31, 2019, a decrease of $6.8 million. The decrease was primarily due to lower stock-based compensation expense of $2.2 million, a $2.1 million decrease in wages and salaries due to higher headcount in 2019, a $2.0 million reduction in commercial operations expense due to our investments in marketing and distribution capabilities in 2019 in support of a potential U.S. launch prior to receiving denial for clearance from the FDA and a $0.7 million reduction in legal expenses. These decreases were partially offset by a $0.2 million impairment loss related to intangible assets in 2020 (related to the customer relationships from the Heuro acquisition), all of which was incurred during the first quarter of 2020 and a $0.1 million loss as the result of the disposal of furniture and fixtures and leasehold improvements.

Amortization Expense

Amortization expense were $0.4 million for the year ended December 31, 2020, compared to $0.1 million for the year ended December 31, 2019, an increase of $0.3 million. The increase was attributable to the intangibles assets being held and amortized for the full year in 2020 compared to two months in 2019.

Change in Fair Value of Derivative Financial Instruments

The change in fair value of derivative financial instruments was a gain of $4 thousand for the year ended December 31, 2020, compared to a gain of $14.1 million for the year ended December 31, 2019.

The change in fair value of derivative financial instruments was primarily attributable a change in our stock price, volatility and the number of derivative financial instruments being measured during the period (see Note 3 to our consolidated financial statements elsewhere in this Annual Report on Form 10-K). The change in the fair value of derivative financial instruments is a non-cash item.

Foreign Exchange Gain

Foreign exchange gain was $189 thousand for the year ended December 31, 2020, compared to a gain of $7 thousand for the year ended December 31, 2019. This was primarily due to fluctuations in the foreign exchange rate as it relates to the amount of Canadian dollars held at the end of each reporting period.

Liquidity and Capital Resources

We currently have limited working capital and liquid assets. The following table summarizes our cash and working capital (which we define as current assets less current liabilities excluding derivative financial instruments) as of December 31, 2020 and 2019 (amounts in thousands):

	As of December 31,	
	2020	2019
Cash	$ 3,331	$ 5,459
Working capital	$ 2,261	$ 3,444

Subsequent to December 31, 2020, we received net proceeds of $10.9 million in the aggregate from the exercise of outstanding warrants and the issuance and sale of common stock and warrants in the Public Offering described below.

From our inception through December 31, 2020, we have generated over $2.0 million in revenue from the commercial sale of products or services. 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 recruitment of patients for treatment in Canada, manufacturing of a commercially viable version of the PoNS device and demonstration of effectiveness sufficient to generate commercial orders by customers for our product. Moreover, because we expect that the revenue opportunity in the United States is significantly greater than in Canada, we believe our ability to generate significant revenue in the future will be dependent upon the receipt of FDA marketing authorization of the PoNS device.

To date, our major sources of cash have been proceeds from various public and private offerings of our common stock and exercises of options and warrants. From June 2014 through December 31, 2020, we raised approximately $106.6 million in gross proceeds from various public and private offerings of our securities as well as the exercise of options and warrants, including during 2020, $9.8 million in aggregate net proceeds from our use of our former At-the-Market program, one registered direct offering and one private placement. In 2021 to date, as described below, we received approximately $10.9 million in net proceeds from the exercise of warrants and the issuance and sale of common stock and warrants in the Public Offering.

For the year ended December 31, 2020, under our former At-the-Market program, we sold and issued 232,526 shares of our common stock with an average price of $21.68 per share. Net proceeds from the At-the-Market program after deducting underwriter's commissions was $4.8 million.

In March 2020, in a registered direct offering, we issued 178,776 shares of our common stock at a price of $12.25 per share and, in a concurrent private placement, unregistered warrants to purchase up to 178,776 shares of our common stock at an exercise price of $16.10 per share. Net proceeds from the offering after deducting underwriter's discounts and commissions and offering expenses paid by us was $1.9 million.

In October 2020, in a private placement, we issued 187,646 shares of our common stock and warrants to purchase up to an aggregate of 93,817 shares of our common stock at a purchase price of $18.20 per unit, consisting of one share and one warrant to purchase 0.50 shares of common stock. The warrants have an initial exercise price of $15.82 per share and are exercisable for a period of three years from the date of issuance. We also issued warrants to the placement agent to purchase 961 shares of common stock, with an exercise price of $19.775 per share. One of our officers and affiliates of another one of our officers and directors participated in the private placement on the same terms and conditions as all other purchasers, except they paid $18.354 per unit and their warrants have an exercise price of $16.1664 per share. Net proceeds from the private placement after underwriter's discounts and commissions and offering expenses paid by us were approximately $3.1 million. Pursuant to the securities purchase agreement for the October 2020 private placement, if we issue any of common stock or common stock equivalents for cash consideration, indebtedness or a combination thereof, with certain exceptions, within twelve months of the closing of the private placement, each purchaser who subscribed for at least $250,000 in the private placement has the right to participate in up to such purchaser's pro rata portion of 30% of the such subsequent financing on the same terms, conditions and price provided for in the subsequent financing.

In January 2021, 81,633 warrants issued in conjunction with the March 2020 registered direct offering were exercised at an exercise price of $16.10 for proceeds of $1.3 million.

On February 1, 2021, in an underwritten public offering (the "Public Offering"), we issued 744,936 shares of common stock and warrants to purchase up to an aggregate of 372,468 shares of common stock at a purchase price of $14.82 per unit, consisting of one share and a warrant to purchase 0.50 shares of common stock. The warrants have an initial exercise price of $16.302 per share and are exercisable for five years from the date of issuance. We also issued warrants to the underwriter to purchase 25,910 shares of common stock, with an exercise price of $18.525 per share. Net proceeds from the Public Offering after underwriter's discounts and commissions and offering expenses paid by us were approximately $9.6 million. Affiliates of one of our officers and directors participated in the Public Offering on the same terms and conditions as all other purchasers.

We intend to use our available capital resources primarily to fund manufacturing activities for the PoNS device, activities related to our submissions for marketing authorization of the PoNS device to the FDA and other regulatory authorities, commercial launch preparations, and for working capital and general corporate purposes.

We believe that our existing capital resources will be sufficient to fund our operations into the first quarter of 2022, but we expect that we will be required to seek additional funding through the sale of equity or debt financing to continue to fund our operations thereafter. 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.

Statements of Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2020 and 2019 (amounts in thousands):

	Year Ended December 31,		Change
	2020	2019	
Net cash used in operating activities	$ (11,738)	$ (20,999)	$ 9,261
Net cash used in investing activities	(9)	(769)	760
Net cash provided by financing activities	9,638	1,653	7,985
Effect of foreign exchange rate changes on cash	(19)	(9)	(10)
Net decrease in cash	$ (2,128)	$ (20,124)	$ 17,996

Year Ended December 31, 2020 Compared to the Year Ended December 31, 2019

Net Cash Used in Operating Activities

Net cash used in operating activities for the year ended December 31, 2020 was $11.7 million. This was comprised of a net loss of $14.1 million, unrealized foreign exchange gains of $0.2 million, gain on lease modification of $0.1 million, change in the fair value of our derivative liabilities of $4 thousand and $1 million net cash used resulting from changes in operating assets and liabilities, partially offset by certain adjustments for non-cash items comprised of stock-based compensation expense of $2.5 million, depreciation and amortization of $0.5 million, provision for inventory reserve of $0.2 million, impairment loss on intangible assets of $0.2 million (related to the customer relationships from the Heuro acquisition), provision for doubtful accounts of $0.1 million and loss on disposal of office furniture of $0.1 million.

Net cash used in operating activities for the year ended December 31, 2019 was $21.0 million. This was comprised of a net loss of $9.8 million, the change in the fair value of our derivative liabilities of $14.1 million and $2.3 million net cash used resulting from changes in operating assets and liabilities, partially offset by certain adjustments for non-cash items comprised of stock-based compensation expense of $4.7 million, depreciation and amortization of $0.2 million, provision for doubtful accounts of $0.2 million, provision for inventory reserve of $0.1 million and unrealized foreign exchange loss of $0.1 million.

Net Cash used in Investing Activities

Net cash used in investing activities for the year ended December 31, 2020 was $9 thousand, which was primarily due to $63 thousand for the purchase of equipment and $7 thousand for internally developed software, offset by $61 thousand in proceeds received from the sale of office furniture.

Net cash used in investing activities for the year ended December 31, 2019 was $0.8 million, which was primarily comprised of $0.4 million for the acquisition of Heuro, and $0.3 million for property and equipment consisting of $0.1 million for computer equipment, $0.1 million for furniture and fixtures at our headquarters location and $0.1 million for equipment that is used in the commercial production of the PoNS device.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the year ended December 31, 2020 was $9.6 million, which was primarily comprised of $2.2 million in gross proceeds received from the March 2020 registered direct offering, $5.0 million in gross proceeds from the sale of common stock under our former At-the-Market program and $3.4 million in gross proceeds received from the October 2020 private placement. These proceeds were partially offset by $1.0 million in issuance costs primarily related to the aforementioned offerings.

Net cash provided by financing activities for the year ended December 31, 2019 was $1.7 million, which was primarily comprised of $1.7 million in gross proceeds received from the November 2019 public offering from the sale of 137,571 shares of our common stock and $0.2 million in proceeds from the exercise of stock options and warrants. These proceeds were partially offset by $0.2 million in issuance costs primarily related to our public offering.

Recently Issued Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which requires measurement and recognition of expected credit losses for financial assets held and requires enhanced disclosures regarding significant estimates and judgments used in estimating credit losses. In November 2019, the FASB issued ASU 2019-10, *Financial Instruments – Credit Losses (Topic 326), Derivatives and Hedging (Topic 815) and Leases (Topic*

842): Effective Dates, which amends the effective date of ASU 2016-13. Public business entities that meeting the definition of an SEC filer, excluding entities eligible to be a Small Reporting Company ("SRC") as defined by the SEC, are required to adopt the standard for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. All other entities are required to adopt the standard for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. We meet the definition of an SRC and therefore the standard will not be effective until the beginning of 2023. We are evaluating the effect that ASU 2016-13 will have on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement*, which adds disclosure requirements to Topic 820 for the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. This ASU is effective for interim and annual reporting periods beginning after December 15, 2019. We adopted this standard as of January 1, 2020 and the adoption did not have a material impact on our consolidated financial statements.

In November 2018, FASB issued ASU 2018-18, C*ollaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606*, which, among other things, provides guidance on how to assess whether certain collaborative arrangement transactions should be accounted for under Topic 606. The amendments in this ASU are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted. We adopted this standard on January 1, 2020 and the adoption did not have a material impact on our consolidated financial statements.

In August 2020, FASB issued ASU 2020-06, *Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40)*, which simplifies accounting for convertible instruments by removing major separation models required under current GAAP. The ASU removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception and it also simplifies the diluted earnings per share calculation in certain areas. The guidance is effective for interim and annual periods beginning after December 15, 2021. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. FASB has specified that an entity should adopt the guidance as of the beginning of its annual fiscal year. The guidance is to be applied using either a full retrospective or modified retrospective method. In applying the full retrospective method, the cumulative effect of the accounting change should be recognized as an adjustment to the opening balance of retained earnings in the first comparative period presented. In applying the modified retrospective method, the cumulative effect of the accounting change should be recognized as an adjustment to the opening balance of retained earnings at the date of adoption. We early adopted ASU 2020-06 effective January 1, 2021 under the modified retrospective approach. We anticipate that the adoption of this guidance will not have a material impact on our consolidated financial statements.

JOBS Act

In April 2012, the Jumpstart Our Business Startups Act of 2012, or JOBS Act, was enacted in the United States. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth public companies. We were an "emerging growth company" until December 31, 2020.

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 Annual Report 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) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, under the direction of the Interim Chief Executive Officer and the Chief Financial Officer, we have evaluated our disclosure controls and procedures as of the end of the period covered by this Annual Report. Based on this evaluation, our Interim 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 Annual Report.

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, 2020. 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, 2020, our internal control over financial reporting was effective.

This Annual Report 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 Annual Report.

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(d) and 15d-15(d) under the Exchange Act that occurred during the quarter ended December 31, 2020 which have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Consulting Arrangement with Jonathan Sackier

On March 8, 2021, the Board and Jonathan Sackier mutually agreed that Mr. Sackier, current Chief Medical Officer of the Company, would transition to a consulting role effective March 8, 2021 (the "Transition Date"). In connection with Mr. Sackier's transition into a consulting role, the Company entered into a Consulting Agreement with Mr. Sackier effective on March 8, 2021 (the "Consulting Agreement"). Pursuant to the Consulting Agreement, Mr. Sackier resigned from his position as an executive officer effective as of the Transition Date, and forfeited all rights to severance under his original employment agreement. The Consulting Agreement provides that Mr. Sackier will receive compensation of $23,333 for the first month of engagement and then $20,000 per month thereafter, in exchange for certain services. The Consulting Agreement will terminate on the one year anniversary of the Transition Date, unless the parties mutually agree in writing to extend the term of the Consulting Agreement. If the term is extended, the Company may terminate the Consulting Agreement upon 12 months' notice. The foregoing summary of the Consulting Agreement does not purport to be complete and is subject to, and qualified in its entirety by, the full text of the Consulting Agreement, a copy of which is filed as Exhibit 10.3 to this Annual Report.

Form of Indemnification Agreement

On March 8, 2021, the Board of Directors of the Company approved a revised form of indemnification agreement (the "Indemnification Agreement") to be entered into between the Company and its current and future directors and executive officers.

The Indemnification Agreement will, among other things, require the Company to indemnify, and advance expenses to, each director and executive officer to the fullest extent permitted by law, including indemnification of expenses such as attorneys' fees, court costs, judgements, fines, penalties, excise taxes and settlement amounts incurred by the director or executive officer in any action or proceeding arising out of such person's services as a director or executive officer. The Indemnification Agreements shall be in addition to any other rights the directors and executive officers may have under the Company's certificate of incorporation and bylaws.

The foregoing description of the Indemnification Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the form of Indemnification Agreement, which is attached as Exhibit 10.24 to this Annual Report.

PART III

We will file a definitive Proxy Statement for our 2021 Annual Meeting of Stockholders (the “2021 Proxy Statement”) with the SEC, pursuant to Regulation 14A, not later than 120 days after the end of our fiscal year. Accordingly, certain information required by Part III has been omitted under General Instruction G(3) to Form 10-K. Only those sections of the 2021 Proxy Statement that specifically address the items set forth herein are incorporated by reference.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by Item 10 is hereby incorporated by reference to the sections of the 2021 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 2021 Proxy Statement under the captions "Executive Compensation" and "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 2021 Proxy Statement under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance under Equity Compensation Plans."

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 2021 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 ACCOUNTANT FEES AND SERVICES

The information required by Item 14 is hereby incorporated by reference to the sections of the 2021 Proxy Statement under the caption "Proposal 2 - Ratification of Independent Registered Public Accounting Firm."

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

The following documents are filed as part of this Annual Report:

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	Bylaws as amended and restated (incorporated by reference to Exhibit 3.3 to the Form 10-Q filed August 9, 2018)
4.1	Form of Warrant (included in Exhibit 4.2)
4.2	Warrant Indenture dated April 18, 2016 by and between Helius Medical Technologies, Inc. and Computershare Investor Services Inc. (incorporated by reference to Exhibit 4.1 to amendment no. 1 to the Form 8-K filed April 18, 2016 and amended on April 20, 2016)
4.3	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)
4.4	Warrant Indenture dated April 11, 2018 by and between Helius Medical Technologies, Inc. and Computershare Trust Company of Canada (incorporated by reference to Exhibit 4.1 to the Form 8-K filed April 12, 2018)
4.5	Form of Warrant (incorporated by reference to Exhibit 4.1 to the Form S-1/A filed January 20, 2021)
4.6	Warrant Agency Agreement (incorporated by reference to Exhibit 4.2 to the Form S-1/A filed January 20, 2021)
4.7*	Description of Registrant's Securities
10.1†	Separation and Release Agreement between Helius Medical Technologies, Inc. and Philippe Deschamps, dated August 23, 2020 (incorporated by reference to Exhibit 10.2 to the Form 8-K filed with the SEC on August 25, 2020)
10.2†	Interim President and CEO Employment Letter Agreement between Helius Medical Technologies, Inc. and Dane C. Andreeff, dated August 23, 2020 (incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on August 25, 2020)
10.3†*	Consulting Agreement between Helius Medical Technologies, Inc. and Jonathan Sackier, dated March 8, 2021
10.4†	Consulting Agreement between Helius Medical, Inc and Mitch Tyler, dated December 10, 2014 (incorporated by reference to Exhibit 10.5 to the Form 10-12G filed with the SEC on February 6, 2015)
10.5	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)
10.6	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)

Exhibit Number	Exhibit
10.7	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)
10.8	Master Cooperative Research and Development Agreement between Helius Medical, Inc, Advanced NeuroRehabilitation, LLC, Yuri Danilov, Mitchell Tyler, Kurt Kaczmarek and U.S. Army Medical Material Agency and U.S. Army Medical Material Development Activity, dated effective February 1, 2013 (incorporated by reference to Exhibit 10.2 to the Form S-1 filed with the SEC on July 14, 2014)
10.9	Notice of Modification No. 1 to Cooperative Research and Development Agreement between Helius Medical, Inc, Advanced NeuroRehabilitation, LLC, Yuri Danilov, Mitchell Tyler, Kurt Kaczmarek and U.S. Army Medical Material Agency and U.S. Army Medical Material Development Activity, dated April 29, 2014 (incorporated by reference to Exhibit 10.5 to the Form S-1 filed with the SEC on July 14, 2014)
10.10	Notice of Modification No. 2 to Cooperative Research and Development Agreement between Helius Medical, Inc, Advanced NeuroRehabilitation, LLC, Yuri Danilov, Mitchell Tyler, Kurt Kaczmarek and U.S. Army Medical Material Agency and U.S. Army Medical Material Development Activity, dated January 12, 2015 (incorporated by reference to Exhibit 10.12 to the Form 10-12G filed with the SEC on February 6, 2015)
10.11	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)
10.12	Commercial Development-to-Supply Program between Helius Medical, Inc and Ximedica, dated October 25, 2013 (incorporated by reference to Exhibit 10.4 to the Form S-1 filed with the SEC on July 14, 2014)
10.13†	Employment Agreement between Helius Medical Technologies, Inc. and Joyce LaViscount, dated October 19, 2015 (incorporated by reference to Exhibit 10.3 to the Form 10-Q filed with the SEC on February 16, 2016)
10.14‡	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)
10.14.1	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)
10.14.2	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)
10.15	Sole-source cost sharing contract between Helius Medical, Inc and the U.S. Army Medical Research and Materiel Command (USAMRMC) dated as of July 7, 2015 (incorporated by reference to Exhibit 10.22 to the Form S-1 filed with the SEC on May 4, 2016)
10.15.1	Amendment to Sole-Source Cost Sharing Contract between Helius Medical, Inc and the U.S. Army Medical Research and Materiel Command (USAMRMC), dated November 7, 2016 (incorporated by reference to Exhibit 10.2 to the Form 8-K filed with the SEC on November 21, 2016)
10.16†	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)
10.16.1†	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)
10.17†	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)
10.17.1†	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)
10.17.2†	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)
10.17.3†	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)

Exhibit Number	Exhibit
10.17.4†	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)
10.20†	2018 Omnibus Incentive Plan, as amended (incorporated by reference to Exhibit 10.2 to the Form 10-Q filed November 8, 2018)
10.20.1†	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)
10.20.2	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)
10.20.3*	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)
10.21	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on March 18, 2020)
10.22	Form of Securities Purchase Agreement dated October 21, 2020 (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on October 26, 2020)
10.23	Non-Employee Director Compensation Policy, effective as of June 10, 2020 (incorporated by reference to Exhibit 10.5 to the Form 10-Q filed on November 12, 2020)
10.24	Form of Indemnification Agreement
21.1*	Subsidiaries of Helius Medical Technologies, Inc.
23.1*	Consent of BDO USA, LLP
31.1*	Certification of Interim 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 Interim 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
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document

* 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 FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
Helius Medical Technologies, Inc.
Newtown, Pennsylvania

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Helius Medical Technologies, Inc. (the "Company") as of December 31, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the years then ended, 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 at December 31, 2020 and 2019, and the results of its operations and its cash flows for the years then ended**,** 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 that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred substantial net losses since its inception, has an accumulated deficit of $118.9 million as of December 31, 2020 and the Company expects to incur further net losses in the development of its business. These conditions raise substantial doubt about its ability to continue as a going concern. Management's plans concerning these matters are also described in Note 1. The consolidated financial statements do not include 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 audits. 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 audits 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 audits 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 audits 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 audits 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 audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated 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 the critical audit matter 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 a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Accounting for Warrants Issued as part of Equity Offerings

As described in Note 3 to the consolidated financial statements, the Company entered into a registered direct offering and a private placement during 2020 that included the issuance of common stock and warrants to purchase common stock. The warrants were

evaluated for proper classification on the balance sheet and it was determined that the warrants issued in these equity offerings should be classified within stockholders' equity.

We identified the accounting for warrants issued as part of these equity offerings as a critical audit matter. Our principal considerations included the existence of subjective judgments related to certain provisions of the warrant agreements in connection with the determination of the classification of the warrants, including provisions related to market volatility and partial cash settlement under certain circumstances. Auditing these elements required especially challenging auditor judgment and significant audit effort, including the need for specialized knowledge and skill in assessing these elements of the agreements.

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

- Reading the agreements related to the warrants issued along with management's technical accounting memos to understand the facts and circumstances within the warrant agreements.

- Utilizing personnel with specialized knowledge and skill in debt and equity accounting to evaluate the appropriateness of management's interpretation on how to apply relevant accounting guidance for the classification of the warrants issued, including evaluating the terms associated with market volatility and partial cash settlement under certain circumstances.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2017.

Philadelphia, Pennsylvania
March 10, 2021

Helius Medical Technologies, Inc.
Consolidated Balance Sheets
(Except for share data, amounts in thousands)

	As of December 31,	
	2020	**2019**
ASSETS		
Current assets		
Cash	$ 3,331	$ 5,459
Accounts receivable, net	74	210
Other receivables	156	364
Inventory, net	389	598
Prepaid expenses	735	610
Total current assets	4,685	7,241
Property and equipment, net	486	712
Other assets		
Goodwill	759	1,242
Intangible assets, net	527	582
Operating lease right-of-use asset, net	90	552
Other assets	—	18
Total other assets	1,376	2,394
TOTAL ASSETS	**$ 6,547**	**$ 10,347**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 747	$ 1,676
Accrued liabilities	1,337	1,519
Operating lease liability	59	172
Derivative financial instruments	—	5
Deferred revenue	281	430
Total current liabilities	2,424	3,802
Non-current liabilities		
Operating lease liability	32	465
Deferred revenue	220	245
TOTAL LIABILITIES	**2,676**	**4,512**
Commitments and contingencies (Note 7)		
STOCKHOLDERS' EQUITY		
Preferred stock, $0.001 par value; 10,000,000 shares authorized, no shares issued and outstanding as of December 31, 2020 and December 31, 2019	—	—
Class A Common stock, $0.001 par value; 150,000,000 shares authorized; 1,484,362 and 877,672 shares issued and outstanding as of December 31, 2020 and December 31, 2019, respectively	1	1
Additional paid-in capital	123,872	111,509
Accumulated other comprehensive loss	(1,099)	(902)
Accumulated deficit	(118,903)	(104,773)
TOTAL STOCKHOLDERS' EQUITY	**3,871**	**5,835**
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 6,547**	**$ 10,347**

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

Helius Medical Technologies, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(Except for share data, amounts in thousands)

	Year Ended December 31,	
	2020	**2019**
Revenue:		
Product sales, net	$ 625	$ 1,454
Fee revenue	9	37
License revenue	27	5
Total operating revenue	**661**	**1,496**
Cost of sales:		
Cost of product sales	388	846
Gross profit	**273**	**650**
Operating expenses:		
Research and development	4,582	8,061
Selling, general and administrative	9,714	16,521
Amortization expense	363	64
Total operating expenses	**14,659**	**24,646**
Operating loss	**(14,386)**	**(23,996)**
Other income:		
Other income	63	95
Change in fair value of derivative financial instruments	4	14,113
Foreign exchange gain	189	7
Total other income	**256**	**14,215**
Net loss	**(14,130)**	**(9,781)**
Other comprehensive loss:		
Foreign currency translation adjustments	(197)	(311)
Comprehensive loss	**$ (14,327)**	**$ (10,092)**
Net loss per share		
Basic	**$ (11.80)**	**$ (12.99)**
Diluted	**$ (11.80)**	**$ (12.99)**
Weighted average shares outstanding		
Basic	**1,197,774**	**752,932**
Diluted	**1,197,774**	**752,932**

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

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

	Common Stock, $0.001 par value		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Shares	Amount				
Balance as of December 31, 2018	**737,938**	**1**	**$ 105,436**	**$ (94,992)**	**$ (591)**	**$ 9,854**
Proceeds from the issuance of common stock from November 2019 Offering	137,571	—	1,685	—	—	1,685
Share issuance costs - November 2019 Offering	—	—	(553)	—	—	(553)
Proceeds from exercise of stock options and warrants	2,136	—	215	—	—	215
Settlement of vested restricted stock units, net of taxes	27	—	—	—	—	—
Reclassification of derivative financial instruments from exercise of warrants	—	—	35	—	—	35
Stock-based compensation	—	—	4,691	—	—	4,691
Foreign currency translation adjustments	—	—	—	—	(311)	(311)
Net loss	—	—	—	(9,781)	—	(9,781)
Balance as of December 31, 2019	**877,672**	**$ 1**	**$ 111,509**	**$ (104,773)**	**$ (902)**	**$ 5,835**

	Common Stock, $0.001 par value		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Shares	Amount				
Balance as of December 31, 2019	**877,672**	**$ 1**	**$ 111,509**	**$ (104,773)**	**$ (902)**	**$ 5,835**
Proceeds from the issuance of common stock from At-the-Market program	232,526	—	5,043	—	—	5,043
Proceeds from issuance of common stock from the March 2020 Offering	178,776	—	1,348	—	—	1,348
Warrant issuance from the March 2020 Offering	—	—	842	—	—	842
Proceeds from issuance of common stock from the October 2020 Private Placement	187,646	—	2,791	—	—	2,791
Warrant issuance from the October 2020 Private Placement	—	—	629	—	—	629
Share issuance costs	—	—	(819)	—	—	(819)
Settlement of restricted stock units	7,792	—	—	—	—	—
Reverse stock split rounddown	(50)	—	—	—	—	—
Stock-based compensation	—	—	2,529	—	—	2,529
Foreign currency translation adjustments	—	—	—	—	(197)	(197)
Net loss	—	—	—	(14,130)	—	(14,130)
Balance as of December 31, 2020	**1,484,362**	**$ 1**	**$ 123,872**	**$ (118,903)**	**$ (1,099)**	**$ 3,871**

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

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

	Year Ended December 31,	
	2020	2019
Cash flows from operating activities		
Net loss	$ (14,130)	$ (9,781)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of derivative financial instruments	(4)	(14,113)
Stock-based compensation expense	2,529	4,691
Unrealized foreign exchange (gain) loss	(182)	70
Depreciation expense	119	127
Amortization expense	363	64
Provision for doubtful accounts	140	220
Provision for inventory reserve	205	50
Intangible asset impairment	184	—
Loss from disposal of property and equipment	110	—
Gain on lease modification	(56)	—
Changes in operating assets and liabilities:		
Accounts receivable	(4)	(438)
Other receivables	226	(278)
Inventory	4	(256)
Prepaid expenses	(125)	(163)
Other current assets	—	264
Operating lease liability	(28)	(13)
Account payable	(635)	(1,116)
Accrued liabilities	(280)	(327)
Deferred revenue	(174)	—
Net cash used in operating activities	**(11,738)**	**(20,999)**
Cash flows from investing activities		
Purchase of property and equipment	(63)	(278)
Proceeds from sale of property and equipment	61	—
Business acquisitions, net of cash acquired	—	(416)
Internally developed software	(7)	(75)
Net cash used in investing activities	**(9)**	**(769)**
Cash flows from financing activities		
Proceeds from the issuances of common stock and warrants	10,653	1,685
Share issuance costs	(1,015)	(247)
Proceeds from the exercise of stock options and warrants	—	215
Proceeds from Paycheck Protection Program Loan	323	—
Repayment of Paycheck Protection Program Loan	(323)	—
Net cash provided by financing activities	**9,638**	**1,653**
Effect of foreign exchange rate changes on cash	(19)	(9)
Net decrease in cash	(2,128)	(20,124)
Cash at beginning of year	5,459	25,583
Cash at end of year	**$ 3,331**	**$ 5,459**
Supplemental disclosure of non-cash cash activities		
Cash paid for interest	$ —	$ —
Cash paid for income taxes	—	—
Supplemental schedule of non-cash investing and financing activities		
Share issuance costs included in accounts payable and accrued liabilities	$ 162	$ 358
Reclassification of derivative instruments from warrant exercise	—	35
Noncash items related to Heuro acquisition	—	1,227

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

1. DESCRIPTION OF BUSINESS

Helius Medical Technologies, Inc. (the "Company"), is neurotech company focused on neurological wellness. The Company's purpose is to develop, license or acquire unique and non-invasive technologies targeted at reducing symptoms of neurological disease or trauma.

The Company's first product, known as the Portable Neuromodulation Stimulator ("PoNS™"), is authorized for sale in Canada as a class II, non-implantable medical device intended for use as a short term treatment (14 weeks) of gait deficit due to symptoms from multiple sclerosis ("MS",) and balance deficit due to mild-to-moderate traumatic brain injury ("mmTBI") and is to be used in conjunction with supervised therapeutic exercise ("PoNS Treatment™"). It is an investigational medical device in the United States, the European Union ("EU"), and Australia ("AUS"). The device is currently under review for de novo classification and clearance by the U.S. Food and Drug Administration (the "FDA") as a potential treatment for gait deficit due to symptoms of MS. It is also under premarket review by the AUS Therapeutic Goods Administration. PoNS Treatment™ is not currently commercially available in the United States, the European Union or Australia.

The Company was incorporated in British Columbia, Canada, on March 13, 2014. On May 28, 2014, the Company completed a continuation via a plan of arrangement whereby the Company moved from being a corporation governed by the British Columbia Corporations Act to a corporation governed by the Wyoming Business Corporations Act. On July 20, 2018, the Company completed its reincorporation from Wyoming to the state of Delaware. The Company is headquartered in Newtown, Pennsylvania. On December 21, 2018, the Company's wholly owned subsidiary, NeuroHabilitation Corporation, changed its name to Helius Medical, Inc ("HMI"). On January 31, 2019, the Company formed another wholly owned subsidiary, Helius NeuroRehab, Inc., ("HNR"), a Delaware corporation. On October 10, 2019, the Company formed Helius Canada Acquisition Ltd. ("HCA"), a company incorporated under the federal laws of Canada and a wholly owned subsidiary of Helius Medical Technologies (Canada), Inc. ("HMC"), a company incorporated under the federal laws of Canada, which acquired Heuro Canada, Inc. ("Heuro") from Health Tech Connex Inc. ("HTC") on October 30, 2019.

The Company's wholly owned subsidiaries are comprised of HMI, HMC, HCA and HNR.

The Company's Class A common stock, par value $0.001 per share ("common stock") is listed on the Nasdaq Capital Market ("Nasdaq") and the Toronto Stock Exchange (the "TSX"). The common stock began trading on the Canadian Securities Exchange on June 23, 2014, under the ticker symbol "HSM" and the trading was subsequently transferred to the TSX on April 18, 2016. On April 11, 2018, the common stock began trading on Nasdaq under the ticker symbol "HSDT" after having traded on the OTCQB in the United States under the ticker symbol "HSDT" since February 10, 2015.

Reverse Stock Split

Effective after the close of business on December 31, 2020, the Company completed a 1-for-35 reverse stock split of its common stock. All share and per share amounts in this Annual Report have been reflected on a post-split basis.

Going Concern Uncertainty

As of December 31, 2020, the Company had cash of $3.3 million. For the year ended December 31, 2020, the Company incurred a net loss of $14.1 million and, as of December 31, 2020, its accumulated deficit was $118.9 million. For the year ended December 31, 2020, the Company had $0.7 million of revenue from the commercial sale of products or services. The Company expects to continue to incur operating losses and net cash outflows until 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 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 on hand, cash received from the sale of its PoNS device in Canada and by raising additional capital through equity or debt financings. As discussed further in Note 10, in January 2021, the Company received $1.3 million in net proceeds from the exercise of warrants issued in the March 2020 registered direct offering and on February 1, 2021, closed a public offering and received net proceeds of approximately $9.6 million. There can be no assurance that the Company will be successful in raising that 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 and planned capital expenditures.

Risks and Uncertainties

COVID-19

On March 11, 2020, the World Health Organization declared the outbreak of a novel coronavirus ("COVID-19") as a global pandemic, which continues to spread throughout the United States and around the world. The Company's business, results of operations and financial condition have been and may continue to be adversely impacted by the COVID-19 pandemic and global economic conditions. The outbreak and spread of COVID-19 has significantly increased economic uncertainty. Authorities implemented numerous measures to try to contain COVID-19, such as travel bans and restrictions, quarantines, shelter in place orders, and business shutdowns. The COVID-19 pandemic initially led to the closure of PoNS Authorized clinic locations across Canada. While all clinics have re-opened, they are all currently operating at reduced capacity, and patients have been and may continue to be less willing to return to these clinics, impacting our commercial activities and our customer engagement efforts. Moreover, the Company's ability to conduct its ongoing clinical experience programs in Canada has been and may continue to be impaired due to trial participants' attendance being adversely affected by COVID-19, leading to further delays in the development and approval of the Company's product candidate. In addition, the COVID-19 pandemic has and may continue to cause delays in the Company's suppliers' ability to ship materials that the Company relies upon, and disruptions in business or governmental operations due to COVID-19 may delay the timing for the submission and approval of the Company's marketing applications with regulatory agencies. Further, the economic impact of the COVID-19 pandemic could affect the Company's ability to access the public markets and obtain necessary capital in order to properly capitalize and continue its operations.

The extent to which the COVID-19 pandemic will continue to impact the Company's business, results of operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted. The Company does not know yet the full extent of the impact of COVID-19 on its future business, operations or the global economy as a whole.

Nasdaq Delisting

On March 23, 2020, the Company received notice from the Staff of Nasdaq that the bid price for the Company's common stock had closed below $1.00 per share for the prior 30 consecutive business day period and that the Company had been granted a 180-day grace period, through September 21, 2020, to regain compliance with Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement"). Thereafter, on April 17, 2020, the Company received an additional notice from the Staff indicating that Nasdaq had temporarily stayed enforcement of the Minimum Bid Price Rule through June 30, 2020, and accordingly, the 180-day grace period applicable to the Company would not expire until December 3, 2020.

On December 4, 2020, the Company received notice from the Staff indicating that the Company was not eligible for an additional 180-day extension to meet the Minimum Bid Price Rule. As a result, the Staff determined that the Company's securities would be subject to delisting unless the Company timely requested a hearing before the Panel. The Company timely submitted a request for a hearing before the Panel, which request stayed any suspension or delisting action by Nasdaq at least until the hearing process concluded and any extension granted by the Panel expired. On January 15, 2021, the Company received notice from the Staff that the bid price deficiency of the Company had been cured, and that the Company was in compliance with all applicable listing standards, and so the scheduled hearing before the Panel was cancelled.

2. SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The Company's reporting currency is the U.S. Dollar ("USD$").

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, derivative financial instruments and deferred income tax asset valuation allowance. Financial statements include estimates, which, by their nature, are uncertain. Actual results could differ from those estimates.

Principles of Consolidation

The accompanying consolidated financial statements reflect the operations of Helius Medical Technologies, Inc. and its wholly owned subsidiaries. The usual condition for a controlling financial interest is ownership of a majority of the voting interests of an entity. However, a controlling financial interest may also exist through arrangements that do not involve controlling voting interests. As such, the Company applies the guidance of the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 810 – *Consolidation* ("ASC 810"), to determine when an entity that is insufficiently capitalized or not controlled through its voting interests, referred to as a variable interest entity should be consolidated. All intercompany balances and transactions have been eliminated.

Concentrations of Credit Risk

The Company is subject to credit risk with respect to its cash. Amounts invested in such instruments are limited by credit rating, maturity, industry group, investment type and issuer. The Company is not currently exposed to any significant concentrations of credit risk from these financial instruments. The Company seeks to maintain safety and preservation of principal and diversification of risk, liquidity of investments sufficient to meet cash flow requirements and a competitive after-tax rate of return.

Receivables

Accounts receivables are stated at their net realizable value. In determining the appropriate allowance for doubtful accounts, the Company considers a combination of factors, such as the aging of trade receivables, its customers' financial strength, and payment history. Changes in these factors, among others, may lead to adjustments in the Company's allowance for doubtful accounts. The calculation of the allowance requires judgment by Company management. As of December 31, 2020, the Company's accounts receivable of $0.1 million, is net of an allowance for doubtful accounts of $0.4 million and is the result of revenue from product sales. As of December 31, 2019, the Company's accounts receivable of $0.2 million, is net of an allowance for doubtful accounts of $0.2 million and is the result of revenue from product sales.

Other receivables included Goods and Services Tax ("GST"), Quebec Sales Tax ("QST") refunds related to the Company's Canadian expenditures of $0.1 million, and receivable from rent deposits of $18 thousand and refunds from research and development ("R&D") tax credits of $1 thousand as of December 31, 2020. Other receivables included refunds from R&D tax credits of $0.2 million and GST and QST refunds related to the Company's Canadian expenditures of $0.1 million as of December 31, 2019.

Inventory

The Company's inventory consists of raw materials, work in progress and finished goods of the PoNS device. Inventory is stated at the lower of cost (average cost method) or net realizable value. Adjustments to reduce the cost of inventory to its net realizable value are made if required. 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. Inventory markdowns to net realizable value of $205 thousand were recorded during the year ended December 31, 2020. Inventory markdowns to net realizable value of $50 thousand were recorded during the year ended December 31, 2019.

As of December 31, 2020 and 2019, inventory consisted of the following (amounts in thousands):

	As of December 31, 2020	As of December 31, 2019
Raw materials	$ 160	$ 144
Work-in-process	440	375
Finished goods	44	129
Inventory	**$ 644**	**$ 648**
Inventory reserve	(255)	(50)
Total inventory, net of reserve	**$ 389**	**$ 598**

Property and Equipment

Property and equipment are carried at cost, less accumulated depreciation. Depreciation is recognized using the straight-line method over the useful lives of the related asset or the term of the related lease. Expenditures for maintenance and repairs, which do not

improve or extend the expected useful life of the assets, are expensed to operations while major repairs are capitalized. The estimated useful life of its leasehold improvements is over the shorter of its lease term or useful life of 5 years, the estimated useful life of furniture and fixtures is 7 years; equipment has an estimated useful life of 15 years and computer software and hardware has an estimated useful life of 3 to 5 years.

The following tables summarizes the Company's property and equipment as of December 31, 2020 and 2019 (amounts in thousands):

	As of December 31,	
	2020	2019
Leasehold improvement	$ 64	$ 182
Furniture and fixtures	93	247
Equipment	335	286
Computer hardware and software	197	182
Property and equipment	689	897
Less accumulated depreciation	(203)	(185)
Property and equipment, net	$ 486	$ 712

Depreciation expense was $119 thousand and $127 thousand for the years ended December 31, 2020 and 2019, respectively.

During 2019, the Company wrote-off $17 thousand of fully depreciated software. During the second quarter of 2020, the Company sold furniture and fixtures with a net book value of $118 thousand for $61 thousand. Additionally, the Company abandoned leasehold improvements with a net book value of $53 thousand. The loss on the disposal of the furniture and fixtures and leasehold improvements of $110 thousand was recorded as selling, general and administrative expense in the consolidated statements of operations and comprehensive loss.

Business Combinations

Transactions in which the Company obtains control of a business are accounted for according to the acquisition method as described in FASB ASC 805 – Business Combinations. The assets acquired and liabilities assumed are recognized and measured at their fair values as of the date control is obtained. Acquisition related costs in connection with a business combination are expensed as incurred. Contingent consideration is recognized and measured at fair value at the acquisition date and until paid re-measured on a recurring basis. It is classified as a liability based on appropriate GAAP.

On October 30, 2019, the Company and HTC entered into a Share Purchase Agreement (the "SPA") whereby the Company, through its wholly owned subsidiary, acquired Heuro from HTC. Under the terms of the SPA, total consideration of approximately CAD$2.1 million (USD$1.6 million) was transferred to HTC, which included (1) cash of CAD$0.5 million (USD$0.4 million), (2) delivery of 55 PoNS devices for which the fair value was determined to be CAD$0.5 million (USD$0.4 million), (3) the forgiveness of the CAD$750 thousand (USD$0.5 million) receivable from the September 2018 strategic alliance agreement and (4) the exclusivity rights granted to HTC in the Co-Promotion Agreement (as defined below) to provide PoNS Treatment in the Fraser Valley and Vancouver metro regions of British Columbia with a determined fair value of CAD$0.4 million (USD$0.3 million). The transaction has been accounted for as a business combination.

The operating results of Heuro have been included in the consolidated statement of operations and comprehensive loss since the date of the acquisition.

The acquisition related costs were $0.1 million and were accounted for as selling, general and administrative expenses in the consolidated statement of operations and comprehensive loss for the year ended December 31, 2019.

Supplemental proforma financial information has not been presented here because the proforma effects of this acquisition are not material to the Company's reported results for any period presented.

The following table summarizes the recognized fair values of identifiable assets acquired and liabilities assumed as of October 30, 2019:

	October 30, 2019 Fair Value
Assets:	
Cash and cash equivalents	$ 1
Other receivables	19
Fixed assets	7
Intangibles	1,053
Goodwill	737
Total assets	**$ 1,817**
Liabilities:	
Accounts payable	186
Other current liabilities	9
Total liabilities	**$ 195**
Net assets acquired	**$ 1,622**

The fair values assigned to identifiable intangible assets assumed were based on management's estimates and assumptions as of such date and are considered finalized. The Company recorded measurement adjustments of $0.4 million during the year ended December 31, 2020, all of which was recorded during the first quarter of 2020. The recorded adjustments related to the recognition of reacquired exclusivity rights.

Acquired intangibles consisted of customer relationships, proprietary technology and reacquired rights. The useful life at acquisition was 1.25 years, 5 years and 3.87 years, respectively, and the acquired intangibles are amortized using the straight-line method.

Factors considered by the Company in determination of goodwill include synergies, strategic fit and other benefits that do not meet the recognition criteria of acquired identifiable intangible assets. The recognized goodwill of $0.7 million is not expected to be deductible for tax purposes.

The fair value of 55 PoNS devices which the Company agreed to transfer to HTC pursuant to the SPA in the amount of CAD$0.5 million will be recognized as revenue within the consolidated statements of operations and comprehensive loss once control has been transferred in accordance with ASC 606. As of December 31, 2019, the control had not been transferred resulting in the fair value being recorded as deferred revenue on the consolidated balance sheet. As of December 31, 2020, the control of 21 devices had been transferred resulting in recognition of revenue for these devices. The fair value of the remaining 34 devices is still recorded as deferred revenue on the consolidated balance sheet.

In connection with the SPA, on October 30, 2019, the Company entered into a Clinical Research and Co-Promotion Agreement with HTC (the "Co-Promotion Agreement"), whereby each company will promote the sales of the PoNS Treatment and the NeuroCatch™ device throughout Canada. This co-promotion arrangement was to terminate upon the earlier of the collection of data from 200 patients in Canada and December 31, 2020, of which December 31, 2020 occurred earlier. Also, subject to certain terms and conditions, Helius granted to HTC the exclusive right to provide the PoNS Treatment in the Fraser Valley and Vancouver metro regions of British Columbia, where HTC has operated a PoNS authorized clinic since February 2019. HTC will 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 right has an initial term of ten years, renewable by HTC for one additional ten year term upon sixty days' written notice to Helius. The Co-Promotion Agreement had a fair value of CAD$360 thousand at the time of acquisition. License revenue will be recognized in connection with the Co-Promotion Agreement ratably over the ten year term.

Goodwill and Other Intangible Assets

Goodwill represents the excess of purchase price over the fair values underlying net assets acquired in an acquisition. All of the Company's goodwill as of December 31, 2020 is the result of the Heuro acquisition discussed above. Goodwill is not amortized, but rather will be tested annually for impairment or more frequently if events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. The Company will test goodwill for impairment annually in the fourth quarter of each year using data as of October 1 of that year.

Goodwill is allocated to, and evaluated for impairment at the Company's one identified reporting unit. Goodwill is tested for impairment by either performing a qualitative evaluation or a quantitative test. The qualitative evaluation is an assessment of factors to

determine whether it is more likely than not that a reporting unit's fair value is less than its carrying amount. The Company may elect not to perform the qualitative assessment for its reporting unit and perform the quantitative impairment test. The quantitative goodwill impairment test requires the Company to compare the carrying value of the reporting unit's net assets to the estimated fair value of the reporting unit.

If the estimated fair value exceeds the carrying value, no further evaluation is required, and no impairment loss is recognized. If the carrying amount of a reporting unit, including goodwill, exceeds the estimated fair value, the excess of the carrying value over the estimated fair value is recorded as an impairment loss, the amount of which is not to exceed the total amount of goodwill allocated to the reporting unit.

The Company's methodology for estimating the fair value of our reporting unit utilizes the income approach. The income approach is based on the Discounted Cash Flow ("DCF") method, which is based on the present value of future cash flows. The principal assumptions utilized in the DCF methodology include long-term growth rates, operating margins, discount rates and future economic and market conditions. There can be no assurance that the Company's estimates and assumptions regarding forecasted cash flow, long-term growth rates and operating margins made for purposes of the annual goodwill impairment test will prove to be accurate predictions of the future.

The COVID-19 pandemic and its continuing impact was considered a triggering event for testing whether goodwill is impaired. The Company performed quantitative assessments at March 31, 2020, June 30, 2020 and September 30, 2020. As a result of these assessments, the Company determined that the estimated fair value of the reporting unit exceeded the carrying value of the reporting unit. Therefore, the Company concluded that goodwill was not impaired as of any of the aforementioned periods. The Company will continue to monitor the impacts of the COVID-19 pandemic in future periods.

Based on the Company's most recent annual impairment analysis as of October 1, 2020, the fair value of the Company's reporting unit exceeded the carrying value, and therefore no indicators of impairment existed for the reporting unit.

The following is a summary of the activity for the years ended December 31, 2020 and December 31, 2019 for goodwill:

Carrying amount at December 31, 2018	$	—
Business acquisition		1,226
Foreign currency translation		16
Carrying amount at December 31, 2019	$	1,242
Business acquisition fair value allocation adjustment		(503)
Foreign currency translation		20
Carrying amount at December 31, 2020	$	759

Definite-lived intangibles consist principally of acquired customer relationships, proprietary software and reacquired rights as well as internally developed software. All are amortized straight-line over their estimated useful lives. Amortization expense related to intangible assets was $0.4 million and $0.1 million during the year ended December 31, 2020 and the year ended December 31, 2019, respectively. During the year ended December 31, 2020, the Company incurred an intangible asset impairment loss of $0.2 million related to the customer relationships, all of which was incurred during the first quarter of 2020, which is included in selling, general and administrative expenses in the accompanying consolidated statement of operations and comprehensive loss.

Intangible assets as of December 31, 2020 and December 31, 2019 consist of the following:

		As of December 31, 2020		As of December 31, 2019	
	Useful Life	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Customer relationships	1.25 years	$ 237	$ (228)	$ 423	$ (55)
Acquired proprietary software	5 years	150	(35)	148	(5)
Reacquired rights	3.87 years	503	(152)	—	—
Internally developed software	3 years	82	(30)	75	(4)
Total intangible assets		$ 972	$ (445)	$ 646	$ (64)

Amortization expense is anticipated to be as follows in future years:

For the Year Ending December 31,	
2021	$ 197
2022	183
2023	122
2024	25
	$ 527

Internally Developed Software Costs

The Company follows ASC 350-40, Accounting for the Costs of Computer Software Developed or Obtained for Internal Use, in accounting for its internally developed software costs. Costs incurred during the preliminary project work stage or conceptual stage, such as determining the performance requirements, system requirements and data conversion, are expensed as incurred. Costs incurred in the application development phase, such as coding, testing for new software and upgrades that result in additional functionality, are capitalized and are amortized using the straight-line method over the useful life of the software, which was determined to be three years. Amortization of these capitalized costs commences when the software becomes ready for its intended use. Costs incurred during the post-implementation stage, such as maintenance and application training, are expensed as incurred.

Leases

On January 1, 2019, the Company adopted ASU No. 2016-02, *Leases*, using the modified retrospective method. The Company elected the package of practical expedients permitted under the transition guidance within the new standard which allowed the Company to carry forward the historical lease

classification. Adoption of this standard resulted in the recording of an operating lease right-of-use ("ROU") asset and corresponding operating lease liabilities of $0.7 million on January 1, 2019.

The Company does not record an operating lease ROU asset and corresponding lease liability for leases with an expected term of twelve months or less and recognizes lease expense for these leases as incurred over the lease term. The Company had only one operating lease, which was for its headquarters office in Newtown, Pennsylvania upon the adoption date. As of December 31, 2020, the Company has not entered into any additional lease arrangements, but did modify the existing lease arrangement. Operating lease ROU assets and operating lease liabilities are recognized upon the adoption date based on the present value of lease payments over the lease term. The Company does not have a public credit rating and as such used a corporate yield with a "CCC" rating by S&P Capital IQ with a term commensurate with the term of its lease as its incremental borrowing rate in determining the present value of lease payments. Lease expense is recognized on a straight-line basis over the lease term. The Company's lease arrangement does not have lease and non-lease components which are to be accounted for separately (see Note 7).

Foreign Currency

The Company's functional currency is the U.S. dollar. Monetary assets and liabilities denominated in foreign currencies are translated into U.S. dollars using exchange rates in effect at the balance sheet date. Opening balances related to non-monetary assets and liabilities are based on prior period translated amounts, and non-monetary assets acquired, and non-monetary liabilities incurred after April 1, 2018 are translated at the approximate exchange rate prevailing at the date of the transaction. Revenue and expense transactions are translated at the approximate exchange rate in effect at the time of the transaction. Foreign exchange gains and losses are included in the consolidated statement of operations and comprehensive loss as foreign exchange gain (loss).

The functional currency of HMC and HCA, the Company's Canadian subsidiaries, is the CAD$ and the functional currency of HMI and HNR is the USD$. Transactions in foreign currencies are recorded into the functional currency of the relevant subsidiary at the exchange rate in effect at the date of the transaction. Any monetary assets and liabilities arising from these transactions are translated into the functional currency at exchange rates in effect at the balance sheet date or on settlement. Revenues, expenses and cash flows are translated at the weighted-average rates of exchanges for the reporting period. The resulting currency translation adjustments are not included in the Company's consolidated statements of operations and comprehensive loss for the reporting period, but rather are accumulated and gains and losses are recorded in foreign exchange gain (loss), as a component of comprehensive loss, within the consolidated statements of operations and comprehensive loss.

Stock-Based Compensation

The Company accounts for all stock-based payments and awards under the fair value-based method. The Company recognizes its stock-based compensation expense using the straight-line method. Compensation cost is not adjusted for estimated forfeitures, but instead is adjusted upon an actual forfeiture of a stock option.

The Company accounts for the granting of stock options to employees and non-employees using the fair value method whereby all awards are measured at fair value on the date of the grant. The fair value of all employee stock options is expensed over the requisite service period with a corresponding increase to additional paid-in capital. Upon exercise of stock options, the consideration paid by the option holder is recorded in additional paid-in capital, while the par value of the shares received is reclassified from additional paid in capital to common stock. Stock options granted to employees are accounted for as liabilities when they contain conditions or other features that are indexed to other than a market, performance or service condition.

In accordance with ASU 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"), stock-based payments to non-employees are measured based on the fair value of the equity instrument issued. Compensation expense for non-employee stock awards is recognized over the requisite service period following the measurement of the fair value on the grant date over the vesting period of the award.

The Company uses the Black-Scholes option-pricing model to calculate the fair value of stock options. The use of the Black-Scholes option-pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the common stock consistent with the expected term of the option, risk-free interest rates, the value of the common stock and expected dividend yield of the common stock. Changes in these assumptions can materially affect the fair value estimate.

Awards of options that provide for an exercise price that is not denominated in: (a) the currency of a market in which a substantial portion of the Company's equity securities trades in, (b) the currency in which the employee's pay is denominated, or (c) the Company's functional currency, are required to be classified as liabilities.

Revenue Recognition

In accordance with FASB's ASC 606, *Revenue from Contracts with Customers*, ("ASC 606"), the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to be entitled in exchange for those goods or services, in an amount that reflects the consideration which the Company expects to be entitled in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, it performs the following five steps:

(i) identify the contract(s) with a customer;
(ii) identify the performance obligations in the contract;
(iii) determine the transaction price;
(iv) allocate the transaction price to the performance obligations in the contract; and
(v) recognize revenue when (or as) the entity satisfies a performance obligation.

The Company applies the five-step model to contracts when it determines that it is probable it will collect substantially all of the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price, after consideration of variability and constraints, if any, that is allocated to the respective performance obligation when the performance obligation is satisfied.

Product Sales, net

During the first half of 2019, product sales were derived from the sale of the PoNS device and certain support services including services from the use of the NeuroCatch™ device, which is owned by HTC and assesses electroencephalogram brain waves related to cognition of patients participating in the PoNS Treatment at neuroplasticity clinics in Canada. The Company acted in an agency capacity for services performed using the NeuroCatch device and remitted CAD$600 for each patient assessed with the NeuroCatch device. According to the supply agreement with each of these clinics, the Company's performance obligation was met when it delivered the PoNS device to the clinic's facility and the clinic assumed title of the PoNS device upon acceptance. As such, revenue is recognized at a point in time. Shipping and handling costs associated with outbound freight before control of a product has been transferred to a customer are accounted for as a fulfillment cost and are included in cost of sales. Further, according to the Company's arrangement with HTC and Heuro, the Company shared 50/50 with Heuro in fees from support services excluding the CAD$600 payment for an assessment using the NeuroCatch device. As described above, the Company modified its arrangement with HTC on October 30, 2019 and product sales were derived from the sale of the PoNS device alone as the NeuroCatch is sold directly to the neuroplasticity clinics in Canada by HTC. For the year ended December 31, 2019, the Company recorded $1.5 million in product sales net of $11 thousand for HTC's portion related to assessments using the NeuroCatch device. For the year ended December 31, 2020, the Company recorded $0.63 million in product sales. As of December 31, 2020, control of 21 of the 55 PoNS devices included as consideration in the Heuro acquisition had been transferred resulting in revenue of $0.1 million being recognized which is included in the aforementioned $0.63 million in product sales for the year ended December 31, 2020. The fair value of the remaining 34 devices is recorded as deferred revenue of $0.3 million on the consolidated balance sheet. The returns during 2020 were the result of warranty

returns for defective products. These returns were insignificant during the year and any future replacements are expected to be insignificant.

Fee Revenue

During the first half of 2019, the Company's agreement with HTC and Heuro also entitled the Company to 50% of the franchise fees collected by Heuro from each franchise agreement Heuro executed with neuroplasticity clinics engaged in providing the PoNS Treatment. There were 3 franchise agreements entered into for the year ended December 31, 2019, all of which occurred in the first half of the year. For the year ended December 31, 2019, the Company recognized $37 thousand as its 50% portion of the franchise fees. This arrangement ended upon the acquisition of Heuro in October 2019. During the first half of 2020, the Company earned fee revenue of $9 thousand for engaging new neuroplasticity clinics to provide the PoNS Treatment, before terminating these agreements in the second quarter of 2020.

License Revenue

As described above, the Company modified its arrangement with HTC on October 30, 2019. License revenue is recognized ratably over the ten-year term as the performance obligation is met in connection with the Co-Promotion Agreement. During the fourth quarter of 2019, the Company recognized revenues of $5 thousand in license fees associated with the Co-Promotion Agreement. For the year ended December 31, 2020, the Company recognized revenues of $27 thousand in license fees associated with the Co-Promotion Agreement. Revenue not yet recognized of $0.2 million is recorded as deferred revenue on the consolidated balance sheet.

As of December 31, 2020, the Company had recorded $0.1 million in current receivables, net and had no contract assets or liabilities on its consolidated balance sheets related to the supply agreements with each clinic. As of December 31, 2019, the Company has recorded $0.2 million in current receivables, net and had no contract assets or liabilities on its consolidated balance sheets related to the supply agreements with each clinic.

Cost of Sales

Cost of product sales includes the cost to manufacture the PoNS device, royalty expenses, freight charges, customs duties, wages and salaries of employees involved in the management of the supply chain and logistics of fulfilling the Company's sales orders. During 2019, until the acquisition of Heuro on October 30, 2019, cost of sales also included certain support services provided by Heuro on the Company's behalf.

Income Taxes

The Company accounts 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 carry-forwards. 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. The Company records a valuation allowance to reduce deferred tax assets to the amount that is believed more likely than not to be realized.

The Company has adopted the provisions of ASC 740 *Income Taxes* regarding accounting for uncertainty in income taxes. The Company initially recognizes tax positions in the financial statements when it is more likely than not the position will be sustained upon examination by the tax authorities. Such tax positions are initially and subsequently measured as the largest amount of the tax benefit that is greater than 50% likely of being realized upon ultimate settlement with the tax authority, assuming full knowledge of the position and all relevant facts. Application requires numerous estimates based on available information. The Company considers many factors when evaluating and estimating its tax positions and tax benefits. These periodic adjustments may have a material impact on the consolidated statements of operations and comprehensive loss. When applicable, the Company classifies penalties and interest associated with uncertain tax positions as a component of income tax expense in its consolidated statements of operations and comprehensive loss.

On March 27, 2020, President Trump signed into law the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"). The CARES Act, among other things, includes provisions relating to refundable payroll tax credits, deferment of employer side social security payments, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations, increased limitations on qualified charitable contributions, and technical corrections to tax depreciation methods for qualified improvement property. The Company continues to examine the impact that the CARES Act may have on its business. Currently, the Company does not believe the CARES Act will have a material impact on its accounting for income taxes.

Research and Development Expenses

Research and development ("R&D") expenses consist primarily of personnel costs, including salaries, benefits and stock-based compensation, clinical studies performed by contract research organizations, development and manufacturing of clinical trial devices and devices for manufacturing testing and materials and supplies as well as regulatory costs related to post market surveillance, quality assurance complaint handling and adverse event reporting. R&D costs are charged to operations when they are incurred.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company operates and manages its business within one operating and reportable segment. Accordingly, the Company reports the accompanying consolidated financial statements in the aggregate in one reportable segment.

Derivative Financial Instruments

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 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. As of December 31, 2020 and 2019, the Company's derivative financial instruments accounted for in accordance with ASC 815 were comprised of warrants issued in connection with both public and/or private securities offerings. Upon settlement of a derivative financial instrument, the instrument is re-measured at the settlement date and the fair value of the underlying instrument is reclassified to equity (see Note 3).

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 instruments will be classified in the consolidated balance sheet as current if the right to exercise or settle the derivative financial instrument lies with the holder.

Fair Value Measurements

The Company accounts for financial instruments in accordance with ASC 820, *Fair Value Measurements and Disclosures* ("ASC 820"). ASC 820 establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy under ASC 820 are described below:

Level 1 – Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

Level 2 – Quoted prices in markets that are not active or financial instruments for which all significant inputs are observable, either directly or indirectly; and

Level 3 – Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

The Company's financial instruments recorded in its consolidated balance sheets consist primarily of cash, accounts receivable, other current receivables, operating lease ROU asset, accounts payable, accrued liabilities, operating lease liability and derivative financial instruments. The book values of these instruments, with the exception of derivative financial instruments, non-current lease liability, operating lease ROU asset and non-current receivables, approximate their fair values due to the immediate or short-term nature of these instruments.

The Company's derivative financial instruments are classified as Level 3 within the fair value hierarchy and required to be recorded at fair value on a recurring basis. Unobservable inputs used in the valuation of these financial instruments include volatility of the underlying share price and the expected term. See Note 3 for the inputs used in the Black-Scholes option-pricing model as of December 31, 2020 and 2019 and the roll forward of the derivative financial instruments. The Company's derivative financial instruments are comprised of warrants which are classified as liabilities.

The following table summarizes the Company's derivative financial instruments within the fair value hierarchy as of December 31, 2020 and 2019 (amounts in thousands):

	Fair Value	Level 1	Level 2	Level 3
December 31, 2020				
Liabilities:				
Derivative financial instruments	$ —	$ —	$ —	$ —
December 31, 2019				
Liabilities:				
Derivative financial instruments	$ 5	$ —	$ —	$ 5

There were no transfers between any of the levels during the years ended December 31, 2020 and 2019.

In addition to assets and liabilities that are recorded at fair value on a recurring basis, the Company's assets and liabilities are also subject to nonrecurring fair value measurements. Generally, assets are recorded at fair value on a nonrecurring basis as a result of impairment charges. Due to the COVID-19 pandemic and the related risks and uncertainties, the Company's customer relationship intangible asset incurred an impairment loss during the year ended December 31, 2020 of $0.2 million, all of which was recorded during the first quarter of 2020, and has a remaining net book value of $9 thousand as of December 31, 2020. The fair value of this intangible asset was determined based on Level 3 measurements within the fair value hierarchy. Inputs to these fair value measurements included estimates of the amount and timing of the asset's net future discounted cash flows based on historical data, current trends and market conditions.

Basic and Diluted Net Income (Loss) per Share

Earnings or loss per share ("EPS") is computed by dividing net income (loss) by the weighted average number of common shares outstanding during the period. Diluted EPS is computed by dividing net income (loss) by the weighted average of all potentially dilutive shares of common stock that were outstanding during the periods presented.

The treasury stock method is used in calculating diluted EPS for potentially dilutive stock options and share purchase warrants, which assumes that any proceeds received from the exercise of in-the-money stock options and share purchase warrants, would be used to purchase common shares at the average market price for the period, unless including the effects of these potentially dilutive securities would be anti-dilutive.

The basic and diluted loss per share for the periods noted below is as follows (amounts in thousands, except for share and per share amounts):

	For the Year Ended December 31,	
	2020	2019
Basic and Diluted		
Numerator		
Net loss	$ (14,130)	$ (9,781)
Denominator		
Weighted-average common shares outstanding - basic and diluted	1,197,774	752,932
Basic and diluted net loss per share	$ (11.80)	$ (12.99)

No incremental common stock equivalents, consisting of outstanding stock options, warrants and restricted stock units, were included in calculating diluted loss per share because such inclusion would be anti-dilutive given the net loss reported for the years ended December 31, 2020 and 2019. Dilutive common stock equivalents excluded from the computation of diluted weighted average shares outstanding were 455,631 and 186,764 for the years ended December 31, 2020 and 2019, respectively.

Recent Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which requires measurement and recognition of expected credit losses for financial assets held and requires enhanced disclosures regarding significant estimates and judgments used in estimating credit losses. In November 2019, the FASB issued ASU 2019-10, *Financial Instruments – Credit Losses (Topic 326), Derivatives and Hedging (Topic 815) and Leases (Topic 842): Effective Dates*, which amends the effective date of ASU 2016-13. Public business entities that meeting the definition of an SEC filer, excluding entities eligible to be a Smaller Reporting Company ("SRC") as defined by the SEC, are required to adopt the standard for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. All other entities are required to adopt the standard for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The Company meets the definition of an SRC and therefore the standard will not be effective until the beginning of 2023. The Company is evaluating the effect that ASU 2016-13 will have on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement*, which adds disclosure requirements to Topic 820 for the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. This ASU is effective for interim and annual reporting periods beginning after December 15, 2019. The Company adopted this standard as of January 1, 2020 and the adoption did not have a material impact on the Company's consolidated financial statements.

In November 2018, FASB issued ASU 2018-18, C*ollaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606*, which, among other things, provides guidance on how to assess whether certain collaborative arrangement transactions should be accounted for under Topic 606. The amendments in this ASU are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted. The Company adopted this standard on January 1, 2020 and the adoption did not have a material impact on the Company's consolidated financial statements.

In August 2020, FASB issued ASU 2020-06, *Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40)*, which simplifies accounting for convertible instruments by removing major separation models required under current GAAP. The ASU removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception and it also simplifies the diluted earnings per share calculation in certain areas. The guidance is effective for interim and annual periods beginning after December 15, 2021. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. FASB has specified that an entity should adopt the guidance as of the beginning of its annual fiscal year. The guidance is to be applied using either a full retrospective or modified retrospective method. In applying the full retrospective method, the cumulative effect of the accounting change should be recognized as an adjustment to the opening balance of retained earnings in the first comparative period presented. In applying the modified retrospective method, the cumulative effect of the accounting change should be recognized as an adjustment to the opening balance of retained earnings at the date of adoption. The Company early adopted ASU 2020-06 effective January 1, 2021 under the modified retrospective approach. The Company anticipates that the adoption of this guidance will not have a material impact on its consolidated financial statements.

3. COMMON STOCK AND WARRANTS

The Company's authorized capital stock pursuant to its Delaware charter consists of 150,000,000 authorized shares of common stock, at a par value per share of $0.001 and 10,000,000 authorized shares of preferred stock at a par value per share of $0.001. Holders of common stock are entitled to vote at any meeting of the Company's stockholders on the basis of one vote per share of common stock owned as of the record date of such meeting. Each share of common stock entitles the holder to receive dividends, if any, as declared by the Company's Board of Directors.

No dividends have been declared since inception of the Company through December 31, 2020. In the event of a liquidation, dissolution or winding-up of the Company, other distribution of assets of the Company among its stockholders for the purposes of winding-up its affairs or upon a reduction of capital, the stockholders shall, share equally, share for share, in the remaining assets and property of the Company.

On April 13, 2018, the Company issued 61,197 shares of its common stock and warrants to purchase 61,197 shares of the Company's common stock in an underwritten public offering at a price of $261.45 per share and accompanying warrant. On April 24, 2018, the Company closed on the sale of an additional 9,179 shares of its common stock and warrants pursuant to the exercise of the over-allotment option (collectively the "April 2018 Offering") granted to the underwriters in connection with the offering at a price of $261.45 per share and accompanying warrants. The Company received net proceeds of $16.3 million from the April 2018 Offering. The fair value of these warrants at issuance was approximately $7.4 million.

Each warrant issued in connection with the April 2018 Offering entitles the holder to acquire one additional share of common stock at an exercise price of CAD$428.75 per share on or before April 10, 2021. Pursuant to the guidance of ASC 815 *Derivatives and*

Hedging, the Company has determined that warrants issued in connection with the April 2018 Offering should be accounted for as liabilities as the ability to maintain an effective registration is outside of the Company's control and that it may be required to settle the exercise of the warrants in cash and because the exercise prices of these warrants are in a currency other than the Company's functional currency. Consequently, the Company determined the fair value of each warrant issuance using the Black-Scholes option-pricing model, with the remainder of the proceeds allocated to the common shares. As of December 31, 2020, 2,025 warrants had been exercised, all during 2018, for gross proceeds of CAD$0.9 million.

The following table summarizes the weighted average assumptions used in estimating the fair value of the warrants granted in the April 2018 Offering using the Black-Scholes option pricing model as of the date of the initial closing of the offering and the date of the closing of the over-allotment option, as well as of December 31, 2020.

	December 31, 2020	April 24, 2018	April 13, 2018
Stock price	CAD $17.15	CAD $376.60	CAD $344.75
Exercise price	CAD $428.75	CAD $428.75	CAD $428.75
Warrant term	0.27 years	3.00 years	3.00 years
Expected volatility	64.48%	64.49%	64.20%
Risk-free interest rate	0.06%	2.02%	1.99%
Dividend rate	0.00%	0.00%	0.00%

On November 22, 2019, the Company issued 137,571 shares of its common stock in an underwritten public offering at a price of $12.25 per share. The Company received net proceeds of $1.1 million, in connection with the November 2019 Offering.

On January 27, 2020, the Company filed a Form S-3 shelf registration under the Securities Act which was declared effective by the SEC on February 6, 2020 (the "2020 Shelf"). In conjunction with the 2020 Shelf, on January 27, 2020, the Company entered into an At The Market Offering Agreement (the "2020 ATM") with H.C. Wainwright & Co., LLC ("Wainwright") under which the Company may offer and sell, from time to time at its sole discretion, to or through Wainwright, acting as agent and/or principal, shares of its common stock having an aggregate offering price of up to $11.34 million, which, in March 2020, was subsequently reduced to $9.15 million, including the shares previously sold under the 2020 ATM. The Company terminated the 2020 ATM effective November 25, 2020. For the year ended December 31, 2020, under the 2020 ATM, the Company sold and issued 232,526 shares of its common stock with an aggregated market value of $5.0 million at an average price of $21.68 per share and paid Wainwright a sales commission of approximately $181 thousand related to those shares.

On March 20, 2020, the Company, in a registered direct offering, issued an aggregate of 178,776 shares of its common stock at a price of $12.25 per share. Additionally, the Company issued unregistered warrants in a concurrent private placement to purchase up to 178,776 shares of its common stock at an exercise price of $16.10 per share. Gross proceeds from the offering (the "March 2020 Offering") were approximately $2.2 million. The underwriting discounts and commissions and offering expenses of $0.3 million were recorded to share issuance costs.

Each warrant issued in connection with the March 2020 Offering entitles the holder to acquire one additional share of common stock at an exercise price of $16.10 per share, which became exercisable on September 20, 2020 and will expire on March 20, 2025. Pursuant to the guidance of ASC 480 *Distinguishing Liabilities from Equity* and ASC 815 *Derivatives and Hedging*, the Company has determined that warrants issued in connection with the March 2020 Offering should be classified as equity as the warrants can be settled with unregistered shares and partial cash settlement under certain circumstances and provisions related to market volatility did not preclude equity classification. The relative fair value of these warrants at issuance was approximately $0.8 million and was included in additional paid-in capital.

The following table summarizes the weighted average assumptions used in estimating the fair value of the warrants granted in the March 2020 Offering using the Black-Scholes option pricing model as of the date of the closing of the offering on March 20, 2020.

	March 20, 2020
Stock price	$ 12.25
Exercise price	$ 16.10
Warrant term	5.50 years
Expected volatility	82.41%
Risk-free interest rate	0.52%
Dividend rate	0.00%

On October 26, 2020, the Company issued units consisting of one share and a warrant to purchase 0.50 shares of common stock, with an aggregate issuance of 187,646 shares of common stock and warrants to purchase an aggregate of 93,817 shares of common stock at a purchase price of $18.20 per unit, resulting in gross proceeds of approximately $3.4 million, excluding the proceeds, if any, that the Company may receive in the future from the exercise of the warrants (the "October 2020 Offering"). The Company incurred $0.3 million in share issuance costs, including placement agent fees. The warrants have an initial exercise price of $15.82 per share and are exercisable for a period of three years from the date of issuance. The Company also issued warrants to the placement agent to purchase 961 shares of common stock, with an exercise price of $19.775 per share. An officer of the Company and affiliates of an officer and director of the Company participated in the October 2020 Offering on the same terms and conditions as all other purchasers, except that they paid $18.354 per unit and their warrants have an exercise price of $16.1665 per share.

Pursuant to the securities purchase agreement for the October 2020 Offering, if the Company issues any shares of common stock or common stock equivalents for cash consideration, indebtedness or a combination thereof, with certain exceptions, within twelve months of the closing of the October 2020 Offering, each purchaser who subscribed for at least $250,000 has the right to participate in up to such purchaser's pro rata portion of 30% of the such subsequent financing on the same terms, conditions and price provided for in the subsequent financing.

Pursuant to the guidance of ASC 480 *Distinguishing Liabilities from Equity* and ASC 815 *Derivatives and Hedging*, the Company has determined that warrants issued in connection with the October 2020 Offering should be classified as equity as the warrants can be settled with unregistered shares and partial cash settlement under certain circumstances, did not preclude equity classification. The relative fair value of these warrants at issuance was approximately $0.6 million and was included in additional paid-in capital.

The following table summarizes the weighted average assumptions used in estimating the fair value of the warrants granted in the October 2020 Offering using the Black-Scholes option pricing model as of the date of the closing of the offering on October 26, 2020.

	October 26, 2020
Stock price	$ 15.92
Exercise price	15.92
Warrant term	3.00 years
Expected volatility	80.91%
Risk-free interest rate	0.18%
Dividend rate	0.00%

The following table summarizes the activities of warrants that the Company accounts for as liabilities and records as derivative financial instruments for the years ended December 31, 2020 and 2019 (amounts in thousands):

	Year Ended December 31,	
	2020	2019
Fair value of warrants at beginning of year	$ 5	$ 13,769
Exercise of warrants	—	(35)
Foreign exchange (gains) losses	(1)	384
Change in fair value of warrants during the year	(4)	(14,113)
Fair value of warrants at end of year	$ —	$ 5

These warrants, which are classified as derivative financial instruments in the Company's consolidated balance sheets are required to be re-measured at each reporting period, with the change in fair value recorded as a gain or loss in the change of fair value of derivative financial instruments, included in other income in the Company's consolidated statements of operations and comprehensive loss. The fair value of the warrants will continue to be classified as a liability until such time as they are exercised, expire or there is an amendment to the respective agreements that renders these financial instruments to be no longer classified as such.

The fair value of all warrants classified as derivative financial instruments outstanding as of December 31, 2020 and 2019 were estimated using the Black-Scholes option-pricing model with the following weighted average assumptions:

	As of December 31,	
	2020	2019
Stock price	CAD $17.15	CAD $43.05
Exercise price	CAD $428.75	CAD $428.75
Warrant term	0.27 years	1.28 years
Expected volatility	64.48%	72.43%
Risk-free interest rate	0.06%	1.72%
Dividend rate	0.00%	0.00%

The following is a summary of warrant activity during the years ended December 31, 2020 and 2019:

	Number of Warrants (by currency denomination of exercise price)		Weighted-Average Exercise Price	
	CAD$	USD$	CAD$	USD$
Outstanding as of December 31, 2018	95,799	18,607	$ 381.15	$ 428.32
Granted	—	—	—	—
Cancelled/Expired	(26,352)	—	262.50	—
Exercised	(1,096)	—	262.50	—
Outstanding as of December 31, 2019	68,351	18,607	$ 428.75	$ 428.32
Granted	—	273,554	—	16.04
Cancelled/Expired	—	(18,607)	—	428.32
Exercised	—	—	—	—
Outstanding and exercisable as of December 31, 2020	68,351	273,554	$ 428.75	$ 16.04

The following table summarizes the Company's warrants outstanding and exercisable as of December 31, 2020:

Number of Warrants Outstanding	Exercise Price	Expiration Date
68,351	CAD$428.75	April 21, 2021
178,776	US$16.10	March 20, 2025
17,431	US$16.1665	October 26, 2023
76,386	US$15.82	October 26, 2023
961	US$19.775	October 26, 2023
341,905		

4. SHARE BASED PAYMENTS

On May 15, 2018, the Company's Board of Directors authorized and approved the adoption of the 2018 Omnibus Incentive Plan (as amended, the "2018 Plan"), which was effective upon approval by the stockholders of the Company on June 28, 2018 and under which an aggregate of 153,031 shares may be issued. This share reserve is the sum of 85,714 new shares, plus the remaining 67,317 shares that remained available for issuance under the Company's 2016 Omnibus Incentive Plan, the predecessor incentive plan (the "2016 Plan") at the time of the adoption of the 2018 Plan. Pursuant to the terms of the 2018 Plan, the Company is authorized to grant stock options, as well as awards of stock appreciation rights, restricted stock, unrestricted shares, restricted stock units ("RSUs"), stock equivalent units and performance-based cash awards. These awards may be granted to directors, officers, employees and eligible consultants. Vesting and the term of an option is determined at the discretion of the Company's Board of Directors. Subsequent to the adoption of the 2018 Plan, the Company ceased granting awards under the 2016 Plan, the predecessor incentive plan. However, outstanding stock options granted prior to the effective date of the 2018 Plan are still governed by the 2016 Plan or the Company's 2014 Stock Incentive Plan, which preceded the 2016 Plan.

As of December 31, 2020, there were an aggregate of 94,485 shares of common stock remaining available for issuance under the 2018 Plan.

For the year ended December 31, 2020, the Company issued 42,417 stock options to employees and directors of which 3,425 were forfeited. The Company issued 571 stock options to consultants during the same period.

The following is a summary of stock option activity for the year ended December 31, 2020 and 2019:

	Number of Options	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price in USD$	Aggregate Intrinsic Value in USD$
Outstanding as of December 31, 2018	94,475	5.16	$ 249.87	$ 8,308
Granted	33,337		162.74	
Forfeited	(13,939)		298.55	
Exercised (1)	(14,855)		96.95	
Outstanding as of December 31, 2019	99,018	7.78	$ 236.63	$ —
Granted	42,988		$ 15.20	
Forfeited/Cancelled	(28,448)		210.57	
Exercised	—		—	
Outstanding as of December 31, 2020	113,558	7.75	$ 159.33	$ —
Exercisable as of December 31, 2020	57,725	6.56	$ 117.90	$ —

(1) For the year ended December 31, 2019, 14,855 stock options were exercised on a cashless basis resulting in 13,818 shares being withheld in satisfaction of the exercise price.

Employee and Director Stock Options

As of December 31, 2020, the unrecognized compensation cost related to non-vested stock options outstanding for employees and directors was $2.4 million which will be recognized over a weighted-average remaining vesting period of approximately 2.3 years. Compensation cost is not adjusted for estimated forfeitures, but instead is adjusted upon an actual forfeiture of a stock option.

For the years ended December 31, 2020 and 2019, the Company granted 42,417 and 33,337 stock options, respectively, to employees and directors at a weighted average exercise price of $15.23 and $162.74, respectively. The fair value of employee and director stock options granted for the years ended December 31, 2020 and 2019 had a weighted average grant date fair value of $9.71 and $105.38 per option, respectively, and they were estimated using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	Year Ended December 31,	
	2020	2019
Stock price	$15.23	$162.74
Exercise price	$15.23	$162.74
Expected term	5.32 years	5.42 years
Expected volatility	75.35%	76.90%
Risk-free interest rate	0.52%	1.96%
Dividend rate	0.00%	0.00%

Consultant Stock Options

For the year ended December 31, 2020, the Company granted 571 stock options to consultants at a weighted average exercise price of $13.58. Stock options granted to the Company's consultants for the year ended December 31, 2020 had a weighted average grant date fair value of $8.18 per share, and they were estimated using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	Year Ended December 31, 2020
Stock price	$13.58
Exercise price	$13.58
Option term	5.27 years
Expected volatility	73.15%
Risk-free interest rate	0.33%
Dividend rate	0.00%

For the year ended December 31, 2019 the Company did not grant any stock options to consultants. As of December 31, 2020, the unrecognized compensation cost related to non-vested stock options outstanding for consultants was $39 thousand which will be recognized over a weighted-average remaining vesting period of 0.8 years.

Restricted Stock Units

Beginning in the fourth quarter of 2019, certain members of the Company's executive management team elected to receive RSUs in lieu of cash compensation under the 2018 Plan that vested upon issuance. The fair value of the RSUs is based on the closing price of the Company's common stock on the day of the grant.

The following is a summary of the Company's RSU activity for the years ended December 31, 2020 and 2019:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value per Unit
Outstanding as of December 31, 2018	27	CAD$350.00
Granted	788	USD$21.17
Vested and settled during 2019 **(1)**	(27)	CAD$350.00
Outstanding as of December 31, 2019	788	USD$21.17
Granted	7,172	USD$15.25
Settled during 2020	(7,792)	USD$17.81
Outstanding as of December 31, 2020	168	USD$13.20

(1) Includes 7 RSUs withheld to satisfy required withholding taxes.

Stock-Based Compensation Expense

Stock-based compensation expense is classified in the Company's consolidated statements of operations and comprehensive loss as follows (amounts in thousands):

	2020	2019
Research and development	$ 933	$ 898
Cost of sales	$ (1)	—
General and administrative	1,597	3,793
Total	$ 2,529	$ 4,691

5. ACCRUED EXPENSES

Accrued expenses consisted of the following (amounts in thousands):

	As of December 31,	
	2020	2019
Employees benefits	$ 496	$ 722
Professional services	292	67
Legal expense	133	81
Royalty fees	12	13
Franchise fees	—	28
Severance	347	606
Other	57	2
	$ 1,337	$ 1,519

Accrued severance expenses as of December 31, 2020 included $0.3 million in severance costs related to the departure of our former chief executive officer in August 2020.

6. INCOME TAXES

The components of net loss (income) are as follows (amounts in thousands):

	Year Ended December 31,	
	2020	2019
U.S.	$ 12,362	$ 7,980
Non-U.S.	1,768	1,801
	$ 14,130	$ 9,781

A reconciliation of the income tax provision computed at statutory rates to the reported income tax provision is as follows (amounts in thousands):

	Year Ended December 31,	
	2020	2019
Statutory tax rate	21.00%	21.00%
Net loss before income taxes	$ 14,130	$ 9,781
Expected income tax recovery	$ (2,967)	$ (2,054)
Increase (decrease) in income tax recovery resulting from:		
Derivative liability	(1)	(2,964)
Share based payments	415	949
Other permanent difference	(21)	(213)
Foreign income taxed at foreign rate	(97)	(99)
Increase in valuation allowance	2,671	4,381
Income tax expense	$ —	$ —

The significant components of the Company's deferred income tax assets and liabilities after applying enacted corporate tax rates are as follows (amounts in thousands):

	As of December 31,	
	2020	2019
Deferred income tax assets (liabilities)		
Operating losses carried forward	$ 24,576	$ 21,318
Tax credits	882	679
Stock compensation	1,616	1,496
Other	1,099	1,293
Valuation allowance	(28,173)	(24,786)
Net deferred income tax asset	$ —	$ —

As of December 31, 2020, the Company has accumulated non-capital losses totaling $5.2 million in Canada and net operating losses of $85.9 million in the United States, which may be available to carry forward and offset future years' taxable income. The losses expire in various amounts starting in 2033.

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 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.

Uncertain Tax Positions

The Company has adopted certain provisions of ASC 740, "Income Taxes", which prescribes a recognition threshold and measurement attribute for the recognition and measurement of tax positions taken or expected to be taken in income tax returns. The provisions also provide guidance on the de-recognition of income tax assets and liabilities, classification of current and deferred income tax assets and liabilities, and accounting for interest and penalties associated with tax positions.

The Company files income tax returns in the U.S. federal jurisdiction, and in various state and foreign jurisdictions. The Company's tax returns are subject to tax examinations by U.S. 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.

As of December 31, 2020, 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.

7. COMMITMENTS AND CONTINGENCIES

(a) On January 22, 2013, the Company entered into a license agreement with Advanced NeuroRehabilitation, LLC ("ANR") for an exclusive right on ANR's patent pending technology, claims and knowhow. In addition to the issuance of 91,628 shares of common stock to ANR, the Company agreed to pay a 4% royalty on net revenue on the sales of devices covered by the patent-pending technology and services related to the therapy or use of devices covered by the patent-pending technology. For the years ended December 31, 2020 and 2019, the Company recorded approximately $22 thousand and $59 thousand, respectively, in royalty expenses in its consolidated statement of operations.

(b) On October 30, 2017, HMI amended the Asset Purchase Agreement with A&B (HK) Company Ltd. ("A&B") which specified that if the Company fails to obtain FDA marketing authorization for commercialization of or otherwise fails to ensure that the PoNS device is available for purchase by the U.S. Government by December 31, 2021, the Company would be subject to a $2.0 million contract penalty payable to A&B, unless the Company receives an exemption for the requirement of FDA marketing authorization from the U.S. Army Medical Material Agency. In December 2018, the U.S. Army notified the Company that they were amending the Agreement such that the satisfaction of the obligation of the contract was changed from FDA marketing authorization of the PoNS device to submitting of an application for marketing authorization of the PoNS device with the FDA. As the Company submitted its application for marketing authorization of the PoNS device to the FDA on August 31, 2018, and with copies of the submission documents provided to the U.S. Army, the Company has met its obligation under the amended

agreement. Based on this amendment the Company has determined that the possibility of a payment under this contractual penalty is remote.

(c) In March 2017, the Company entered into a lease for office space in Newtown, Pennsylvania. The initial term of the lease was from July 1, 2017 through December 31, 2022, with an option to extend until 2027. In July 2017, the Company amended the contract to commence the lease on July 17, 2017 through January 16, 2023, with an option to extend until January 2028. Lease extension options were not included in the lease term as it was not reasonably certain that the Company would elect to utilize the option to extend. Monthly rent plus utilities were approximately $20 thousand per month beginning in January 2018 with a 3% annual increase.

In May 2020, the Company terminated its lease and entered into a new lease (the "Lease Amendment") for a smaller footprint of the current office space in Newtown, Pennsylvania. Lease payments under the original contract will be made through December 2020. The Lease Amendment was determined to be a partial termination that qualified as a change of accounting of the existing lease and not a separate contract. As such, the ROU assets and operating lease liabilities were remeasured using an incremental borrowing rate at the date of modification. The carrying value of the ROU asset decreased on a basis proportionate to the partial termination by approximately $0.4 million and the related lease liability decreased by approximately $0.4 million. The Company recorded a gain of approximately $0.1 million resulting from the difference between the reduction in the lease liability and the proportionate reduction of the ROU asset. This amount is recorded as a component of other income in the consolidated statement of operations and comprehensive loss for the year ended December 31, 2020. The initial lease term of the Lease Amendment is from July 1, 2020 through June 30, 2021, with options to extend for successive six month periods. Two lease extension options were included in the lease term as it was reasonably certain that the Company would elect to utilize the option to extend for this period of time. Monthly rent plus utilities will be approximately $5 thousand per month beginning in January 2021 with a 3% annual increase.

The following table summarizes the Company's operating lease information including future minimum lease payments under a non-cancellable lease (amounts in thousands):

For the Year Ending December 31,	**2020**	**2019**
Operating lease cost	$ 107	$ 224
Operating lease - operating cash flows	$ 253	$ 246
Weighted average remaining lease term	1.50 years	3.05 years
Weighted average discount rate	7.2%	15.1%
Future minimum lease payments under non-cancellable lease as of December 31, 2020 were as follows:		
For the Period Ending December 31,		
2021	$ 63	
2022	32	
Total future minimum lease payments	**95**	
Less imputed interest	(4)	
Total liability	**$ 91**	

Reported as of December 31,	**2020**	**2019**
Current operating lease liability	59	172
Non-current operating lease liability	32	465
Total	**$ 91**	**$ 637**

(d) On December 29, 2017, HMI (formerly known as NeuroHabilitation Corporation) entered into a Manufacturing and Supply Agreement ("MSA") with Key Tronic Corporation ("Key Tronic"), for the manufacture and supply of the Company's PoNS device based upon the Company's product specifications as set forth in the MSA. Per the agreement, the Company shall provide to Key Tronic a rolling forecast for the procurement of parts and material and within normal lead times based on estimated delivery dates for the manufacture of the PoNS device. The term of the agreement is for three years and the agreement will automatically renew for additional consecutive terms of one year, unless cancelled by either party upon 180-day written notice to the other party prior to the end of the then current term. On June 1, 2020, HMI extended the existing manufacturing agreement with Key Tronic for a second three year term from December 29, 2020 until December 31, 2023. As of December 31, 2020, the Company did not have any outstanding commitments to Key Tronic to complete the Company's forecast for the procurement of materials necessary for the delivery of PoNS devices.

(e) The Company was granted a $323 thousand loan on April 13, 2020 under the Paycheck Protection Program (the “PPP Loan”) established under the CARES Act. The Company planned to use the proceeds from the PPP Loan for covered payroll costs, rent and utilities in accordance with the relevant terms and conditions of the CARES Act. However, based upon subsequent guidance issued by the Federal Government, including a presumption that publicly traded companies may not be eligible for a PPP loan, the Company returned the PPP Loan proceeds in May 2020 and paid interest for the period of time the loan was outstanding.

8. VARIABLE INTEREST ENTITIES

A variable interest entity ("VIE") is an entity that either (i) has insufficient equity to permit the entity to finance its activities without additional subordinated financial support, or (ii) has equity investors who lack the characteristics of a controlling financial interest. Under ASC 810, an entity that holds a variable interest in a VIE and meets certain requirements would be considered to be the primary beneficiary of the VIE and is required to consolidate the VIE in its consolidated financial statements. In order to be considered the primary beneficiary of a VIE, an entity must hold a variable interest in the VIE and have both:

- the power to direct the activities that most significantly impact the economic performance of the VIE; and
- the right to receive benefits from, or the obligation to absorb losses of the VIE that could be potentially significant to the VIE.

The Company regularly assesses its relationships with contractual third party and other entities for potential VIE’s. In making this assessment, the Company considers the potential that its contracts or other arrangements provide subordinated financial support, absorb losses or rights to residual returns of the entity and the ability to directly or indirectly make decisions about the entity’s activities. If the Company determines that it is the primary beneficiary of a VIE, the Company consolidates the statements of operations and financial condition of the VIE into its consolidated financial statements.

Unconsolidated Variable Interest Entity

Prior to the acquisition of Heuro on October 30, 2019 (see Note 2), the Company utilized the consolidation guidance under ASC 810 to determine whether Heuro was a VIE, and if so, whether the Company was the primary beneficiary of Heuro. Prior to the aforementioned acquisition, the Company had concluded that Heuro was a VIE based on the fact that the equity investment at risk in Heuro was not sufficient. The Company’s variable interests in Heuro arose from a profit sharing arrangement with Heuro. In determining whether the Company was the primary beneficiary and whether the Company had the right to receive benefits and the obligation to absorb losses that could potentially be significant to the VIE, the Company evaluated its economic interest in Heuro.

This evaluation considered all relevant factors of Heuro’s structure, including its capital structure, contractual rights to earnings (losses) as well as other contractual arrangements that had the potential to be economically significant. Following the guidance in ASC 810, although the Company had the obligation to absorb losses prior to October 30, 2019, the Company concluded that it was not the primary beneficiary, as it did not have the power to direct the activities that most significantly affected the economic performance of Heuro. The significant economic activities identified were financing activities, research and development activities, commercialization activities, supply and distribution activities, business strategy activities and clinic expansion activities. The evaluation of each of these factors in reaching a conclusion about the potential significance of the Company’s economic interests and control was a matter that required the exercise of professional judgement.

Accordingly, prior to October 30, 2019, the Company did not consolidate Heuro in its consolidated financial statements nor did the Company have any carrying amounts for assets and liabilities relating to the variable interest in the VIE. Upon completion of the acquisition of Heuro on October 30, 2019, the Company consolidates Heuro’s results in its consolidated financial statements.

9. RELATED PARTY TRANSACTIONS

For the years ended December 31, 2020 and 2019, the Company paid approximately $5 thousand and $27 thousand, respectively, in consulting fees to a director of the Company. As of December 31, 2020, the Company did not have an accrued liability for consulting fees to a director of the Company.

The Company’s Chief Financial Officer/Chief Operating Officer and affiliates of the Company’s Interim Chief Executive Officer subscribed for units in the Company’s October 2020 Offering.

10. SUBSEQUENT EVENTS

In January 2021, 81,633 warrants issued in conjunction with the March 2020 Offering were exercised at an exercise price of $16.10 per share for gross proceeds of $1.3 million.

On February 1, 2021, in an underwritten public offering (the “Public Offering”), the Company issued 744,936 shares of common stock and warrants to purchase up to an aggregate of 372,468 shares of common stock at a purchase price of $14.82 per unit, consisting of one share and a warrant to purchase 0.50 shares of common stock. The warrants have an initial exercise price of $16.302 per share and are exercisable for a period of five years from the date of issuance. The Company also issued warrants to the underwriter to purchase 29,797 shares of common stock, with an exercise price of $18.525 per share. Net proceeds from the Public Offering after underwriter’s discounts and commission and offering expenses paid by us were approximately $9.6 million. Affiliates of the Company’s Interim Chief Executive Officer participated in the Public Offering on the same terms and conditions as all other purchasers.

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 10, 2021

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

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 10, 2021
Dane C. Andreeff
Interim President, Chief Executive Officer and Director

By /s/ Joyce LaViscount — Date: March 10, 2021
Joyce LaViscount
Chief Financial Officer and Chief Operating Officer (Principal Financial Officer and Principal Accounting Officer)

By /s/ Blane Walter — Date: March 10, 2021
Blane Walter
Director

By /s/ Mitchell E. Tyler — Date: March 10, 2021
Mitchell E. Tyler
Director

By /s/ Edward M. Straw — Date: March 10, 2021
Edward M. Straw
Director

By /s/ Jeffrey S. Mathiesen — Date: March 10, 2021
Jeffrey S. Mathiesen
Director

Exhibit 4.7

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following summary of the terms of our capital stock is qualified in its entirety by reference to our certificate of incorporation, as amended ("Certificate of Incorporation") and amended and restated bylaws ("Bylaws"), copies of which are filed as exhibits to our Annual Report on Form 10-K of which this Exhibit 4.5 is a part, and the applicable provisions of the Delaware General Corporation Law ("DGCL").

Our Certificate of Incorporation authorizes us to issue up to 150,000,000 shares of Class A Common Stock and 10,000,000 shares of preferred stock, par value $0.001 per share, all of which shares of preferred stock are currently undesignated. Our board of directors may establish the rights and preferences of the preferred stock from time to time.

Common Stock

Voting

Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Our stockholders do not have cumulative voting rights. Because of this, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose.

Dividends

Subject to preferences that may be applicable to any then-outstanding preferred stock, holders of our common stock are entitled to receive ratably those dividends, if any, as may be declared from time to time by the board of directors out of legally available funds.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then-outstanding shares of preferred stock.

Rights and Preferences

Holders of our common stock have no preemptive, conversion or subscription rights and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate in the future.

Preferred Stock

Our board of directors has the authority under our Certificate of Incorporation, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock. The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of us and may adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. It is not possible to state the actual effect of the issuance of any shares of preferred stock on the rights of holders of common stock until the board of directors determines the specific rights attached to that preferred stock.

Description of Outstanding Warrants

As of March 5, 2021, there were warrants outstanding to purchase 594,186 shares of common stock issuable upon the exercise of warrants at a weighted-average exercise price of US$16.32, and warrants outstanding to purchase 68,351 shares of common stock

issuable upon the exercise of warrants at a weighted-average exercise price of CAD$428.75 (or US$338.46 based on the exchange rate on March 5, 2021). Certain of these warrants have a net exercise provision under which its holder may, in lieu of payment of the exercise price in cash, surrender the warrant and receive a net amount of shares based on the fair market value of our common stock at the time of exercise of the warrant after deduction of the aggregate exercise price. Each of these warrants also contains provisions for the adjustment of the exercise price and the aggregate number of shares issuable upon the exercise of the warrant in the event of dividends, share splits, reorganizations and reclassifications and consolidations. Certain of these warrants provide that, subject to limited exceptions, a holder will not have the right to exercise any portion of its warrants if the holder, together with its affiliates, would beneficially own over 4.99% of our then outstanding common stock following such exercise; provided, however, that upon prior notice to us, the warrant holder may increase its ownership, provided that in no event will the ownership exceed 9.99%.

Anti-Takeover Provisions

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, those shares owned (1) by persons who are directors and also officers and (2) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines a “business combination” to include the following:

- merger or consolidation involving the corporation or any direct or indirect majority-owned subsidiary of the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder (in one transaction or a series of transactions);
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation or by any direct or indirect majority-owned subsidiary of the corporation of any stock of the corporation or of such subsidiary to the interested stockholder;
- any transaction involving the corporation or any direct or indirect majority-owned subsidiary of the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an “interested stockholder” as an entity or person who, together with the person’s affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

Certificate of Incorporation and Amended and Restated Bylaws

Our Certificate of Incorporation provides that the authorized number of directors may be changed only by resolution of the board of directors, and vacancies and newly created directorships on the board of directors may, except as otherwise required by law or determined by the board of directors, only be filled by a majority vote of the directors then serving on the board of directors, even though less than a quorum.

Our Amended and Restated Bylaws provide that all stockholder actions must be effected at a duly called meeting of stockholders and eliminate the right of stockholders to act by written consent without a meeting. Our Amended and Restated Bylaws

also provide that only our Chairman of the board of directors, Chief Executive Officer or the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors may call a special meeting of stockholders.

Our Amended and Restated Bylaws also provide that stockholders seeking to present proposals before a meeting of stockholders to nominate candidates for election as directors at a meeting of stockholders must provide timely advance notice in writing, and specify requirements as to the form and content of a stockholder's notice. At any meeting of stockholders for the election of directors at which a quorum is present, the election will be determined by a plurality of the votes cast by the stockholders entitled to vote at the election.

Our Certificate of Incorporation and Amended and Restated Bylaws provide that the stockholders cannot amend many of the provisions described above except by a vote of 66 2/3% or more of our outstanding Common stock. As described above, our Certificate of Incorporation gives our board of directors the authority, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series.

The combination of these provisions will make it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of us by replacing our board of directors. Since our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce our vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts. We believe that the benefits of these provisions, including increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure our company, outweigh the disadvantages of discouraging takeover proposals, because negotiation of takeover proposals could result in an improvement of their terms.

Choice of Forum

Our Certificate of Incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our Certificate of Incorporation or our Amended and Restated Bylaws; or
- any action asserting a claim against us that is governed by the internal affairs doctrine.

The provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act.

The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any action, a court could find the choice of forum provisions contained in our Certificate of Incorporation to be inapplicable or unenforceable in such action. Our Certificate of Incorporation further provides that the federal district courts of the United States 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.

Participation Rights of Investors in October 2020 Private Placement

Pursuant to the securities purchase agreement for the October 2020 Private Placement, if we issue any shares of common stock or common stock equivalents for cash consideration, indebtedness or a combination thereof, with certain exceptions, within twelve months of the closing of the private placement, each purchaser who subscribed for at least $250,000 in the private placement has the right to participate in up to such purchaser's pro rata portion of 30% of the such subsequent financing on the same terms, conditions and price provided for in the subsequent financing.

Registration Rights of A&B

Pursuant to the terms of convertible notes issued to A&B (HK) Company Limited in October 2015 and December 2015, we agreed to register any shares issued upon the conversion of such convertible notes upon the request of A&B (HK) Company Limited. As of March 5, 2021, A&B (HK) Company Limited beneficially owned 71,306 shares of Common stock that were issued upon the conversion of such convertible notes.

Transfer Agent and Registrar

The transfer agent and the registrar for the Company is American Stock Transfer & Trust Company LLC, 6201 15th Avenue, Brooklyn, New York 11219; Telephone: 800-937-5449.

Common Stock Listing

Our common stock is listed on the Nasdaq Capital Market under the symbol “HSDT” and on the TSX under the symbol “HSM.”

CONSULTING AGREEMENT

This **Consulting Agreement** (this ***"Agreement"***) is made as of March 8, 2021 (the ***"Effective Date"***), between **Helius Medical Technologies, Inc.**, a Delaware corporation, having a principal place of business at 642 Newtown Yardley Road, Suite 100, Newtown, Pennsylvania 18940 (the ***"Company"***), and **Dr. Jonathan Sackier**, whose address is Flat 4, Westfield, 15 Kidderpore Ave, London NW3 7SF UK (***"Consultant"***).

Recitals

The Company desires to retain Consultant, and Consultant desires to be engaged by the Company, to perform certain consulting services pursuant to the terms and conditions of this Agreement.

Agreement

refore, in consideration of the foregoing and the terms, conditions and covenants hereinafter set forth, the Company and Consultant agree as follows:

1. Certain Definitions. Capitalized terms used in this Agreement and not otherwise defined shall have the following meanings:

(a) ***"Company Documents and Materials"*** means documents or other media, whether in tangible or intangible form, that contain or embody Proprietary Information or any other information concerning the business, operations or plans of the Company, whether such documents or media have been prepared by Consultant or by others. Company Documents and Materials include, without limitation, blueprints, drawings, photographs, charts, graphs, notebooks, tests, test results, experiments, customer lists, computer disks, tapes or printouts, sound recordings and other printed, electronic, typewritten or handwritten documents or information, sample products, prototypes and models.

(b) ***"Inventions"*** means, without limitation, all software programs or subroutines, source or object code, algorithms, improvements, inventions, works of authorship, trade secrets, technology, designs, formulas, ideas, processes, techniques, know-how and data, whether or not patentable or copyrightable, made or discovered or conceived or reduced to practice or developed by Consultant, either alone or jointly with others.

(c) ***"Proprietary Information"*** means information that was or will be developed, created, or discovered by or on behalf of the Company, or which became or will become known to, or was or is conveyed to the Company, which has commercial value in the Company's business, whether or not patentable or copyrightable, including, without limitation, information about software programs and subroutines, source and object code, algorithms, trade secrets, designs, technology, know-how, processes, data, ideas, techniques, inventions, works of authorship, formulae, business and product development plans, customer lists, terms of compensation and performance levels of the Company's employees and consultants, the Company's customers and other information concerning the Company's actual or anticipated business, research or development, or which is received in confidence by or for the Company from any other person or entity.

(d) ***"Services"*** means the consulting services to be performed by Consultant on behalf of the Company described on Exhibit A attached hereto.

2. Services. The Company hereby engages Consultant, and Consultant accepts such engagement, to perform the Services. Consultant shall provide the Services at such specific times and at such particular locations as Consultant and the Company mutually determine from time to time.

3. Term. The term of this Agreement shall commence on the Effective Date and terminate on the date that is one (1) year after the Effective Date, unless the parties mutually agree in writing to extend the term of this Agreement. Notwithstanding the foregoing, (a) either party may terminate this Agreement for any reason upon giving not less than twelve months' notice to the other party the "Notice Period", (b) the Company may terminate

this Agreement immediately in the event of any embezzlement, insubordination, fraud or deceit in Consultant's performance of Consultant's obligations hereunder and (c) either party may terminate this Agreement immediately upon occurrence of any of the following events: (i) the breach of this Agreement by the other party, which breach is not cured within ten (10) days after written notice of such breach or (ii) the dissolution, voluntary or involuntary bankruptcy of either party, or assignment by either party of all or substantially all of its assets for the benefit of creditors. Notwithstanding the termination of this Agreement, any liability or obligation of either party which may have accrued prior to such termination shall continue in full force and effect, including but not limited to the rights and obligations of the parties hereto under Sections 6 through 29 of this Agreement.

4. COMPENSATION.

(a) Compensation. In consideration of Consultant's performance of the Services, the Company shall pay Consultant at a rate of $23,333.00 for the first month of engagement and then $20,000.00 per month thereafter for the Services rendered by Consultant during the term of this Agreement. In addition to the forgoing, Consultant will be eligible for consideration to receive a bonus or portion of a bonus for 2020 performance for Consultant's past contributions as an employee of the Company. At their sole discretion, the Compensation Committee of the Board of Directors will assess payout levels based on the Company's performance against 2020 objectives and will make a recommendation accordingly. Furthermore, the Compensation Committee of the Board of Directors will consider additional incentive remuneration in stock or cash for the Consultant's role in achieving key milestones such as (but not limited to) FDA clearance for PoNS for MS, TGA clearance for PoNS, Health Canada licenses for additional indications, or adoption by Helius of license to commercialize ENT/DG technology.

(b) Obligation to Invoice. For the Services rendered during any calendar month during the term of this Agreement, Consultant must submit an invoice for such Services to the Company no later than the last day of the next following calendar month and, provided that Consultant satisfies such deadline, the Company shall pay such invoice on a net thirty (30) days after the date the Company receives such invoice. Consultant expressly waives the right to recover payments for the Services which were not invoiced to the Company by the last day of the next following calendar month. The Company may pay untimely invoices in the Company's sole and absolute discretion, and Consultant acknowledges that the Company's payment of untimely invoices does not constitute waiver of the Company's right to refuse payment for untimely invoices in the future.

(c) Taxes and IRS Form 1099. The Company will, if applicable, issue an IRS Form 1099 to Consultant for all compensation paid by the Company to Consultant under this Agreement. Consultant will file all income, unemployment, and/or other employment tax returns, and pay all income, unemployment, and/or other employment taxes, applicable to the compensation received by Consultant hereunder, in a manner consistent with Consultant being an independent contractor, and not an employee, of the Company. Upon the Company's request, Consultant shall provide documentation demonstrating that Consultant has paid all required taxes with respect to the compensation provided pursuant to this Agreement.

5. EXPENSES. The Company shall reimburse Consultant for reasonable, documented and actual expenses incurred by Consultant in connection with his performance of the Services; provided, however, that Consultant shall not incur any such expense relating to a single activity or trip in excess of $200.00 (the ***"Threshold Amount"***) without first obtaining the written consent and approval of the Company. The Company will reimburse Consultant $150 per month for telecommunications and internet expenses. The Company shall make any such reimbursement within thirty (30) days after receipt of an invoice therefor, accompanied by receipts, vouchers or other written evidence of the expenses incurred. The Company shall have no obligation to reimburse Consultant for expenses in excess of the Threshold Amount that were not approved in advance by the Company.

6. DISCLOSURE. Pursuant to applicable governmental laws, rules and regulations, Consultant understands and acknowledges that the Company may be required to disclose to relevant governmental authorities the payments made by or on behalf of the Company to Consultant under this Agreement, as well as the purpose and nature of such payments. Consultant shall keep accurate records regarding payments made and expenses incurred in connection with this Agreement and shall provide the Company with such information upon request. The Company will have the right to disclose (including on the Company's website) and report, as may be required by applicable law (including the Physician Payment Sunshine Act set forth in Section 6002 of the Patient Protection

and Affordable Care Act of 2010, and similar state reporting laws), or as otherwise desired by the Company (a) information relating to the Services, including without limitation, all payments, reimbursement for expenses, or other transfers of value made in other than monetary form, (b) identifying information concerning Consultant, and (c) any other information relating to this Agreement.

7. CONFIDENTIALITY OF PROPRIETARY INFORMATION.

(a) Nature of Information. Consultant understands that the Company possesses and will possess Proprietary Information which is important to its business. Consultant understands that Consultant's engagement creates a relationship of confidence and trust between the Company and Consultant with respect to Proprietary Information.

(b) Property of the Company. Consultant acknowledges and agrees that all Company Documents and Materials, Proprietary Information and all patents, patent rights, copyrights, trade secret rights, trademark rights and other rights (including, without limitation, intellectual property rights) anywhere in the world in connection therewith is and shall be the sole property of the Company. Consultant hereby assigns to the Company any and all rights, title and interest Consultant may have or acquire in any Proprietary Information or Company Documents and Materials.

(c) Confidentiality. At all times, both during the term of Consultant's engagement by the Company and after Consultant's termination, Consultant shall keep in confidence and trust and shall not use or disclose any Proprietary Information or anything relating to it without the prior written consent of the Board, except as may be necessary in the ordinary course of performing the Services.

(d) Compelled Disclosure. In the event that Consultant is requested in any proceeding to disclose any Proprietary Information, Consultant shall give the Company prompt notice of such request so that the Company may seek an appropriate protective order. If, in the absence of a protective order, Consultant is nonetheless compelled by any court or tribunal of competent jurisdiction to disclose Proprietary Information, Consultant may disclose such information without liability hereunder; provided, however, that Consultant gives the Company notice of the Proprietary Information to be disclosed as far in advance of its disclosure as is practicable and uses Consultant's best efforts to obtain assurances that confidential treatment will be accorded to such Proprietary Information.

(e) Records. Consultant agrees to make and maintain adequate and current written records, in a form specified by the Company, of all Inventions, trade secrets and works of authorship assigned or to be assigned to the Company pursuant to this Agreement.

(f) Handling of the Company Documents and Materials. Consultant agrees that during Consultant's engagement by the Company, Consultant shall not remove any Company Documents and Materials from the business premises of the Company or deliver any Company Documents and Materials to any person or entity outside the Company, except as Consultant may be required to do in connection with performing the Services. Consultant further agrees that, immediately upon the termination of Consultant's engagement for any reason, or during Consultant's engagement if so requested by the Company, Consultant shall return all Company Documents and Materials, apparatus, equipment and other physical property, or any reproduction of such property, excepting only (i) Consultant's personal copies of personnel records and records relating to Consultant's compensation; and (ii) Consultant's copy of this Agreement.

8. INVENTIONS.

(a) Disclosure. Consultant shall promptly disclose in writing to the Board or to such person designated by the Board all Inventions made during the term of Consultant's engagement with the Company related to the Services. Consultant shall also disclose to the Board all Inventions made, discovered, conceived, reduced to practice or developed by Consultant either alone or jointly with others, within six (6) months after the termination of Consultant's engagement with the Company which resulted, in whole or in part, from Consultant's prior engagement with the Company and are related to the Services. Such disclosures shall be received by the Company in confidence,

to the extent such Inventions are not assigned to the Company pursuant to subsection (b) below, and do not extend the assignments made in such subsection.

(b) Assignment of Inventions to the Company. Consultant agrees that all Inventions which Consultant makes, discovers, conceives, reduces to practice or develops (in whole or in part, either alone or jointly with others) during Consultant's engagement related to the Services, shall be the sole property of the Company to the maximum extent permitted by law and Consultant agrees to assign and hereby does assign to the Company all right, title and interest to the Inventions.

(c) Works Made for Hire. Consultant agrees that the Company shall be the sole owner of all patents, patent rights, copyrights, trade secret rights, trademark rights and all other intellectual property or other rights in connection with Inventions related to the Services. Consultant further acknowledges and agrees that such Inventions related to the Services, including, without limitation, any computer programs, programming documentation and other works of authorship, are "works made for hire" for purposes of the Company's rights under copyright laws. Consultant hereby assigns to the Company any and all rights, title and interest Consultant may have or acquire in such Inventions. If in the course of Consultant's engagement with the Company, Consultant incorporates into a Company product, process or machine or a prior Invention or improvement not related to the Services that is owned by Consultant or in which Consultant has an interest, the Consultant will negotiate in good faith, a non-exclusive, royalty-free, irrevocable, perpetual, sublicensable, worldwide license to make, have made, modify, use, market, sell and distribute such prior Invention as part of or in connection with such product, process or machine. If in the course of Consultant's engagement with the Company, Consultant incorporates into a Company product, process or machine a prior Invention or improvement related to the Services owned by Consultant or in which Consultant has an interest, Consultant agrees to assign and hereby does assign all rights and interest in the Invention to the Company.

(d) Cooperation. Consultant agrees to perform, during and after Consultant's engagement, all acts deemed necessary or desirable by the Company to permit and assist it, at the Company's expense, in further evidencing and perfecting the assignments made to the Company under this Agreement and in obtaining, maintaining, defending and enforcing patents, patent rights, copyrights, trademark rights, trade secret rights or any other rights in connection with such Inventions and improvements related to the Services in any and all countries. Such acts may include, without limitation, execution of documents and assistance or cooperation in legal proceedings. Consultant hereby irrevocably designates and appoints the Company and its duly authorized officers and agents, as Consultant's agents and attorney-in-fact, coupled with an interest, to act for and on Consultant's behalf and in Consultant's place and stead, to execute and file any documents, applications or related findings and to do all other lawfully permitted acts strictly limited to furthering the purposes set forth above in this Section 8(d), including, without limitation, the perfection of assignment and the prosecution and issuance of patents, patent applications, filing with the FDA, copyright applications and registrations, trademark applications and registrations or other rights in connection with such Inventions and improvements related to the Services with the same legal force and effect as if executed by Consultant.

(e) Assignment or Waiver of Moral Rights. Any assignment of copyright hereunder (and any ownership of a copyright as a work made for hire) includes all rights of paternity, integrity, disclosure and withdrawal and any other rights that may be known as or referred to as "Moral Rights" (collectively, ***"Moral Rights"***). To the extent such Moral Rights cannot be assigned under applicable law and to the extent the following is allowed by the law in the various countries where Moral Rights exist, Consultant hereby waives such Moral Rights and consents to any action of the Company that would violate such Moral Rights in the absence of such consent.

(f) Holdover Assignment.

(i) Consultant agrees to, with reasonable compensation and after the Notice Period or termination of Consultant's engagement with the Company for any reason (1) disclose immediately to the Company all Inventions related to the Services, patentable or not; (2) assist, at the Company's expense such applications for United States patents and foreign patents covering such Inventions related to the Services as the Company may request; (3) assign to the Company without further compensation to Consultant the entire title and rights to all such Inventions and applications related to the Services that Consultant may have; and (4) execute, acknowledge, deliver, or act as otherwise necessary at the request of the Company all such papers, including but not limited to patent applications,

assignments, power of attorney, as necessary to secure the Company the full rights to such Inventions and applications related to the Services. If such activities are required of Consultant after

(ii) The Inventions related to the Services which shall come under this Section 8(f) shall include all Inventions related to the Services that (1) Consultant conceives, reduces to practice, or otherwise makes or develops, either solely or jointly with others, within one year after the termination of this Agreement; (2) are in any way based on any trade secret or confidential or proprietary information that Consultant learned during Consultant's engagement with the Company; (3) result from any work performed by Consultant for the Company under this Agreement; or (4) are in any way related to the subject matter or activities of Consultant's engagement with the Company.

9. Non-Solicitation or Hire of the Company Employees. During the term of this Agreement and for one (1) year thereafter, Consultant shall not solicit any employee of the Company to leave the Company or to accept employment with Consultant or any other entity. As part of this restriction, Consultant shall not (a) interview or provide any input to any entity regarding any such employee during such time period, or (b) without the consent of the Company, which shall not be unreasonably withheld, retain or hire in any capacity, either individually or for any person or entity by which Consultant may be engaged or with which Consultant may be affiliated, any person who is or was employed by the Company at any time during the term of this Agreement and six (6) months after the termination of this Agreement.

10. Non-Solicitation of Non-Employees. During the term of this Agreement and for one (1) year thereafter, Consultant shall not attempt, directly or indirectly, to solicit, entice, hire or otherwise induce any non-employee consultant, vendor or advisor of the Company to terminate their association with the Company.

11. Arrangement Non-Exclusive. Consultant agrees that, if Consultant enters into an agreement with another entity that is in the business of tongue-based neuromodulation or therapy-based neuromodulation related to TBI, Multiple Sclerosis or Stroke, it will constitute a conflict of interest with this Agreement and Consultant shall promptly notify the Company of such conflict in writing. The Company may, at its option, elect to terminate this Agreement upon receipt of Consultant's notice by, and upon, giving notice of such election to Consultant.

12. Company Authorization for Publication. Prior to Consultant's submitting or disclosing for possible publication or dissemination outside the Company any material prepared by Consultant that incorporates information that concerns the Company's business or anticipated research, Consultant agrees to deliver a copy of such material to the Board for review. Within twenty (20) days following such submission, the Company agrees to notify Consultant in writing whether the Company believes such material contains any Proprietary Information or Inventions related to the Services, and Consultant agrees to make such deletions and revisions as are reasonably requested by the Company to protect its Proprietary Information and Inventions related to the Services. Consultant further agrees to obtain the written consent of the Company prior to any review of such material by persons outside the Company.

13. Former Employer or Former Client Information. Consultant represents and warrants to the Company that Consultant's performance of all of the terms of this Agreement and engagement as a consultant of the Company do not and shall not breach any agreement to keep in confidence proprietary information, knowledge or data acquired by Consultant from any prior employer or client of Consultant in confidence or in trust prior to Consultant's engagement by the Company, or violate the terms of any covenant not to compete between Consultant and any other such person or entity. Consultant shall not disclose to the Company or use in performing services for the Company any confidential or proprietary information belonging to any previous employer or client of Consultant. Consultant represents and warrants to the Company that Consultant can perform and render the Services for the Company without disclosing or using in the performance of the Services for the Company any confidential or proprietary information belonging to any previous employer or client of Consultant. Consultant has not entered into and Consultant shall not enter into any agreement, either written or oral, in conflict herewith or in conflict with Consultant's engagement with the Company.

14. INDEPENDENT CONTRACTOR. The Company and Consultant mutually understand and agree that Consultant shall be at all times acting and performing as an independent contractor. Nothing in this Agreement is intended to create an employer/employee relationship or a joint venture relationship between the parties. The parties agree that Consultant is not eligible for any compensation, fringe benefits, pension, workers' compensation, sickness or health insurance benefits, or other similar benefits accorded employees of the Company. The parties agree that the Company will not withhold any sums for income tax, unemployment insurance, social security, or any other withholding pursuant to any law or requirement of any governmental body on behalf of Consultant. Consultant acknowledges and agrees that the Company has no obligation under local, state, or federal laws regarding Consultant and that the total commitment and liability of the Company in regard to any arrangement with, or work performed by, Consultant hereunder is to pay the fees and expenses pursuant to the provisions of this Agreement. Consultant shall indemnify and hold the Company harmless from any and all loss, damage, claims, payments, or liability arising with respect to any such payment, withholdings, and benefits, if any. Nothing in this Agreement is intended to allow the Company to exercise control or direction over the manner or method by which Consultant performs the Services under the terms of Consultant's engagement by the Company.

15. COMPLIANCE.

(a) Consultant will become familiar with and comply with the Company's policies and, coincidental with the execution of this Agreement, Consultant will execute a statement of acknowledgement and agreement that Consultant has read and will comply with the Company's Compliance Policies.

(b) Both parties to this Agreement agree to comply with all applicable federal, state, and local laws and regulations in performing their obligations under this Agreement. Both parties to this Agreement expressly acknowledge that the federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b), prohibits the payment or receipt of remuneration as an inducement or reward for the referral, purchase, or ordering of items or services for which payment may be made in whole or in part under a federal health care program. It is the intention of the parties that this Agreement be performed in accordance with the anti-kickback statute. If any portion of this Agreement is found, by any court or agency with jurisdiction over the subject matter of the Agreement, not to be in compliance with the anti-kickback statute, that portion of the Agreement shall be deemed to be retroactively amended and reformed as necessary to comply with the statute, and the parties shall cooperate in taking any steps necessary to ensure such compliance.

16. WARRANTIES.

(a) Consultant represents and warrants that Consultant: (i) is skilled and experienced in providing the Services, and will perform the Services in a professional and workmanlike manner customary in the industry; (ii) has, and will maintain throughout the term of this Agreement, all training, licenses, certifications, and information necessary for safely and properly performing the Services; (iii) will perform the Services in accordance with the terms and conditions of this Agreement and all applicable laws, ordinances and regulations; (iv) has not been found by any agency to have violated any statutes, rules, or regulations concerning the conduct of clinical research or services substantially similar to the Services; nor has received any agency letter alleging the same; (v) has not been terminated from any investigation or research project by a sponsor or agency for misconduct; and (vi) has not been subject to any disciplinary actions by any applicable boards of medicine, institutional review boards, or other similar agencies, nor been subject to any other restrictions or sanctions related to allegations of research or professional misconduct.

(b) Consultant further represents and warrants that (i) Consultant has the full and unrestricted right to disclose any information, know-how, materials, knowledge or data disclosed by Consultant to the Company in the performance of this Agreement; and (ii) the data and Inventions will not infringe any third party intellectual property rights. Consultant agrees to promptly notify Company in writing in the event that any of the foregoing warranties change.

(c) Consultant further warrants that s/he has never been, is not currently, and during the term of this Agreement will not be: (i) excluded, debarred, suspended, or otherwise ineligible to participate in any federal health care program (e.g., Medicare, Medicaid, Tricare) or any U.S. government procurement or non-procurement program (i.e., listed on the Department of Health and Human Services Office of Inspector General's List of Excluded

Individuals and Entities, www.oig.hhs.gov/exclusions, or the General Services Administration's System for Award Management, www.sam.gov); (ii) debarred by the FDA pursuant to 21 U.S.C. § 335a(a) or (b) from providing services in any capacity to a person that has an approved or pending drug product application; (iii) the subject of an FDA debarment investigation or proceeding (or similar proceeding of a foreign equivalent); (iv) convicted of or under indictment for a crime for which an individual or entity could be debarred under 21 U.S.C. § 335a(a) or (b); or (v) convicted of or under indictment for a criminal offense (A) bearing on trustworthiness or (B) that falls within the scope of 42 U.S.C. §§ 1320a-7, 1395ccc, 1395c-5, and/or regulations promulgated thereunder; nor is s/he or will s/he be an employer, employee, partner, shareholder, member, subsidiary, or affiliate of any person or entity described above.

(d) Consultant shall immediately notify the Company in writing if, at any time during the term of this Agreement, (i) any representation or warranty of Consultant contained in this Agreement shall no longer be true and correct, or (ii) Consultant becomes aware of any known, suspected, or alleged violation of law or breach of agreement by the Company, by Consultant, or by any third party relating to the Services or the Company

17. **Maintenance of Records.** During the term of this Agreement and until the expiration of five (5) years after the furnishing of the Services pursuant to this Agreement, Consultant shall make available, upon written request of the Company or its designee, any records maintained by Consultant regarding any of the Services performed hereunder by Consultant.

18. **No Authority to Bind.** Consultant shall have no power or authority to execute any agreements or contracts for or on behalf of the Company or to bind the Company in any other manner.

19. **No Assignment.** This Agreement may not be assigned by either party without the written consent of the other party; provided, however, that the Company may assign this Agreement to any purchaser of all or substantially all of its assets or business (by merger, asset sale, equity sale or otherwise) without Consultant's consent. Any attempted pledge of any of the rights under this Agreement or assignment of this Agreement without the prior consent of the Company's shall be void. This Agreement is binding upon and inures to the benefit of the parties hereto and their respective permitted successors and assigns.

20. **Severability.** Consultant agrees that if one or more provisions of this Agreement are held to be unenforceable under applicable law, such provisions shall be excluded from this Agreement and the balance of the Agreement shall be interpreted as if such provision were so excluded and shall be enforceable in accordance with its terms.

21. **Binding Effect.** This Agreement shall inure to the benefit of and be binding upon, the parties and their respective successors and permitted assigns.

22. **Amendment.** This Agreement may not be amended except by mutual written Agreement of the parties.

23. **Equitable Relief.** Each party acknowledges that a breach by the other party of this Agreement may cause the non-breaching party irreparable harm, for which an award of damages would not be adequate compensation and agrees that, in the event of such a breach or threatened breach, the non-breaching party will be entitled to equitable relief, including in the form of a restraining order, orders for preliminary or permanent injunction, specific performance, and any other relief that may be available from any court[, and the parties hereby waive any requirement for the securing or posting of any bond or the showing of actual monetary damages in connection with such relief. These remedies shall not be deemed to be exclusive but shall be in addition to all other remedies available under this Agreement at law or in equity, subject to any express exclusions or limitations in this Agreement to the contrary.

24. **Notices.** All notices, requests, demands and other communications required or permitted hereunder shall be in writing and shall be mailed by registered or certified mail, postage prepaid, sent by facsimile or electronic or otherwise delivered by hand, messenger or courier service addressed to the address of such party set forth in the introductory paragraph of this Agreement or to such address directed by a party in writing. Each

such notice, request, demand or other communication shall for all purposes of this Agreement be treated as effective or having been given (a) if delivered by hand, messenger or courier service, when delivered (or if sent via a nationally-recognized overnight courier service, freight prepaid, specifying next-business-day delivery, one business day after deposit with the courier), or (b) if sent via mail, at the earlier of its receipt or five (5) days after the same has been deposited in a regularly-maintained receptacle for the deposit of the United States mail, addressed and mailed as aforesaid, or (c) if sent via electronic mail, when directed to the relevant electronic mail address, if sent during normal business hours of the recipient, or if not sent during normal business hours of the recipient, then on the recipient's next business day. In the event of any conflict between the Company's books and records and this Agreement or any notice delivered hereunder, the Company's books and records will control absent fraud or error.

25. **Entire Agreement.** This Agreement including all exhibits and appendices to this Agreement, which are incorporated herein by reference) constitutes the complete and exclusive statement of the agreement between the parties, and supersedes all prior agreements, including the December 1, 2014 Employment Agreement and associated Amendments (the "Employment Agreement"), proposals, negotiations and communications between the parties, both oral and written, regarding the subject matter hereof. Consultants acknowledges and agrees that he is not owed any further amount from the Company under the Employment Agreement. Notwithstanding the above, any options that were granted to Consultant by the Company while serving as an employee of the Company shall continue to vest in accordance with the vesting schedules as set forth in the applicable option agreements through the term of this Agreement and/or any Notice Period if applicable. Consultant will have 90 days from the latter of (i) the date of termination of this Agreement or (ii) the last day of the Notice Period to exercise any vested options.

26. **Waiver and Release.** In exchange for the payments and other consideration under this Agreement, Consultant of his own free will, voluntarily waives, releases and forever discharges Company and its respective past and present officers, directors, employees, investors, stockholders, administrators, subsidiaries, affiliates, predecessor and successor corporations and assigns, attorneys and insurers (the "Company Released Parties") of and from any and all actions or causes of action, suits, grievances, claims, debts, charges, complaints, contracts (whether oral or written, express or implied from any source), claims for recall or reinstatement and promises, whatsoever, in law or equity, which Consultant, or Consultant's heirs, executors, administrators, successors and assigns, may have, or may have knowledge of or may be charged with knowledge of, as of the date of this Agreement for, upon, or by reason of any matter, cause or thing whatsoever including, but not limited to, any and all matters arising out of Employee's employment by Company, including, but not limited to, any violation of: (i) the following federal statutes, as amended: Title VII of the Civil Rights Act of 1964; Sections 1981 through 1988 of Title 42 of the United States Code; the Employee Retirement Income Security Act of 1974; the Vocational Rehabilitation Act of 1973; the Age Discrimination in Employment Act of 1967 ("ADEA"); the Older Workers Benefit Protection Act of 1990 ("OWBPA"); the Family and Medical Leave Act; the WARN Act; and the Americans with Disabilities Act of 1990; and (ii) or any other state or federal statute (or constitution), including but not limited to any claim based upon race, sex, national origin, ancestry, religion, age, mental or physical disability, marital status, sexual orientation, retaliation or denial of Family and Medical Leave; claims arising under the Employee Retirement Income Security Act of 1978 ("ERISA"), or pertaining to ERISA-regulated benefits; claims for wages, vacation pay, severance pay, bonus compensation, commissions, deferred compensation, other remuneration of any kind or character; or any other federal, state or local law governing labor relations; claims for any obligations, agreements, express or implied contracts; claims for defamation, invasion of privacy, assault and battery, intentional or negligent infliction of emotional distress, negligence, gross negligence, estoppel, conspiracy or misrepresentation; express or implied duties of good faith and fair dealing; wrongful discharge, violations of public policy; and/or torts for any and all alleged acts, omissions or events up or any other claim which Consultant ever had, now has, or may have, known or unknown, as of the date of execution of this Agreement. Consultant states that he knows of no violation of state, federal, or municipal law or regulation by any of the Company Released Parties, and knows of no ongoing or pending investigation, charge, or complaint by any agency charged with enforcement of state, federal, or municipal law or regulation. Consultant agrees he shall not receive any monetary damages, recovery and/or relief of any type related to any released claim(s), whether pursued by him or any governmental agency, other person or group; provided that nothing in the Agreement prevents him from participating in the whistleblower program maintained by the Securities and Exchange Commission and receiving a whistleblower award thereunder.

27. **Acknowledgment of Waiver of Claims under ADEA.** Consultant acknowledges that he is waiving and releasing any rights he may have under the OWBPA, the ADEA, and that this waiver and release is knowing and voluntary. Consultant acknowledges that the consideration given for this waiver and release is in addition to anything of value to which he was already entitled. Consultant further acknowledges that he has been advised by this writing that (a) he should consult with an attorney prior to executing this Agreement; (b) he has at least twenty-one (21) days within which to consider this Agreement and that if he signed this Agreement before expiration of that twenty-one (21) calendar day period, he did so knowingly and voluntarily and with the intent of waiving his right to utilize the full twenty-one (21) calendar day consideration period; and (c) he has seven (7) days following his execution of this Agreement to revoke the Agreement (the "Revocation Period"). Communication of any such revocation by Consultant to the Company shall be provided in writing and mailed by certified or registered mail with return receipt requested and shall be addressed to the Company at its principal corporate offices to the attention of the Chief Executive Officer. This Agreement shall not be effective until the Revocation Period has expired.

28. **Governing Law; Consent to Jurisdiction; Waiver of Jury Trial.** This Agreement shall be governed by and construed in accordance with the internal laws of the State of Pennsylvania, without regard to its principles of conflicts of laws. Each of the parties hereto irrevocably submits to the exclusive jurisdiction of the state and federal courts of the State of Pennsylvania for the purpose of any suit, action, proceeding or judgment relating to or arising out of this Agreement and the transactions contemplated hereby. Service of process in connection with any such suit, action or proceeding may be served on each party hereto anywhere in the world by the same methods as are specified for the giving of notices under this Agreement. Each of the parties hereto irrevocably consents to the jurisdiction of any such court in any such suit, action or proceeding and to the laying of venue in such court. Each party hereto irrevocably waives any objection to the laying of venue of any such suit, action or proceeding brought in such courts and irrevocably waives any claim that any such suit, action or proceeding brought in any such court has been brought in an inconvenient forum. EACH OF THE PARTIES HERETO WAIVES ANY RIGHT TO REQUEST A TRIAL BY JURY IN ANY LITIGATION WITH RESPECT TO THIS AGREEMENT AND REPRESENTS THAT COUNSEL HAS BEEN CONSULTED SPECIFICALLY AS TO THIS WAIVER.

29. **Collection Costs and Attorneys' Fees.** If a party shall fail to perform an obligation or otherwise breaches one or more of the terms of this Agreement, the other party may recover from the non-performing breaching party all its costs (including actual attorneys' and investigative fees) to enforce the terms of this Agreement.

30. **Counterparts/Electronic Execution and Delivery.** This Agreement may be executed in one or more counterparts and by facsimile, each of which shall constitute an original and all of which together shall constitute one and the same instrument. Signatures of the parties transmitted by facsimile or via .pdf format shall be deemed to be their original signatures for all purposes. The words "execution," "signed," "signature," and words of like import shall be deemed to include electronic signatures or the keeping of records in electronic form, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for in any applicable law, including the Federal Electronic Signatures in Global and National Commerce Act, the Pennsylvania Uniform Electronic Transactions Act, or any other similar state laws based on the Uniform Electronic Transactions Act. This Agreement and any signed agreement or instrument entered into in connection with this Agreement, and any amendments hereto or thereto, to the extent delivered by means of a facsimile machine or electronic mail (any such delivery, an ***"Electronic Delivery"***), will be treated in all manner and respects as an original agreement or instrument and will be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person. At the request of any party hereto or to any such agreement or instrument, each other party hereto or thereto will re-execute original forms thereof and deliver them to all other parties. No party hereto or to any such agreement or instrument will raise the use of Electronic Delivery to deliver a signature or the fact that any signature or agreement or instrument was transmitted or communicated through the use of Electronic Delivery as a defense to the formation of a contract, and each such party forever waives any such defense, except to the extent such defense related to lack of authenticity.

Signatures on the Following Page

In Witness Whereof, the Company and Consultant have made this Agreement effective as of the date first set forth above.

CONSULTANT:	**THE COMPANY:**
/s/ Jonathan Sackier **Dr. Jonathan Sackier**	**Helius Medical Technologies, Inc.** By:/s/ Dane Andreeff Name:Dane Andreeff Title: CEO and President

EXHIBIT A

DESCRIPTION OF SERVICES

1. **Consultation Services.** The Company hereby employs the Consultant to serve in the capacity of Medical Counsel of the Company and will participate in business development opportunities, fundraising activities at the request of the CEO and COO/CFO, and other strategic projects at the request of management.

2. **Time Devoted by Consultant.** Consultant shall devote time of no more than 20 hours per week on average to support the delivery of the Services.

3. **Place Where Service Will Be Rendered.** Consultant will perform most services in accordance with this Agreement remotely. In addition, the Consultant will perform the Services on the telephone and at such other places as designated by the Company to perform these services in accordance with this Agreement.

FORM OF INDEMNIFICATION AGREEMENT

This Indemnification Agreement ("**Agreement**") is made as of [ ] by and between Helius Medical Technologies, Inc., a Delaware corporation (the "**Company**"), and [ ] ("**Indemnitee**").

RECITALS

WHEREAS, highly competent persons have become more reluctant to serve corporations as directors or officers or in other capacities unless they are provided with adequate protection through insurance or adequate indemnification against inordinate risks of claims and actions against them arising out of their service to and activities on behalf of the corporation and due to the fact that such exposure frequently bears no relationship to compensation paid to such officers and directors;

WHEREAS, the Company and Indemnitee recognize that plaintiffs often seek damages in such large amounts and the costs of litigation may be so enormous (whether or not the case is meritorious), that the defense and/or settlement of such litigation is often beyond the personal resources of directors and officers;

WHEREAS, the Company's Bylaws, as amended and restated, provide for the indemnification of the officers and directors of the Company to the fullest extent permitted by the General Corporation Law of the State of Delaware (the "**DGCL**"). The Bylaws expressly provide that the indemnification provisions set forth therein are not exclusive and contemplate that contracts may be entered into between the Company and its directors and officers with respect to indemnification;

WHEREAS, Section 145 of the DGCL empowers the Company to indemnify its officers, directors, employees and agents by agreement and to indemnify persons who serve, at the Company's request, as the directors, officers, employees or agents of other corporations or enterprises;

WHEREAS, Section 102(b)(7) of the DGCL allows the Company to include in its Certificate of Incorporation a provision limiting or eliminating the personal liability of a director for monetary damages in respect of claims by shareholders and corporations for breach of certain fiduciary duties, and the Company has so provided in its Certificate of Incorporation that each director shall be exculpated from such liability to the maximum extent permitted by law;

WHEREAS, the Company, after reasonable investigation, has determined that the liability insurance coverage presently available to the Company may be inadequate in certain circumstances to cover all possible exposure for which Indemnitee should be protected;

WHEREAS, the uncertainties relating to such insurance and to indemnification have increased the difficulty of attracting and retaining highly competent persons to serve as directors and officers;

WHEREAS, the Board has determined that the increased difficulty in attracting and retaining such persons is detrimental to the best interests of the Company's stockholders and that the Company should act to assure such persons that there will be increased certainty of such protection in the future;

WHEREAS, it is reasonable, prudent and necessary for the Company contractually to obligate itself to indemnify, and to advance expenses on behalf of, such persons to the fullest extent permitted by

applicable law so that they will serve or continue to serve the Company free from undue concern that they will not be so indemnified;

WHEREAS, this Agreement is a supplement to and in furtherance of the Company's Certificate of Incorporation, as corrected, and Bylaws and any resolutions adopted pursuant thereto, and shall not be deemed a substitute therefor, nor to diminish or abrogate any rights of Indemnitee thereunder; and

WHEREAS, Indemnitee does not regard the protection available under the Company's Certificate of Incorporation, Bylaws and insurance as adequate in the present circumstances, and may not be willing to serve as an officer or director without adequate protection, and the Company desires Indemnitee to serve in such capacity. Indemnitee is willing to serve, continue to serve and to take on additional service for or on behalf of the Company on the condition that he be so indemnified.

NOW, THEREFORE, in consideration of the premises and the covenants contained herein, the Company and Indemnitee do hereby covenant and agree as follows:

Section 1. Services to the Company. Indemnitee agrees to serve as a director or officer of the Company or, at the request of the Company, as a director, officer, employee, agent or fiduciary of another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise. Indemnitee may at any time and for any reason resign from such position (subject to any other contractual obligation or any obligation imposed by operation of law), in which event the Company shall have no obligation under this Agreement to continue Indemnitee in such position with respect to actions taken following any such resignation becoming effective. This Agreement shall not be deemed an employment contract between the Company (or any of its subsidiaries or any other corporation, limited liability company, partnership, joint venture, trust employee benefit plan or other enterprise of which Indemnitee was serving at the Company's request as a director, officer, employee, agent or fiduciary) and Indemnitee. Indemnitee specifically acknowledges that Indemnitee's employment with the Company (or any of its subsidiaries or any other corporation, limited liability company, partnership, joint venture, trust employee benefit plan or other enterprise of which Indemnitee was serving at the Company's request as a director, officer, employee, agent or fiduciary), if any, is at will, and the Indemnitee may be discharged at any time for any reason, with or without cause, except as may be otherwise provided in any written employment contract between Indemnitee and the Company (or any of its subsidiaries or any other corporation, limited liability company, partnership, joint venture, trust employee benefit plan or other enterprise of which Indemnitee was serving at the Company's request as a director, officer, employee, agent or fiduciary). The foregoing notwithstanding, this Agreement shall continue in force after Indemnitee has ceased to serve as an officer or director of the Company.

Section 2. Definitions. As used in this Agreement:

(a) A "**Change in Control**" shall be deemed to occur upon the earliest to occur after the date of this Agreement of any of the following events:

i. Acquisition of Stock by Third Party. Any Person (as defined below) is or becomes the Beneficial Owner (as defined below), directly or indirectly, of securities of the Company representing thirty-five percent (35%) or more of the combined voting power of the Company's then outstanding securities;

ii. Change in Board. During any period of two (2) consecutive years (not including any period prior to the execution of this Agreement), individuals who at the beginning of such period constitute the Board, and any new director (other than a director designated by a person who has

entered into an agreement with the Company to effect a transaction described in Section 2(a)i, Section 2(a)iii or Section 2(a)iv) whose election by the Board or nomination for election by the Company's stockholders was approved by a vote of at least two-thirds of the directors then still in office who either were directors at the beginning of the period or whose election or nomination for election was previously so approved, cease for any reason to constitute at least a majority of the members of the Board;

iii. Corporate Transactions. The effective date of a merger or consolidation of the Company with any other entity, other than a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior to such merger or consolidation continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) more than 51% of the combined voting power of the voting securities of the surviving entity outstanding immediately after such merger or consolidation and with the power to elect at least a majority of the board of directors or other governing body of such surviving entity;

iv. Liquidation. The approval by the stockholders of the Company of a complete liquidation of the Company or an agreement for the sale or disposition by the Company of all or substantially all of the Company's assets; and

v. Other Events. There occurs any other event of a nature that would be required to be reported in response to Item 6(e) of Schedule 14A of Regulation 14A (or a response to any similar item on any similar schedule or form) promulgated under the Exchange Act (as defined below), whether or not the Company is then subject to such reporting requirement.

For purposes of this Section 2(a), the following terms shall have the following meanings:

(A) "**Exchange Act**" shall mean the Securities Exchange Act of 1934, as amended.

(B) "**Person**" shall have the meaning as set forth in Sections 13(d) and 14(d) of the Exchange Act; *provided, however*, that Person shall exclude (i) the Company, (ii) any trustee or other fiduciary holding securities under an employee benefit plan of the Company, and (iii) any corporation owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their ownership of stock of the Company.

(C) "**Beneficial Owner**" shall have the meaning given to such term in Rule 13d-3 under the Exchange Act; *provided, however*, that Beneficial Owner shall exclude any Person otherwise becoming a Beneficial Owner by reason of the stockholders of the Company approving a merger of the Company with another entity.

(b) "**Corporate Status**" describes the status of a person who is or was a director, officer, employee, agent or fiduciary of the Company or of any other corporation, limited liability company, partnership or joint venture, trust, employee benefit plan or other enterprise which such person is or was serving at the request of the Company.

(c) "**Disinterested Director**" means a director of the Company who is not and was not a party to the Proceeding in respect of which indemnification is sought by Indemnitee.

(d) "**Expenses**" shall include all reasonable attorneys' fees, retainers, court costs, transcript costs, fees of experts, witness fees, travel expenses, duplicating costs, printing and binding costs, telephone charges, postage, delivery service fees, and all other disbursements or expenses of the types customarily incurred in connection with prosecuting, defending, preparing to prosecute or defend, investigating, being or preparing to be a witness in, or otherwise participating in, a Proceeding. Expenses also shall include (i) Expenses incurred in connection with any appeal resulting from any Proceeding, including without limitation the premium, security for, and other costs relating to any cost bond, supersedeas bond, or other appeal bond or its equivalent, and (ii) for purposes of Section 13(d) only, Expenses incurred by Indemnitee in connection with the interpretation, enforcement or defense of Indemnitee's rights under this Agreement, by litigation or otherwise. Expenses, however, shall not include amounts paid in settlement by Indemnitee or the amount of judgments or fines against Indemnitee.

(e) "**Independent Counsel**" means a law firm, or a member of a law firm, that is experienced in matters of corporation law and neither presently is, nor in the past five years has been, retained to represent: (i) the Company or Indemnitee in any matter material to either such party (other than with respect to matters concerning the Indemnitee under this Agreement, or of other indemnitees under similar indemnification agreements), or (ii) any other party to the Proceeding giving rise to a claim for indemnification hereunder. Notwithstanding the foregoing, the term "Independent Counsel" shall not include any person who, under the applicable standards of professional conduct then prevailing, would have a conflict of interest in representing either the Company or Indemnitee in an action to determine Indemnitee's rights under this Agreement. The Company agrees to pay the reasonable fees and expenses of the Independent Counsel referred to above and to fully indemnify such counsel against any and all Expenses, claims, liabilities and damages arising out of or relating to this Agreement or its engagement pursuant hereto.

(f) "**Proceeding**" shall include any threatened, pending or completed action, suit, arbitration, alternate dispute resolution mechanism, investigation, inquiry, administrative hearing or any other actual, threatened or completed proceeding, whether brought in the right of the Company or otherwise and whether of a civil, criminal, administrative, legislative, or investigative nature, including any appeal therefrom, in which Indemnitee was, is or will be involved as a party, potential party, non-party witness or otherwise by reason of the fact that Indemnitee is or was a director or officer of the Company, by reason of any action taken by him or of any action on his part while acting as director or officer of the Company, or by reason of the fact that he is or was serving at the request of the Company as a director, officer, employee or agent of another corporation, limited liability company, partnership, joint venture, trust or other enterprise, in each case whether or not serving in such capacity at the time any liability or expense is incurred for which indemnification, reimbursement, or advancement of expenses can be provided under this Agreement; except one initiated by an Indemnitee to enforce his rights under this Agreement.

Section 3. Indemnity in Third-Party Proceedings. The Company shall indemnify Indemnitee in accordance with the provisions of this Section 3 if, by reason of his Corporate Status, Indemnitee is, or is threatened to be made, a party to or a participant in any Proceeding, other than a Proceeding by or in the right of the Company to procure a judgment in its favor. Pursuant to this Section 3, Indemnitee shall be indemnified to the fullest extent permitted by applicable law against all Expenses, judgments, penalties, fines and amounts paid in settlement actually and reasonably incurred by Indemnitee or on his behalf in connection with such Proceeding or any claim, issue or matter therein, if Indemnitee acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the Company and, in the case of a criminal proceeding had no reasonable cause to believe that his conduct was unlawful.

Section 4. Indemnity in Proceedings by or in the Right of the Company. The Company shall indemnify Indemnitee in accordance with the provisions of this Section 4 if, by reason of his Corporate

Status, Indemnitee is, or is threatened to be made, a party to or a participant in any Proceeding by or in the right of the Company to procure a judgment in its favor. Pursuant to this Section 4, Indemnitee shall be indemnified to the fullest extent permitted by applicable law against all Expenses actually and reasonably incurred by him or on his behalf in connection with such Proceeding or any claim, issue or matter therein, if Indemnitee acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the Company. No indemnification for Expenses shall be made under this Section 4 in respect of any claim, issue or matter as to which Indemnitee shall have been finally adjudged by a court to be liable to the Company, unless and only to the extent that the Delaware Court of Chancery or any court in which the Proceeding was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, Indemnitee is fairly and reasonably entitled to indemnification.

Section 5. Indemnification for Expenses of a Party Who is Wholly or Partly Successful. Notwithstanding any other provisions of this Agreement, to the fullest extent permitted by applicable law and to the extent that Indemnitee is, by reason of his Corporate Status, a party to (or a participant in) and is successful, on the merits or otherwise, in any Proceeding or in defense of any claim, issue or matter therein, in whole or in part, the Company shall indemnify Indemnitee against all Expenses actually and reasonably incurred by him in connection therewith. If Indemnitee is not wholly successful in such Proceeding but is successful, on the merits or otherwise, as to one or more but less than all claims, issues or matters in such Proceeding, the Company shall indemnify Indemnitee against all Expenses actually and reasonably incurred by him or on his behalf in connection with each successfully resolved claim, issue or matter. If the Indemnitee is not wholly successful in such Proceeding, the Company also shall indemnify Indemnitee against all Expenses reasonably incurred in connection with a claim, issue or matter related to any claim, issue, or matter on which the Indemnitee was successful. For purposes of this Section and without limiting the foregoing, if any Proceeding is disposed of, on the merits or otherwise (including a disposition without prejudice), without (i) the disposition being adverse to Indemnitee, (ii) an adjudication that Indemnitee was liable to the Company, (iii) a plea of guilty or nolo contendere by Indemnitee, (iv) an adjudication that Indemnitee did not act in good faith and in a manner Indemnitee reasonably believed to be in or not opposed to the best interests of the Company and (v) with respect to any criminal proceeding, an adjudication that Indemnitee had reasonable cause to believe Indemnitee's conduct was unlawful, Indemnitee shall be considered for purposes of this Agreement to have been successful with respect thereto.

Section 6. Indemnification For Expenses of a Witness. Notwithstanding any other provision of this Agreement, to the fullest extent permitted by applicable law and to the extent that Indemnitee is, by reason of his Corporate Status, a witness or otherwise participates in any Proceeding to which Indemnitee is not a party, he shall be indemnified against all Expenses actually and reasonably incurred by him or on his behalf in connection therewith.

Section 7. Additional Indemnification.

(a) Notwithstanding any limitation in Section 3, Section 4, or Section 5, the Company shall indemnify Indemnitee to the fullest extent permitted by applicable law if Indemnitee, by reason of his Corporate Status, is a party to or threatened to be made a party to any Proceeding (including a Proceeding by or in the right of the Company to procure a judgment in its favor) against all Expenses, judgments, fines and amounts paid in settlement actually and reasonably incurred by Indemnitee in connection with the Proceeding.

(b) For purposes of Section 7(a), the meaning of the phrase "**to the fullest extent permitted by applicable law**" shall include, but not be limited to:

i. to the fullest extent permitted by the provision of the DGCL that authorizes or contemplates additional indemnification by agreement, or the corresponding provision of any amendment to or replacement of the DGCL, and

ii. to the fullest extent authorized or permitted by any amendments to or replacements of the DGCL adopted after the date of this Agreement that increase the extent to which a corporation may indemnify its officers and directors.

Section 8. Exclusions. Notwithstanding any provision in this Agreement, the Company shall not be obligated under this Agreement to make any indemnity in connection with any claim made against Indemnitee:

(a) for any Proceedings with respect to which final judgment is rendered against Indemnitee for payment of (i) an accounting of profits made from the purchase and sale (or sale and purchase) by Indemnitee of securities of the Company within the meaning of Section 16(b) of the Exchange Act (as defined in Section 2(a) hereof) or similar provisions of state statutory law or common law, or (ii) any reimbursement of the Company by the Indemnitee of any bonus or other incentive-based or equity-based compensation or of any profits realized by the Indemnitee from the sale of securities of the Company, as required in each case under the Exchange Act (including any such reimbursements that arise from an accounting restatement of the Company pursuant to Section 304 of the Sarbanes-Oxley Act of 2002 (the "**Sarbanes-Oxley Act**"), or the payment to the Company of profits arising from the purchase and sale by Indemnitee of securities in violation of Section 306 of the Sarbanes-Oxley Act), or

(b) any Proceeding involving the enforcement of non-compete and/or non-disclosure agreements or the non-compete and/or non-disclosure provisions of employment, consulting or similar agreements the Indemnitee may be a party to with the Company or any subsidiary of the Company or any other applicable foreign or domestic corporation, partnership, joint venture, trust or other enterprise, if any; or

(c) except as provided in Section 13(d) of this Agreement, in connection with any Proceeding (or any part of any Proceeding) initiated by Indemnitee, including any Proceeding (or any part of any Proceeding) initiated by Indemnitee against the Company or its directors, officers, employees or other indemnitees, unless (i) the Board authorized the Proceeding (or any part of any Proceeding) prior to its initiation or (ii) the Company provides the indemnification, in its sole discretion, pursuant to the powers vested in the Company under applicable law.

Section 9. Advances of Expenses. The Company shall advance, to the extent not prohibited by law, the Expenses incurred by Indemnitee by reason of his Corporate Status in connection with any Proceeding, and such advancement shall be made within thirty (30) days after receipt by the Corporation of (i) a statement or statements from Indemnitee requesting such advance or advances from time to time, whether prior to or after final disposition of any Proceeding, and (ii) an undertaking by or on behalf of Indemnitee to repay such amount or amounts, only if, and to the extent that, it shall ultimately be determined that Indemnitee is not entitled to be indemnified by the Corporation as authorized by this Agreement or otherwise. Such undertaking shall be accepted without reference to the financial ability of Indemnitee to make such repayment. Advances shall be unsecured and interest free. Advances shall include any and all reasonable Expenses incurred pursuing an action to enforce this right of advancement, including Expenses incurred preparing and forwarding statements to the Company to support the advances claimed. This Section 9 shall not apply to any claim made by Indemnitee for which indemnity is excluded pursuant to Section 8 or to any Proceeding for which the Company has assumed the defense thereof in accordance with Section 10(b) of this Agreement.

Section 10. Procedure for Notification and Defense of Claim.

(a) Indemnitee shall notify the Company in writing of any matter with respect to which Indemnitee intends to seek indemnification or advancement of Expenses hereunder as soon as reasonably practicable following the receipt by Indemnitee of written notice thereof. The written notification to the Company shall include a description of the nature of the Proceeding and the facts underlying the Proceeding. To obtain indemnification under this Agreement, Indemnitee shall submit to the Company a written request, including therein or therewith such documentation and information as is reasonably available to Indemnitee and is reasonably necessary to determine whether and to what extent Indemnitee is entitled to indemnification following the final disposition of such action, suit or proceeding. The omission by Indemnitee to notify the Company hereunder will not relieve the Company from any liability which it may have to Indemnitee hereunder or otherwise than under this Agreement unless, and to the extent that, such failure actually and materially prejudices the interests of the Company, and any delay in so notifying the Company shall not constitute a waiver by Indemnitee of any rights under this Agreement. The Secretary of the Company shall, promptly upon receipt of such a request for indemnification, advise the Board in writing that Indemnitee has requested indemnification.

(b) In the event the Company shall be obligated to pay the Expenses of Indemnitee with respect to a Proceeding, as provided in this Agreement, the Company shall be entitled to assume the defense of such Proceeding, with counsel reasonably acceptable to Indemnitee, upon delivery of written notice of its election to do so. After delivery of such notice, approval of such counsel by Indemnitee and retention of such counsel by the Company, the Company will not be liable to Indemnitee under this Agreement for any fees of counsel subsequently incurred by Indemnitee with respect to the same Proceeding, provided that (1) Indemnitee shall have the right to employ Indemnitee's own counsel in such Proceeding at Indemnitee's expense and (2) if (i) the employment of counsel by Indemnitee has been previously authorized in writing by the Company, (ii) counsel to the Company or Indemnitee shall have reasonably concluded that there may be a conflict of interest or position, or reasonably believes that a conflict is likely to arise, on any significant issue between the Company and the Indemnitee in the conduct of such defense or (iii) the Company shall not, in fact, have employed counsel to assume the defense of such Proceeding, then the fees and expenses of Indemnitee's counsel shall be at the expense of the Company, except as otherwise expressly provided by this Agreement.

(c) The Company will be entitled to participate in the Proceeding at its own expense.

Section 11. Procedure Upon Application for Indemnification.

(a) Upon written request by Indemnitee for indemnification pursuant to Section 10(a), a determination, if required by applicable law, with respect to Indemnitee's entitlement thereto shall be made in the specific case: (i) if a Change in Control shall have occurred after the date of this Agreement, by Independent Counsel in a written opinion to the Board, a copy of which shall be delivered to Indemnitee; or (ii) if a Change in Control shall not have occurred after the date of this Agreement, (A) by a majority vote of the Disinterested Directors, even though less than a quorum of the Board, (B) by a committee of Disinterested Directors designated by a majority vote of the Disinterested Directors, even though less than a quorum of the Board, (C) if there are no such Disinterested Directors or, if such Disinterested Directors so direct, by Independent Counsel in a written opinion to the Board, a copy of which shall be delivered to Indemnitee or (D) if so directed by the Disinterested Directors, by the stockholders of the Company; and, if it is so determined that Indemnitee is entitled to indemnification, payment to Indemnitee shall be made within ten (10) days after such determination. Indemnitee shall cooperate with the person, persons or entity making such determination with respect to Indemnitee's entitlement to indemnification, including providing to such person, persons or entity upon reasonable advance request any documentation or

information which is not privileged or otherwise protected from disclosure and which is reasonably available to Indemnitee and reasonably necessary to such determination. Any costs or Expenses (including attorneys' fees and disbursements) incurred by Indemnitee in so cooperating with the person, persons or entity making such determination shall be borne by the Company (irrespective of the determination as to Indemnitee's entitlement to indemnification) and the Company hereby indemnifies and agrees to hold Indemnitee harmless therefrom.

(b) In the event the determination of entitlement to indemnification is to be made by Independent Counsel pursuant to Section 11(a) hereof, the Independent Counsel shall be selected as provided in this Section 11(b). If a Change in Control shall not have occurred after the date of this Agreement, the Independent Counsel shall be selected by the Board, and the Company shall give written notice to Indemnitee advising him of the identity of the Independent Counsel so selected. If a Change in Control shall have occurred after the date of this Agreement, the Independent Counsel shall be selected by Indemnitee (unless Indemnitee shall request that such selection be made by the Board, in which event the preceding sentence shall apply), and Indemnitee shall give written notice to the Company advising it of the identity of the Independent Counsel so selected. In either event, Indemnitee or the Company, as the case may be, may, within ten (10) days after such written notice of selection shall have been given, deliver to the Company or to Indemnitee, as the case may be, a written objection to such selection; *provided*, *however*, that such objection may be asserted only on the ground that the Independent Counsel so selected does not meet the requirements of "Independent Counsel" as defined in Section 2 of this Agreement, and the objection shall set forth with particularity the factual basis of such assertion. Absent a proper and timely objection, the person so selected shall act as Independent Counsel. If such written objection is so made and substantiated, the Independent Counsel so selected may not serve as Independent Counsel unless and until such objection is withdrawn or a court has determined that such objection is without merit. If, within twenty (20) days after the submission by Indemnitee or the Company, as the case may be, of a written objection, no Independent Counsel shall have been selected and not objected to, either the Company or Indemnitee may petition a court of competent jurisdiction for resolution of any objection which shall have been made by the Company or Indemnitee to the other's selection of Independent Counsel and/or for the appointment as Independent Counsel of a person selected by the Court or by such other person as the Court shall designate, and the person with respect to whom all objections are so resolved or the person so appointed shall act as Independent Counsel under Section 11(a) hereof. Upon the due commencement of any judicial proceeding or arbitration pursuant to Section 13(a) of this Agreement, Independent Counsel shall be discharged and relieved of any further responsibility in such capacity (subject to the applicable standards of professional conduct then prevailing).

Section 12. Presumptions and Effect of Certain Proceedings.

(a) In making a determination with respect to entitlement to indemnification hereunder, the person or persons or entity making such determination shall, to the fullest extent not prohibited by law, presume that Indemnitee is entitled to indemnification under this Agreement if Indemnitee has submitted a request for indemnification in accordance with Section 10(a) of this Agreement, and the Company shall, to the fullest extent not prohibited by law, have the burden of proof to overcome that presumption in connection with the making by any person, persons or entity of any determination contrary to that presumption. Neither the failure of the Company (including by its directors or independent legal counsel) to have made a determination prior to the commencement of any action pursuant to this Agreement that indemnification is proper in the circumstances because Indemnitee has met the applicable standard of conduct, nor an actual determination by the Company (including by its directors or independent legal counsel) that Indemnitee has not met such applicable standard of conduct, shall be a defense to the action or create a presumption that Indemnitee has not met the applicable standard of conduct.

(b) Subject to Section 13(e), if the person, persons or entity empowered or selected under Section 11 of this Agreement to determine whether Indemnitee is entitled to indemnification shall not have made a determination within sixty (60) days after receipt by the Company of the request therefor, the requisite determination of entitlement to indemnification shall, to the fullest extent not prohibited by law, be deemed to have been made and Indemnitee shall be entitled to such indemnification, absent (i) a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's statement not materially misleading, in connection with the request for indemnification, or (ii) a prohibition of such indemnification under applicable law; *provided*, *however*, that such 60-day period may be extended for a reasonable time, not to exceed an additional thirty (30) days, if the person, persons or entity making the determination with respect to entitlement to indemnification in good faith requires such additional time for the obtaining or evaluating of documentation and/or information relating thereto; and provided, further, that the foregoing provisions of this Section 12(b) shall not apply (i) if the determination of entitlement to indemnification is to be made by the stockholders pursuant to Section 11(a) of this Agreement and if (A) within fifteen (15) days after receipt by the Company of the request for such determination the Board has resolved to submit such determination to the stockholders for their consideration at an annual meeting thereof to be held within seventy-five (75) days after such receipt and such determination is made thereat, or (B) a special meeting of stockholders is called within fifteen (15) days after such receipt for the purpose of making such determination, such meeting is held for such purpose within sixty (60) days after having been so called and such determination is made thereat, or (ii) if the determination of entitlement to indemnification is to be made by Independent Counsel pursuant to Section 11(a) of this Agreement.

(c) The termination of any Proceeding or of any claim, issue or matter therein, by judgment, order, settlement or conviction, or upon a plea of nolo contendere or its equivalent, shall not (except as otherwise expressly provided in this Agreement) of itself adversely affect the right of Indemnitee to indemnification or create a presumption that Indemnitee did not act in good faith and in a manner which he reasonably believed to be in or not opposed to the best interests of the Company or, with respect to any criminal Proceeding, that Indemnitee had reasonable cause to believe that his conduct was unlawful.

(d) Reliance as Safe Harbor. For purposes of any determination of good faith, Indemnitee shall be deemed to have acted in good faith if Indemnitee's action is based on the records or books of account of the Company or other corporation, limited liability company, partnership, joint venture, trust employee benefit plan or other enterprise of which Indemnitee was serving as a director, officer, employee, agent or fiduciary, including financial statements, or on information supplied to Indemnitee by the officers of the Company or other corporation, limited liability company, partnership, joint venture, trust employee benefit plan or other enterprise of which Indemnitee was serving as a director, officer, employee, agent or fiduciary in the course of their duties, or on the advice of legal counsel for the enterprise or on information or records given or reports made to the Company or other corporation, limited liability company, partnership, joint venture, trust employee benefit plan or other enterprise of which Indemnitee was serving as a director, officer, employee, agent or fiduciary by an independent certified public accountant or by an appraiser or other expert selected with the reasonable care by the Company or other corporation, limited liability company, partnership, joint venture, trust employee benefit plan or other enterprise of which Indemnitee was serving as a director, officer, employee, agent or fiduciary. The provisions of this Section 12(d) shall not be deemed to be exclusive or to limit in any way the other circumstances in which the Indemnitee may be deemed to have met the applicable standard of conduct set forth in this Agreement.

(e) Actions of Others. The knowledge and/or actions, or failure to act, of any other director, officer, agent or employee of the Company or other corporation, limited liability company, partnership, joint venture, trust employee benefit plan or other enterprise of which Indemnitee was serving

as a director, officer, employee, agent or fiduciary shall not be imputed to Indemnitee for purposes of determining the right to indemnification under this Agreement.

Section 13. Remedies of Indemnitee.

(a) Subject to Section 13(e), in the event that (i) a determination is made pursuant to Section 11 of this Agreement that Indemnitee is not entitled to indemnification under this Agreement, (ii) advancement of Expenses is not timely made pursuant to Section 9 of this Agreement, (iii) no determination of entitlement to indemnification shall have been made pursuant to Section 11(a) of this Agreement within ninety (90) days after receipt by the Company of the request for indemnification, (iv) payment of indemnification is not made pursuant to Section 5 or Section 6 or the last sentence of Section 11(a) of this Agreement within ten (10) days after receipt by the Company of a written request therefor, (v) payment of indemnification pursuant to Section 3, Section 4 or Section 7 of this Agreement is not made within ten (10) days after a determination has been made that Indemnitee is entitled to indemnification, or (vi) in the event that the Company or any other person takes or threatens to take any action to declare this Agreement void or unenforceable, or institutes any litigation or other action or Proceeding designed to deny, or to recover from, the Indemnitee the benefits provided or intended to be provided to the Indemnitee hereunder, Indemnitee shall be entitled to an adjudication by a court of his entitlement to such indemnification or advancement of Expenses. Alternatively, Indemnitee, at his option, may seek an award in arbitration to be conducted by a single arbitrator pursuant to the Commercial Arbitration Rules of the American Arbitration Association. Indemnitee shall commence such proceeding seeking an adjudication or an award in arbitration within 180 days following the date on which Indemnitee first has the right to commence such proceeding pursuant to this Section 13(a); *provided*, *however*, that the foregoing clause shall not apply in respect of a proceeding brought by Indemnitee to enforce his rights under Section 5 of this Agreement. The Company shall not oppose Indemnitee's right to seek any such adjudication or award in arbitration.

(b) In the event that a determination shall have been made pursuant to Section 11(a) of this Agreement that Indemnitee is not entitled to indemnification, any judicial proceeding or arbitration commenced pursuant to this Section 13 shall be conducted in all respects as a de novo trial, or arbitration, on the merits and Indemnitee shall not be prejudiced by reason of that adverse determination. In any judicial proceeding or arbitration commenced pursuant to this Section 13 the Company shall have the burden of proving Indemnitee is not entitled to indemnification or advancement of Expenses, as the case may be.

(c) If a determination shall have been made pursuant to Section 11(a) of this Agreement that Indemnitee is entitled to indemnification, the Company shall be bound by such determination in any judicial proceeding or arbitration commenced pursuant to this Section 13, absent (i) a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's statement not materially misleading, in connection with the request for indemnification, or (ii) a prohibition of such indemnification under applicable law.

(d) The Company shall, to the fullest extent not prohibited by law, be precluded from asserting in any judicial proceeding or arbitration commenced pursuant to this Section 13 that the procedures and presumptions of this Agreement are not valid, binding and enforceable and shall stipulate in any such court or before any such arbitrator that the Company is bound by all the provisions of this Agreement. It is the intent of the Company that the Indemnitee not be required to incur legal fees or other Expenses associated with the interpretation, enforcement or defense of Indemnitee's rights under this Agreement by litigation or otherwise because the cost and expense thereof would substantially detract from the benefits intended to be extended to the Indemnitee hereunder. The Company shall indemnify Indemnitee against any and all Expenses and, if requested by Indemnitee, shall (within ten (10) days after receipt by the Company of a written request therefor) advance, to the extent not prohibited by law, such

Expenses to Indemnitee, which are incurred by Indemnitee in connection with any action brought by Indemnitee for indemnification or advance of Expenses from the Company under this Agreement or under any directors' and officers' liability insurance policies maintained by the Company, regardless of whether Indemnitee ultimately is determined to be entitled to such indemnification, advancement of Expenses or insurance recovery, as the case may be.

(e) Notwithstanding anything in this Agreement to the contrary, no determination as to entitlement to indemnification under this Agreement shall be required to be made prior to the final disposition of the Proceeding.

Section 14. Non-exclusivity; Survival of Rights; Insurance;.

(a) The rights of indemnification and to receive advancement of Expenses as provided by this Agreement shall not be deemed exclusive of any other rights to which Indemnitee may at any time be entitled under applicable law, the Company's Certificate of Incorporation, the Company's By-laws, any agreement, a vote of stockholders or a resolution of directors, or otherwise. No amendment, alteration or repeal of this Agreement or of any provision hereof shall limit or restrict any right of Indemnitee under this Agreement in respect of any action taken or omitted by such Indemnitee in his Corporate Status prior to such amendment, alteration or repeal. To the extent that a change in Delaware law, whether by statute or judicial decision, permits greater indemnification or advancement of Expenses than would be afforded currently under the Company's Certificate of Incorporation, the Company's By-laws and this Agreement, it is the intent of the parties hereto that Indemnitee shall enjoy by this Agreement the greater benefits so afforded by such change. No right or remedy herein conferred is intended to be exclusive of any other right or remedy, and every other right and remedy shall be cumulative and in addition to every other right and remedy given hereunder or now or hereafter existing at law or in equity or otherwise. The assertion or employment of any right or remedy hereunder, or otherwise, shall not prevent the concurrent assertion or employment of any other right or remedy.

(b) To the extent that the Company maintains an insurance policy or policies providing liability insurance for directors, officers, employees, or agents of the Company or of any other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise which such person serves at the request of the Company, Indemnitee shall be covered by such policy or policies in accordance with its or their terms to the maximum extent of the coverage available for any such director, officer, employee or agent under such policy or policies. If, at the time of the receipt of a notice of a claim pursuant to the terms hereof, the Company has director and officer liability insurance in effect, the Company shall give prompt notice of the commencement of such proceeding to the insurers in accordance with the procedures set forth in the respective policies. The Company and the Indemnitee shall thereafter take all necessary or desirable action to cause such insurers to pay, on behalf of the Indemnitee, all amounts payable as a result of such proceeding in accordance with the terms of such policies.

(c) The Company's obligation to indemnify or advance Expenses hereunder to Indemnitee who is or was serving at the request of the Company as a director, officer, employee or agent of any other corporation, limited liability company, partnership, joint venture, trust, employee benefit plan or other enterprise shall be reduced by any amount Indemnitee has actually received as indemnification or advancement of Expenses from such other corporation, limited liability company, partnership, joint venture, trust, employee benefit plan or other enterprise.

(d) The Company hereby acknowledges that, in addition to the rights provided in Article V of the Bylaws and this Agreement, Indemnitee may have certain rights to indemnification, advancement of Expenses and/or insurance (an "**Indemnity Right**") provided by another Person, whether

now or in the future (a "**Third Party Indemnitor**"). Notwithstanding anything to the contrary herein, the Company hereby agrees that in the event Indemnitee has an Indemnity Right, the Company (A) is the indemnitor of first resort (i.e., its obligations to indemnify Indemnitee are primary and any obligation of the applicable Third Party Indemnitor or its insurers to advance Expenses or to provide indemnification for the same Expenses or liabilities incurred by Indemnitee is secondary and excess); (B) shall be required to advance the full amount of Expenses incurred by Indemnitee and shall be liable for the full amount of all Expenses, judgments, penalties, fines and amounts paid in settlement by Indemnitee or on his behalf to the extent legally permitted and as required hereunder, without regard to any rights Indemnitee may have against the Third Party Indemnitor or its insurers; and (C) irrevocably waives, relinquishes and releases the Third Party Indemnitor and such insurers from any and all claims against the Third Party Indemnitor or such insurers for contribution, by way of subrogation or any other recovery of any kind in respect thereof. In furtherance and not in limitation of the foregoing, the Company agrees that in the event that any Third Party Indemnitor or its insurer should advance any Expenses or make any payment to Indemnitee for matters subject to advancement or indemnification by the Company pursuant to this Agreement or otherwise, the Company shall promptly reimburse such Third Party Indemnitor or insurer and that such Third Party Indemnitor or insurer shall be subrogated to all of the claims or rights of Indemnitee hereunder or otherwise including to the payment of Expenses in an action to collect. The Company agrees that any Third Party Indemnitor or its insurer not a party hereto shall be an express third party beneficiary of this Section 14, able to enforce such Section 14 of this Agreement according to its terms.

Section 15. Severability. If any provision or provisions of this Agreement shall be held to be invalid, illegal or unenforceable for any reason whatsoever: (a) the validity, legality and enforceability of the remaining provisions of this Agreement (including without limitation, each portion of any Section of this Agreement containing any such provision held to be invalid, illegal or unenforceable, that is not itself invalid, illegal or unenforceable) shall not in any way be affected or impaired thereby and shall remain enforceable to the fullest extent permitted by law; (b) such provision or provisions shall be deemed reformed to the extent necessary to conform to applicable law and to give the maximum effect to the intent of the parties hereto; and (c) to the fullest extent possible, the provisions of this Agreement (including, without limitation, each portion of any Section of this Agreement containing any such provision held to be invalid, illegal or unenforceable, that is not itself invalid, illegal or unenforceable) shall be construed so as to give effect to the intent manifested thereby.

Section 16. Enforcement. The Company expressly confirms and agrees that it has entered into this Agreement and assumed the obligations imposed on it hereby in order to induce Indemnitee to serve as a director or officer of the Company, and the Company acknowledges that Indemnitee is relying upon this Agreement in serving as a director or officer of the Company.

Section 17. Entire Agreement. Supersedes Prior Agreements. This Agreement constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and supersedes all prior agreements and understandings, oral, written and implied, between the parties hereto with respect to the subject matter hereof; *provided, however*, that this Agreement is a supplement to and in furtherance of the Certificate of Incorporation of the Company, the employment agreement between the Company and Indemnity and applicable law, and shall not be deemed a substitute therefor, nor to diminish or abrogate any rights of Indemnitee thereunder.

Section 18. Modification and Waiver. No supplement, modification or amendment of this Agreement shall be binding unless executed in writing by the parties thereto. No waiver of any of the provisions of this Agreement shall be deemed or shall constitute a waiver of any other provisions of this Agreement nor shall any waiver constitute a continuing waiver.

Section 19. Notice by Indemnitee. Indemnitee agrees promptly to notify the Company in writing upon being served with any summons, citation, subpoena, complaint, indictment, information or other document relating to any Proceeding or matter which may be subject to indemnification or advancement of Expenses covered hereunder. The failure of Indemnitee to so notify the Company shall not relieve the Company of any obligation which it may have to the Indemnitee under this Agreement or otherwise except to the extent the Corporation is prejudiced in its defense of such action, suit or proceeding as a result of such failure.

Section 20. Notices. All notices, requests, demands and other communications under this Agreement shall be in writing and shall be deemed to have been duly given if (a) delivered by hand and receipted for by the party to whom said notice or other communication shall have been directed, (b) mailed by certified or registered mail with postage prepaid, on the third business day after the date on which it is so mailed, (c) mailed by reputable overnight courier and receipted for by the party to whom said notice or other communication shall have been directed or (d) sent by facsimile transmission, with receipt of oral confirmation that such transmission has been received:

(a) If to Indemnitee, at the address indicated on the signature page of this Agreement, or such other address as Indemnitee shall provide to the Company.

(b) If to the Company to

Helius Medical Technologies, Inc.
642 Newtown Yardley Rd #100
Newtown, PA 18940
Attention: Chief Executive Officer

or to any other address as may have been furnished to Indemnitee by the Company.

Section 21. Contribution. To the fullest extent permissible under applicable law, if the indemnification provided for in this Agreement is unavailable to Indemnitee for any reason whatsoever, the Company, in lieu of indemnifying Indemnitee, shall contribute to the amount incurred by Indemnitee, whether for judgments, fines, penalties, excise taxes, amounts paid or to be paid in settlement and/or for Expenses, in connection with any claim relating to an indemnifiable event under this Agreement, in such proportion as is deemed fair and reasonable in light of all of the circumstances of such Proceeding in order to reflect (i) the relative benefits received by the Company and Indemnitee as a result of the event(s) and/or transaction(s) giving cause to such Proceeding; and/or (ii) the relative fault of the Company (and its directors, officers, employees and agents) and Indemnitee in connection with such event(s) and/or transaction(s).

Section 22. Applicable Law and Consent to Jurisdiction. This Agreement and the legal relations among the parties shall be governed by, and construed and enforced in accordance with, the laws of the State of Delaware, without regard to its conflict of laws rules. Except with respect to any arbitration commenced by Indemnitee pursuant to Section 13(a) of this Agreement, the Company and Indemnitee hereby irrevocably and unconditionally (i) agree that any action or proceeding arising out of or in connection with this Agreement shall be brought only in the Chancery Court of the State of Delaware (the “Delaware Court”), and not in any other state or federal court in the United States of America or any court in any other country, (ii) consent to submit to the exclusive jurisdiction of the Delaware Court for purposes of any action or proceeding arising out of or in connection with this Agreement, (iii) appoint, to the extent such party is not otherwise subject to service of process in the State of Delaware, irrevocably Corporation Services Company as its agent in the State of Delaware as such party’s agent for acceptance of legal process

in connection with any such action or proceeding against such party with the same legal force and validity as if served upon such party personally within the State of Delaware, (iv) waive any objection to the laying of venue of any such action or proceeding in the Delaware Court, and (v) waive, and agree not to plead or to make, any claim that any such action or proceeding brought in the Delaware Court has been brought in an improper or inconvenient forum.

Section 23. Identical Counterparts. This Agreement may be executed in one or more counterparts, each of which shall for all purposes be deemed to be an original but all of which together shall constitute one and the same Agreement. Only one such counterpart signed by the party against whom enforceability is sought needs to be produced to evidence the existence of this Agreement.

Section 24. Miscellaneous. Use of the masculine pronoun shall be deemed to include usage of the feminine pronoun where appropriate. The headings of the paragraphs of this Agreement are inserted for convenience only and shall not be deemed to constitute part of this Agreement or to affect the construction thereof.

IN WITNESS WHEREOF, the parties have caused this Agreement to be signed as of the day and year first above written.

HELIUS MEDICAL TECHNOLIGIES, INC.

By: _____
Name:
Title:

INDEMNITEE

_____
Name:

Address: _____

_____

_____

[*SIGNATURE PAGE TO INDEMNIFICATION AGREEMENT*]

Exhibit 21.1

SUBSIDIARIES OF HELIUS MEDICAL TECHNOLOGIES, INC

ENTITY NAME	**JURISDICTION**
Helius Medical, Inc.	Delaware
Helius Medical Technologies (Canada), Inc.	Canada
Helius NeuroRehab, Inc.	Delaware
Helius Canada Acquisition Ltd.	Canada
Heuro Canada, Inc.	Canada

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

Helius Medical Technologies, Inc.
Newtown, Pennsylvania

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-236101), Form S-1 (No. 333-250974 and 333-248824) and Form S-8 (No. 333-204155, 333-218095 and 333-229724) of Helius Medical Technologies, Inc., of our report dated March 10, 2021, relating to the consolidated financial statements of Helius Medical Technologies, Inc., which appears in this Annual Report on Form 10-K for the year ended December 31, 2020. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ BDO USA, LLP

Philadelphia, Pennsylvania
March 10, 2021

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 10, 2021

/s/ Dane C. Andreeff
Dane C. Andreeff
Interim Chief Executive Officer and Director
(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, Joyce LaViscount, 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 10, 2021

/s/ Joyce LaViscount
Joyce LaViscount
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, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Dane C. Andreeff, as Interim Chief Executive Officer of the Company, and Joyce LaViscount, 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 10, 2021

/s/ Dane C. Andreeff

Dane C. Andreeff
Interim Chief Executive Officer and Director
(Principal Executive Officer)

/s/ Joyce LaViscount

Joyce LaViscount
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.