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, 2019

☐ **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 Section 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 (Section §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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the common equity held by non-affiliates of the registrant on June 28, 2019, based on the closing price on that date of $2.20, was approximately $41,928,863. As of March 9, 2020, there were 31,784,522 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 2020 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, 2019.

TABLE OF CONTENTS

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. 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, other products not yet developed or acquired, 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, potential infringement of our intellectual property, future litigation waged against us and its outcome, any product liability we may incur, the sufficiency of our operating insurance, including sufficient product liability insurance, our limited operating history, our dependence on a small number of employees, employee conflicts of interest, our dependence on outside scientists and third party research institutions, our future expenses and cash flow, our ability to become profitable, our future financing arrangements, our ability to accurately report our financial position, our accountants' future perspective including any going concerns, our ability to maintain effective internal controls, any future stock price, the potential dilution of the stock from future sales of the Company's equity securities, future disclosure requirements, future regulatory risks, our relationship with the U.S. Army, 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. These and additional risks and uncertainties are more fully described in this Annual Report and our other public filings with the Securities and Exchange Commission or the SEC.

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. Factors that could cause the actual results to differ materially from those in the forward-looking statements include future economic, competitive, reimbursement and regulatory conditions; new product introductions, demographic trends, the intellectual property landscape, litigation, financial market conditions, continued availability of capital, and, future business decisions made by us and our competitors. All of these factors are difficult or impossible to predict accurately and many of them are beyond our control. Investors are cautioned that any such forward-looking statements are not guarantees of future performance and actual results or developments may differ materially from those projected in the forward-looking statements. Undue reliance should not be placed on forward looking statements, which speak only as of the date they are made. Except as required by applicable securities laws, we undertake no obligation to update or alter these forward-looking statements (and expressly disclaim any such intention or obligation to do so) in the event that management's beliefs, estimates, opinions, or other factors should change.

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 independent third-party sources, including independent industry publications, reports by market research firms and other independent 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 review of internal surveys, general information discussed in the industry, and independent 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 report and other publications.

PART I

ITEM 1. BUSINESS

Overview

We are a neurotech company focused on neurological wellness. Our purpose is to develop, license and acquire unique and non-invasive platform technologies that amplify the brain's ability to heal itself and reduce symptoms of neurological disease or trauma.

Our first product, known as the Portable Neuromodulation Stimulator, or PoNS™, is an authorized class II, non-implantable, medical device in Canada intended for use as a short term treatment (14 weeks) of chronic balance deficit due to mild-to-moderate traumatic brain injury, or mmTBI, and is to be used in conjunction with physical therapy. The PoNS™ is an investigational medical device in the United States, the European Union, or EU, and Australia, or AUS, and it is currently under review for clearance from the AUS Therapeutic Goods Administration. PoNS Treatment™ is currently not commercially available in the United States, the European Union or Australia. The PoNS Treatment™ is a combination of neuromodulation with the PoNS device and targeted therapeutic activities and/or cognitive therapy. It is the first and only treatment that combines neurostimulation of cranial nerves via the tongue to restore lost function.

We were incorporated in British Columbia, Canada on March 13, 2014. On May 28, 2014, we were reincorporated from British Columbia to the State of Wyoming, and on July 20, 2018, we were reincorporated from the State of Wyoming to the State of Delaware. We are headquartered in Newtown, Pennsylvania.

On December 21, 2018, our wholly owned subsidiary NeuroHabilitation Corporation, or NHC, changed its name to Helius Medical, Inc, or HMI. On January 31, 2019, we formed another wholly owned subsidiary, Helius NeuroRehab, Inc., or HNR, a Delaware corporation, which will operate a commercial site for the delivery of PoNS Treatment to patients with balance and gait disorders upon FDA clearance. On October 10, 2019, we formed Helius Canada Acquisition Ltd., or HCA, a company incorporated under the federal laws of Canada and a wholly owned subsidiary of Helius Medical Technologies (Canada), Inc., or HMC, a company incorporated under the federal laws of Canada, which acquired Heuro Canada, Inc., or Heuro, from Health Tech Connex Inc., or HTC, on October 30, 2019 (see Note 2).

Our 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"). Our 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, our common stock began trading on the 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.

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 quarterly report on Form 10-Q have been reflected on a post-split basis.

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 targeted physical and / or cognitive therapy. The therapy 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 nerves in the tongue that have direct pathways to the brain, through the brain stem. The combination of mild stimulation with therapeutic activities 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 assessments gives the clinician and the patient a unique and powerful method to assess treatment progress. The patient re-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 life functions including sensory perception and movement. From the brain stem, these impulses travel throughout the brain and activate or reactivate neurons and structures involved in human function. Researchers believe that targeted physical therapy

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 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 chronic 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 chronic 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 physical therapy. While physical therapy can help to promote balance recovery, individuals are often unable to return to their full function and are left living with a chronic balance deficit.

Prior to the development of the PoNS device, there were no treatments available that were clinically proven and indicated to treat long-term balance deficit. A few studies have suggested that physical therapy 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 proven that physical therapy 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 physical therapy alone for the treatment of chronic balance deficit following mmTBI. Consequently, we believe that there is a large potential commercial opportunity for the PoNS Treatment in the treatment of chronic 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.

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 and 93,000 in Canada. 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.

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.

PoNS Clinical Trials and Scientific Support in mmTBI

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 chronic balance deficit due to mmTBI.

The trial was launched in 2015 in conjunction with the U.S. Army Medical Research and Materiel Command 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 standardized targeted 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 chronic 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 chronic 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 mmTBI ever performed.
- Participants who had a profound, chronic balance disorder resistant to conventional physical therapy, and with a prognosis of a lifetime of this disability were, on average, in the normal range of balance following the 14 weeks of treatment.
- In a subset of nine participants, MRI scans revealed structural changes in the brain resulting from the neuromodulation inducing neuroplastic effect.
- 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' chronic 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 suggests that there was an independent device effect.

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. 39 patients with MS were treated with PoNS in Canada between March 2019 and September 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.

Regulatory Status Worldwide

Canadian Regulatory Status: mmTBI

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 chronic balance deficit due to mmTBI.

Canadian Regulatory Status: MS

On February 27, 2020, we submitted a Canadian Class II license amendment application for the treatment of gait deficit in patients with mild and moderate MS symptoms. Also as indicated by Health Canada, our 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

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 mild and moderate MS are sufficient to demonstrate a favorable risk/benefit profile, as required for de novo clearance. Novel treatments for MS are highlighted as a specific target of the FDA as a high unmet medical need disease. We plan to submit to the FDA for this high unmet medical need in the second half of 2020.

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 chronic 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 chronic 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 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 clearance of de novo submission 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.

Based on this revised protocol, we estimate that enrollment will begin in April 2020 with the completion of the trial and submission to the FDA in the second quarter of 2021.

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 and have received and answered all the questions supplied to date and wait for the TGA's decision.

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 chronic balance deficit related to mmTBI. Under our agreements with the U.S. Army 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 chronic 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 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.

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 provided 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 party 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. 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 (10) years, renewable by HTC for one additional ten (10) year term upon sixty (60) 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 416,666 shares of common stock at a price of $4.80 per share and 208,333 warrants exercisable at $7.20 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 1,111,111 shares of common stock at a price of $4.50 per share and 555,556 warrants exercisable at $6.75 per share for a period of three years from the date of issuance. In November 2017, A&B exercised 208,333 warrants at a price of $7.20 per share and we received gross proceeds of $1.5 million. During the first quarter of 2018, A&B exercised its remaining 555,556 warrants at a price of $6.75 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.

Russia Distribution Agreement

In November 2014, we signed a development and distribution agreement with Altair LLC to apply for registration and distribution of the PoNS device in the territories of the former Soviet Union. Through March 31, 2019, we were entitled to receive a 7% royalty on sales of the devices within the territories. Altair terminated the distribution agreement effective May 20, 2019. We did not make any commercial sales in the territories pursuant to this distribution agreement.

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 will be 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.

Commercialization

Canadian Commercialization

Based on the collective experience of our patients that have completed the 14-week PoNS Treatment have been encouraging, and consistent with the results of our two clinical trials, one for 5 weeks and the other for 14 weeks, commercial 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 shown improvement in comfortable gait speed, a measure of their ability to walk, with a meaningful clinical difference at the end of their treatment. We believe that the consistency of the patient results from our initial commercial experience supports our plans to expand access PoNS Treatment in Canada.

In March 2019, we began the initial commercialization of our PoNS Treatment in Canada, where our PoNS device is the first and only device authorized for the treatment of balance deficit due to mmTBI.

Throughout 2019, we made important progress in advancing and refining our commercialization strategy in Canada

We increased access to our PoNS Treatment by expanding our authorized clinic network throughout Canada to include 7 clinics locations by the end of the year, exceeding our goal for 2019.

We also developed and pursued several marketing initiatives to raise awareness of PoNS Treatment. Specifically:

- We developed a digital marketing campaign focused on raising awareness of awareness of the PoNS Treatment among patients, physiatrists and physical therapists. Most recently, we re-launched our ponstreatment.ca website and continued to

build upon our social media-based marketing efforts, with the creation of relevant content for patients and the broader concussion community.

- We leveraged our Medical Affairs specialists to raise awareness of PoNS treatment among key opinion leaders and target important constituents in the industry, including industry associations and advocacy groups. We collaborated, and continue to collaborate, with several major concussion advocacy groups including the Ontario Brain Injury Association (OBIA), Brain Injury Canada (BIC), Brain Injury Society of Toronto (BIST) and others to promote PoNS Treatment and drive awareness through their respective conferences and meetings.
- We attended major industry conferences, including OBIA in November 2019, the Niagara Brain Injury meeting in December 2019 and the University Health Network TBI conference in February 2020, and have identified other key conferences to attend in 2020, including the Brain Injury Canada Conference.

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.

We created a local Canadian commercial team consisting of a Vice President/General Manager, a Director of Business Development, a Reimbursement Specialist, a Clinic Operations Manager and a national sales professional to manage our commercial activities going forward.

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 connection with this initiative, our Canadian commercial team refined our targeting criteria for the clinics that we engage with and authorize to provide PoNS Treatment. Specifically, they prioritized clinics with a large existing commercial focus on neurorehabilitation, established referral networks with other medical facilities for the treatment of patients with neurological conditions and significant reimbursement experience and payor relationships with respect to the treatment of neurological conditions. Further, they prioritized clinics within Ontario, and specifically the Greater Toronto Area, or GTA, given the disproportionate population disbursement in Canada (40% of all Canadians live in Ontario).

We have authorized 7 new clinic locations in the first two months of 2020 for a total of 14 clinic locations to provide PoNS Treatment across Canada. In addition, we have a clinical experience program through University Health Network Toronto at 3 private clinic locations with an opportunity to transition to commercial treatment centers. We expect that it will take the newly authorized clinics time to work the PoNS Treatment into the clinic rotation but are confident that our focus on authorizing clinics which meet our refined targeting criteria will drive efficiency and PoNS sales performance.

In addition to pursuing this expansion plan, we modified our go-to-market pricing model in 2020 based on direct market feedback. Our modified pricing model is focused on reducing the need for clinics and patients to pay large, upfront costs at the start of treatment.

In parallel with our commercialization efforts, we, in concert with input from insurers, have created a value dossier on behalf of the clinics and patients to fully demonstrate in both scientific and financial terms, the merits of PoNS Treatment for claimants. This will be provided to our clinics across Canada to submit as part of treatment plans with reimbursement applications. Our reimbursement strategy is focused initially in the auto accident insurance and workers compensation, or WC, market as well as long-term disability cases.

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 completion of our registrational clinical trial and submission to FDA on our application for de novo classification and clearance.

In this pre-commercial phase, we are focused on building relationships with key large neurorehabilitation centers, generating important data on outcomes of the PoNS Treatment 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 mmTBI-related balance deficit following FDA marketing authorization.

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 six 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, we have maintained solid relationships with the U.S. sites and expect several to become clinical trial sites for TBI-002.

U.S. Commercialization

To commercialize the PoNS Treatment in the United States following FDA marketing authorization, 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 beyond the initial six clinic centers that will be trained to deliver the PoNS Treatment through our CEP program. Care of patients with brain injuries 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 physiatrists, neurologists 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 provide broad access and reimbursement for the PoNS Treatment over time. At launch, prior to the initiation of 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. 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 have marketing authorization to commercialize the PoNS Treatment in Russia and Uzbekistan. As previously discussed, we have developed a clinical relationship with Altair LLC, a Russian distribution company. Whereby, we were entitled to receive a 7% royalty on sales of the devices within the territories. Altair terminated the distribution agreement effective May 20, 2019. 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.

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 have entered into a consulting agreement with a UK-based company with expertise in the development of new services in the healthcare industry. The goal is to leverage local market insights to develop a comprehensive commercialization strategy and tactical plan for launch of the PoNS Treatment in the UK. This approach will allow us to focus our internal infrastructure on the Canadian and United States launches while assessing our opportunity in the EU and 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 Therapeutic Goods Administration, or TGA, in Australia during the third quarter of 2019. We are working with consultants in Australia with expertise in market development to build our go-to-market strategy.

Coverage and Reimbursement

With the clearance of the PoNS device for FDA marketing authorization, 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 non-traditional payers may be among the earliest to provide coverage and reimbursement for the PoNS Treatment. Therefore, we plan to focus 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.

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. 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.

In parallel, we will engage with the Centers for Medicare & Medicaid Services, or CMMS, and select commercial payers, with a recognition that obtaining coverage and reimbursement from government and commercial payers is likely to take at least 24 months. Because there are no approved treatments for chronic balance deficit due to mmTBI and there is a high-unmet need among patients, we anticipate that there will be demand to access the PoNS Treatment following FDA marketing authorization. We have contracted with McKesson to set up and deploy a reimbursement hub for the PoNS Treatment, following FDA marketing authorization. This will provide patients with the means to navigate potential reimbursement and to demonstrate patient demand for the PoNS Treatment to 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 secrets of neuro-modulation which now establishes neurostimulation as a legitimate and scientifically validated 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 neuro-stimulation 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 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, 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.

On April 17, 2017, we announced that the USPTO had issued two medical method patents (U.S. Patent Nos. 9,597,501 and 9,597,504) that together further protect the intellectual property rights for our core asset, the PoNS device therapeutic techniques. These patents bolster the current family of PoNS patents protecting various forms of targeted physical therapy combinations with both skin and oral cavity stimulation using the PoNS device or any equivalent neurostimulation device. On May 23, 2017, we announced that the USPTO had issued its first method patent (US Patent No. 9,656,069) that features claims directed to the use of the PoNS device for human performance improvement rather than rehabilitation therapy.

Company Owned Intellectual Property

As of December 31, 2019, we have filed 31 U.S. patent applications related to various technical and ornamental aspects of the PoNS device: 15 non-provisional patent applications that describe various technical features in the current version device and 16 design patent applications describing various ornamental designs. We are the sole assignee for these 31 U.S. patent filings. In addition to the first issued patent (U.S. Patent No. 9,072,889), the USPTO has issued 12 utility patents and 16 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	Pending	N/A	N/A	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
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

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. On October 31, 2014, we filed a trademark application with the USPTO for the PoNS mark. On May 23, 2019 we filed trademark applications with the USPTO for the Helius and Helius Medical 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 regulated as a Class II medical device. We utilized the *de novo* classification procedures to seek U.S. marketing authorization for the PoNS device, 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, introducing the product could be delayed or canceled, which could cause our launch to be delayed. 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, 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

The PoNS device is subject to premarket notification and clearance under section 510(k) of the FDCA. 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 down-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 is required to classify the device within 120 days following receipt of the *de novo* application. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are 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.

As previously discussed, we utilized the *de novo* classification process to request our marketing authorization for the PoNS device for balance disorder in mmTBI, 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 down-classification, 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 Federal Trade Commission 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 payors 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 payors, 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 program Anti-Kickback Statute and the federal Civil False Claims Act.

The federal health care programs Anti-Kickback Statute (“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 Anti-Kickback Statute 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;
- 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 Australia Therapeutic Goods Administration, or TGA during the third quarter of 2019.

Third-Party Payor 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 payors 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 payors, including, in the United States, governmental payors 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 payor, whether governmental or private, has its own process and standards for determining whether it will cover and reimburse a procedure or particular product. Private payors often rely on the lead of the governmental payors 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. 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 payors.

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 payors 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 payors 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

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. 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 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 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 Federal Trade Commission or 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, or the FTCA, 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. Individually 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 protected health information, or 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. The CCPA may increase our compliance costs and potential liability.

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 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, or WBCA.

Acquisition of NeuroHabilitation Corporation and Concurrent Financing

On June 13, 2014, we completed the acquisition of 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 7,060,016 shares of our Class A common stock, or 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 3,048,000 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$5.00 per share for a period of two years.

Listing of our Common Stock on the CSE, TSX, OTCQB and Nasdaq

Following our Reverse Merger, we obtained approval of the listing of our common stock on the Canadian Securities Exchange, or CSE. On April 18, 2016, our common stock was listed on the Toronto Stock Exchange, or TSX, under the symbol “HSM.” At the same time, we delisted our common stock from the CSE. Our Warrants were also approved for listing on the TSX on April 18, 2016. 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, or Nasdaq, and ceased to trade on the OTCBQ.

Reverse Stock Split

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.

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.

As a result, following the reincorporation, we authorized capital stock pursuant to our Delaware charter 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 directors.

Formation of Helius NeuroRehab Inc.

In January 2019, we formed 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.

Formation of Helius Canada Acquisition Ltd.

On October 10, 2019, we formed HCA, a company incorporated under the federal laws of Canada, which is a wholly owned subsidiary of Helius Medical Technologies (Canada), Inc. HCA was formed to facilitate the acquisition of Heuro Canada Inc. that was completed on October 30, 2019.

Acquisition of Heuro Canada Inc.

On October 30, 2019, we acquired Heuro, a company incorporated under the federal laws of Canada, which is a wholly owned subsidiary of HCA, from Health Tech Connex, Inc, or HTC (see Note 2).

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 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.

Employees

We have a diverse, multi-cultural workforce comprised of engaged individuals with appropriate qualifications and competencies to support our growth. Members of our senior management team have an average of over 25 years of experience in the health sciences industry with recognized leadership expertise in their functional areas.

As of December 31, 2019, we had 19 full time employees and four consultants. Given the change in our United States regulatory timeline in 2019, we have prioritized our resources to support our resubmission to the FDA and commercialization efforts in Canada. As a result, 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.

Business Uncertainties and Going Concern Risk

To date we have generated $2.0 million in revenue from the commercial sale of products or services. There are a number of conditions that we must satisfy before we will be able to generate sufficient revenue, 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, our ability to generate significant revenue in the future will be dependent upon the receipt of FDA marketing authorization of the PoNS device for treating balance disorder associated with mmTBI. Because we have generated limited revenues from commercialization, we are dependent entirely on funding from outside investors. There is no guarantee that such funding will be available at all or in sufficient amounts to satisfy our required expenditures. Furthermore, even if we were able to raise sufficient capital to successfully design and manufacture a commercially viable version of the PoNS device and to receive FDA approval, a CE Mark or TGA clearance, we do not currently have any contracts or other arrangements to sell the PoNS device other than our Canadian distribution agreement. Accordingly, we cannot know that we will ever be able to generate sufficient revenue from the sales of products or services to achieve or maintain profitability.

Additionally, based on management's assessment, there is substantial doubt about the Company's ability to continue as a going concern. This means that there is substantial doubt that we can continue as an on-going business beyond May of 2020. While we had $5.5 million of cash as of December 31, 2019, we do not currently have sufficient resources to accomplish all of the above conditions necessary for us to generate sufficient revenues to fund our operations. In reviewing this filing, you should carefully consider this uncertainty, the risks described in the section entitled "Risk Factors" and other risks described throughout this Annual Report.

RISK FACTORS

An investment in our common stock involves a number of very significant risks. You should carefully consider the following risks and uncertainties in addition to other information in this Annual Report in evaluating our company and its business before purchasing shares of our common stock. Our business, operating results and financial condition could be seriously harmed due to any of the following risks. The risks described below may not be all of the risks facing our company. Additional risks not presently known to us or that we currently consider immaterial may also impair our business operations. You could lose all or part of your investment due to any of these risks.

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, 2019 and 2018, we incurred a net loss of $9.8 million and $28.6 million, respectively, and used cash in operations of $21.0 million and $19.6 million, respectively. We have an accumulated deficit of $104.8 million as of December 31, 2019. 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.

We currently have limited working capital and liquid assets. We had cash of $5.5 million at December 31, 2019. To date we have not generated significant revenue from the commercial sale of products or services. There are a number of conditions that we must satisfy before we will be able to generate significant revenue, including but not limited to FDA marketing authorization of the PoNS device for mmTBI, manufacturing of a commercially-viable version of the PoNS device, obtaining favorable reimbursement from third party payers, and demonstration of effectiveness sufficient to generate commercial orders by customers for our product. We do not currently have sufficient resources to accomplish all of these conditions necessary for us to generate significant revenue, and we believe our existing capital resources will be insufficient to fund our operations beyond May of 2020. We will therefore require substantial additional funds in order to continue to conduct the research and development and regulatory authorization activities necessary to bring our product to market, to establish effective marketing and sales capabilities and to develop other product candidates. We may never succeed in achieving regulatory authorization for our current product candidate in the United States, Europe or Australia. We may be unable to raise the additional funding to finance our business on commercially reasonable terms, or at all. 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.

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, 2019 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. For example, we believe our existing capital resources will be insufficient to fund our operations beyond May of 2020. 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. 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. 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. 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 these jurisdictions, 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. We intend to generate additional data to address the FDA's concerns and resubmit our request for de novo classification. However, the FDA has substantial discretion in the de novo review process and may refuse to accept our application or may decide that our new 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 chronic balance deficit in patients with mmTBI 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.

We may 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.

Before obtaining marketing authorization from regulatory authorities for the sale of the PoNS device, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidate. Clinical trials are expensive, time consuming and uncertain as to outcome. We cannot guarantee that clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of testing. Delays can be costly and could negatively affect our ability to complete a clinical trial and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize the PoNS device. If we are unable to complete such planned clinical trials, or are unsuccessful in doing so, we will be unable to advance the PoNS device to regulatory authorization and commercialization, which would harm our business, financial condition, results of operations.

Our PoNS technology is a new, "untested" 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 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. While the effectiveness of our PoNS technology to treat balance disorders related to mmTBI or any other neurological disorder has not been established in studies conducted in a controlled environment, it remains a new, "untested," and therefore unproven treatment. Such 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 physical therapy 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 these third-party manufacturers and distributors 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 these third-party manufacturers and distribution providers 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 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, and 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 products beyond our single product by commercializing new potential product candidates, 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 mmTBI, which is currently our only indication for our only product candidate. 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.

Outbreaks of communicable diseases in various parts of China and other countries may materially and adversely affect our business, financial condition and results of operations.

We may face risks related to health epidemics or outbreaks of communicable diseases. For example, there have been recent outbreaks in several countries, including China, of a highly transmissible and pathogenic coronavirus. The outbreak of such communicable diseases could result in a widespread health crisis that could adversely affect general commercial activity and the economies and financial markets of many countries. Since some of our business partners are in China and other Asian countries, including manufacturing operations for components of the PoNS device, an outbreak of communicable diseases in Asia or elsewhere, or the perception that such an outbreak could occur, and the measures taken by the governments of countries affected could adversely affect our business, financial condition or results of operations. For example, an outbreak could significantly disrupt our business by limiting our ability to travel or ship materials within or outside China and forcing temporary closure of facilities that we rely upon.

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 arrangements with A&B, 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* reclassification 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. 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. We intend to generate additional data to address the FDA's concerns and resubmit our request for de novo classification. However, the FDA has substantial discretion in the de novo review process and may refuse to accept our application or may decide that our new 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 mmTBI, introducing the product could be delayed or canceled, which would cause our launch to be delayed or cancelled. In addition, the FDA may determine that the PoNS device requires the more costly, lengthy and uncertain pre-market approval process. For example, if the FDA disagrees with our determination that the *de novo* classification procedures are the appropriate path to obtain marketing authorization for the PoNS device, the FDA may require us to submit a PMA application, which is generally more costly and more burdensome and can take several years from the time the application is submitted to the FDA until an approval is obtained.

Moreover, we are currently developing the PoNS device for other potential 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* down-classification, 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* down-classification, 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 a clinical trial 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. Clinical trials are complex, expensive and may proceed more slowly than anticipated, and we cannot be certain that our product candidate will be shown to be safe and effective for human use.

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. However, we intend to generate additional data, including additional clinical data, to address the FDA's concerns and resubmit our request for *de novo* classification. 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.

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

As we are required to conduct clinical trials to obtain FDA marketing authorization, we 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 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.

Our commercialization strategy is premised on 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 reimbursement code so that the PoNS device is covered under Medicare and Medicaid. 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. 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, 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. 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.

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. 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.

We are heavily dependent upon the ability and expertise of our Chief Executive Officer 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, and in particular Philippe Deschamps, our President and Chief Executive Officer, Joyce LaViscount, our Chief Financial Officer and Chief Operating Officer, Jonathan Sackier, our Chief Medical Officer. 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.

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 plan to 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 intend to rely on distributors to sell our product. We cannot assure you that we will succeed in 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 independent distributors with significant technical knowledge. In addition, the commissions we pay our distributors could

increase over time, which would result in higher sales and marketing expenses. Furthermore, 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.

While we have executed an exclusive strategic alliance agreement with HTC and Heuro, we cannot guarantee the commercial success of this agreement, since Heuro is a newly formed entity and has no history of successfully developing clinic systems to commercialize a medical device 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," and is currently in a transition period. 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).

As a result of the use of our product candidates in clinical trials, and if and when we sell 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 an "emerging growth company" under the Jumpstart Our Business Startups Act of 2012, or JOBS Act, and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company" as defined in the JOBS Act. As an "emerging growth company", we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of section 404 of the Sarbanes-Oxley Act of 2002, reduced disclosure obligations regarding executive compensation in our period reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation, shareholder approval of any golden parachute payments not previously approved and presenting the relationship between executive compensation actually paid and our financial performance. We will remain an "emerging growth company" until December 31, 2020. 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 be

more volatile. Additionally, we have irrevocably elected to comply with new or revised accounting standards even though we are an emerging growth company.

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 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 over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. 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 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. 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. 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. 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.

Risks Related to Our Common Stock

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 the sale of equity securities, 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.

An active trading market for our common stock on Nasdaq may not continue to develop or be sustained.

Although our common stock is listed on Nasdaq, as of April 2018, 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.

If we are not able to comply with the applicable Nasdaq continued listing requirements or standards, Nasdaq could delist our common stock.

Our common stock is currently listed on Nasdaq. 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.

In the event that our common stock is delisted from Nasdaq and is not eligible for quotation or listing on another market or exchange, trading of our common stock could be conducted only in the over-the-counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board. In such event, it could become more difficult to dispose of, or obtain accurate price quotations for, our common stock, and there would likely be a reduction in our coverage by securities analysts and the news media, which could cause the price of our common stock to decline further. In addition, it may be difficult for us to raise additional capital if we are not listed on a major exchange.

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 Nasdaq on 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 will likely 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; and a substantial, sustained decline in the price of shares of our common stock below the minimum Nasdaq listing requirement could cause our common stock to be delisted from such exchange, further reducing market liquidity. 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.

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.

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.

Holders of our Warrants will have no rights as shareholders until such holders exercise their Warrants and acquire our common shares.

Until holders of Warrants acquire common shares upon exercise of the Warrants, holders of Warrants will have no rights with respect to the common shares underlying such Warrants. Upon exercise of the Warrants, the holders thereof will be entitled to exercise the rights of common shareholders only as to matters for which the record date occurs after the exercise date.

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.

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 10,444 square feet of lease office space. The lease terminates in January 2023, with an option to extend until January 2028. Monthly rent plus utilities is approximately $21 thousand per month, with a 3% annual increase. Our registered office and registered agent is located at Corporation Trust Company, 1209 Orange Street, Wilmington, DE 19801.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we are subject to various legal proceedings and claims that arise in the ordinary course of our business activities. 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, other than as set forth below in respect of the matters described below. 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.

On or about July 9, 2019, a putative shareholder class action lawsuit, *Caramahai v. Helius Medical Technologies, Inc. et al.*, Case No. 1:19-cv-06365 (S.D.N.Y.), was filed against the Company and three of our individual officers in the Southern District of New York, or the *Caramahai* Action. The lawsuit alleges that the Company made materially false and misleading statements regarding the prospects for FDA approval of Helius's application for de novo classification and marketing authorization of its PoNS device in the United States. As a result of these alleged misstatements, the *Caramahai* Action asserts claims on behalf of shareholders who bought or sold Helius common stock between from November 9, 2017 to April 10, 2019 for alleged violations of the federal securities laws, specifically Section 10(b) and Rule 10b-5 of the Securities Exchange Act of 1934, as amended.

On or about July 31, 2019, a putative shareholder class action lawsuit, *Evans v. Helius Medical Technologies, Inc. et al.*, Case No. 1:19-cv-07171 (S.D.N.Y.), was filed against the Company and three of our individual officers in the Southern District of New York, or the *Evans* Action. The *Evans* Action alleges similar claims as the *Caramahai* Action.

On September 9, 2019, three Helius shareholders each filed motions in the *Caramahai* and *Evans* cases seeking to consolidate the two proceedings into a single putative class action. The individual motions also sought to have the movant appointed as Lead Plaintiff and have the movant's attorneys appointed as Lead Counsel. On September 13 and 17, 2019, respectively, two of the movants filed notices withdrawing their motions on the ground that they did not appear to have "the largest financial interest in the relief sought by the class." The motion filed by the third movant remains pending before the Court and unopposed.

While we believe that each of the *Caramahai* Action and the *Evans* Action is without merit and intend to vigorously defend our position in each case, we recognize that additional putative class actions or related proceedings may be filed. Given that each of these legal proceedings is in its early stages, we are unable to predict the probable outcomes at this time.

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" and we have a series of warrants that trade on the TSX.

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

Holders

As of March 9, 2020, there were approximately 61 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. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this filing, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a neurotech company focused on neurological wellness. Our purpose is to develop, license and acquire unique and non-invasive platform technologies that amplify the brain's ability to heal itself and reduce symptoms of neurological disease or trauma.

Our first product, known as the Portable Neuromodulation Stimulator ("PoNS™"), is an authorized class II, non-implantable, medical device in Canada intended for use as a short term treatment (14 weeks) of chronic balance deficit due to mild-to-moderate traumatic brain injury (mmTBI) and is to be used in conjunction with physical therapy. The PoNS™ is an investigational medical device in the United States, the European Union ("EU"), and Australia ("AUS"), and it is currently under review for clearance from the AUS Therapeutic Goods Administration. PoNS Treatment™ is currently not commercially available in the United States, the European Union or Australia. The PoNS device, when combined with targeted therapeutic activities and/or cognitive therapy, or PoNS Treatment™, is the first and only treatment that combines neurostimulation of cranial nerves via the tongue to restore lost function.

On December 21, 2018, our wholly owned subsidiary NeuroHabilitation Corporation, or NHC, changed its name to Helius Medical, Inc, or HMI. On January 31, 2019, we formed another wholly owned subsidiary, Helius NeuroRehab, Inc., or HNR, a Delaware corporation, which will operate a commercial site for the delivery of PoNS Treatment to patients with balance and gait disorders upon FDA clearance. On October 10, 2019, we formed Helius Canada Acquisition Ltd., or HCA, a company incorporated under the federal laws of Canada and a wholly owned subsidiary of Helius Medical Technologies (Canada), Inc., or HMC, a company incorporated under the federal laws of Canada, which acquired Heuro Canada, Inc., or Heuro, from Health Tech Connex Inc., or HTC, on October 30, 2019.

Since our inception, we have incurred significant operating losses. Our net loss was $9.8 million and $28.6 million for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, we had an accumulated deficit of $104.8 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. In addition, if we obtain marketing authorization, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Further, we may incur expenses in connection with the in-license or acquisition of other potential products.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. 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. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements, as, and when, needed, we may have to reduce the scope of our operations and planned capital expenditures or sell certain assets, including intellectual property assets.

As of December 31, 2019, we had cash of $5.5 million. 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. However, we do not currently have sufficient resources to accomplish all of the conditions necessary for us to generate revenue. For this reason, there is substantial doubt that we can continue as a going concern for the next 12 months unless we obtain additional capital to pay or reduce our expenditures.

Business Update

Canadian Regulatory Status: mmTBI

In October 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 chronic balance deficit due to mmTBI.

Canadian Regulatory Status: MS

On February 27, 2020, we submitted a Canadian Class II license amendment application for the treatment of gait deficit in patients with mild and moderate MS symptoms. Also as indicated by Health Canada, our 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

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 mild and moderate MS are sufficient to demonstrate a favorable risk/benefit profile, as required for de novo clearance. Novel treatments for MS are highlighted as a specific target of the FDA as a high unmet medical need disease. We plan to submit to the FDA for this high unmet medical need in the second half of 2020.

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 chronic 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 chronic 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 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 clearance of de novo submission 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.

Based on this revised protocol, we estimate that enrollment will begin in April 2020 with the completion of the trial and submission to the FDA in the second quarter of 2021.

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 and have received and answered all the questions supplied to date and wait for the TGA's decision.

Clinical Experience Program

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 to learn from and build relationships with the key large neurorehabilitation clinics, train and certify physical therapists and generate health economic, return-to work and clinical date to inform our payer strategy.

Overall, we enrolled six 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, we have maintained solid relationships with the U.S. sites and expect several to become clinical trial sites for TBI-002.

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 a clinic expansion phase of the alliance with the addition of 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 arrangement 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 (for additional information, see Note 7 to the consolidated financial statements elsewhere in this Annual Report on Form 10-K).

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 provided 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. 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 (10) years, renewable by HTC for one additional ten (10) year term upon sixty (60) days' written notice to us.

Canadian Commercialization

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 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 shown improvement in comfortable gait speed, a measure of their ability to walk, 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.

In March 2019, we began the initial commercialization of our PoNS Treatment in Canada, where our PoNS device is the first and only device authorized for the treatment of balance deficit due to mmTBI.

Throughout 2019, we made important progress in advancing and refining our commercialization strategy in Canada

We increased access to our PoNS Treatment by expanding our authorized clinic network throughout Canada to include 7 clinic locations by the end of the year, exceeding our goal for 2019.

We also developed and pursued several marketing initiatives to raise awareness of PoNS Treatment. Specifically:

- We developed a digital marketing campaign focused on raising awareness of awareness of the PoNS Treatment among patients, physiatrists and physical therapists. Most recently, we re-launched our ponstreatment.ca website and continued to build upon our social media-based marketing efforts, with the creation of relevant content for patients and the broader concussion community.
- We leveraged our Medical Affairs specialists to raise awareness of PoNS treatment among key opinion leaders and target important constituents in the industry, including industry associations and advocacy groups. We collaborated, and continue to collaborate, with several major concussion advocacy groups including the Ontario Brain Injury Association (OBIA), Brain Injury Canada (BIC), Brain Injury Society of Toronto (BIST) and others to promote PoNS Treatment and drive awareness through their respective conferences and meetings.
- We attended major industry conferences, including OBIA in November 2019, the Niagara Brain Injury meeting in December 2019 and the University Health Network TBI conference in February 2020, and have identified other key conferences to attend in 2020, including the Brain Injury Canada Conference.

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.

We created a local Canadian commercial team consisting of a Vice President/General Manager, a Director of Business Development, a Reimbursement Specialist, a Clinic Operations Manager and a national sales professional to manage our commercial activities going forward.

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 connection with this initiative, our Canadian commercial team refined our targeting criteria for the clinics that we engage with and authorize to provide PoNS Treatment. Specifically, they prioritized clinics with a large existing commercial focus on neurorehabilitation, established referral networks with other medical facilities for the treatment of patients with neurological conditions and significant reimbursement experience and payor relationships with respect to the treatment of neurological conditions. Further, they prioritized clinics within Ontario, and specifically the Greater Toronto Area, or GTA, given the disproportionate population disbursement in Canada (40% of all Canadians live in Ontario).

We have authorized 7 new clinic locations in the first two months of 2020 for a total of 14 clinic locations to provide PoNS Treatment across Canada. In addition, we have a clinical experience program through University Health Network Toronto at 3 private clinic locations with an opportunity to transition to commercial treatment centers. We expect that it will take the newly authorized clinics time to work the PoNS Treatment into the clinic rotation but are confident that our focus on authorizing clinics which meet our refined targeting criteria will drive efficiency and PoNS sales performance.

In addition to pursuing this expansion plan, we modified our go-to-market pricing model in 2020 based on direct market feedback. Our modified pricing model is focused on reducing the need for clinics and patients to pay large, upfront costs at the start of treatment.

In parallel with our commercialization efforts, we, in concert with input from insurers, have created a value dossier on behalf of the clinics and patients to fully demonstrate in both scientific and financial terms, the merits of PoNS Treatment for claimants. This will be provided to our clinics across Canada to submit as part of treatment plans with reimbursement applications. Our reimbursement strategy is focused initially in the auto accident insurance and workers compensation, or WC, market as well as long-term disability cases.

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.

Reverse Stock Split

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.

Change in Functional Currency

Prior to April 1, 2018, our functional currency was the Canadian dollar, or CAD$. We re-assessed our functional currency and determined that as of April 1, 2018, our functional currency had changed from the CAD$ 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.

Financings

For the year ended December 31, 2019, we raised $1.7 million in gross proceeds from one underwritten public offering issuing 4,815,010 shares of our common stock.

Components of Our Results of Operations

Revenue

During the year ended December 31, 2019, we recognized $1.5 million in revenue, of which $1.46 million was generated through product sales of our PoNS device in Canada pursuant to our executed supply agreements with neuroplasticity clinics, $37 thousand was generated through 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. During the year ended December 31, 2018, we recognized $0.5 million in license fee revenue as consideration for the rights granted by us to Heuro under an exclusive strategic alliance agreement.

Cost of Sales

Cost of sales is comprised of 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 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.

General and Administrative Expenses

G&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 G&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 Securities and Exchange Commission, or 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 and proprietary software recognized in connection with the acquisition of Heuro had remaining useful lives at acquisition of 1.25 years and 5 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, 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.

License Revenue

Prior to the fourth quarter of 2018, we had not generated revenue. During the fourth quarter of 2018, as part of our exclusive strategic alliance agreement, we transferred a license to Heuro in order for it to develop the clinic systems to facilitate the commercialization of the PoNS Treatment in Canada. The license was a functional license as it had stand-alone functionality. As such, we recognized revenue once control transferred, which occurred in the fourth quarter of 2018 when regulatory approval of the PoNS device in Canada was obtained and the commercialization of the product, as defined within the agreement, began. The agreement provided 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 considered this to be a significant financing component and as such, the amount reflected in our consolidated statements of operations and comprehensive loss was discounted. The discount rate utilized to measure revenue and the related receivable was determined based on the rate that would be reflected in a separate financing transaction with the customer. During the fourth quarter of 2018, we recognized revenues of $0.5 million in license fees when we satisfied our performance obligation. As described in Note 2 to the consolidated financial statements, 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. During the fourth quarter of 2019, we recognized revenues of $5 thousand in license fees associated with the Co-Promotion Agreement. Revenue not yet recognized of $0.3 million is recorded as deferred revenue on the consolidated balance sheet.

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 $1.5 million in product sales net of $11 thousand for HTC's portion related to assessments using the NeuroCatch device. As described in Note 2 to the consolidated financial statements, we modified our arrangement with HTC on October 30, 2019. As of December 31, 2019, the control of the 55 PoNS devices included as consideration in the Heuro acquisition had not been transferred resulting in the fair value of the devices being recorded as deferred revenue of $0.4 million on the consolidated balance sheet. Revenue will be recognized for these devices as control is transferred. The only returns during 2019 were the result of warranty returns for defective products. These returns were insignificant during the year and any future replacements are expected to be immaterial.

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. For the year ended December 31, 2019, we recognized $37 thousand as our 50% portion of the franchise fees. 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.

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.*

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 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.

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

Results of Operations

The following table summarizes our results of operations for the years ended December 31, 2019 and 2018 (amounts in thousands):

	Year Ended December 31,		
	2019	2018	Change
Revenue:			
Product sales, net	$ 1,454	$ —	$ 1,454
Fee revenue	37	—	37
License revenue	5	478	(473)
Total operating revenue	**1,496**	**478**	**1,018**
Cost of sales:			
Cost of product sales	846	—	846
Gross profit	**650**	**478**	**172**
Operating expenses:			
Research and development	8,061	9,939	(1,878)
Selling, general and administrative	16,521	17,214	(693)
Amortization expense	64	—	64
Total operating expenses	**24,646**	**27,153**	**(2,507)**
Operating loss	(23,996)	(26,675)	2,679
Other income (expense):			
Other income	95	63	32
Change in fair value of derivative financial instruments	14,113	(3,577)	17,690
Foreign exchange gain	7	1,566	(1,559)
Total other income (expense)	14,215	(1,948)	16,163
Net loss	**$ (9,781)**	**$ (28,623)**	**$ 18,842**

Year Ended December 31, 2019 Compared to Year Ended December 31, 2018

Revenue

For the year ended December 31, 2019, we recognized revenue of $1.5 million, of which $1.46 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. For the year ended December 31, 2018, we recognized license fee revenue of $0.5 million under an exclusive strategic alliance agreement.

Cost of Sales

For the year ended December 31, 2019, we incurred $0.8 million in our costs of sales. This 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. We had no cost of sales for the year ended December 31, 2018.

Research and Development Expenses

Research and development, or R&D, expenses were $8.1 million for the year ended December 31, 2019, compared to $9.9 million for the year ended December 31, 2018, a decrease of approximately $1.9 million. The decrease was primarily driven by a $3.3 million reduction in product development costs due to the completion of the PoNS device development and transfer to the scale manufacturer and a $0.4 million decrease in regulatory consulting expenses as that work was performed in-house during 2019. These decreases were partially offset by a $1.1 million increase in medical affairs expenses related to our medical science liaison's efforts in the delivery of our clinical and scientific data and clinical education to key opinion leaders, professional societies and practitioners to help enhance our PoNS Treatment at home and in the clinic as well as feedback that can be incorporated in our PoNS device and training materials. Wages and salaries also increased by $0.9 million due to increased regulatory and quality management headcount to support our Canadian launch.

General and Administrative Expenses

General and administrative, or G&A, expenses were $16.5 million for the year ended December 31, 2019, compared to $17.2 million for the year ended December 31, 2018, a decrease of $0.7 million. The decrease was primarily due to lower stock-based compensation expense of $3.4 million, which was mainly the result of the change in our functional currency. During the second quarter of 2018, all of our outstanding stock options were revalued due to the liability classification of our stock options as a result of a change in our functional currency in April 2018 as the exercise price of our stock options were denominated in a currency other than our functional currency. Consulting fees decreased $1.0 million. These decreases were partially offset by higher commercial operations expenses of $1.8 million as we invested in reimbursement, marketing and distribution capabilities in support of our US launch prior to receiving denial for clearance from the FDA, as well as an increase in wages and salaries of $0.9 million to support our commercial launch, and an additional increase of $0.6 million in severance expense. Bad debt expense increased $0.2 million due to customer collectability exposure associated with us generating product sales for the first time in 2019.

Change in Fair Value of Derivative Financial Instruments

The change in fair value of derivative financial instruments was a gain of $14.1 million for the year ended December 31, 2019, compared to a loss of $3.6 million for the year ended December 31, 2018.

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 (Loss)

Foreign exchange gain was $7 thousand for the year ended December 31, 2019, compared to a gain of $1.6 million for the year ended December 31, 2018. 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

Our financial statements have been prepared assuming that we will continue as a going concern and, accordingly, do not include adjustments relating to the recoverability and realization of assets and classification of liabilities that might be necessary should we be unable to continue in operation. 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, 2019, we raised approximately $95.9 million in gross proceeds from various public and private offerings of our securities as well as the exercise of options and warrants, including $1.1 million in net proceeds from our 2019 public offering, after deducting underwriters' discounts and commissions and offering expenses paid by us.

In November 2019, we issued 4,815,010 shares of our common stock in an underwritten public offering at a price of $0.35 per share. Net proceeds from the offering after deducting underwriter's discounts and commissions and offering expenses was $1.1 million. 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.

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, 2019 and 2018 (amounts in thousands):

	As of December 31,	
	2019	2018
Cash	$ 5,459	$ 25,583
Working capital	$ 3,444	$ 22,757

We currently have limited working capital and liquid assets. Our cash as of December 31, 2019 was $5.5 million. To date, we have recognized revenue of $1.5 million from the commercial sale of our products or services. There are a number of conditions that we must satisfy before we will be able to generate revenue from the commercialization of the PoNS Treatment, 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, our ability to generate significant revenue in

the future will be dependent upon the receipt of FDA marketing authorization of the PoNS device for treating balance disorder associated with mmTBI.

We will require additional funding to fund our ongoing activities. We believe that our existing capital resources will be insufficient to fund our operations beyond May of 2020. 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, 2019 and 2018 (amounts in thousands):

	Year Ended December 31,		
	2019	2018	Change
Net cash used in operating activities	$ (20,999)	$ (19,621)	$ (1,378)
Net cash used in investing activities	(769)	(440)	(329)
Net cash provided by financing activities	1,653	40,028	(38,375)
Effect of foreign exchange rate changes on cash	(9)	54	(63)
Net (decrease) increase in cash	$ (20,124)	$ 20,021	$ (40,145)

Year Ended December 31, 2019 Compared to the Year Ended December 31, 2018

Net Cash Used in Operating Activities

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 $2.2 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, bad debt expense of $0.2 million and unrealized foreign exchange loss of $0.1 million.

Net cash used in operating activities for the year ended December 31, 2018 was $19.6 million. This was comprised of a net loss of $28.6 million, adjusted for non-cash items including the change in the fair value of our derivative liabilities of $3.6 million, stock-based compensation expense of $8.1 million, which amounts were partially offset by unrealized foreign exchange gain of $1.7 million and changes in operating assets and liabilities of $1.0 million.

Net Cash used in Investing Activities

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 will be used in the commercial production of the PoNS device. Net cash used in investing activities for the year ended December 31, 2018 was $0.4 million, which was primarily comprised of $0.2 million for furniture and fixtures at our headquarters location and a $0.2 million laser marking equipment that will be 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, 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 4,815,010 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.

Net cash provided by financing activities for the year ended December 31, 2018 was $40.0 million, which was primarily comprised of $38.5 million received from offerings of our common stock and warrants. In April 2018, we received approximately $18.4 million in gross proceeds from a public offering from the sale of 2,463,185 shares of our common stock and accompanying warrants. In November 2018, we received approximately $20.1 million in a public offering from the sale of 2,439,394 shares of our common stock. For the year ended December 31, 2018, we also received approximately $4.7 million in proceeds from the exercise of stock options and warrants. These proceeds were partially offset by $3.2 million in issuance costs primarily related to our public offering.

Off Balance Sheet Arrangements

In September 2018, we entered into an exclusive strategic alliance agreement with HTC and Heuro. Under the terms of the agreement, the parties developed a clinic system to facilitate the commercialization of the PoNS Treatment in Canada. Prior to October 30, 2019, the arrangement 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. This agreement was amended as a result of the acquisition of Heuro on October 30, 2019. Refer to Note 2 for more information.

To the best of management's knowledge, there are no off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our results of operations or financial condition other than that described above and in Note 8 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

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 will adopt the standard as of January 1, 2020 and anticipate an increase in Level 3 fair value disclosures within the footnotes to the 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 will adopt the standard as of January 1, 2020. In conjunction with the acquisition of Heuro on October 30, 2019, we entered into a co-promotion agreement with HTC which meets the definition of a collaborative agreement. Certain components of the co-promotion agreement fall under the scope of ASC 606 and will be accounted for accordingly.

JOBS Act

In April 2012, the 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 have 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.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

See pages F-1 – F-29 following the signature page of this Annual Report.

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 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 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, 2019. 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, 2019, 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 smaller reporting company, our management's report was not subject to attestation by our registered public accounting firm pursuant to rules of the Securities and Exchange Commission 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. In October 2019, we identified a material weakness in our internal control over financial reporting when we became aware that we had been a victim of a criminal fraud that law enforcement authorities refer to as business email compromise fraud, which involved impersonation of our vendor and fraudulent demands for wire transfers that targeted our finance department. We immediately responded to the criminal fraud. Despite our response, the fraud resulted in a transfer of approximately $0.1 million. To date, no funds have been recovered. As a result of this matter, during the fourth quarter of 2019, enhancements were made to our controls relating to electronic payments, including by wire transfer of funds. These enhancements include additional verification and documentation procedures to be followed prior to the initiation or approval of electronic payments by or for us. We believe these enhancements increase the ability of our personnel to identify and block attempts by third parties to fraudulently initiate electronic payments from us. Our management believes that the foregoing actions will help improve our internal controls over financial reporting. Other than the actions described above, 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, 2019 which have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

We will file a definitive Proxy Statement for our 2020 Annual Meeting of Stockholders (the “2020 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 2020 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 2020 Proxy Statement under the captions "Information Regarding the Board of Directors and Corporate Governance," "Election of Directors," "Executive Officers" and "Section 16(a) Beneficial Ownership Reporting Compliance."

ITEM 11. EXECUTIVE COMPENSATION

The information required by Item 11 is hereby incorporated by reference to the sections of the 2020 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 2020 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 2020 Proxy Statement under the captions "Transactions with Related Persons" and "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 2020 Proxy Statement under the caption "Ratification of Selection of Independent Auditors."

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	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*	Description of Registrant's Securities
10.1†	Employment Agreement between Helius Medical Technologies, Inc. and Philippe Deschamps, dated June 13, 2014 (incorporated by reference to Exhibit 99.1 to the Form S-1 filed with the SEC on July 14, 2014)
10.2†	Amendment Agreement to the Employment Agreement between Helius Medical Technologies, Inc. and Philippe Deschamps, dated September 1, 2014 (incorporated by reference to Exhibit 99.5 to the Amendment to Form S-1 filed with the SEC on September 23, 2014)
10.3†	Employment Agreement between Helius Medical Technologies, Inc. and Jonathan Sackier, dated December 1, 2014 (incorporated by reference to Exhibit 10.4 to the Form 10-12G filed with the SEC on April 15, 2015)
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)
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)

Exhibit Number	Exhibit
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)
10.15	Notice of Modification No. 3 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 December 28, 2016 (incorporated by reference to Exhibit 2.1 to the Form 8-K filed with the SEC on December 31, 2015)
10.16	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)
10.16.1	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)
10.17.1	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)
10.18	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)
10.18.1	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)
10.18.2	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)
10.18.3	2016 Omnibus Incentive Plan Form of U.S. Option Grant Agreement (incorporated by reference to Exhibit 4.8 to the Registration Statement on Form S-8 filed with the SEC on May 18, 2017)
10.18.4	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)
10.19	Commercial lease agreement dated March 29, 2017 between Helius Medical, Inc and 660 Tudor Square, L.P. (incorporated by reference to Exhibit 10.26 to the Transition Report on Form 10-K filed with the SEC on April 3, 2017)
10.20	Modification No. 4 to the Amended Cooperative Research and Development Agreement, dated September 6, 2017 (incorporated by reference to Exhibit 2.1 to the Form 8-K filed September 12, 2017)
10.20.1	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)
10.21	Amendment of Solicitation/Modification of Contract of Sole-Source Cost Sharing Agreement with the U.S. Army Medical Research and Materiel Command), dated November 7, 2017 (incorporated by reference to Exhibit 10.2 to the Form 10-Q filed with the SEC on November 9, 2017)

Exhibit Number	Exhibit
10. 22‡	Commercial contract manufacturing agreement dated December 29, 2017 between Helius Medical, Inc and Key Tronic Corporation (incorporated by reference to Exhibit 10.29 to the Form 10-K filed March 12, 2018)
10.23†	Employment agreement between Helius Medical Technologies, Inc. and Jennifer Laux, dated July 9, 2018, (incorporated by reference to Exhibit 10.1 to the Form 10-Q filed August 9, 2018)
10.24	2018 Omnibus Incentive Plan, as amended (incorporated by reference to Exhibit 10.2 to the Form 10-Q filed November 8, 2018)
10.25	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)
10.26	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)
10.27	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)
21.1*	Subsidiaries of Helius Medical Technologies, Inc.
23.1*	Consent of BDO USA, LLP
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes – Oxley Act of 2002
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes – Oxley Act of 2002
32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes – Oxley Act of 2002
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, 2019 and 2018, 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, 2019 and 2018, 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 $104.8 million as of December 31, 2019 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.

/s/ BDO USA, LLP

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

Philadelphia, Pennsylvania
March 12, 2020

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

	As of December 31,	
	2019	**2018**
ASSETS		
Current assets		
Cash	$ 5,459	$ 25,583
Accounts receivable, net	210	177
Other receivables	364	98
Inventory, net of reserve	598	392
Prepaid expenses	610	447
Other current assets	—	264
Total current assets	7,241	26,961
Property and equipment, net	712	554
Other assets		
Goodwill	1,242	—
Intangible assets, net	582	—
Operating lease right-of-use asset, net	552	—
Non-current receivables	—	294
Other assets	18	18
Total other assets	2,394	312
TOTAL ASSETS	**$ 10,347**	**$ 27,827**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 1,676	$ 2,392
Accrued liabilities	1,519	1,812
Operating lease liability	172	—
Derivative financial instruments	5	13,769
Deferred revenue	430	—
Total current liabilities	3,802	17,973
Non-current liabilities		
Operating lease liability	465	—
Deferred revenue	245	—
TOTAL LIABILITIES	**4,512**	**17,973**
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, 2019 and December 31, 2018	—	—
Class A common stock, $0.001 par value; 150,000,000 shares authorized; 30,718,554 and 25,827,860 shares issued and outstanding as of December 31, 2019 and December 31, 2018, respectively	31	26
Additional paid-in capital	111,479	105,411
Accumulated other comprehensive loss	(902)	(591)
Accumulated deficit	(104,773)	(94,992)
TOTAL STOCKHOLDERS' EQUITY	**5,835**	**9,854**
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 10,347**	**$ 27,827**

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

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

	Year Ended December 31,	
	2019	**2018**
Revenue:		
Product sales, net	$ 1,454	**$ —**
Fee revenue	37	—
License revenue	5	478
Total operating revenue	**1,496**	**478**
Cost of sales:		
Cost of product sales	846	—
Gross profit	**650**	**478**
Operating expenses:		
Research and development	8,061	9,939
Selling, general and administrative	16,521	17,214
Amortization expense	64	—
Total operating expenses	**24,646**	**27,153**
Operating loss	**(23,996)**	**(26,675)**
Other income (expense):		
Other income	95	63
Change in fair value of derivative financial instruments	14,113	(3,577)
Foreign exchange gain	7	1,566
Total other income (expense)	**14,215**	**(1,948)**
Net loss	**(9,781)**	**(28,623)**
Other comprehensive loss:		
Foreign currency translation adjustments	(311)	(638)
Comprehensive loss	**$ (10,092)**	**$ (29,261)**
Net loss per share		
Basic	**$ (0.37)**	**$ (1.26)**
Diluted	**$ (0.37)**	**$ (1.26)**
Weighted average shares outstanding		
Basic	**26,352,642**	**22,786,192**
Diluted	**26,352,642**	**22,786,192**

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

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

	Common Stock, $0.001 par value		Common Stock, no par value		Additional		Accumulated Other	
	Shares	Amount	Shares	Amount	Paid-In Capital	Accumulated Deficit	Comprehensive Loss	Total
Balance as of December 31, 2017	**—**	**$ —**	**20,178,226**	**$ 52,230**	**$ 6,602**	**$ (66,369)**	**$ 47**	**$ (7,490)**
Proceeds from the issuance of common stock and accompanying warrants from April 2018 Offering	—	—	2,463,185	18,400	—	—	—	18,400
Fair value of liability-classified warrants issued in connection with April 2018 Offering	—	—	—	(7,372)	—	—	—	(7,372)
Share issuance costs - April 2018 Offering	—	—	—	(1,273)	—	—	—	(1,273)
Proceeds from the exercise of stock options and warrants	—	—	736,130	4,637	—	—	—	4,637
Stock-based compensation expense - prior to change in corporate domicile	—	—	—	—	1,047	—	—	1,047
Reclassification of liability-classified warrants upon exercise	—	—	—	3,748	—	—	—	3,748
Settlement of vested restricted stock units, net of taxes	—	—	705	—	(2)	—	—	(2)
Reclassification of exercised compensation options and warrants from additional paid-in capital	—	—	—	110	(110)	—	—	—
Reclassification of April 2016 compensation options and warrants from additional paid-in capital to derivative financial instruments due to change in functional currency	—	—	—	—	(1,586)	—	—	(1,586)
Reclassification of USD denominated warrants from derivative financial instruments to additional paid-in capital due to change in functional currency	—	—	—	—	2,478	—	—	2,478
Reclassification of equity-classified stock options to stock-based compensation liability due to change in functional currency	—	—	—	—	(4,182)	—	—	(4,182)
Reclassification from other current liabilities due to exercise of stock options	—	—	—	32	—	—	—	32
Reclassification of non-employee options recorded as derivative financial instruments due to modification of options	—	—	—	—	1,206	—	—	1,206
Reclassification of stock-based compensation due to modification of options	—	—	—	—	10,338	—	—	10,338
Reclassification upon change in corporate domicile	23,378,246	23	(23,378,246)	(70,512)	70,489	—	—	—
Proceeds from issuance of common stock in connection with November 2018 Offering	2,439,394	3	—	—	20,123	—	—	20,126
Proceeds from exercise of stock options	10,220	—	—	—	26	—	—	26
Share issuance costs - November 2018 Offering	—	—	—	—	(1,867)	—	—	(1,867)
Stock-based compensation expense - after change in corporate domicile	—	—	—	—	849	—	—	849
Net loss	—	—	—	—	—	(28,623)	—	(28,623)
Foreign currency translation adjustments	—	—	—	—	—	—	(638)	(638)
Balance as of December 31, 2018	**25,827,860**	**$ 26**	**—**	**$ —**	**$ 105,411**	**$ (94,992)**	**$ (591)**	**$ 9,854**

	Common Stock, $0.001 par value		Common Stock, no par value		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	
	Shares	Amount	Shares	Amount	Capital	Deficit	Loss	Total
Balance as of December 31, 2018	**25,827,860**	**$ 26**	**—**	**$ —**	**$ 105,411**	**$ (94,992)**	**$ (591)**	**$ 9,854**
Proceeds from the issuance of common stock from November 2019 Offering	4,815,010	5	—	—	1,680	—	—	1,685
Share issuance costs - November 2019 Offering	—	—	—	—	(553)	—	—	(553)
Proceeds from exercise of stock options and warrants	74,720	—	—	—	215	—	—	215
Settlement of vested restricted stock units, net of taxes	964	—	—	—	—	—	—	—
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	**30,718,554**	**$ 31**	**—**	**$ —**	**$ 111,479**	**$ (104,773)**	**$ (902)**	**$ 5,835**

(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,	
	2019	**2018**
Cash flows from operating activities		
Net loss	$ (9,781)	$ (28,623)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	127	59
Amortization expense	64	—
Provision for doubtful accounts	220	—
Change in fair value of derivative financial instruments	(14,113)	3,577
Stock-based compensation expense	4,691	8,095
Unrealized foreign exchange loss (gain)	70	(1,711)
Changes in operating assets and liabilities:		
Accounts receivable	(438)	(259)
Other receivables	(278)	394
Prepaid expenses	(163)	(95)
Inventory	(206)	(392)
Other current assets	264	(264)
Operating lease liability	(13)	—
Account payable	(1,116)	(1,087)
Accrued liabilities	(327)	685
Net cash used in operating activities	**(20,999)**	**(19,621)**
Cash flows from investing activities		
Purchase of property and equipment	(278)	(440)
Business acquisitions, net of cash acquired	(416)	—
Internally developed software	(75)	—
Net cash used in investing activities	**(769)**	**(440)**
Cash flows from financing activities		
Proceeds from the issuances of common stock and warrants	1,685	38,526
Share issuance costs	(247)	(3,161)
Proceeds from the exercise of stock options and warrants	215	4,663
Net cash provided by financing activities	**1,653**	**40,028**
Effect of foreign exchange rate changes on cash	(9)	54
Net (decrease) increase in cash	(20,124)	20,021
Cash at beginning of year	25,583	5,562
Cash at end of year	**$ 5,459**	**$ 25,583**
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	$ 358	$ 52
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 and 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 an active, therapeutic, class II medical device authorized for sale in Canada intended as a short term treatment (14 weeks) of chronic balance deficit due to mild-to-moderate traumatic brain injury ("mmTBI") and is to be used in conjunction with therapeutic activities ("PoNS Treatment™"). It is an investigational medical device in the United States, the European Union ("EU"), and Australia ("AUS"), and it is currently under review for clearance by the AUS Therapeutic Goods Administration. PoNS Treatment™ is not currently commercially available in the United States, the European Union or Australia.

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, which will operate a commercial site for the delivery of PoNS Treatment to patients with balance and gait disorders upon FDA clearance. 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 (see Note 2).

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

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.

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 January 22, 2018, the Company completed a 1-for-5 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, 2019, the Company had cash of $5.5 million. For the year ended December 31, 2019, the Company incurred a net loss of $9.8 million and, as of December 31, 2019, its accumulated deficit was $104.8 million. For the year ended December 31, 2019, the Company had $1.5 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 raise substantial doubt about the Company's ability to continue as a going concern within one year after the date of 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.

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. 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.

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 significant financing component associated with revenue, fair value-pricing model for stock-based compensation and derivative financial instruments. 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 (see Note 8). All intercompany balances and transactions have been eliminated. Certain prior period amounts have been reclassified to conform to current period presentation.

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 required allowance requires judgment by Company management. As of December 31, 2019, the Company's accounts receivable of $0.4 million, is net of an allowance for doubtful accounts of $0.2 million and is the result of revenue from product sales. As of December 31, 2018, accounts receivable consisted primarily of amounts owed related to license revenue of approximately $0.5 million recognized in 2018 resulting from the Company's arrangement with HTC and Heuro, of which $0.3 million was classified as a non-current receivable. As described below, the Company modified its arrangement with HTC on October 30, 2019.

Other receivables included refunds from research and development ("R&D") tax credits of $0.2 million and Goods and Services Tax and Quebec Sales Tax refunds related to the Company's Canadian expenditures of $0.1 million as of December 31, 2019. Other receivables included refunds from research and development ("R&D") tax credits of $0.1 million as of December 31, 2018.

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 $50 thousand were recorded during the year ended December 31, 2019.

As of December 31, 2019 and 2018, inventory consisted of the following (amounts in thousands):

	As of December 31, 2019	As of December 31, 2018
Raw materials	$ 144	$ 392
Work-in-process	375	—
Finished goods	129	—
Inventory	**$ 648**	**$ 392**
Inventory reserve	(50)	—
Total inventory, net of reserve	**$ 598**	**$ 392**

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, 2019 and 2018 (amounts in thousands):

	As of December 31,	
	2019	2018
Leasehold improvement	$ 182	$ 182
Furniture and fixtures	247	185
Equipment	286	219
Computer hardware and software	182	44
Property and equipment	897	630
Less accumulated depreciation	(185)	(76)
Property and equipment, net	$ 712	$ 554

Depreciation expense of $127 thousand and $59 thousand for the years ended December 31, 2019 and 2018, respectively. During 2019, the Company wrote-off $17 thousand of fully depreciated software.

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 paid 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 CAD$750 thousand (USD$0.6 million) 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 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.

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	564
Goodwill	1,226
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 current estimates and assumptions and is considered preliminary. The Company believes that the most recent information available provides a reasonable basis for assigning fair value, but anticipates receiving additional information, and as such, the provisional measurements of fair value are subject to change. The Company will finalize the amounts recognized as it obtains the information necessary to complete the analysis, but no later than one year from the acquisition date.

Acquired intangibles consisted of customer relationships and proprietary technology. The remaining useful life at acquisition was 1.25 years and 5 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 $1.2 million is not expected to be deductible for tax purposes.

The fair value of the 55 PoNS devices 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.

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 terminates upon the earlier of the collection of data from 200 patients in Canada and December 31, 2020. 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 (10) years, renewable by HTC for one additional ten (10) year term upon sixty (60) 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, 2019 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.

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

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

		As of December 31, 2019	
	Useful Life	Gross Carrying Amount	Accumulated Amortization
Customer relationships	1.25 years	$ 423	$ (55)
Acquired proprietary software	5 years	148	(5)
Internally developed software	3 years	75	(4)
Total intangible assets		$ 646	$ (64)

Amortization expense related to the intangible assets was $64 thousand for the year ended December 31, 2019.

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

For the Year Ending December 31,	
2020	$ 393
2021	83
2022	51
2023	30
2024	25
	$ 582

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. The Company's condensed consolidated balance sheets for reporting periods beginning on or after January 1, 2019 are presented under the new guidance, while prior period amounts were not adjusted and continue to be reported in accordance with previous guidance.

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. As of December 31, 2019, the

Company had only one operating lease, which was for its headquarters office in Newtown, Pennsylvania upon the adoption date. As of December 31, 2019, the Company has not entered into any additional lease arrangements. 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. As of December 31, 2019, approximately $0.1 million of the Company’s operating lease ROU asset had been amortized (see Note 7).

Foreign Currency

Prior to April 1, 2018, the Company's functional currency was the Canadian dollar (“CAD$”). Translation gains and losses from the application of the USD$ as the reporting currency during the period that the Canadian dollar was the functional currency were included as part of cumulative currency translation adjustment, which is reported as a component of stockholders' equity (deficit) as accumulated other comprehensive income (loss).

The Company re-assessed its functional currency and determined that, as of April 1, 2018, its functional currency had changed from the CAD$ to the USD$ based on management's analysis of changes in the primary economic environment in which the Company operates. 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.

For periods commencing April 1, 2018, 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.

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 conditions.

Prior to the adoption of ASU No. 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting (“ASU 2018-07”)* during the third quarter of 2018, stock-based payments to non-employees were measured at the fair value of the consideration received, or the fair value of the equity instruments issued, or liabilities incurred, whichever was more reliably measurable, and the fair value of stock-based payments to non-employees was re-measured at the end of each reporting period until the counterparty performance was completed, with any change therein recognized over the vesting period of the award and in the same manner as if the Company had paid cash instead of paying with or using equity-based instruments. The fair value of the stock-based payments to non-employees that were fully vested and non-forfeitable as of the grant date was measured and recognized at that date. Following the adoption of ASU 2018-07, stock-based payments to non-employees are now being measured based on the fair value of the equity instrument issued and 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. The change in the Company's functional currency, effective April 1, 2018 resulted in the reclassification of outstanding stock options that were previously denominated in CAD$ from equity- to liability-classified options (see Note 4). Liability classified options are re-measured to their fair values at the end of each reporting date with changes in the fair value recognized in stock-based compensation expense or additional paid-in capital until settlement or cancellation. Under FASB's ASC 718– Compensation – Stock Compensation, when an award is reclassified from equity to liability, if at the reclassification date the original vesting conditions are expected to be satisfied, then the minimum amount of compensation cost to be recognized is based on the grant date fair value of the original award. Fair value changes below this minimum amount are recorded in additional paid-in capital. In June 2018, the Company's Board of Directors approved subject to the consent of the holders of such options the modification of outstanding stock options with exercise prices denominated in CAD$ to convert the exercise prices of such options to USD$ based on the prevailing USD$/CAD$ exchange rates on the dates of the grants for such modified stock options. During the third quarter of 2018, employee and non-employee option holders owning stock options representing an aggregate of 2,741,146 shares of common stock consented to the modification. Employee stock options with a fair value of $10.3 million on August 8, 2018, which were previously classified as stock-based compensation liability, were reclassified to equity during the third quarter of 2018. Following these reclassifications, the Company no longer has any liability-classified stock options (see Note 4).

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:

(vi) identify the contract(s) with a customer;
(vii) identify the performance obligations in the contract;
(viii) determine the transaction price;
(ix) allocate the transaction price to the performance obligations in the contract; and
(x) 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.

License Revenue

Prior to the fourth quarter of 2018, the Company had not generated revenue. During the fourth quarter of 2018, as part of its exclusive strategic alliance agreement, the Company transferred a license to Heuro in order for it to develop the clinic systems to facilitate the commercialization of the PoNS Treatment in Canada. The license was a functional license as it had stand-alone functionality. As such, the Company recognized revenue once control transferred, which occurred in the fourth quarter of 2018 when regulatory approval of the PoNS device in Canada was obtained and the commercialization of the product, as defined within the agreement, began. The agreement provided to pay the Company CAD$750 thousand in three annual payments of CAD$250 thousand beginning December 31, 2019, in consideration for the exclusivity right the Company granted to Heuro. The Company considered this to be a significant financing component and as such, the amount reflected in its consolidated statements of operations and comprehensive loss was discounted. The discount rate utilized to measure revenue and the related receivable was determined based on the rate that would be reflected in a separate financing transaction with the customer. During the fourth quarter of 2018, the Company recognized revenues of $0.5 million in license fees when it satisfied its performance obligation. As described above, the Company modified its 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. During the fourth quarter of 2019, the Company recognized revenues of $5 thousand in license fees associated with the Co-Promotion Agreement. Revenue not yet recognized of $0.3 million is recorded as deferred revenue on the consolidated balance sheet.

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. 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, the Company recorded $1.5 million in product sales net of $11 thousand for HTC's portion related to assessments using the NeuroCatch device. As described above, the Company modified its arrangement with HTC on October 30, 2019. As of December 31, 2019, the control of the 55 PoNS devices included as consideration in the Heuro acquisition had not been transferred resulting in the fair value of the devices being recorded as deferred revenue of $0.4 million on the consolidated balance sheet. Revenue will be recognized for these devices as control is transferred. The only returns during 2019 were the result of warranty returns for defective products. These returns were insignificant during the year and any future replacements are expected to be immaterial.

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. For the year ended December 31, 2019, the Company recognized $37 thousand as its 50% portion of the franchise fees. 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.

As of December 31, 2019, the Company had 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. As of December 31, 2019, the Company did not have any receivables on its consolidated balance sheets related to license revenue pursuant to the Company's arrangement with HTC and Heuro due to the modification of its arrangement with HTC on October 30, 2019. As of December 31, 2018, the Company has recorded $0.2 million and $0.3 million in current and non-current receivables, respectively, and had no contract assets or liabilities on its consolidated balance sheets related to license revenue pursuant to the Company's arrangement with HTC and Heuro.

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 and 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.

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 condensed consolidated statements of operations and comprehensive loss. As of December 31, 2019 and 2018, the Company's derivative financial instruments were comprised of warrants issued in connection with both public and/or private securities offerings. During the third quarter of 2018, the non-employee stock options were reclassified to equity following the modification of these stock options. 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 4).

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, receivables, accounts payable, accrued liabilities, and derivative financial instruments. The book values of these instruments, with the exception of derivative financial instruments 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, 2019 and 2018 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 and stock-based compensation liability within the fair value hierarchy as of December 31, 2019 and 2018 (amounts in thousands):

	Fair Value	Level 1	Level 2	Level 3
December 31, 2019				
Liabilities:				
Derivative financial instruments	$ 5	$ —	$ —	$ 5
December 31, 2018				
Assets:				
Non-current receivable	$ 294	$ —	$ —	$ 294
Liabilities:				
Derivative financial instruments	$ 13,769	$ —	$ —	$ 13,769

There were no transfers between any of the levels during the years ended December 31, 2019 and 2018.

Basic and Diluted 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,	
	2019	2018
Basic and Diluted		
Numerator		
Net loss	$ (9,781)	$ (28,623)
Denominator		
Weighted-average common shares outstanding - basic and diluted	26,352,642	22,786,192
Basic and diluted net loss per share	$ (0.37)	$ (1.26)

The following outstanding securities have been excluded from the computation of diluted weighted shares outstanding for the periods noted below, as they would have been anti-dilutive due to the Company's losses for the years ended December 31, 2019 and 2018 and because the exercise price of certain of these outstanding securities were greater than the average closing price of the Company's common stock.

	For the Year Ended December 31,	
	2019	2018
Options outstanding	3,467,292	3,308,049
RSUs	27,697	964
Warrants outstanding	3,043,605	4,004,304
Total	6,538,594	7,313,317

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 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. 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 will adopt the standard as of January 1, 2020 and anticipates an increase in Level 3 fair value disclosures within the footnotes to the 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 will adopt the standard as of January 1, 2020. In conjunction with the acquisition of Heuro on October 30, 2019, the Company entered into a co-promotion agreement with HTC which meets the definition of a collaborative agreement. Certain components of the co-promotion agreement fall under the scope of ASC 606 and will be accounted for accordingly.

3. COMMON STOCK AND WARRANTS

On June 28, 2018, at the Company's 2018 Annual Meeting of Shareholders, the Company's shareholders approved the Company's reincorporation from the state of Wyoming to the state of Delaware. On July 20, 2018, the Company completed its reincorporation from Wyoming to the state of Delaware.

As a result, following the Company's reincorporation, 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, 2019. 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 18, 2016, the Company closed its short form prospectus offering in Canada and a concurrent U.S. private placement (the "April 2016 Offering") of units (the "Units") with gross proceeds to the Company of $7.2 million through the issuance of Units at a price of CAD$5.00 per Unit. Each Unit consists of one share of common stock in the capital of the Company (a "Common Share') and one-half of one Common Share purchase warrant (each whole warrant, a "Warrant"). Each Warrant entitled the holder thereof to acquire one additional Common Share at an exercise price of CAD$7.50 on or before April 18, 2019. Mackie Research Capital Corporation (the "Agent") acted as agent and sole bookrunner in connection with the April 2016 Offering. The Company paid the Agent a cash commission of $0.3 million and granted to the Agent compensation options exercisable to purchase 87,210 Units at an exercise price of CAD$5.00 per Unit for a period of 24 months from the closing of the April 2016 Offering. The Company incurred other cash issuance costs of $1.1 million related to this offering. During the year ended December 31, 2019, 38,351 warrants were exercised. On April 18, 2019, 922,348 warrants were cancelled due to their expiration.

On May 2, 2016, the Company closed the sale of the additional units issued pursuant to the exercise of the over-allotment option granted to the Agent in connection with the April 2016 Offering. The April 2016 Offering was made pursuant to a short form prospectus filed with the securities regulatory authorities in each of the provinces of Canada, except Québec. Pursuant to the exercise of the over-allotment option, the Company issued an additional 218,025 units at a price of CAD$5.00 per unit for additional gross proceeds to the Company of $0.9 million, bringing the total aggregate gross proceeds to the Company under the Offering to $8.1

million. Each over-allotment unit consisted of one share of common stock in the capital of the Company and one-half of one Common Share purchase warrant. Each over-allotment warrant entitles the holder thereof to acquire one additional over-allotment Common Share at an exercise price of CAD$7.50 on or before April 18, 2019. In connection with the closing of the over-allotment option, the Company paid the Agent a cash commission of $0.1 million and granted to the Agent compensation options exercisable to purchase 13,081 over-allotment units at an exercise price of CAD$5.00 per unit for a period of 24 months from the over-allotment closing. As of December 31, 2018, all remaining outstanding compensation options had been cancelled due to their expiration.

For the year ended December 31, 2018, the Company recorded a $0.1 million gain in change in fair value of derivative financial instruments due to the expiration of both the April 18, 2016 and May 2, 2016 compensations options.

The proceeds from the April 2016 Offering were allocated on a relative fair value basis between the common stock and the warrants issued. The warrants issued in connection with the April 2016 Offering were classified within equity in the Company's consolidated balance sheets. These warrants were recorded in additional paid-in capital in the Company's consolidated balance sheets at their fair value. As discussed in Note 1, due to the change in the Company's functional currency, as of April 1, 2018, these warrants were reclassified to liabilities as derivative financial instruments on the Company's consolidated balance sheet as they are now priced in a currency other than the Company's functional currency. This resulted in the Company recording a $4.7 million increase in derivative financial instruments and a $1.4 million reduction in additional paid-in capital on its consolidated balance sheet and a $3.3 million loss related to the change in fair value of derivative financial instruments on its consolidated statement of operations and comprehensive loss during the year ended December 31, 2018.

The following table summarizes the weighted average assumptions used in estimating the fair value of the warrants granted in the April 2016 Offering using the Black-Scholes option pricing model as of the grant date and as of April 1, 2018 and December 31, 2018:

	December 31, 2018	April 1, 2018	Grant Date
Stock price	CAD$12.80	CAD$12.87	CAD$5.45
Exercise price	CAD$7.50	CAD$7.50	CAD$7.50
Warrant term	0.30 years	1.05 years	3.0 years
Expected volatility	83.56%	71.13%	83.83%
Risk-free interest rate	1.64%	1.60%	0.60%
Dividend rate	0.00%	0.00%	0.00%

On February 16, 2017, the Company completed an underwritten registered public offering and issued an aggregate of 1,311,000 shares of common stock for gross proceeds of $9.2 million. The Company incurred cash issuance costs of $1.2 million in connection with this offering.

In June 2017, the Company completed a non-brokered private placement of 800,000 shares of common stock for gross proceeds of $5.4 million. The Company incurred approximately $9 thousand in share issuance cost related to the private placement.

In December 2017, the Company completed a three-tranche non-brokered private placement (the "December 2017 financing") for an aggregate of 646,016 units for gross proceeds of approximately $6.3 million. Each unit consisted of one share of common stock and one share purchase warrant, and was sold at a price of $9.80 per unit. Each warrant entitles the holder to acquire one additional share of common stock and is exercisable over a period of 36 months following the respective closing of the December 2017 financing at an exercise price of $12.25 per warrant share. The first tranche, which closed on December 22, 2017, was for 270,915 units for which the Company received gross proceeds of approximately $2.6 million. The second tranche, which closed on December 28, 2017, was for 171,020 units for which the Company received approximately $1.7 million, while the third tranche, which closed on December 29, 2017, was for 204,081 units for which the Company received $2.0 million. The Company paid $0.1 million in share issuance costs related to the December 2017 financing.

As a result of the change in the Company's functional currency, these warrants have been reclassified from liabilities as derivative financial instruments to additional paid-in capital in the Company's consolidated balance sheet. As of April 1, 2018, $2.5 million, was reclassified from derivative financial instruments to additional paid-in capital, representing the fair value of warrants having USD$ exercise prices. There was no impact to the Company's consolidated statement of operations and comprehensive loss as a result of this reclassification as the fair value of these warrants on April 1, 2018, was the same as of March 31, 2018, the most recent date that the fair value of these warrants was re-measured.

The following table summarizes the weighted average assumptions used in estimating the fair value of the warrants granted in the December 2017 financing using the Black-Scholes option pricing model as of the grant dates and on April 1, 2018.

	April 1, 2018	December 29, 2017	December 28, 2017	December 22, 2017
Stock price	$ 10.11	$ 12.32	$ 12.45	$ 10.60
Exercise price	$ 12.25	$ 12.25	$ 12.25	$ 12.25
Warrant term	2.7 years	3.0 years	3.0 years	3.0 years
Expected volatility	65.40%	60.24%	60.24%	60.24%
Risk-free interest rate	2.39%	1.98%	2.00%	2.01%
Dividend rate	0.00%	0.00%	0.00%	0.00%

On April 13, 2018, the Company issued 2,141,900 shares of its common stock and warrants to purchase 2,141,900 shares of the Company's common stock in an underwritten public offering at a price of $7.47 per share and accompanying warrant. Gross proceeds from the offering were approximately $16.0 million. On April 24, 2018, the Company closed on the sale of an additional 321,285 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 $7.47 per share and accompanying warrants. Gross proceeds from the exercise of the over-allotment option was $2.4 million. BTIG, LLC and Echelon Wealth Partners acted as joint book-running managers for the April 2018 Offering. The Company paid approximately $1.1 million in underwriting discounts and commissions and incurred offering expenses of approximately $1.0 million in connection with the April 2018 Offering, resulting in net proceeds of $16.3 million from the April 2018 offering. The underwriting discounts and commissions and offering expenses were allocated between share issuance costs and expenses based on the relative fair values of common stock and warrants issued in connection with the April 2018 Offering, resulting in the recording of approximately $0.8 million of expenses in the Company's consolidated statement of operations and comprehensive loss. 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$12.25 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, as a result of the change in the Company's functional currency (see Note 2), 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, 2019, 70,900 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, 2019.

	December 31, 2019	April 24, 2018	April 13, 2018
Stock price	CAD $1.23	CAD $10.76	CAD $9.85
Exercise price	CAD $12.25	CAD $12.25	CAD $12.25
Warrant term	1.28 years	3.00 years	3.00 years
Expected volatility	72.43%	64.49%	64.20%
Risk-free interest rate	1.72%	2.02%	1.99%
Dividend rate	0.00%	0.00%	0.00%

On November 19, 2018, the Company issued 2,121,212 shares of its common stock in an underwritten public offering at a price of $8.25 per share. Gross proceeds from the offering were $17.5 million. On November 2018, the Company closed on the sale of an additional 318,182 shares of its common stock pursuant to the exercise of the over-allotment option (collectively the "November 2018 offering") granted to the underwriters in connection with the offering at a price of $8.25 per share. Gross proceeds from the exercise of the over-allotment option was $2.6 million. BTIG LLC and Oppenheimer & Co acted as joint book-running managers for the November 2018 offering. The Company paid approximately $1.2 million in underwriting discounts and commissions and incurred offering expenses of approximately $0.7 million, of which $0.1 million was accrued as of December 31, 2018, resulting in net proceeds of $18.3 million.

On November 22, 2019, the Company issued 4,815,010 shares of its common stock in an underwritten public offering at a price of $0.35 per share. Gross proceeds from the offering (the "November 2019 Offering") were approximately $1.7 million. HC Wainwright

acted as book-running manager for the November 2019 Offering. The Company paid approximately $0.1 million in underwriting discounts and commissions and incurred offering expenses of approximately $0.5 million, resulting in net proceeds of $1.1 million, in connection with the November 2019 Offering.

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, 2019 and 2018 (amounts in thousands):

	Year Ended December 31,	
	2019	2018
Fair value of warrants at beginning of year	$ 13,769	$ 6,941
Issuance of warrants	—	7,372
Exercise of warrants	(35)	(3,012)
Fair value of previously classified equity warrants	—	5,049
Fair value of previously classified liability warrants reclassified to additional paid-in capital	—	(2,478)
Foreign exchange losses (gains)	384	(872)
Change in fair value of warrants during the year	(14,113)	769
Fair value of warrants at end of year	$ 5	$ 13,769

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 (expense) 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, 2019 and 2018 were estimated using the Black-Scholes option-pricing model with the following weighted average assumptions:

	As of December 31,	
	2019	2018
Stock price	CAD $1.23	CAD$12.80
Exercise price	CAD $12.25	CAD$10.89
Warrant term	1.28 years	1.71 years
Expected volatility	72.43%	75.31%
Risk-free interest rate	1.72%	1.80%
Dividend rate	0.00%	0.00%

The following is a summary of warrant activity during the years ended December 31, 2019 and 2018:

	Number of Warrants (by currency denomination of exercise price)		Weighted-Average Exercise Price	
	CAD$	USD$	CAD$	USD$
Outstanding as of December 31, 2017	1,011,505	1,343,404	$ 7.38	$ 10.25
Granted	2,476,843	—	12.22	—
Expired	(22,699)	(136,528)	5.00	15.00
Exercised	(112,665)	(555,556)	9.88	6.75
Outstanding as of December 31, 2018	3,352,984	651,320	$ 10.89	$ 12.24
Granted	—	—	—	—
Cancelled/Expired	(922,348)	—	7.50	—
Exercised	(38,351)	—	7.50	—
Outstanding and exercisable as of December 31, 2019	2,392,285	651,320	$ 12.25	$ 12.24

The following table summarizes the Company's warrants outstanding and exercisable as of December 31, 2019:

Number of Warrants Outstanding	Exercise Price	Expiration Date
3,795	US$10.75	June 26, 2020
1,509	US$10.75	July 17, 2020
270,915	US$12.25	December 22, 2020
171,020	US$12.25	December 28, 2020
204,081	US$12.25	December 29, 2020
2,392,285	CAD$12.25	April 21, 2021
3,043,605		

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 ("2018 Plan"), under which an aggregate of 5,356,114 shares may be issued. This share reserve is the sum of 3,000,000 new shares, plus the remaining 2,356,114 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 ("RSU"), 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, 2019, there were an aggregate of 4,068,771 shares of common stock remaining available for grant under the Company's 2018 Plan.

For the year ended December 31, 2019, the Company issued 1,167,658 stock options to employees and directors of which 138,900 were forfeited. The Company did not issue any stock options to consultants.

The following is a summary of stock option activity for the year ended December 31, 2019 and 2018:

	Number of Options	Weighted Average Exercise Price in USD$	Aggregate Intrinsic Value in USD$
Outstanding as of December 31, 2017	2,448,646		
Granted	1,011,406	10.12	
Forfeited	(53,503)	9.89	
Exercised (1)	(98,500)	3.10	
Outstanding as of December 31, 2018	3,308,049	$ 7.14	$ 8,308
Granted	1,167,658	$ 4.65	
Forfeited/Cancelled	(488,415)	8.53	
Exercised (2)	(520,000)	2.77	
Outstanding as of December 31, 2019	3,467,292	$ 6.76	$ -
Exercisable as of December 31, 2019	1,885,531	$ 3.86	$ -

(1) For the year ended December 31, 2018, 8,500 stock options were exercised on a cashless basis resulting in 3,280 shares being withheld in satisfaction of the exercise price.

(2) For the year ended December 31, 2019, 520,000 stock options were exercised on a cashless basis resulting in 483,631 shares being withheld in satisfaction of the exercise price.

Upon the change in the Company's functional currency effective April 1, 2018, stock options previously classified as equity were classified as liabilities. On April 1, 2018, these options had a fair value of approximately $10.0 million, which was recorded as stock-based compensation liability in the Company's consolidated balance sheet, of which approximately $4.2 million was reclassified from additional paid-in capital and the remainder was recorded as additional stock-based compensation expense in the Company's consolidated statement of operations and comprehensive loss. In June 2018, the Company's Board of Directors' approved the modification of all outstanding stock options with exercise prices denominated in CAD$ to convert the exercise prices of such options

to USD$, subject to the consent of the holders of such options. On August 8, 2018, following the consent of option holders, the Company re-measured stock options for which all holders had consented to the modification and recorded $0.3 million reduction to stock-based compensation liability and reclassified $10.3 million from liability to equity. The incremental expense as a result of the modification was immaterial to the Company's consolidated statement of operations and comprehensive loss for the year ended December 31, 2018.

The following table summarizes stock options outstanding and exercisable by employees and directors as of December 31, 2019:

Number of Options Outstanding	Expiration Date	Options Outstanding Remaining Contractual Life (In Years)	Exercise Price	Fair Value Post Modification (1)	Grant Date Fair Value	Number of Options Exercisable
20,000	December 8, 2024	4.94	$ 12.72	$ 2.18	$ —	20,000
80,000	December 8, 2024	4.94	$ 12.72	$ 2.18	$ —	80,000
20,000	March 16, 2025	5.20	$ 12.52	$ 2.43	$ —	20,000
150,000	October 21, 2025	5.80	$ 3.20	$ 6.57	$ —	150,000
20,000	December 31, 2025	6.00	$ 4.48	$ 5.86	$ —	20,000
595,000	July 13, 2026	6.53	$ 5.35	$ 5.18	$ —	595,000
20,000	August 8, 2026	6.60	$ 4.98	$ 5.42	$ —	20,000
617,000	April 17, 2027	7.29	$ 8.13	$ 7.54	$ —	308,500
6,146	May 18, 2027	7.37	$ 7.35	$ 4.75	$ —	6,146
10,000	May 18, 2027	7.37	$ 7.35	$ 7.65	$ —	5,000
20,000	August 8, 2027	7.60	$ 10.38	$ 7.38	$ —	10,000
20,000	April 9, 2028	8.27	$ 9.03	$ 8.01	$ —	5,000
337,500	May 15, 2028	8.37	$ 10.99	$ 7.89	$ —	183,438
55,513	August 22, 2028	8.64	$ 10.23	$ —	$ 7.21	13,878
375	September 4, 2028	8.67	$ 10.19	$ —	$ 7.19	375
50,000	September 10, 2028	8.69	$ 10.34	$ —	$ 7.30	12,500
50,000	September 24, 2028	8.73	$ 9.71	$ —	$ 6.79	12,500
75,000	October 15, 2028	8.79	$ 8.75	$ —	$ 6.19	75,000
10,000	October 29, 2028	8.82	$ 9.71	$ —	$ 6.87	2,500
5,000	November 19, 2028	8.88	$ 8.00	$ —	$ 5.66	5,000
7,500	January 22, 2029	9.06	$ 7.65	$ —	$ 5.30	—
7,500	February 4, 2029	9.09	$ 7.26	$ —	$ 5.03	—
543,758	March 28, 2029	9.23	$ 6.76	$ —	$ 4.62	88,694
215,000	August 7, 2029	9.60	$ 2.03	$ —	$ 1.37	—
40,000	August 19, 2029	9.63	$ 1.93	$ —	$ 1.30	—
150,000	September 23, 2029	9.72	$ 1.73	$ —	$ 1.20	—
30,000	September 30, 2029	9.74	$ 1.65	$ —	$ 1.11	—
20,000	October 1, 2029	9.75	$ 1.68	$ —	$ 0.98	—
15,000	October 14, 2029	9.78	$ 1.45	$ —	$ 0.98	—
3,190,292						1,633,531

(1) Reflects fair value of modified stock options on August 8, 2018

As of December 31, 2019, the unrecognized compensation cost related to non-vested stock options outstanding for employees and directors was $6.0 million which will be recognized over a weighted-average remaining vesting period of 2.8 years. The Company recognizes compensation expense for only the portion of awards that are expected to vest.

During the fourth quarter of 2017, upon a review of the Company's equity compensation awards granted under the 2016 Plan, the Company determined that it had inadvertently exceeded the annual per-person sub-limits involving an option award previously granted to a current executive officer. The aggregate amount of common stock represented by this excess award was 60,000 shares. This excess award was deemed to have been granted outside of the 2016 Plan and, as such, the Company applied liability accounting to the award. As a result, this excess award was to be re-measured at the end of each reporting period until such time that the

Company's stockholders approved the excess award, at which time the liability would be reclassified to equity. On June 28, 2018, the Company's stockholders approved the excess award. On August 8, 2018, upon the modification of the exercise price of this stock option to convert such exercise price from CAD$ to USD$ as described above this excess award was re-measured again and reclassified from liability to equity for the portion of the option that had vested.

For the years ended December 31, 2019 and 2018, the Company granted 1,167,658 and 996,406 stock options, respectively, to employees and directors at a weighted average exercise price of $4.65 and $10.12, respectively. The fair value of employee and director stock options granted for the years ended December 31, 2019 and 2018 had a weighted average grant date fair value of $3.01 and $7.78 per option, respectively, and they were estimated using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	Year Ended December 31,	
	2019	2018
Stock price	$4.65	$11.21
Exercise price	$4.65	$10.12
Expected term	5.42 years	6.25 years
Expected volatility	76.90%	78.99%
Risk-free interest rate	1.96%	2.67%
Dividend rate	0.00%	0.00%

Non-Employee Stock Options

For the year ended December 31, 2019, the Company did not grant any stock options to consultants. For the year ended December 31, 2018 the Company granted 15,000 stock options to consultants at a weighted average exercise price of $10.23. Stock options granted to the Company's consultants for the year ended December 31, 2018 had a weighted average grant date fair value of $8.87 per share, and they were estimated using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	Year Ended December 31,
	2018
Stock price	$10.23
Exercise price	$10.23
Option term	10 years
Expected volatility	90.17%
Risk-free interest rate	2.82%
Dividend rate	0.00%

The following table summarizes stock options outstanding and exercisable by consultants as of December 31, 2019:

Number of Options Outstanding	Expiration Date	Options Outstanding Remaining Contractual Life (In Years)	Exercise Price	Fair Value Post Modification (1)	Grant Date Fair Value	Number of Options Exercisable
30,000	December 8, 2024	4.94	$ 12.72	$ 2.18	$ —	30,000
110,000	October 28, 2025	5.82	$ 3.18	$ 6.59	$ —	110,000
72,000	October 3, 2026	6.75	$ 5.15	$ 5.35	$ —	72,000
20,000	May 18, 2027	7.37	$ 7.35	$ 7.65	$ —	10,000
15,000	August 8, 2027	7.60	$ 10.38	$ 7.38	$ —	7,500
15,000	November 6, 2027	7.84	$ 16.20	$ 6.98	$ —	7,500
15,000	August 22, 2028	8.64	$ 10.23	$ —	$ 8.87	15,000
277,000						252,000

(1) Reflects fair value of modified stock options on August 8, 2018

As of December 31, 2019, the unrecognized compensation cost related to non-vested stock options outstanding for consultants was $0.1 million which will be recognized over a weighted-average remaining vesting period of 1.6 years.

During the third quarter of 2018, following the redenomination of the exercise prices of stock options from CAD$ to USD$, stock options awarded to consultants that are performing services for NHC ceased to be accounted for as derivative financial instruments. As a result, following the re-measurement of stock options granted to the Company's consultants on August 8, 2018, all vested stock options granted to these consultants were reclassified from liability to equity.

The following table summarizes non-employee stock options that had been accounted for as derivative financial instruments during the year ended December 31, 2018 (amounts in thousands):

	Year Ended December 31, 2018
Fair value of non-employee stock options at beginning of year	$ 2,637
Exercise of non-employee options	(737)
Cancelled	—
Foreign exchange gains	(38)
Change in fair value of non-employee stock options during the year	(656)
Reclassification to additional paid-in capital	(1,206)
Fair value of non-employee stock options at end of year	$ —

The fair value of non-employee stock options previously classified as liabilities and recorded as derivative financial instruments which were subsequently reclassified to equity following the modification of stock option previously on August 8, 2018 were estimated using the Black-Scholes option pricing model with the following weighted-average assumptions as of August 8, 2018:

	August 8, 2018
Stock price	CAD$12.14
Exercise price	CAD$4.38
Expected life	0.93 years
Expected volatility	73.18%
Risk-free interest rate	1.95%
Dividend rate	0.00%

Restricted Stock Units

During the second quarter of 2017, the Company granted RSUs to certain employees under the 2016 Plan that were scheduled to vest over a three-year period, with 25% vesting immediately. The fair value of the RSUs was based on the closing price of the Company's common stock on the date of grant.

During 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 was 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, 2019 and 2018:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value per Unit
Outstanding as of January 1, 2018	1,928	CAD$10.00
Vested and settled during 2018 **(1)**	(964)	CAD$10.00
Outstanding as of December 31, 2018	964	CAD$10.00
Granted	27,697	USD$0.61
Vested and settled during 2019 **(1)**	(964)	CAD$10.00
Outstanding as of December 31, 2019	27,697	USD$0.61

(1) Includes 259 RSUs withheld to satisfy required withholding taxes.

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

	2019	2018
Research and development	$ 898	$ 939
General and administrative	3,793	7,156
Total	$ 4,691	$ 8,095

5. ACCRUED EXPENSES

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

	As of December 31,	
	2019	2018
Employees benefits	$ 722	$ 876
Professional services	67	518
Legal expense	81	253
Royalty fees	13	—
Franchise fees	28	—
Rent	—	98
Severance	606	66
Other	2	1
	$ 1,519	$ 1,812

6. INCOME TAXES

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

	Year Ended December 31,	
	2019	2018
U.S.	$ 7,980	$ 29,013
Non-U.S.	1,801	(390)
	$ 9,781	$ 28,623

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,	
	2019	2018
Statutory tax rate	21.00%	21.00%
Net loss before income taxes	$ 9,781	$ 28,623
Expected income tax recovery	$ (2,054)	$ (6,011)
Increase (decrease) in income tax recovery resulting from:		
Derivative liability	(2,964)	877
Share based payments	949	1,279
Other permanent difference	(213)	(376)
Foreign income taxed at foreign rate	(99)	23
Increase in valuation allowance	4,381	4,208
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,	
	2019	2018
Deferred income tax assets (liabilities)		
Operating losses carried forward	$ 21,318	$ 16,028
Tax credits	679	1,217
Stock compensation	1,496	1,447
Other	1,293	85
Valuation allowance	(24,786)	(18,777)
Net deferred income tax asset	$ —	$ —

As of December 31, 2019, the Company has accumulated non-capital losses totaling $3.6 million in Canada and net operating losses of $75.3 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.

On December 22, 2017, the U.S. Government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act ("The Act"). The Act makes broad changes to the U.S. tax code, including, but not limited to, (i) reducing the U.S federal corporate tax rate from 35% to 21%; (ii) eliminating the corporate alternative minimum tax; (iii) creating a new limitation on deductible interest expense; (iv) creating the base erosion and anti-abuse tax, a new minimum tax; (v) limitation on the deductibility of certain executive compensation; (vi) enhancing the option to claim accelerated depreciation deductions on qualified property, and (vii) changing rules related to uses and limitations of net operating loss carryforwards created in tax years beginning after December 31, 2017. The Act reduced the corporate tax rate to 21%, effective January 1, 2018.

The Company completed its determination of the accounting implications of The Act on its tax accruals as of December 31, 2018 and made estimates primarily comprised of the re-measurement of federal net deferred tax assets resulting from the permanent reduction in the U.S. statutory corporate tax rate to 21% from 34%.

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, 2019, 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 3,207,005 shares of common stock, 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, 2019 and 2018, the Company recorded approximately $59 thousand and $0, respectively, in royalty expenses in its consolidated statement of operations.

(b) On October 30, 2017, HMI amended the Asset Purchase Agreement with 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 November 2014, the Company signed a development and distribution agreement with Altair LLC to apply for registration and distribution of the PoNS device in the territories of the former Soviet Union. Through March 31, 2019, the Company was entitled to receive a 7% royalty on sales of the devices within the territories. Altair terminated the distribution agreement effective May, 20, 2019. The Company made no commercial sales in the territories pursuant to the distribution agreement.

(d) In March 2017, the Company entered into a lease for office space in Newtown, Pennsylvania. The initial term of the lease is 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. It is not reasonably certain at this point in time that the Company will elect to utilize the option to extend. Monthly rent plus utilities will be approximately $20 thousand per month beginning in January 2018 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 as of December 31, 2019 (amounts in thousands):

For the Year Ending December 31, 2019		
Operating lease cost	$	224
Operating lease - operating cash flows	$	246
Weighted average remaining lease term		3.05 years
Weighted average discount rate		15.1%
Future minimum lease payments under non-cancellable lease as of December 31, 2019 were as follows:		
For the Period Ending December 31,		
2020	$	253
2021		260
2022		267
2023		10
Total future minimum lease payments		**790**
Less imputed interest		(153)
Total liability	**$**	**637**
Reported as of December 31, 2019		
Current operating lease liability		172
Non-current operating lease liability		465
Total	**$**	**637**

(e) 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. As of December 31, 2019, the Company had a $0.1 million obligation to Key Tronic to complete the Company's forecast for the procurement of materials necessary for the delivery of PoNS devices.

(f) In September 2018, the Company entered into an exclusive strategic alliance agreement with HTC and Heuro to establish up to 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, the Company entered into the clinic expansion phase of this alliance with the addition of three new PoNS authorized clinics, bringing the total number of clinics authorized to treat patients with the PoNS device to five in Canada. The agreement also provided for HTC to pay the Company CAD$750 thousand in three annual payments of CAD$250 thousand beginning December 31, 2019, in consideration for the exclusivity right the Company granted to Heuro. The Company and HTC governed the agreement through a joint steering committee, and each funded up to 50% of Heuro's operating budget as agreed upon by a joint steering committee and shared in the net profits and losses of Heuro on a 50/50 basis. On October 30, 2019, the Company entered into a Share Purchase Agreement with HTC to purchase Heuro. The receivable was considered part of the consideration for acquisition and was imbedded in the purchase price allocation. See Note 2 for details of the transaction. For the years ended December 31, 2019 and 2018, the Company recorded $0.1 million and $0.2 million, respectively, in expenses for its share of the estimated costs incurred by Heuro. Additionally, for the year ended December 31, 2018, the Company recorded $0.2 million of expenses incurred by the Company in performing services on behalf of Heuro. The aforementioned expenses were recorded as general and administrative expenses in the Company's consolidated statement of operations and comprehensive loss. During the year ended December 31, 2019, the Company recorded $0.1 million in cost of sales for services rendered in the Company's consolidated statement of operations and comprehensive loss. Further for the year ended December 31, 2019, the Company recognized $37 thousand in fee revenue related to its arrangement with HTC and Heuro (see Note 2).

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 (see Note 7(f)). 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, 2019 and 2018, the Company paid approximately $27 thousand and $33 thousand, respectively, in consulting fees to a director of the Company. As of December 31, 2019, the Company owed $5 thousand to a director for consulting services.

During April 2016, the Company entered into a consulting agreement with Montel Media, Inc. (“Montel Media”), pursuant to which Montel Media provides consulting services for the promotion of the Company’s clinical trials and ongoing media and marketing strategies. Under the agreement, Montel Media received $15 thousand per month. During the first quarter of 2018, the Company terminated its agreement with Montel Media. Montel Media is owned by Montel Williams, who beneficially owns greater than 5% of the Company’s common stock. The Company paid Montel Media $45 thousand for the year ended December 31, 2018 pursuant to the consulting agreement. The Company made no payments to Montel Media for the year ended December 31, 2019

For the year ended December 31, 2018, a benefit of $0.3 million, which included a foreign exchange gain of $18 thousand was included in the change in fair value of derivative financial instruments as the fair value of stock-based compensation attributed to the options granted to a director for consulting services rendered with respect to the design and development of the PoNS device. With the adoption of ASC 2018-07 during the third quarter of 2018, all non-employee stock-based compensation are no longer recorded as derivative financial instruments.

The Company’s Chief Medical Officer was a founding member of Clinvue LLC (“Clinvue”), a company that provided regulatory advisory services to the Company until it ceased operations during the fourth quarter of 2018. The Company paid Clinvue approximately $0.1 million for consulting services in the year ended December 31, 2018. The Company made no payments to Clinvue for the year ended December 31, 2019.

10. SOLE-SOURCE COST-SHARING AGREEMENT AND COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT

In July 2015, the Company entered into a sole source cost sharing agreement with the U.S. Army Medical Research and Materiel Command (“USAMRMC”). Under the terms of the contract, the USAMRMC reimbursed the Company up to $3.0 million to conduct a registrational trial investigating the safety and effectiveness of the PoNS device for the treatment of chronic balance deficits due to mmTBI. Reimbursement of expenses under the agreement was based on a schedule of milestones related to the completion of subjects in the trial. The original contract expired on December 31, 2016; however, the Company extended the agreement through December 31, 2017. On November 7, 2017, the Company received another extension of the contract agreement to December 31, 2018.

In addition, during the third quarter of 2017, the Company announced the execution of an extension to its Cooperative Research and Development Agreement with the USAMRMC through 2018 and extended the deadline for commercialization of the PoNS device to December 31, 2021.

In December 2018, the U.S. Army notified the Company that they were amending the U.S. Army 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. The Company satisfied this obligation when it submitted its application for marketing authorization of the PoNS device to the FDA on August 31, 2018, and provided copies of the submission documents to the U.S. Army.

As of December 31, 2018, the Company had received a total of $3.0 million with respect to expenses reimbursed for amounts owed to the Company for completion of development milestones. All reimbursement amounts received are credited directly to the accounts in which the original expenses were recorded, including research and development, wages and salaries, and legal expenses.

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 12, 2020

By: /s/ Philippe Deschamps
Philippe Deschamps
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/ Philippe Deschamps — Date: March 12, 2020
Philippe Deschamps
President, Chief Executive Officer and Director

By /s/ Joyce LaViscount — Date: March 12, 2020
Joyce LaViscount
Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)

By /s/ Blane Walter — Date: March 12, 2020
Blane Walter
Director

By /s/ Mitchell E. Tyler — Date: March 12, 2020
Mitchell E. Tyler
Director

By /s/ Edward M. Straw — Date: March 12, 2020
Edward M. Straw
Director

By /s/ Huaizheng Peng — Date: March 12, 2020
Huaizheng Peng
Director

By /s/ Thomas E. Griffin — Date: March 12, 2020
Thomas E. Griffin
Director

By /s/ Dane Andreeff — Date: March 12, 2020
Dane Andreeff
Director

Exhibit 4.5

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

The following is a description of our common stock and provisions of our Articles of Incorporation and amended and restated bylaws, each of which are incorporated by reference as an exhibit to the Annual Report on Form 10-K to which this Exhibit 4.5 is a part. This summary does not purport to be complete and is qualified in its entirety by the full text of our aforementioned Articles of Incorporation and amended and restated bylaws and by applicable law.

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.

Voting

Holders of our Class A Common Stock are entitled to receive notice of and attend any general meeting of the Company. In addition, holders of our Class A Common Stock shall have the right to vote at any such meeting on the basis of one vote for each such share held.

Dividends

Holders of our Class A Common Stock shall, in the absolute discretion of the Board, be entitled to receive dividends as and when declared by the directors out of monies of the Company properly applicable to the payment of dividends. We have never declared or paid any cash dividends on our Class A Common Stock. We currently intend to retain future earnings, if any, to finance the expansion of our business. As a result, we do not anticipate paying any cash dividends in the foreseeable future.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of our Class A Common Stock will be entitled to share ratably in the net assets legally available for distribution to shareholders 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

In the event of the liquidation, dissolution or winding-up of the Company or other distribution of assets of the Company for the purpose of winding-up its affairs or upon a reduction of capital the holders of our Class A Common Stock shall share equally, share for share, in the assets and property of the Company.

Anti-Takeover Effects of Our Articles of Incorporation and Wyoming General Corporation Law

Our Articles of Incorporation provide for unlimited authorized shares of our Class A Common Stock. Our authorized but unissued shares of Class A Common Stock will be available for future issuance without shareholder approval. These additional shares may be utilized for a variety of corporate purposes, including future public offerings to raise additional capital, corporate acquisitions and employee benefit plans. The existence of unlimited authorized but unissued shares of Class A Common Stock could render more difficult or discourage an attempt to obtain control of a majority of our Class A Common Stock by means of a proxy contest, tender offer, merger or otherwise.

Though not now, we may be or in the future we may become subject to Wyoming's control share law. The law focuses on the acquisition of a "controlling interest" which means the ownership of outstanding voting shares sufficient, but for the control share law, to enable the acquiring person to exercise the following proportions of the

voting power of the corporation in the election of directors: (i) one-fifth or more but less than one-third, (ii) one-third or more but less than a majority, or (iii) a majority or more. The ability to exercise such voting power may be direct or indirect, as well as individual or in association with others. The effect of the control share law is that the acquiring person, and those acting in association with it, obtains only such voting rights in the control shares as are conferred by a resolution of the shareholders of the corporation, approved at a special or annual meeting of shareholders. The control share law contemplates that voting rights will be considered only once by the other shareholders. Thus, there is no authority to strip voting rights from the control shares of an acquiring person once those rights have been approved. If the shareholders do not grant voting rights to the control shares acquired by an acquiring person, those shares do not become permanent non-voting shares. The acquiring person is free to sell its shares to others. If the buyers of those shares themselves do not acquire a controlling interest, their shares do not become governed by the control share law. If control shares are accorded full voting rights and the acquiring person has acquired control shares with a majority or more of the voting power, any shareholder of record, other than an acquiring person, who has not voted in favor of approval of voting rights is entitled to demand fair value for such shareholder's shares.

Wyoming's control share law may have the effect of discouraging takeovers of the corporation. In addition to the control share law, Wyoming has a business combination law which prohibits certain business combinations between Wyoming corporations and "interested stockholders" for three years after the "interested stockholder" first becomes an "interested stockholder," unless the corporation's board of directors approves the combination in advance. For purposes of Wyoming law, an "interested stockholder" is any person who is (i) the beneficial owner, directly or indirectly, of fifteen percent or more of the voting power of the outstanding voting shares of the corporation, or (ii) an affiliate or associate of the corporation and at any time within the three previous years was the beneficial owner, directly or indirectly, of fifteen percent or more of the voting power of the then outstanding shares of the corporation. The definition of the term "business combination" is sufficiently broad to cover virtually any kind of transaction that would allow a potential acquirer to use the corporation's assets to finance the acquisition or otherwise to benefit its own interests rather than the interests of the corporation and its other shareholders. The effect of Wyoming's business combination law is to potentially discourage parties interested in taking control of the Company from doing so if it cannot obtain the approval of our Board.

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.

Registration Rights of A&B

Pursuant to the terms of the Company's $7,000,000 Credit Facility with A&B Company Limited (the "Credit Facility"), we have agreed to register the shares of Class A Common Stock issued or issuable under the

terms of the Credit Facility upon the request of A&B Company Limited. A&B Company Limited currently has beneficial ownership over 11,458,334 shares of our Class A Common Stock, consisting of 7,638,889 shares of Class A Common stock and warrants to purchase 3,819,445 additional shares of Class A Common Stock.

Transfer Agent and Registrar

The transfer agent and the registrar for the Company is Computershare Investor Services Inc., located at 100 University Avenue, 8th Floor, Toronto, Ontario, M5J 2Y1 and 510 Burrard Street, 2nd Floor, Vancouver, British Columbia, V6C 3B4

Common Stock Listing

Our Class A Common Stock is listed on Nasdaq under the symbol “HSDT” and on the TSX under the symbol “HSM.”

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 S3 (No. 333-236101) and Form S-8 (No. 333-204155, 333-218095 and 333-229724) of Helius Medical Technologies, Inc., of our report dated March 12, 2020, 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, 2019. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ BDO USA, LLP

Philadelphia, Pennsylvania
March 12, 2020

Exhibit 31.1

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

I, Philippe Deschamps, 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;

   (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 12, 2020

/s/ Philippe Deschamps
Philippe Deschamps
President, 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;

   (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 12, 2020

/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, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Philippe Deschamps, as 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 his 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 12, 2020

/s/ Philippe Deschamps

Philippe Deschamps
President, 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.