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, 2021
or
☐ **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.**

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

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

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

Registrant's telephone number, including area code: (215) 944-6100
Securities registered pursuant to Section 12(b) of the Act:

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

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

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

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

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

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

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

Large accelerated filer ☐ Accelerated filer ☐

Non-accelerated filer ☒ Smaller reporting company ☒

Emerging growth company ☐

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

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

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

The aggregate market value of the common equity held by non-affiliates of the registrant on June 30, 2021, based on the closing price on that date of $16.99 per share, was approximately $37,214,794. As of March 4, 2022, there were 3,794,269 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 Securities and Exchange Commission pursuant to Regulation 14A in connection with the registrant's 2022 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, 2021.

Audit Firm Id: 243 Auditor Name: BDO USA, LLPAuditor Location: Philadelphia, PA, United States

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., or HMC, and Helius Canada Acquisition Ltd., or HCA, unless the context otherwise requires. All financial information is stated in U.S. dollars unless otherwise specified. Our financial statements are prepared in accordance with accounting principles generally accepted in the United States, or U.S. GAAP.

FORWARD-LOOKING STATEMENTS

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

The forward-looking statements in this Annual Report include but are not limited to statements relating to: the Company's future growth and operational progress, including manufacturing activities for the PoNS device, receipt of prescriptions and progress of commercialization of the PoNS device in the U.S., the COVID-19 pandemic including its impact on the Company, clinical development plans, product development activities, plans for U.S. Food and Drug Administration, or FDA, filings and their subsequent approvals, other foreign or domestic regulatory filings, the safety and effectiveness of our product, our market awareness, our ability to compete effectively, the ability and limitation of our manufacturing source(s), our distribution network, the adequacy of our intellectual property protection, our future patent approvals, our future expenses and cash flow, our ability to become profitable, our future financing arrangements, our accountants' future perspective including any going concerns, any future stock price, our ability to build commercial infrastructure, and our ability to receive reimbursement coverage under Medicare, Medicaid or under other insurance plans.

Such forward-looking statements are necessarily based upon a number of estimates and assumptions that, while considered reasonable by Helius, are inherently subject to significant business, economic, competitive political and social uncertainties and contingencies. The factors and assumptions used by management of the Company to develop such forward-looking statements include, but are not limited to, uncertainties associated with the Company's capital requirements to achieve its business objectives, availability of funds, including that funding from our purchase agreement with Lincoln Park Capital Fund, LLC may be limited or be insufficient to fund our operations, the ability to find additional sources of funding, the impact of the COVID-19 pandemic, manufacturing, labor shortage and supply chain risks, including risks related to manufacturing delays, build a commercial team and build relationships with Key Opinion Leaders, neurology experts and neurorehabilitation centers the Company's ability to train physical therapists in the supervision of the use of the PoNS treatment, the Company's ability to secure contracts with rehabilitation clinics, the Company's ability to obtain national Medicare coverage and to obtain a reimbursement code so that the PoNS device is covered by Medicare and Medicaid, the Company's ability to build internal commercial infrastructure, secure state distribution licenses, market awareness of the PoNS device, future clinical trials and the clinical development process, the product development process and FDA regulatory submission review and approval process, other development activities, ongoing government regulation and other factors included in the section entitled "Risk Factors."

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

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

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

SUMMARY RISK FACTORS

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

- We have a history of losses and may not achieve or sustain profitability in the future;
- We will require additional financing to carry out our plan of operations, and failure to obtain such financing may cause our business to fail;
- We currently only have one product, the PoNS device, which is authorized for commercial distribution in Canada, Australia, and in the U.S. for treatment of MS, and we have not obtained authorization to distribute the PoNS device commercially in Europe or in the U.S. for other indications and may never obtain such authorizations;
- We may encounter substantial delays in planned clinical trials, and planned clinical trials may fail to demonstrate the safety and efficacy of the PoNS device to the satisfaction of regulatory authorities;
- Generation of revenue related to the PoNS technology is dependent on the PoNS Therapy being prescribed by physicians in the U.S. and our ability to train physical therapists in the supervision of the use of the PoNS Therapy;
- Market awareness of the PoNS device is limited, and the neuromodulation market is new and uncertain;
- We are dependent on third-party scientists and research institutions, in part, for research and development and on third parties for the manufacture and distribution of our product;
- The COVID-19 pandemic and outbreaks of communicable diseases may continue to materially and adversely affect our business, financial condition and results of operations;
- Third parties may gain access to our technology if our intellectual property protection is insufficient;
- We may be subject to various litigation claims and legal proceedings, including intellectual property litigation, which may adversely affect our business;
- Commercialization of our product outside of Canada, Australia, and the U.S. for indications other than MS is dependent on obtaining market authorization from the FDA and foreign regulatory authorities, which will require significant time, research, development, and clinical study expenditures and ultimately may not be successful;
- Failure to secure contracts with workers' compensation and third-party administrators or rehabilitation clinics could have a negative impact on our sales and would have a material adverse effect on our business, financial condition and operating results;
- Failure to obtain a reimbursement code from the U.S. Department of Health and Human Services so that the PoNS device is covered by Medicare and Medicaid could have a negative impact on our intended sales and would have a material adverse effect on our business, financial condition and operating results;
- If we fail to comply with healthcare laws, we could face substantial penalties and financial exposure;
- We face ongoing government scrutiny and regulation in connection with the development of product candidates and following marketing authorization;
- After commercialization, a product recall or the discovery of serious safety issues with our products could have a significant adverse impact on us; and
- We have been the victim of a cyber-related crime, and our controls may not be successful in avoiding future cyber-related crimes.
- We are reliant on third-party, single-sourced contract manufacturing, exposing us to risks that could delay our sales or result in higher costs or lost product revenues.

INDUSTRY AND MARKET DATA

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

PART I

ITEM 1. BUSINESS

Overview

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

Our product, known as the Portable Neuromodulation Stimulator, or PoNS®, is an innovative non-implanted medical device, inclusive of a controller and mouthpiece, which delivers mild electrical stimulation to the surface of the tongue to provide treatment of gait deficit and chronic balance deficit. PoNS has marketing clearance in the U.S. for use in the U.S. as a short term treatment of gait deficit due to mild-to-moderate symptoms for multiple sclerosis, or MS, and is to be used as an adjunct to a supervised therapeutic exercise program in patients 22 years of age and over by prescription only. We are currently accepting prescriptions for PoNS in the U.S., and we expect the first commercial sales to occur in the near term. PoNS is authorized for sale in Canada for two indications: (i) 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, or PoNS Therapy™; and (ii) for use as a short term treatment (14 weeks) of gait deficit due to mild and moderate symptoms from MS and it is to be used in conjunction with physical therapy. It has been commercially available in Canada since March 2019. PoNS is authorized for sale as a Class IIa medical device in Australia and we are currently seeking a business partner to commercialize and distribute PoNS in Australia.

PoNS Device

The PoNS device is a non-implanted medical device comprised of a controller and a mouthpiece that are connected by a cord. The controller is worn around the neck and the mouthpiece sits on the tongue during treatment. PoNS Therapy, or the “Therapy”, utilizes the PoNS device in conjunction with supervised therapeutic exercise. 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 Therapy is completed over a period of 14 weeks. The first 2 weeks of the Therapy are administered in a rehabilitation or physical therapy clinic by a PoNS trained therapist. The remaining 12 weeks are completed at home with weekly clinic visits to monitor progress, assess improvements and ensure the therapy level is still appropriate. When the device is on, the 143 gold-plated electrodes on the mouthpiece send mild electrical signals to the tongue. These impulses stimulate sensory nerves in the tongue that have direct pathways to the brain, through the brain stem. The combination of mild stimulation with supervised therapeutic exercise may enhance the neuroplastic effect, potentially resulting in functional improvements in balance and gait. During each clinic visit and at the end of the 14-week Therapy, the clinic downloads the PoNS usage data from the device and reviews it with the patient. This usage data in combination with the detail of the completed treatment assessments gives the clinician and the patient a unique and powerful method to assess treatment progress. The patient initiates their Therapy sessions with the PoNS device under the supervision of the clinicians through regular check ins.

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

Design

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

Figure 1
The Portable Neuromodulation Stimulator, PoNS device

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

Figure 2

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

Overview of Multiple Sclerosis and Current Available Treatments

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

Findings from a National MS Society study estimate that nearly 1 million people in the U.S. are living with MS of which approximately 25-30% are on Medicare and 93,000 people in Canada are living with MS. The National MS Society estimates that 2.3 million people

live with MS globally. The U.S. and Canada have the highest rates of MS, with 309 cases per 100,000 in the U.S., and 291 cases per 100,000 in Canada, respectively. Given the nature of this neurodegenerative disease, these individuals and their caretakers are active in exploring treatment options that may resolve or delay the progression of symptoms. There is also a well-established advocacy framework.

Mobility disability and walking impairment are among the most debilitating consequences of MS with approximately 85% of individuals diagnosed with MS reporting gait impairment as a major limitation in their daily lives. Gait is one of the most important bodily functions for MS patients and gait parameters, such as walking speed and stride length, have been shown to be significant predicators of patient independence in daily activities. A survey of 436 patients found that 45% reported a mobility disability in the first month following diagnosis, with upwards of 90% of patients reporting a mobility disability within 10 years of their diagnosis. Additionally, 50-80% of MS patients suffer from balance and gait dysfunction and over 50% fall at least once a year. It has also been reported that unemployment rates in MS patients range from 24-80% with higher rates associated with decreased ambulation and mobility. The Centers for Disease Control, or CDC, reports that individuals with disabilities, like MS, that result in limited mobility are at greater risk for health problems including injury, mental health and depression, overweight and obesity, pain, pressure sores or ulcers and other issues.

A 2016 economic analysis of MS found the total lifetime costs per person with MS to be $4.1 million, with average yearly healthcare costs ranging from $30 thousand to $100 thousand based on the severity of the disease. Since the exact cause of MS is still unknown, there is no known prevention. Although there is no cure for MS yet, treatments can manage symptoms. MS medications are designed to lessen the frequency of relapses and slow the progression of the disease, but none have proven to halt progression of the disease.
While there are several disease-modifying medications approved by the FDA 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 Therapy on improvement in gait.

Overview of mmTBI and Current Available Treatments

There are an estimated 14.5 million people globally, with over 1.5 million in the U.S. and 350,000 in Canada, living with balance deficit due to mmTBI. Every year in the U.S. and Canada, there are approximately 420,000 and 20,000 newly diagnosed mmTBIs, respectively, resulting in balance deficit. This condition often has a significant impact on one's quality of life, negatively affecting independence, employability, productivity, mental health and participation in the community. Rehabilitation is often required following a mmTBI for resulting motor, cognitive and behavioral impairments. The current standard of care to address balance issues following a mmTBI is supervised therapeutic exercise. While supervised therapeutic exercise can help to promote balance recovery, individuals are often unable to return to their full function and are left living with a balance deficit.

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

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 NeuroCom 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 (RWE) in MS patients treated with PoNS in Canada.

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

PoNS Clinical Trials and Scientific Support in mmTBI

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

PoNS Registrational Clinical Trial in mmTBI

We completed our registrational clinical trial (TBI-001) of the PoNS Therapy for persons with mmTBI in 2017. It was a double-blind randomized, controlled study of the safety and effectiveness of the PoNS Therapy using translingual noninvasive stimulation in participants with balance deficit due to mmTBI.

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

Trial Design

All participants provided a prior neuroradiologic report (obtained at least one year after the most recent mmTBI), if available, and completed demographic and quality of life surveys and a medical history during an initial screening visit. Participants who met the initial screening entrance criteria were scheduled for an MRI of the head, a neuropsychiatric evaluation, the 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 Therapy, 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 Therapy in the HFP and LFP arms both produced responses of greater than 15 points on the SOT composite score that were not significantly different from one another, the secondary endpoint would be calculated by combining the two groups and comparing the response to baseline at week two and week five. This would imply that both devices had a clinical effect.

The primary effectiveness endpoint demonstrated a trend toward a higher responder rate in the HFP arm (with 71.2% of subjects experiencing a greater than 15 point improvement on the SOT composite score) than in the LFP arm (with 63.5% of subjects experiencing a greater than 15 point improvement on the SOT composite score), $p<0.081$. The primary effectiveness endpoint was not reached because of the significant therapeutic effect observed in the LFP arm. Because both arms produced responses of greater than 15 points on the SOT composite score that were not significantly different from one another, the secondary effectiveness endpoint was calculated per the statistical analysis plan, as described above. The secondary effectiveness endpoints demonstrated statistically and clinically significant increases in SOT composite scores:

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

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

- We successfully met the primary and secondary safety endpoints as measured by a decrease in falls at week two and 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 Therapy. 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 Therapy 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 Therapy 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 Therapy 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 Therapy.

Conclusion:

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

Overall Conclusion from the Two mmTBI Trials.

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

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

Regulatory Status Worldwide

Canadian Regulatory Status: mmTBI and MS

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

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

U.S. Regulatory Status: MS

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

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

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

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

On January 14, 2021, the Centers for Medicare & Medicaid Services, or CMS, issued the final rule (CMS-3372-F), 42 C.F.R. § 405.603 on the new Medicare coverage pathway referred to as Medicare Coverage of Innovative Technology, or MCIT, for FDA-designated breakthrough medical devices. The MCIT rule will provide national Medicare coverage as early as the same day as FDA market authorization for breakthrough devices and coverage would last for four years. To be eligible for coverage through MCIT, the breakthrough device must be used for the FDA approved or cleared indication(s) for use. Manufacturers will be able to opt in to MCIT and choose a start date for coverage anytime within two years from the date of FDA market authorization, but coverage will only be valid for four years from market authorization regardless of opt in date. At the end of the four year period, manufacturers are expected to have obtained coding for the specific product which can then be used as the reimbursement pathway for commercial payers. CMS announced MCIT was delayed from becoming effective March 15, 2021 to May 15, 2021 with an additional comment period during that time. On May 14, 2021, CMS announced it further delayed the effective date of the final rule until December 15, 2021 to provide CMS an opportunity to determine appropriate next steps. On September 15, 2021, CMS published a proposal that would repeal the MCIT pathway. Following a 30-day comment period included in the proposal, CMS announced on November 12, 2021 that it was repealing MCIT to address concerns that the provisions in the final rule may have not been sufficient to protect Medicare patients. While we will continue to monitor this, we also remain focused on building out our reimbursement strategy for both commercial and government payers. We are still working to understand current Medicare requirements and policies for coverage, coding, and payment

of durable medical equipment and assess how the PoNS device may be treated with respect to coding, coverage, and reimbursement under the Medicare program.

In September 2021, we started activities to setup and implement a new study as part of a Therapeutic Experience Program, or TEP, with NYU Langone Health as our first Center of Excellence clinical site. The TEP is a Helius-sponsored, open label observations, interventional multi-center outcome research trial designed to assess adherence to on-label PoNS therapy for improvement in gait deficits with MS in a real-world clinical setting. The study will measure subjects' adherence to PoNS therapy, which combines the PoNS device with physical therapy, to better understand the relationship between adherence to the treatment regimen and therapeutic functional outcome. The primary endpoint of the study is maintenance of gait improvement from the end of supervised therapy (Phase 1) to the end of unsupervised therapy (Phase 2) in relation to the subject's adherence to PoNS therapy. The secondary endpoints are improvement of gait and balance deficit over time, and clinical global impression of change. The study will be conducted at ten to twelve Centers of Excellence across the U.S., with an estimated average of four PoNS devices per site. Enrollment is expected to commence in first half of 2022 and continue throughout the year. Approximately forty to fifty patients with MS are expected to participate in the study.

U.S. Regulatory Status: Stroke

In August 2021, we received Breakthrough Designation for the PoNS device as a potential treatment for dynamic gait and balance deficits due to symptoms from stroke, to be used as an adjunct to a supervised therapeutic exercise program in patients 22 years of age and over. With Breakthrough Designation received, a clinical trial of PoNS therapy in stroke patients in collaboration with Medical University of South Carolina is planned to commence in the second quarter of 2022 with initial patient enrollments beginning in the second half of 2022.

U.S. Regulatory Status: mmTBI

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

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

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

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

Based on the receipt of the FDA's final minutes from the pre-submission meeting, we are assessing the feasibility of a clinical program to advance the development of a study aimed to obtain clearance for gait and balance deficits in mmTBI if nondilutive financing to fund the program becomes available.

European Regulatory Status

In December 2018, we submitted an application for 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 will reconsider submitting to the EU when conditions stabilize.

Australian Regulatory Status

In the third quarter of 2019, we initiated the submission of our application to the Therapeutic Goods Administration, or TGA. We supplemented our submission with additional data based on questions supplied to date and provided responses to additional questions during the third quarter of 2020. In November 2021, we received market authorization from the TGA for the sale of PoNS as a Class IIa medical device. In Australia, PoNS is intended for short term use by healthcare professionals as an adjunct to a therapeutic exercise program to improve balance and gait. PoNS is not intended to be used alone without an exercise program. We are working to establish a distribution partner for Australia but currently do not expect to have commercial sales of PoNS in Australia in 2022.

Partnerships and Agreements

Canadian Strategic Alliance

On October 30, 2019, we and Health Tech Connex, Inc., or HTC entered into a Share Purchase Agreement, or the SPA, whereby we, through our wholly owned subsidiary, acquired Heuro from HTC. Under the terms of the SPA, total consideration of approximately $1.6 million was paid to HTC, which included (1) the repayment to HTC for their investment in the set-up of Heuro's initial commercial infrastructure including the establishment of five authorized PoNS clinics across Canada, (2) the current market value of 55 PoNS devices which we also are to provide to HTC under the SPA, (3) the CAD$750 thousand receivable from the September 2018 strategic alliance agreement and (4) the sale of exclusivity rights granted to HTC in the Co-Promotion Agreement, as defined below, to provide PoNS Therapy 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 Therapy and the NeuroCatch™ device throughout Canada. The co-promotion arrangement terminated in accordance with its terms on December 31, 2020. Also, subject to certain terms and conditions, we granted to HTC the exclusive right to provide the PoNS Therapy in the Fraser Valley and Vancouver metro regions of British Columbia, where HTC has operated a PoNS authorized clinic since February 2019. HTC 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. On January 31, 2022, we notified HTC of its material breaches under the Co-Promotion Agreement, which HTC failed to cure under the terms of the Co-Promotion Agreement, and as such, it is our position that this exclusivity right is no longer in effect.

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 validated the performance of the engineering, design verification testing and product documentation to support our FDA submission. Cambridge also assisted us in the identification of, and transition to, our commercial-scale manufacturer.

On December 29, 2017, we selected Keytronic Corporation, or Keytronic, as our contract-manufacturing partner for the PoNS device after a competitive selection process. The commercial design of the PoNS device is manufactured and assembled at Keytronic's facility located in Oakdale, Minnesota. Keytronic manufactured devices for engineering and design verification testing and for our FDA submission as well as commercial devices for launch inventory. Keytronic has multiple locations across the U.S., 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. Keytronic 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. HMI maintains a compliant quality management system certified to ISO 13485:2016 and compliant with MDSAP requirements for the U.S., Canada and Australia.

In July 2021, we entered into a contract with Healthlink International Inc. to provide third party logistics for domestic and Canadian shipment and order fulfillment, and to provide warehousing services for finished goods. Healthlink is a life science solutions company, specializing in logistics, temperature-controlled warehousing, fulfillment and freight management as well as back-office services, including multilingual customer service, financial services and VAT management.

Commercialization

Canadian Commercialization Efforts

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

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

Following in-depth market analysis and field intelligence, our Canadian commercial team began an expansion plan to increase the number of authorized PoNS clinics. During the year ended December 31, 2021, we authorized 6 new clinical locations to have 37 clinic locations across Canada as of December 31, 2021. In addition to continuing to increase the number of clinic locations, we have shifted our focus to driving patient throughput to these clinics. Sales performance in Canada continues to be impacted by the COVID-19 pandemic due to space restrictions that the provincial governments have imposed as well as the risk tolerance of patients and therapists.

In collaboration with Toronto Rehabilitation Institute (part of University Health Network) we are continuing our clinical experience program, the results of which we will look to publish in 2022.

We continue to refine our go-to-market pricing model. In 2020, we implemented a modified pricing approach which is focused on reducing the need for clinics and patients to pay large, upfront costs at the start of treatment. We have also experimented with various promotional pricing programs resulting in lower unit prices for both PoNS system purchases and mouthpieces in order to increase access to the PoNS Therapy and drive market awareness which we believe resulted in an increase in the volume of units sold, beginning in the second half of 2020. We extended the promotional pricing through the end of 2021 including any order placed and accepted, but not fulfilled before December 31, 2021. The promotional pricing was discontinued in 2022 when new pricing was established.

The value dossiers for mmTBI and MS that were created in mid-2020 to fully demonstrate in both scientific and financial terms, the merits of PoNS Therapy for claimants are now being utilized along with submissions from clinics on behalf of their patients. The dossiers are provided to our clinics across Canada to submit as part of treatment plans with reimbursement applications to the payer community. Our reimbursement strategy for mmTBI is focused initially on the auto collision insurance and workers' compensation, or WC, market as well as long-term disability cases. Our reimbursement strategy for MS is focused on commercial insurers/extended health benefits.

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

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

U.S. Commercialization Activities

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

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

We are currently accepting prescriptions for PoNS in the United States, and we anticipate our first commercial sales in the near term. We have targeted specific Key Opinion Leaders (i.e., neurologists and physiatrists) and their associated neurorehabilitation centers, where selected physical therapists will be trained to deliver the PoNS Therapy. Importantly, this focused strategy will also allow us to measure patient outcomes to determine if they are similar to those observed in our clinical trials. To further develop and implement the PoNS commercialization strategy, we have hired a Vice President of Sales and Marketing, North America, have identified the initial launch areas within the U.S., and we have continued to build out our commercial team, including field sales, reimbursement specialists, and marketing and operational support commensurate with PoNS sales activity.

During 2021, we contracted with an industry consultant to conduct a health economic study of PoNS. Based upon the results of this study and comparing PoNS to other medical devices utilizing similar patented technologies, we established a U.S. list price for the PoNS device of $25,700, comprised of $17,800 for the controller and $7,900 for the mouthpiece. We are pursuing commercial insurance coverage and Medicare reimbursement for PoNS within the Durable Medical Equipment, or DME, benefit category. While there are currently no applicable Healthcare Common Procedure Coding System, or HCPCS, codes to describe the PoNS device or mouthpiece, we intend to use miscellaneous codes – E1399 (Miscellaneous durable medical equipment) and A9999 (Miscellaneous DME supply or accessory, not otherwise specified) until specific HCPCS codes are created. We have applied for unique HCPCS codes during the third quarter of 2021, which is a nine month process from application until coding is to be effective, if assigned. We also intend to provide broad access and reimbursement for the PoNS Therapy over time through commercial insurers. Prior to the initiation of CMS or broad commercial payer coverage, we anticipate the primary source of sales will be self-pay patients. We expect to support the cost of the PoNS Therapy by offering a cash pay discount, collaborating with third parties to provide self-pay patients with financing options as well as working with advocacy groups and charitable organizations to help self-pay patients access our technology. In general, we anticipate that it will take at least 24 months to obtain broad coverage and reimbursement among government and private payers.

Commercialization in Other Markets

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

We submitted an application to the TGA in Australia during the third quarter of 2019. We supplemented our submission with additional data based on questions supplied to date and provided responses to additional questions during the third quarter of 2020. In November 2021, we received market authorization from the TGA for the sale of PoNS as a Class IIa medical device. In Australia, PoNS is authorized as a non-implanted neurostimulator intended for short term used by healthcare professionals as an adjunct to a therapeutic exercise program to improve balance and gait. PoNS is not intended to be used alone without an exercise program. We are working to establish a distribution partner for Australia but currently do not expect to have commercial sales of PoNS in Australia in 2022.

COVID-19 Pandemic

On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 as a global pandemic, which has spread throughout the U.S. and around the world. The Company’s business, results of operations and financial condition have been and may continue to be adversely impacted by the COVID-19 pandemic and global economic conditions. The outbreak and spread of COVID-19 has significantly increased economic uncertainty. Authorities implemented, and continue to implement, numerous measures to try to contain the virus, such as travel bans and restrictions, quarantines, shelter in place orders, and business shutdowns. The COVID-19 pandemic initially led to the closure of PoNS authorized clinic locations across Canada from March until June 2020. Patients who completed their initial training in the clinics prior to the closures were able to continue working independently in the at-home portion of the treatment, with remote check-ins with their certified therapists. While all clinics have re-opened, as of December 31, 2021, they were all operating at reduced capacity, which limited operations to 50% capacity during the second half of 2021. Some patients have begun to return to these clinics for treatment, but patients have been and may continue to be less willing to return to the clinics due to COVID-19, impacting our commercial activities and our customer engagement efforts. This was especially true in the first half of 2021, as cases of COVID-19 increased significantly in Canada and additional restrictions, shelter in place orders, and business shutdowns were imposed. The rate of vaccination increased throughout all provinces throughout 2021, facilitating the lifting of some of the previously imposed restrictions. Thus far during the first quarter of 2022, capacity has remained at the 50% threshold with the expectation that the capacity limit will increase as provinces continue to lift restrictions. We continue to monitor the impact of COVID-19 and adjust our operations as the circumstances change.

We have expanded our services to include remote training and treatment, but the long-term viability of these remote programs is still being assessed. Additionally, current and planned clinical experience programs and clinical trials in Canada have experienced and may

continue to experience delays in the programs as trial participant attendance has generally decreased as a result of the pandemic, and clinics and clinical research sites have experienced delays and difficulties in recruiting and re-hiring clinical site staff.

The COVID-19 pandemic has and may continue to cause delays in or the suspension of our business partners manufacturing operations, our research and product development activities, our regulatory workstreams, our research and development activities and other important commercial functions. We are also dependent upon our suppliers for the manufacture of our PoNS device. In the second quarter of 2020, two of our business partners diverted resources towards other activities related to COVID-19, resulting in delays in our product development activities. Such diversion of suppliers' resources may occur again in the future, and the pandemic could limit our suppliers' ability to travel or ship materials or force temporary closure of facilities that we rely upon. Manufacturing delays have occurred and may also occur as the result of labor shortages. Two of our suppliers experienced significant labor shortages as a result of COVID-19 from the end of November 2021 through early January 2022 which reduced the available resources needed to build and test product which may delay the timing for the submission and approval of our marketing applications with regulatory agencies. Further, the economic impact of the COVID-19 pandemic could affect our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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

Coverage and Reimbursement

Canadian Reimbursement

We believe that traditional life and health payers may be among the earliest to provide coverage and reimbursement for the PoNS Therapy, and therefore, we are focusing on gaining coverage for the PoNS Therapy through them. Life and health encompasses long- and short-term disability claims. Because these payers are responsible for both medical expenses and lost wages, they have an incentive to seek ways to help injured employees to return to work. As part of our commercial treatment program in Canada, we will collect both outcomes and return to work data, which we plan to utilize with life and health, provincial workers compensation insurance programs, and property and casualty insurers to demonstrate both the clinical and economic value associated with the PoNS Therapy.

U.S. Reimbursement

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

On January 14, 2021, the Centers for Medicare & Medicaid Services, or CMS, issued the final rule (CMS-3372-F), 42 C.F.R. § 405.603 on the new Medicare coverage pathway referred to as Medicare Coverage of Innovative Technology, or MCIT, for FDA-designated breakthrough medical devices. The purpose of the MCIT rule was to provide national Medicare coverage as early as the same day as FDA market authorization for breakthrough devices and coverage would last for four years. On September 15, 2021, CMS published a proposal that would repeal the MCIT pathway. Following a 30-day comment period included in the proposal, CMS announced on November 12, 2021 that it was rescinding the MCIT final rule to address concerns that the provisions in the final rule may have not been sufficient to protect Medicare patients. While we will continue to monitor this, we also remain focused on building out our reimbursement strategy for both commercial and government payers. We continue to work with Medicare requirements and policies for coverage, coding, and payment of durable medical equipment and assess how the PoNS device may be treated with respect to coding, coverage, and reimbursement under the Medicare program.

Competition

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

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

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

Advantages of the PoNS Therapy

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

- The PoNS Therapy stimulates the trigeminal nerve which developing science has implicated to be beneficial in some neurological disorder models. The PoNS Therapy 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 Therapy.

- 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 via a portable, non-implanted device. This allows for the integration of neurostimulation with a wide range of therapies previously unexplored for neurological rehabilitation.

Intellectual Property

Licensed Intellectual Property

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

U.S. Patent Application No.	Application Filing Date	Status	U.S. Patent No.	Issue Date	Subject Matter
12/348,301	1/4/2009	Issued	8,849,407	9/30/2014	non-invasive neurostimulation of the skin combined with simultaneous physical therapy to provide neurorehabilitation of a patient to treat various maladies including, e.g., TBI, stroke and Alzheimer's disease
14/340,144	7/24/2014	Issued	8,909,345	12/9/2014	non-invasive neurostimulation within a patient's mouth combined with physical therapy to provide neurorehabilitation of a patient to treat various maladies including, e.g., TBI, stroke, and Alzheimer's disease
14/341,141	7/25/2014	Issued	9,020,612	4/28/2015	non-invasive neurostimulation within a patient's mouth combined with cognitive therapy to provide neurorehabilitation of a patient resulting in improved reading comprehension and increased attention span as well as the treatment various maladies including, but not limited to, TBI, stroke, and Alzheimer's disease
14/615,766	2/6/2015	Issued	9,656,078	5/23/2017	non-invasive neurostimulation within a patient's mouth combined with stimulation of the patient's vision, hearing, vestibular systems, or somatosensory systems for the treatment of tinnitus
14/689,462	4/17/2015	Issued	9,597,501	3/21/2017	non-invasive neurostimulation of a patient's skin combined with cognitive therapy to provide neurorehabilitation of a patient resulting in improved reading comprehension and increased attention span as well as the treatment various maladies including, e.g., TBI, stroke, and Alzheimer's disease
14/815,171	7/31/2015	Issued	9,597,504	3/21/2017	non-invasive neurostimulation of a patient's mouth combined with therapy to provide neurorehabilitation of a patient, with a focus on features of a neurostimulation device
15/207,029	7/11/2016	Issued	9,656,069	5/23/2017	non-invasive neurostimulation of a subject's oral cavity while the subject engages in an exercise in order to enhance a subject's proficiency in the exercise
15/283,894	10/3/2016	Issued	10,293,163	5/21/2019	non-invasive neurostimulation of a subject's oral cavity or skin while the subject engages in a physical or cognitive exercise in order to enhance 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
16/376,595	4/5/2019	Issued	11,185,696	11/30/2021	Utility patent application covering non-invasive neurostimulation of a subject's oral cavity or skin while the subject engages in a physical or cognitive exercise in order to enhance a subject's proficiency in the exercise
16/450,915	6/24/2019	Allowed	N/A	N/A	Non-invasive neurostimulation of a subject's oral cavity or skin while the subject engages in a physical or cognitive exercise in order to enhance a subject's proficiency in the exercise

61/019,061 (Provisional)	1/4/2008	Expired	N/A	N/A	N/A
61/020,265 (Provisional)	1/10/2008	Expired	N/A	N/A	N/A

U.S. Patent Nos. 8,909,345; 9,020,612; 9,656,078; 9,597,501; 9,597,504; 9,656,069; 10,293,163; 10,328,263; and 11,185,696 claim priority to U.S. Patent No. 8,849,407.

A U.S. provisional patent application provides the means to establish an early effective filing date for a later filed nonprovisional patent application. Therefore, though the two provisional applications have expired, they establish a priority date for U.S. Patent Nos. 8,909,345; 9,020,612; 9,656,078; 9,597,501; 9,597,504; 9,656,069; 10,293,163; 10,328,263; and 11,185,696, and any future filings that claim priority. We intend to file additional continuation applications in the United States Patent and Trademark Office, or USPTO, claiming priority to U.S. Provisional Patent Application Nos. 61/019,061 and 61/020,265 to protect other aspects of the PoNS device and related non-invasive neurostimulation techniques.

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

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

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

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

Company Owned Intellectual Property

As of March 7, 2022, we have filed 36 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 21 design patent applications describing various ornamental designs. We are the sole assignee for these 36 U.S. patent filings. In addition to the first issued patent (U.S. Patent No. 9,072,889), the USPTO has issued 14 utility patents and 21 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	4/10/2017	Issued	10,258,790	4/16/2019	Utility application covering overall system design, including controller and mechanical details of the mouthpiece
15/602,055	5/22/2017	Issued	10,463,850	11/5/2019	Utility application covering methods of manufacturing the mouthpiece
16/005,624	6/11/2018	Issued	10,709,887	7/14/2020	Utility patent application covering methods of placing a mouthpiece in a patient’s mouth prior to engaging in NINM
16/384,016	4/15/2019	Issued	11,197,994	12/14/2021	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	D751214	3/8/2016	Design patent covering an alternative controller not used in the current PoNS device
29/510,746	12/3/2014	Issued	D750266	2/23/2016	Design patent covering an alternative mouthpiece not used in the current PoNS device
29/510,749	12/3/2014	Issued	D750268	2/23/2016	Design patent covering an alternative mouthpiece not used in the current PoNS device
29/510,747	12/3/2014	Issued	D751213	3/8/2016	Design patent covering an alternative mouthpiece not used in the current PoNS device
29/510,748	12/3/2014	Issued	D750267	2/23/2016	Design patent covering an alternative mouthpiece not used in the current PoNS device
29/510,750	12/3/2014	Issued	D753315	4/5/2016	Design patent covering mouthpiece used in the current PoNS device
29/510,751	12/3/2014	Issued	D751722	3/15/2016	Design patent covering an alternative controller not used in the current PoNS device
29/510,752	12/3/2014	Issued	D752766	3/29/2016	Design patent covering an alternative controller not used in the current PoNS device
29/510,753	12/3/2014	Issued	D753316	4/5/2016	Design patent covering an alternative controller not used in the current PoNS device
29/510,744	12/3/2014	Issued	D760397	6/28/2016	Design patent covering alternative system design used in the current PoNS device
29/510,756	12/3/2014	Issued	D759830	6/21/2016	Design patent covering alternative system design used in the current PoNS device
29/681,984	2/28/2019	Issued	D891084	7/28/2020	Design patent covering mouthpiece retainer case design used in the current PoNS device
29/681,990	2/28/2019	Issued	D894601	9/1/2020	Design patent covering carry case design used in the current PoNS device
29/682,001	2/28/2019	Issued	D907221	1/5/2021	Design patent covering alternative system design used in the current PoNS device
29/681,993	2/28/2019	Issued	D927005	8/3/2021	Design patent covering alternative system design used in the current PoNS device
29/681,997	2/28/2019	Issued	D916300	4/13/2021	Design patent covering alternative system design used in the current PoNS device

In addition to our U.S. patents, we have been granted 20 foreign utility patents (nine in Australia, five in Russia, one in Canada, 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 33 foreign design patents (three in Australia, nine in Canada, six 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	11/30/2015	Issued	2015355211	11/16/2017	Utility patent covering overall system design, including controller and mechanical details of the mouthpiece
2015355212	11/30/2015	Issued	2015355212	12/21/2017	Utility patent covering center of gravity of the mouthpiece
2017218934	8/21/2017	Issued	2017218934	1/3/2018	Utility patent covering overall system design, including controller and mechanical details of the mouthpiece
2017276270	12/14/2017	Issued	2017276270	6/28/2018	Utility patent covering authentication techniques
2018204184	6/12/2018	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	1/10/2019	Issued	2019200175	10/24/2019	Utility patent covering the locators of the mouthpiece
2019246836	10/10/2019	Issued	2019246836	12/14/2021	Utility patent covering methods for placing a mouthpiece in a patient's mouth

Canadian Application No.	Application Filing Date	Status	Canadian Patent No.	Issue Date	Subject Matter
2969729	11/30/2015	Issued	2969729	10/26/2021	Utility application covering overall system design, including controller and mouthpiece, and authentication techniques

Eurasian Application No.	Application Filing Date	Status	Eurasian Patent No.	Issue Date	Subject Matter
201790009	11/30/2015	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	11/30/2015	Issued	3226962	7/3/2019	Utility application covering overall system design, including controller and mouthpiece
15812899.1	11/30/2015	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	11/30/2015	Issued	2649512	4/3/2018	Utility patent covering overall system design, including controller and mouthpiece
2017123041	11/30/2015	Issued	2652571	4/26/2016	Design patent covering the controller design currently used in the PoNS device
2018108570	11/30/2015	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	11/30/2015	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	8/16/2016	Design patent covering the mouthpiece design currently used in the PoNS device
2015501881	6/3/2015	Issued	98947	7/16/2016	Design patent covering the controller design currently used in the PoNS device

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	6/2/2015	Issued	002712026-0001 - 002712026-0007	9/4/2015	Design patents covering several aspects of the system design currently used in the PoNS device
006753877	8/23/2019	Issued	006753877-0001 – 006753877-0008	11/21/2019	Design patents covering the controller design used in the PoNS device

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 13 foreign utility patent applications that are currently pending: three in Europe, two in each of Australia, Canada and Russia and one in each of China, Israel, and the U.K., and one design patent application that is currently pending in Canada:

Australian Application No.	Application Filing Date	Status	Australian Patent No.	Issue Date	Subject Matter
2020228618	2/26/2020	Pending	N/A	N/A	Utility application covering computer systems and methods for enhancing neurorehabilitation
2019246836	10/10/2019	Allowed	N/A	N/A	Utility patent covering methods for placing a mouthpiece in a patient's mouth

Canadian Application No.	Application Filing Date	Status	Canadian Patent No.	Issue Date	Subject Matter
2969731	11/30/2015	Allowed	N/A	N/A	Utility application covering various aspects of the mouthpiece such as shape, center of gravity, and the locators
3131684	2/26/2022	Pending	N/A	N/A	Utility application covering computer systems and methods for enhancing neurorehabilitation
189954	8/28/2019	Pending	N/A	N/A	Design patent covering non-invasive neurostimulation device

Chinese Application No.	Application Filing Date	Status	Chinese Patent No.	Issue Date	Subject Matter
202080031721.1	2/26/2020	Pending	N/A	N/A	Utility application covering computer systems and methods for enhancing neurorehabilitation

European Application No.	Application Filing Date	Status	European Patent No.	Issue Date	Subject Matter
19183730.1	11/30/2015	Pending	N/A	N/A	Utility application covering overall system design, including controller and mouthpiece
19190373.1	11/30/2015	Pending	N/A	N/A	Utility patent application covering methods of placing a mouthpiece in a patient's mouth prior to engaging in NINM
20712806.7	2/26/2020	Pending	N/A	N/A	Utility application covering computer systems and methods for enhancing neurorehabilitation

Israel Application No.	Application Filing Date	Status	Israel Patent No.	Issue Date	Subject Matter
285901	2/26/2020	Pending	N/A	N/A	Utility application covering computer systems and methods for enhancing neurorehabilitation

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

U.K. Application No.	Application Filing Date	Status	U.K. Patent No.	Issue Date	Subject Matter
2113774.0	2/26/2020	Pending	N/A	N/A	Utility application covering computer systems and methods for enhancing neurorehabilitation

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

We are the owner of the 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, the Helius Medical mark in the U.S., and the PoNS Therapy mark in the U.S.

Government Regulation

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

FDA Regulation of Medical Devices

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

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

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

The FDA Review, Clearance and Approval Processes

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

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

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

Class III devices, consisting of devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a predicate device. The safety and effectiveness of Class III devices cannot be assured solely by general or special controls. Submission and FDA approval of a premarket approval, or PMA, application is required before marketing of a Class III device can proceed. As with 510(k) submissions, unless subject to an exemption, PMA submissions are subject to user fees. The PMA process is much more demanding than the 510(k) premarket notification process.

A PMA application, which is intended to demonstrate that the device is safe and effective, must be supported by extensive data, typically including data from preclinical studies and human clinical trials.

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

510(k) Clearance Process

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

Before the FDA will accept a 510(k) submission for substantive review, the FDA will first assess whether the submission satisfies a minimum threshold of acceptability. If the FDA determines that the 510(k) submission is incomplete, the FDA will issue a "Refuse to Accept" letter which generally outlines the information the FDA believes is necessary to permit a substantive review and to reach a determination regarding substantial equivalence. An applicant must submit the requested information before the FDA will proceed with additional review of the submission. Once the 510(k) submission is accepted for review, by regulation, the FDA has 90 days to review and issue a determination. As a practical matter, clearance often takes longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence.

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

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

De novo Classification Process

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

If the manufacturer sought reclassification into Class II, the manufacturer was to include a draft proposal for special controls necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. The FDA may reject the reclassification petition if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk or that general controls would be inadequate to control the risks and special controls cannot be developed.

FDA granted *de novo* classification for the PoNS device for gait deficit in MS, which resulted in Class II classification. In order to be placed in Class II, the FDA required reasonable assurance of safety and effectiveness of the PoNS device. Under Class II, general controls (e.g., premarket notification) and special controls (e.g., specific performance testing) are applicable.

Obtaining FDA marketing authorization, de novo classification and clearance, or approval for medical devices is expensive and uncertain, generally takes several years, and generally requires detailed and comprehensive scientific and clinical data. Notwithstanding the expense, these efforts may never result in FDA authorization for commercial distribution. Even if we were to obtain regulatory authorization, it may not be for the uses we believe are important or commercially attractive, in which case we would not be permitted to market our product for those uses.

Clinical Trials

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

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

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

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

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

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

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

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

Healthcare providers, physicians, and third party payers will play a primary role in the recommendation and use of any products for which we obtain marketing approval. Our future arrangements with third party payers, healthcare providers and physicians may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any device for which we obtain marketing approval. In the U.S., our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the CMS, other divisions of the United States Department of Health and Human Services (e.g., the Office of Inspector General), the United States Department of Justice and individual United States Attorney offices within the Department of Justice, and state and local governments. The applicable laws and regulations include the federal health care programs Anti-Kickback Statute, or AKS, and the federal Civil False Claims Act.

The AKS makes it illegal for any person, including a device manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration, directly or indirectly, in cash or in kind, that is intended to induce or reward referrals, including the purchase, recommendation, or order of a particular device, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by up to ten years in prison, criminal fines, administrative civil money penalties and exclusion from participation in federal healthcare programs. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it.

The Federal Civil False Claims Act imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities (including manufacturers) for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment of government funds or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties of between $11,463 and $22,927 (adjusted annually for inflation) for each separate false claim and the potential for exclusion from participation in federal healthcare programs. Conduct that violates the False Claims Act also may implicate various federal criminal statutes. The government may deem manufacturers to have “caused” the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. Claims which include items or services resulting from a violation of the federal AKS also are deemed false or fraudulent claims for purposes of the False Claims Act. Our future marketing and activities relating to the reporting of wholesaler or estimated retail prices for our products and other information affecting federal, state and third-party reimbursement for our products, and the sale and marketing of our product and any future product candidates, are subject to scrutiny under this law.

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

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

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

Health Canada

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

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

European Union

We submitted an application for a CE Mark of the PoNS device with our UK based notified body in December 2018. In August 2019 we withdrew our application from the EU marketing process due to notified body activities being delayed by Brexit and the upcoming medical devices regulation changes. We have engaged G-MED NA as our registrar 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 which now excludes the UK. Some EU member states have additional notification requirements that we expect to satisfy before we launch our PoNS Therapy in those member states. Once the PoNS device is placed into the EU market, post market requirements apply including but not limited to:

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

Australia

We submitted our application for marketing authorization to the TGA during the third quarter of 2019. We supplemented our submission with additional data based on questions supplied to date and provided responses to additional questions during the third quarter of 2020. In November 2021, we received market authorization from the TGA for the sale of PoNS as a Class IIa medical device. In Australia,

PoNS is indicated for short term use by healthcare professionals as an adjunct to a therapeutic exercise program to improve balance and gait. PoNS is not intended to be used alone without an exercise program.

Data Privacy and Security Laws; Breaches

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

In addition, certain state laws govern the privacy and security of health information in certain circumstances, some of which may be more stringent, broader in scope or offer greater individual rights with respect to PHI, than HIPAA, and many of which differ from each other, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, California enacted the California Consumer Privacy Act, or the CCPA, on June 28, 2018, which took effect on January 1, 2020. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Additionally, many of the more ambiguous provisions of the CCPA have yet to be fully interpreted and applied, and numerous amendments have been proposed and are working their way through legislature. Consequently, the CCPA currently presents many compliance questions that remain unresolved. The CCPA may increase our compliance costs and potential liability. In addition to the CCPA, numerous other states' legislatures are considering similar laws that will require ongoing compliance efforts and investment.

In the European Union, as of May 25, 2018, Regulation 2016/676, known as the General Data Protection Regulation, or GDPR, replaced the Data Protection Directive with respect to the processing of personal data in the European Union. The GDPR imposes many requirements for controllers and processors of personal data, including, for example, higher standards for obtaining consent from individuals to process their personal data, more robust disclosures to individuals and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention and secondary use of information, increased requirements pertaining to health data and pseudonymized (i.e., key-coded) data and additional obligations when we contract third-party processors in connection with the processing of the personal data. The GDPR allows EU member states to make additional laws and regulations further limiting the processing of genetic, biometric or health data. Failure to comply with the requirements of GDPR and the applicable national data protection laws of the EU member states may result in fines of up to €20 million or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties.

Our Corporate History Highlights

Formation and Arrangement with Boomerang Oil, Inc.

We were originally incorporated in British Columbia, Canada on March 13, 2014 under the British Columbia Business Corporations Act, or the BCBCA, as "0996445 B.C. Ltd." On March 25, 2014, and amended on April 8, 2014, we entered into an arrangement agreement with Boomerang Oil, Inc. (formerly known as 0922327 B.C. Ltd.) and 0995162 B.C. Ltd. to reorganize the business structure of such three entities in such a manner which would allow Boomerang Oil, Inc. to spin us out to become an independent entity that is a reporting issuer in Canada and for us to complete a reverse take-over of 0995162 B.C. Ltd. As a result of the arrangement agreement, we became a reporting issuer in the provinces of British Columbia and Alberta. In addition, the arrangement resulted in 0995162 B.C. Ltd. becoming our wholly owned subsidiary. The assets of 0995162 B.C. Ltd. consisted of cash and 0995162 B.C. Ltd.'s interest in a letter agreement pursuant to which it had agreed to acquire all of the outstanding shares of HMI, a Delaware corporation, and to seek a listing on a recognized stock exchange.

Reincorporation in Wyoming

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

Acquisition of NeuroHabilitation Corporation and Concurrent Financing

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

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

Reincorporation in Delaware

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

Formation of Helius NeuroRehab Inc.

In January 2019, we formed Helius NeuroRehab, Inc., or HNR, a Delaware corporation, which is a wholly owned subsidiary of Helius Medical Technologies, Inc. with the intent to operate a clinic focusing on the delivery of PoNS Therapy to patients with balance and gait disorders. HNR remains dormant and there are currently no plans to utilize it as originally intended.

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

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

Listing of our Common Stock

Following our Reverse Merger, we obtained approval of the listing of our common stock on the Canadian Securities Exchange, or CSE, on June 23, 2014. On April 18, 2016, our common stock was listed on the TSX under the symbol "HSM." At the same time, we delisted our common stock from the CSE. We voluntarily delisted from the TSX effective as of the close of trading on September 9, 2021. The Company's common stock also began being quoted on the OTC Markets, or OTCQB, under the ticker symbol "HSDT" on February 10, 2015. On April 11, 2018, our common stock began trading on the Nasdaq Capital Market under the ticker symbol "HSDT" and ceased to be quoted on the OTCQB. As of the date of this Annual Report, our common stock continues to trade on the Nasdaq Capital Market.

Reverse Stock Split

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

Following such meeting, our board of directors approved a final reverse stock split ratio of 1-for-35, and we filed with the Secretary of State of the State of Delaware a Certificate of Amendment to our Certificate of Incorporation to effect the reverse stock split. The reverse stock split was effective as of 5:00 pm Eastern Time on December 31, 2020, and our common stock began trading on a split-adjusted basis on The Nasdaq Capital Market and Toronto Stock Exchange on January 4, 2021. The reverse stock split did not change the par

value of our stock or the authorized number of common or preferred shares. All share and per share amounts for all periods presented in this Annual Report have been retroactively adjusted for the reverse stock split effected on December 31, 2020.

Corporate Information

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

Human Capital Resources

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

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

As of December 31, 2020, we had 19 full time employees, no part time employees, two full time consultants and five part time consultants. During 2021, we expanded our workforce to prepare for our commercial launch in the US following the receipt in March 2021 of marketing authorization from the FDA of the PoNS device for use as a short term treatment of gait deficit due to mild-to-moderate systems of MS, and as such, as of December 31, 2021, we had 26 full time employees, no part time employees, seven full time consultants and three part time consultants.

None of our employees were covered by collective bargaining agreements. We have not experienced any interruptions of operations due to disputes with our employees.

Talent Acquisition, Development and Retention. Hiring, developing, and retaining high-performing employees is important to our operations and we are focused on creating experiences that foster growth, performance and retention. Retaining and acquiring the right talent in this competitive environment, particularly at speed and scale, will continue to be a priority as we have obtained FDA de novo classification and clearance of the PoNS device. Our workforce reflects talent from diverse perspectives.

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

ITEM 1A. RISK FACTORS

RISK FACTORS

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

Risks Related to Our Financial Position and Need for Capital

We have incurred substantial net losses since our inception and anticipate that we will continue to incur substantial net losses for the foreseeable future. We may never achieve or sustain profitability.

We have incurred substantial net losses since our inception. For the years ended December 31, 2021 and 2020, we incurred a net loss of $18.1 million and $14.1 million, respectively, and used cash in operations of $13.4 million and $11.7 million, respectively. We have an accumulated deficit of $137.0 million as of December 31, 2021. Our losses have resulted primarily from costs incurred in connection with our design, manufacturing and development activities, research and development activities, building our commercial infrastructure, stock-based compensation, legal, advertising, marketing and investor relations, and general and administrative expenses associated with our operations. Although we have received a medical device license from Health Canada to market the PoNS device in Canada, marketing authorization from the FDA for the sale of our PoNS device in the U.S., market authorization from the TGA in Australia, and even if we are successful in obtaining marketing authorization from additional foreign regulatory authorities to launch outside of the U.S., we expect to continue to incur substantial losses for the foreseeable future as we continue to research and develop and seek regulatory marketing authorization for our product candidate.

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

We will require additional financing to carry out our plan of operations and if we are unable to obtain such financing, our business may fail.

From our inception through December 31, 2021, we have generated approximately $2.6 million in revenue from the commercial sales of products or services. Because we have generated limited revenues from commercialization, our operations to date have been principally financed through public and private offerings of our common stock and convertible debt and exercises of options and warrants. There are a number of conditions that we must satisfy before we will be able to generate sufficient revenue to fund our operations, including but not limited to the recruitment of patients for treatment, and demonstration of effectiveness sufficient to generate commercial orders by customers for our product. Moreover, because we expect that the revenue opportunity in the U.S. is significantly greater than in Canada, we believe our ability to generate significant revenue in the future will be dependent upon the speed and success of our commercial launch in the U.S. during 2022.

These factors raise substantial doubt about our ability to continue as a going concern through at least 12 months from the date of this Annual Report. While we had $11.0 million of cash as of December 31, 2021, we do not currently have sufficient resources to accomplish all of the above conditions necessary for us to generate sufficient revenues to achieve profitability, and we will require additional financing to fund our operations beyond the beginning of the third quarter of 2022. There is no guarantee that such funding will be available at all or in sufficient amounts to satisfy our required expenditures.

If we are unable to obtain additional financing as needed, we may be forced to reduce the scope of our operations and planned capital expenditures or sell certain assets, including intellectual property, and we may be forced to cease or wind down operations, seek protection under the provisions of the U.S. Bankruptcy Code, or liquidate and dissolve our company, which would have a material adverse effect on the value of our common stock.

Raising additional capital by issuing securities or through debt financings or licensing arrangements may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product on terms unfavorable to us.

Our operations to date have principally been financed by public and private offerings of our common stock and convertible debt and exercises of options and warrants and, since inception, we have raised $130.6 million in gross proceeds from equity financings. Until we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings, or other capital sources, including potential collaborations with other companies or other strategic transactions. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of such securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through strategic partnerships with third parties, we may have to relinquish valuable rights to our technologies or product, future revenue streams, research programs or product candidates, or otherwise grant licenses on terms that are not favorable to us. If we are unable to raise additional capital when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts for our product or our 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, 2021 includes an explanatory paragraph stating that our recurring losses from operations and net capital deficiency raise substantial doubt about our ability to continue as a going concern. If we are unable to obtain sufficient funding, our business, prospects, financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. Future reports from our independent registered public accounting firm may also contain statements expressing substantial doubt about our ability to continue as a going concern. We believe our existing capital resources will be sufficient to fund our operations into the third quarter of 2022. However, in light of the commercial launch of PoNS Therapy in the U.S. beginning in 2022, we expect our expenses to increase throughout 2022, particularly as we invest in marketing and distribution capabilities, make improvements to our manufacturing process and product design, and add additional personnel. We also expect our expenses to increase if and as we conduct trials of PoNS Therapy, such as the TEP, or if and as we decide to pursue further regulatory approvals, or maintain, expand and protect our intellectual property portfolio. Other than our right to cause Lincoln Park to purchase shares of our common stock under the LPC Purchase Agreement, which is subject to certain limitations and conditions, we do not have any committed external source of funds. There can be no assurance that we will be successful in raising additional capital or that such capital, if available, will be on terms that are acceptable to us. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our consolidated financial statements, and investors will likely lose all or a part of their investment. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all.

Risks Related to the Development and Commercialization of our Product

We currently only have one product which is approved in the U.S. only for treatment of gait deficit and otherwise only in Canada and Australia.

We currently have no products authorized for commercial distribution in Europe, or in any other country outside of Canada, the U.S. and Australia. In the U.S. we have not received marketing authorization for use of the PoNS device other than for MS. In addition, the FDA has previously rejected our de novo application for marketing authorization of the PoNS device for mmTBI. In respect of Europe, we are developing the PoNS device for use in the neuromodulation market, but we cannot begin marketing and selling the device in Europe until we obtain applicable authorizations from the European Union (Notified Body). 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 or rejection of a regulatory application altogether.

We plan to develop the PoNS device for other indications, or symptoms caused by neurological disorders, and will be required to commit our own resources to fund development of any other indications and each would require separate regulatory clearance or other marketing authorization in other territories. The costs of such development efforts and regulatory clearance or other marketing authorization could

be substantial and would likely require additional funding, and each such indication would be subject to the same foregoing risks and uncertainties for FDA clearance/authorization.

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

On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 as a global pandemic, which has spread throughout the U.S. and around the world. The Company's business, results of operations and financial condition have been and may continue to be adversely impacted by the COVID-19 pandemic and global economic conditions. The outbreak and spread of COVID-19 has significantly increased economic uncertainty. Authorities implemented, and continue to implement, numerous measures to try to contain the virus, such as travel bans and restrictions, quarantines, shelter in place orders, and business shutdowns. The COVID-19 pandemic initially led to the closure of PoNS authorized clinic locations across Canada from March until June 2020. Patients who completed their initial training in the clinics prior to the closures were able to continue working independently in the at-home portion of the treatment, with remote check-ins with their certified therapists. While all clinics have re-opened, as of December 31, 2021, they were all operating at reduced capacity, which limited operations to 50% capacity during the second half of 2021. Some patients have begun to return to these clinics for treatment, but patients have been and may continue to be less willing to return to the clinics due to COVID-19, impacting our commercial activities and our customer engagement efforts. This was especially true in the first half of 2021, as cases of COVID-19 increased significantly in Canada and additional restrictions, shelter in place orders, and business shutdowns were imposed. The rate of vaccination increased throughout all provinces throughout 2021, facilitating the lifting of some of the previously imposed restrictions. Thus far during the first quarter of 2022, capacity has remained at the 50% threshold with the expectation that the capacity limit will increase as provinces continue to lift restrictions. We continue to monitor the impact of COVID-19 and adjust our operations as the circumstances change.

We have expanded our services to include remote training and treatment, but the long-term viability of these remote programs is still being assessed. Additionally, current and planned clinical experience programs and clinical trials have experienced and may continue to experience delays in the programs as trial participant attendance has generally decreased as a result of the pandemic, and clinics and clinical research sites have experienced delays and difficulties in recruiting and re-hiring clinical site staff.

The COVID-19 pandemic has and may continue to cause delays in or the suspension of our business partners manufacturing operations, our research and product development activities, our regulatory workstreams, our research and development activities and other important commercial functions. We are also dependent upon our suppliers for the manufacture of our PoNS device. In the second quarter of 2020, two of our business partners diverted resources towards other activities related to COVID-19, resulting in delays in our product development activities. Such diversion of suppliers' resources may occur again in the future, and the pandemic could limit our suppliers' ability to travel or ship materials or force temporary closure of facilities that we rely upon. Manufacturing delays have occurred and may also occur as the result of labor shortages. Two of our suppliers experienced significant labor shortages as a result of COVID-19 from the end of November 2021 through early January 2022 which reduced the available resources needed to build and test product resulting in production delays of the PoNS devices. Disruptions in business operations or governmental operations due to COVID-19 may delay the timing for the submission and approval of our marketing applications with regulatory agencies. Further, the economic impact of the COVID-19 pandemic could affect our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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

- Changes in local regulations as part of a response to the COVID-19 pandemic may require us to change the way PoNS Authorized clinic locations operate or our clinical experience programs or clinical trials are conducted and may result in unexpected costs;
- Some patients may be unable, or continue to be unwilling, to visit or return to our PoNS Authorized clinic locations;
- Necessary interactions with local regulators, ethics committees and other important agencies and contractors may be delayed due to limitations in employee resources or forced furlough of government employees;
- The timing of our interactions with the FDA may be delayed due to absenteeism by federal employees or the diversion of their efforts and attention to approval of other therapeutics or other activities related to COVID-19;
- Our ability to complete necessary pre-commercialization activities may be impeded, which could delay our commercial launch in the U.S.;
- Healthcare resources may be diverted away from PoNS Authorized clinic locations, our clinical experience programs and the conduct of clinical trials;
- We may experience delays in receiving approval from local regulatory authorities to initiate future clinical trials;
- Future key clinical trial activities may be delayed, such as clinical trial site monitoring, due to limitation on travel imposed or recommended by federal or state governments, employers and others; and

- We may experience delays in timeline for product availability, including related to staffing shortages, both generally and due to employee illness.

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

Worldwide economic and social instability could adversely affect our revenue, financial condition, or results of operations.

The health of the global economy, and the credit markets and the financial services industry in particular, as well as the stability of the social fabric of our society, affects our business and operating results. For example, the credit and financial markets may be adversely affected by the current conflict between Russia and Ukraine and measures taken in response thereto. If the credit markets are not favorable, we may be unable to raise additional financing when needed or on favorable terms. Our customers may experience financial difficulties or be unable to borrow money to fund their operations, which may adversely impact their ability to purchase our products or to pay for our products on a timely basis, if at all. In addition, adverse economic conditions, such as recent supply chain disruptions and labor shortages and persistent inflation, have impacted, and may continue to adversely impact our suppliers' ability to provide our manufacturer with materials and components, which may negatively impact our business. These economic conditions make it more difficult for us to accurately forecast and plan our future business activities.

Our PoNS technology is a novel form of neurostimulation therapy, and the medical community tends not to adopt new therapies very rapidly. If physicians elect not to prescribe the PoNS Therapy, or if we cannot train physical therapists in the supervision of the use of the PoNS Therapy, we will be unable to generate significant revenue, if any.

Our deployment strategy in the U.S. depends on physicians prescribing the PoNS Therapy to patients with relevant neurological disorders and physical therapists being trained in the supervision of patients' use of our treatment. Novel technologies are usually more slowly adopted by the medical community, as the medical community tends to be very conservative. Physicians may elect not to use our products for a variety of reasons, including:

- lack or perceived lack of evidence supporting the beneficial characteristics of our technology;
- limited long-term data on the use of PoNS technology for therapy;
- physicians' perception that there are insufficient advantages of our product relative to currently available products or compared to supervised therapeutic exercise alone;
- our inability to effectively train physical therapists in the supervision of patients' use of 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 Therapy 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.

If we are unable to expand our sales and marketing infrastructure, and execute other steps necessary to penetrate market opportunities and produce our PoNS device, we may not be successful in commercializing our PoNS device in the U.S.

We are an early stage development company with limited resources, and have not generated significant revenues to date. To achieve commercial success and generate sufficient revenue in the U.S. for our PoNS device, we will need to further expand our sales and marketing infrastructure to drive adoption of our PoNS device. There is significant competition for sales personnel experienced in relevant medical device sales. We expect that we will face significant challenges as we recruit and subsequently grow our sales and marketing infrastructure. If we are unable to attract and retain sufficient, and skilled, sales and marketing representatives, our sales could be adversely affected. If one of our sales or marketing representatives were to depart and be retained by one of our competitors, they could help competitors solicit business from customers, which could further harm our sales. In addition, if our sales and marketing representatives or educators fail to achieve their objectives or if we are not able to recruit and retain a network of educators, we may not be able to successfully train healthcare providers on the use of our PoNS device, which could delay new sales and harm our reputation.

We anticipate that we will derive nearly all of our U.S. revenue from the sales of our PoNS device. As a result, our financial condition and operating results will be highly dependent on the ability of our sales representatives to adequately promote, market and sell our PoNS device. If we are unable to expand our sales and marketing capabilities, we may not be able to effectively commercialize our existing or planned products, or enhance the strength of our brand, either of which could impair our projected sales growth and have an adverse impact on our business.

Risks Related to our Reliance on Third Parties

We are, and will continue to be, dependent in significant part on outside scientists and third-party research institutions for our research and development in order to be able to commercialize our product.

We currently have a limited number of employees and resources available to perform the research and development necessary to commercialize our PoNS Therapy and potential future product candidates. We therefore rely, and will continue to rely, on third-party research institutions, collaborators and consultants for this capability. Such third-party research institutions, collaborators and consultants may determine to cease providing services to us at any time, which would delay our product development and commercialization.

We depend on third parties for the manufacture and distribution of our product and the loss of our third-party manufacturer and distributor could harm our business.

We depend on our third-party contract manufacturing partner to manufacture and supply our PoNS device for clinical and commercial purposes, and this contract manufacturer manufactured the units for our engineering and device verification testing and is building the launch quantities for commercialization. Additionally, we depend on a different third-party distribution partner to warehouse and ship our products to customers. Our reliance on a third-party manufacturer and a distribution provider to supply us with our PoNS device and to provide such other distribution services exposes us to risks that could delay our sales or result in higher costs or lost product revenues. In addition, our manufacturers have experienced and could continue to experience difficulties, including, but not limited to, those caused by the COVID-19 pandemic, in securing long-lead time components, achieving volume production, quality control and

quality assurance or suffer shortages of qualified personnel, or fail to follow and remain in compliance with the FDA-mandated Quality System Regulations, or QSR, compliance which is required for all medical devices, or fail to document their compliance to QSRs, any of which could result in their inability to manufacture sufficient quantities of our commercially available product to meet market demand or lead to significant delays in the availability of materials for our product and/or FDA enforcement actions against them and/or us.

If we are unable to obtain adequate supplies of our product that meet our specifications and quality standards, it will be difficult for us to compete effectively. While we have supply and quality agreements in place with our manufacturer, they may change the terms of our future orders or choose not to supply us with products in the future. Furthermore, if such manufacturer fails to perform its obligations, we may be forced to purchase our product from other third-party manufacturers, which we may not be able to do on reasonable terms or in sufficient time, if at all. In addition, if we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer or the reverification of an existing manufacturer could negatively affect our ability to produce and distribute our product in a timely manner.

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

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

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

Risks Related to Intellectual Property

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

We regard our intended and future intellectual property as important to our success, and we intend to rely on patent law to protect our proprietary rights. Despite our precautions, unauthorized third parties may copy certain portions of our devices or products or reverse engineer or obtain and use information that we regard as proprietary. We may seek additional patents in the future. We do not know if any future patent application will be issued with the scope of the claims, we seek, if at all or whether any patents we receive will be challenged or invalidated. Thus, we cannot assure you that any intellectual property rights that we may receive can be successfully asserted in the future or that they will not be invalidated, circumvented or challenged. In addition, the laws of some foreign countries do not protect proprietary rights to the same extent, as do the laws of the U.S. Our means of protecting any proprietary rights we may receive in the U.S. or abroad may not be adequate and competitors may independently develop a similar technology. Any failure to protect our proprietary information and any successful intellectual property challenges or infringement proceedings against us could have a material adverse effect on our business, financial condition and results of operations.

We may be subject to various litigation claims and legal proceedings, including intellectual property litigation, such as patent infringement claims, which could adversely affect our business.

We, as well as certain of our directors and officers, may be subject to claims or lawsuits. These lawsuits may result in significant legal fees and expenses and could divert management’s time and other resources. If the claims contained in these lawsuits are successfully asserted against us, we could be liable for damages and be required to alter or cease certain of our business practices or product lines. Any of these outcomes could cause our business, financial performance and cash position to be negatively impacted.

Additionally, our commercial success will also depend, in part, on not infringing on the patents or proprietary rights of others. There can be no assurance that the technologies and products used or developed by us will not infringe such rights. If such infringement occurs and we are not able to obtain a license from the relevant third party, we will not be able to continue the development, manufacture, use, or sale of any such infringing technology or product. There can be no assurance that necessary licenses to third-party technology will be available at all or on commercially reasonable terms. In some cases, litigation or other proceedings may be necessary to defend against or assert claims of infringement or to determine the scope and validity of the proprietary rights of third parties. Any potential litigation could result in substantial costs to, and diversion of, our resources and could have a material and adverse impact on us.

An adverse outcome in any such litigation or proceeding could subject us to significant liabilities, require us to cease using the subject technology or require us to license the subject technology from the third party, all of which could have a material adverse effect on our business.

There are risks to our intellectual property based on our international business operations.

We may face risks to our technology and intellectual property as a result of our conducting business outside of the U.S., including as a result of our strategic arrangement with A&B (and subsequent transfer of assets to CMS and CMS Medical Hong Kong Limited), and particularly in jurisdictions that do not have comparable levels of protection of corporate proprietary information and assets such as intellectual property, trademarks, trade secrets, know-how and customer information and records. While these risks are common to many companies, conducting business in certain foreign jurisdictions, housing technology, data and intellectual property abroad, or licensing technology to joint ventures with foreign partners may have more significant exposure. Pursuant to our agreement with A&B, we transferred ownership of certain of our Asian patents, patent applications, and product support material for the PoNS device from us to A&B and granted to A&B, among other things, an exclusive license to market, promote, distribute and sell the PoNS device solely within specified Asian territories. Subsequently. A&B partnered with other companies in other foreign jurisdictions in connection with the development and manufacturing of the PoNS device, which may expose us to material risks of theft of our proprietary information and other intellectual property, including technical data, manufacturing processes, data sets or other sensitive information. For example, our product or components may be reverse engineered by other business partners or other parties, which could result in our patents being infringed or our know-how or trade secrets stolen. The risk can be by direct intrusion wherein technology and intellectual property is stolen or compromised through cyber intrusions or physical theft through corporate espionage, including with the assistance of insiders, or via more indirect routes.

Risks Related to Government Regulation

Before we can market and sell our products, 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 Therapy for use in the U.S., we are required to obtain marketing authorization via a *de novo* classification and clearance request for our product or approval of pre-market approval application from the FDA, unless an exemption from pre-market review applies. We will also be required to comply with costly and more often time-consuming regulatory requirements by foreign regulatory authorities, including Europe, if we want to sell our products in such regions and countries. While we have marketing authorization for the PoNS Therapy in the U.S. for use as a short term treatment of gait deficit due to mild-to-moderate symptoms of MS and in Canada for sale as a class II, non-implanted, medical device for treatment of gait deficit due to symptoms from MS and balance deficit due to mmTBI in conjunction with supervised therapeutic exercise, and marketing authorization in Australia, we have not received regulatory authorization or approval in any other region or country for any indication. The process of obtaining regulatory authorizations or approvals, including completion of the *de novo* classification process, to market a medical device can be costly and time consuming, and we may not be able to successfully obtain pre-market reviews on a timely basis, if at all.

In April 2019, the FDA declined our request for de novo classification of the PoNS device for use to improve balance in patients with mmTBI. In reaching its conclusion, the FDA noted that it did not have sufficient information to discern the relative independent contributions of the PoNS device and physical therapy to establish sufficient evidence of effectiveness based on our clinical trials. In October 2019, we had a pre-submission meeting where the FDA provided feedback needed to help complete the design of a new clinical trial intended to address the FDA's request for a trial that demonstrates the benefit of the PoNS Therapy compared to physical therapy alone. In January 2020, we received the FDA's feedback on the minutes from the October 2019 pre-submission meeting. In its feedback, the FDA provided post-meeting notes with specific recommendations regarding the trial design that were not discussed in the October 2019 pre-submission meeting. Based on the receipt of the FDA's final minutes from the pre-submission meeting, we are assessing the feasibility of a clinical program to advance the development of a study aimed to obtain clearance for gait and balance deficits in mmTBI if nondilutive financing to fund the program becomes available.

The FDA has substantial discretion in the de novo review process and may refuse to accept any future application(s) or may decide that our data are insufficient to grant the de novo request and require additional pre-clinical, clinical, or other studies. In addition, varying

interpretations of the data obtained from pre-clinical and clinical testing could delay, limit, or prevent marketing authorization from the FDA or other regulatory authorities.

Moreover, in addition to continuing our pursuit of an indication for stroke and mmTBI with the FDA, we are currently considering the development of the PoNS device for other potential indications, including cerebral palsy, Parkinson's disease, baby boomers balance, and neurological wellness, as well as expanding the label of our current indications.

If the FDA requires us to go through a lengthier, more rigorous examination for the PoNS device for any of these indications or any other indications we may pursue, as it has for the PoNS device in the indication for mmTBI, introducing the product could be delayed or canceled, which would cause our launch to be delayed or cancelled. In addition, the FDA may determine that the PoNS device requires the more costly, lengthy and uncertain pre-market approval process. For example, if the FDA disagrees with our determination that the *de novo* classification procedures are the appropriate path to obtain marketing authorization for the PoNS device, the FDA may require us to submit a PMA application, which is generally more costly and more burdensome and can take several years from the time the application is submitted to the FDA until an approval is obtained.

Obtaining and maintaining FDA marketing authorization will be costly, may result in time-consuming delays and will subject us to ongoing compliance costs and regulatory risk for non-compliance.

Even though we have obtained FDA market clearance for our product as a treatment for MS, obtaining FDA marketing authorization, *de novo* classification and clearance, or PMA approval for medical devices for additional indications can be expensive and uncertain, generally takes from several months to several years, and generally requires detailed and comprehensive scientific and clinical data. Notwithstanding the expense, these efforts may never result in FDA authorization.

The FDA can delay, limit or deny authorization of a device for many reasons, including:

- we may not be able to demonstrate to the FDA's satisfaction that our product candidate is safe and effective for its intended users;
- the data from our pre-clinical studies and clinical trials may be insufficient to support authorization, where required; and
- the manufacturing process or facilities we use may not meet applicable requirements.

In addition, the FDA may change its authorization policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay marketing authorization of our products under development. Any delay in, or failure to receive or maintain clearance or approval for our product candidate could prevent us from generating revenue from our product candidate and adversely affect our business operations and financial results.

Market authorization for our product as a treatment for MS and even if granted, a 510(k) clearance, *de novo* classification and clearance, or pre-market approval for additional indications will likely place substantial restrictions on how our device is marketed or sold, and the FDA will continue to place considerable restrictions on our products and operations. For example, the manufacture of medical devices must comply with the FDA's QSR. In addition, manufacturers must register their manufacturing facilities, list the products with the FDA, and comply with requirements relating to labeling, marketing, complaint handling, adverse event and medical device reporting, reporting of corrections and removals, and import and export. The FDA monitors compliance with the QSR and these other requirements through periodic inspections. If our facilities or those of our manufacturers or suppliers are found to be in violation of applicable laws and regulations, or if we or our manufacturers or suppliers fail to take satisfactory corrective action in response to an adverse inspection, the regulatory authority could take enforcement action, including any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications of repair, replacement, refunds, detention or seizure of our products;
- product recalls;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for marketing authorization of new products or modified products;
- withdrawing marketing authorizations that have already been granted;
- refusing to provide Certificates for Foreign Government;
- refusing to grant export approval for our products; or
- pursuing criminal prosecution.

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 have in the past and may be required to conduct clinical trials to support a de novo submission or PMA application for the PoNS device with respect to one or more indications and we expect to be required to conduct clinical trials to support regulatory marketing authorization for future product candidates.

In order to commercialize our product candidate in the U.S. with respect to specified indications, we may be required by the FDA to submit an application for premarket approval, or PMA, for review and approval by the FDA. A PMA application must be submitted to the FDA if our device cannot be cleared through the 510(k) clearance process, down classified via the *de novo* process, or is not exempt from premarket review by the FDA. In April 2019, the FDA declined our request for *de novo* classification and clearance for mmTBI, in part due to insufficient clinical evidence regarding effectiveness of our product from mmTBI. Following a pre-submission meeting with the FDA, we are assessing the feasibility of a clinical program to advance the development of a study aimed to obtain clearance for gait and balance deficits in mmTBI if nondilutive financing to fund the program becomes available.

We could also be required to submit a PMA application for potential future product candidates. If we are required by the FDA to submit a PMA application, the FDA will also require us to conduct clinical trials. We will receive marketing authorization from the FDA to commercialize products requiring a clinical trial only if we can demonstrate to the satisfaction of the FDA, through well designed and properly conducted clinical trials, that our product candidate is safe, effective, and otherwise meet the appropriate standards required for marketing authorization for specified indications.

We have and may continue to encounter substantial delays in planned clinical trials, or our planned clinical trials for other indications using the PoNS device may fail to demonstrate the safety and efficacy of the PoNS device to the satisfaction of applicable regulatory authorities.

We are currently in the process of preparing to commence multiple clinical trials, and may continue to pursue additional clinical trials in the future. Clinical trials are complex, expensive, time consuming, uncertain as to outcome and are subject to substantial and unanticipated delays. Before we may begin clinical trials, if a clinical trial is determined to present a significant risk, we may be required to submit and obtain approval for an investigational device exemption, or IDE, that describes, among other things, the manufacture of, and controls for, the device and a complete investigational plan. Clinical trials generally involve a substantial number of patients in a multi-year study. Because we do not have the infrastructure necessary to conduct clinical trials, we will have to hire one or more contract research organizations, or CROs, to conduct trials on our behalf. CRO contract negotiations may be costly and time consuming and we will rely heavily on the CRO to ensure that our trials are conducted in accordance with regulatory and industry standards. We may encounter problems with our clinical trials and any of those problems could cause us or the FDA to suspend those trials or delay the analysis of the data derived from them. Moreover, any failure to abide by the applicable regulatory requirements by us, our CROs, and/or clinical trial sites may result in regulatory enforcement action against such third parties or us.

We cannot guarantee that clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of testing. Delays, including, but not limited to those caused by the COVID-19 pandemic, can be costly and could negatively affect our ability to complete a clinical trial and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize the PoNS device. If we are unable to complete such planned clinical trials, or are unsuccessful in doing so, we may be unable to advance the PoNS device to regulatory authorization and commercialization, which would harm our business, financial condition, and results of operations.

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

Since we may conduct clinical trials to obtain FDA marketing authorization, we will need to rely heavily on third parties over the course of our clinical trials, and as a result will have limited control over the clinical investigators and limited visibility into their day-to-day activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. These third parties and we are required to comply with current good clinical practices, or cGCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these cGCPs through periodic inspections of trial sponsors, principal investigators, and trial sites. If we or any of these third parties fail to comply with applicable cGCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional nonclinical or clinical trials before approving our marketing applications or may subject them or us to regulatory enforcement actions. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the cGCP regulations. In addition, our clinical trials may be required to be conducted with a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory marketing authorization process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our clinical trials are not and will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical, clinical, and nonclinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies or other drug development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed, or terminated and we may not be able to complete development of, obtain regulatory marketing authorization of or successfully commercialize our product candidate. As a result, our financial results and the commercial prospects for our product candidate would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

If any of our relationships terminate with these third-party CROs, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays occur, which can materially affect our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition, and prospects.

We may be required to suspend or discontinue clinical trials due to side effects or other safety risks that could preclude approval of our products.

Our clinical trials may be suspended at any time for a number of reasons. We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to participants. In addition, regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to participants.

If we are unable to secure contracts with WC and third-party administrators or rehabilitation clinics who treat patients with gait deficit due to symptoms from MS or balance issues associated with mmTBI, this could have a negative impact on our intended sales and would have a material adverse effect on our business, financial condition and operating results.

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

If we are unable to obtain a reimbursement code from the U.S. Department of Health and Human Services so that the PoNS device is covered under Medicare and Medicaid, this could have a negative impact on our intended sales and would have a material adverse effect on our business, financial condition and operating results.

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

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

In the U.S., the commercial success of our existing product and any future products will depend, in part, on the extent to which governmental payers at the federal and state levels, including Medicare and Medicaid, private health insurers and other third-party payers provide coverage for and establish adequate reimbursement levels for procedures utilizing our products. On January 12, 2021, the CMS stated that it was finalizing a new Medicare coverage pathway, MCIT for FDA-designated breakthrough medical devices. The purpose of the MCIT rule was to provide national Medicare coverage as early as the same day as FDA market authorization for breakthrough devices and coverage would last for four years. Under its terms, manufacturers were to have been able to opt-in to MCIT and choose a start date for coverage anytime within two years from the date of FDA market authorization. In November 2021, the MCIT was rescinded

and therefore we could not rely on MCIT for purposes of obtaining Medicare coverage for our product. 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 products face in the market and could have a material adverse effect on our business.

Many hospitals and clinics in the U.S. 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 U.S. has experienced a trend toward cost containment as government and private payers seek to control healthcare costs by paying service providers lower rates. While we believe that 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.

The availability of payments from Medicare, Medicaid or other third-party payers for our products which now or in the future have marketing authorization in the U.S. 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 products and product candidates, even while in development, are subject to extensive government scrutiny. We may be subject to governmental, regulatory and other legal proceedings relative to advertising, promotion, and marketing, and communications with study subjects and healthcare professionals, which could have a significant negative effect on our business.

We are subject to governmental oversight and associated civil and criminal enforcement relating to medical device advertising, promotion, and marketing, and such enforcement is evolving and intensifying. Communications regarding our products in development and regarding our clinical trials may subject us to enforcement if they do not comply with applicable laws. In the U.S., we are potentially subject to enforcement from the FDA, other divisions of the Department of Health and Human Services, the U.S. Federal Trade Commission, or the FTC, the Department of Justice, and state and local governments. Other parties, including private plaintiffs, also are commonly bringing suit against pharmaceutical and medical device companies. We may be subject to liability based on the actions of individual employees and third-party contractors carrying out activities on our behalf.

Even after marketing authorization for our product is obtained, we are subject to extensive post-market regulation by the FDA and equivalent foreign competent authorities. Our failure to meet strict regulatory requirements could require us to pay fines, incur other costs or even close our facilities.

Even after we have obtained the proper regulatory clearance or approval to market a product, the FDA has the power to require us to conduct post-market studies. These studies can be very expensive and time-consuming to conduct. Failure to complete such studies in a timely manner could result in the revocation of clearance or approval and the recall or withdrawal of the product, which could prevent us from generating sales from that product in the U.S.

The FDA has broad enforcement powers, and any regulatory enforcement actions or inquiries, or other increased scrutiny on us, could dissuade some healthcare professionals from using our products and adversely affect our reputation and the perceived safety and efficacy of our products.

We are also required to comply with the FDA’s Quality System Regulation, or QSR, which covers the methods used in, and the facilities and controls used for, the design, manufacture, quality assurance, labeling, packaging, sterilization, storage, shipping, installation and servicing of our marketed products.

The FDA enforces these requirements via periodic announced and unannounced inspections of manufacturing facilities. In addition, in the future, regulatory authorities and/or customers may require specific packaging of sterile products, which could increase our costs and the price of our products.

Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the product from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

After commercialization, 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.

Any changes in the laws or regulations that govern the clearance and approval processes relating to our current, planned and future products could make it more difficult and costly to obtain clearance or approval for new products or to produce, market and distribute existing products. Significant delays in receiving clearance or approval or the failure to receive clearance or approval for any new products would have an adverse effect on our ability to expand our business. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing clearance that we may have obtained and we may not achieve or sustain profitability.

Risks Related to our Business Operations

If our expenses are greater than anticipated, then we will have fewer funds with which to pursue our plan of operations and our financing requirements will be greater than anticipated.

We may find that the costs of carrying out our plan of operations are greater than we anticipate. We expect our expenses to increase over time in connection with our ongoing activities, particularly if and as we: expand our commercialization efforts of our PoNS device in the U.S. for MS; make improvements to our manufacturing process and product design; launch clinical trials for stroke and other

indications; pursue further regulatory approvals; maintain, expand and protect our intellectual property portfolio; and add additional personnel. Increased operating costs may cause the amount of financing that we require to increase. Investors may be more reluctant to provide additional financing if we cannot demonstrate that we can control our operating costs. There is no assurance that additional financing required as a result of our operating costs being greater than anticipated will be available to us. If we do not control our operating expenses, then we will have fewer funds with which to carry out our plan of operations with the result that our business may fail.

Our ability to use net operating losses to offset future taxable income may be subject to certain limitations.

Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code substantial changes in a corporation's ownership may limit the amount of net operating losses, or NOLs, that can be utilized annually in the future to offset the corporation's (and the corporation's affiliates') U.S. federal and state taxable income. Specifically, this limitation may arise in the event of a cumulative change in ownership of more than 50% within any three-year period. The amount of the annual limitation is determined based on the value of the corporation that underwent the ownership change, immediately before the ownership change. Subsequent ownership changes may further affect any limitation in future years (including by way of exercising of warrants).

We may undertake a study to analyze and determine if any historical ownership changes of us or our subsidiary HMI have occurred to determine if there are any permanent limitations on our ability to utilize NOLs in the future. If we determine that an ownership change has occurred, the limitations on the use of our NOLs could increase our U.S. federal and state tax liability and reduce the amount of cash available for distribution to shareholders or otherwise adversely affect the value of an investment in our common stock or warrants.

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

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

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

In June 2016, a referendum was passed in the United Kingdom to leave the European Union, commonly referred to as "Brexit." This decision created an uncertain political and economic environment in the United Kingdom and other European Union countries. The United Kingdom formally left the European Union on January 31, 2020 and the transition period provided for in the withdrawal agreement entered by the United Kingdom and the European Union ended on December 31, 2020. In December 2020, the United Kingdom and the European Union agreed on a trade and cooperation agreement that will apply provisionally after the end of the transition period until it is ratified by the parties to the agreement. On December 31, 2020, the United Kingdom passed legislation giving effect to the trade and cooperation agreement, with the European Union formally adopting the agreement in April 2021. The trade and cooperation agreement covers the general objectives and framework of the relationship between the United Kingdom and the European Union. Depending on the application of the terms of the trade and cooperation agreement, we could face new regulatory costs and challenges.

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

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

As a result of the use of our product in clinical trials, and through the sale of our products, we may be liable for product liability claims and we may not carry sufficient product liability insurance.

The PoNS device and any devices and product candidates that we may develop in the future may expose us to potential liability from personal injury claims by clinical trial subjects and, if commercially sold, end-users of the product. We maintain clinical trial liability insurance and carry product liability insurance to protect us against the risk that in the future a product liability claim or product recall could materially and adversely affect our business. Inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of our intended product. We cannot assure you that when we commence distribution of our product that we will be able to obtain or maintain adequate coverage on acceptable terms, or that such insurance will provide adequate coverage against all potential claims. Moreover, even if we maintain adequate insurance, any successful claim could materially and adversely affect our reputation and prospects and divert management's time and attention. If we are sued for any injury allegedly caused by our future products, our liability could exceed our total assets and our ability to pay the liability.

We are a "smaller reporting company" under federal securities laws and we cannot be certain whether the reduced reporting requirements applicable to such companies will make our common stock less attractive to investors.

We are a "smaller reporting company" under federal securities laws. For as long as we continue to be a smaller reporting company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies, including, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We will remain a smaller reporting company so long as our public float remains less than $250 million as of the last business day of our most recently-completed second fiscal quarter. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may decline or be more volatile.

Investors could lose confidence in our financial reports, and the value of our common stock may be adversely affected, if our internal controls over financial reporting are found not to be effective by management or by our independent registered public accounting firm.

As long as we remain a non-accelerated filer, we are exempt from the attestation requirement in the assessment of our internal control over financial reporting by our independent auditors pursuant to section 404(b) of the Sarbanes-Oxley Act of 2002 but are required to make our own internal assessment of the effectiveness of our internal controls over financial reporting. The existence of one or more material weaknesses, such as the material weakness we identified in October 2019, could affect the accuracy and timing of our financial reporting.

Investors could lose confidence in our financial reports, and the value of our common stock may be harmed, if our internal controls over financial reporting are found not to be effective by management or by our independent registered public accounting firm.

Several people who work for us on a part-time consulting basis may be subject to conflicts of interest.

Several people who provide services to us are part-time consultants. Each may devote part of his working time to other business endeavors, including consulting relationships with other corporate entities, and may have responsibilities to these other entities. Because of these relationships, some of the persons who provide services to us may be subject to conflicts of interest. Such conflicts may include deciding how much time to devote to our affairs, as well as what business opportunities should be presented to us.

Our business and operations would suffer in the event of computer system failures, cyber-attacks or a deficiency in our cyber-security.

Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions (including ransomware attacks) over the Internet, attachments to emails, persons inside our

organization, or persons with access to systems inside our organization. No network or system can ever be completely secure, and the risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. For example, in October 2019, we were the victim of a business email compromise fraud which resulted in our incurring a loss of approximately $0.1 million. If any such attack, intrusion or other event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs for an indeterminate period of time. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In some cases, data cannot be reproduced. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur material legal claims and liability, damage to our reputation, and the further development of the PoNS device or any future product candidate could be delayed. If a security breach results in the exposure or unauthorized disclosure of personal information, we could incur additional costs associated with data breach notification and remediation expenses, investigation costs, regulatory penalties and fines, and legal proceedings. Our insurance coverage may not be adequate to cover all the costs related to such breaches or attacks.

Challenges to our tax positions in U.S. or non-U.S. jurisdictions, the interpretation and application of recent U.S. tax legislation or other changes in U.S. or non-U.S. taxation of our operations could harm our business, revenue and financial results.

We operate, or intend to operate, in a number of tax jurisdictions globally, including in the U.S. at the federal, state and local levels, and in several other countries, and we therefore are or will be subject to review and potential audit by tax authorities in these various jurisdictions. Significant judgment is required in determining our worldwide provision for income taxes and other tax liabilities, and tax authorities may disagree with tax positions we take and challenge our tax positions. Successful unilateral or multi-jurisdictional actions by various tax authorities may increase our worldwide effective tax rate, result in additional taxes or other costs or have other material consequences, which could harm our business, revenue and financial results.

Our effective tax rate may also change from year to year or vary materially from our expectations based on changes or uncertainties in the mix of activities and income allocated or earned among various jurisdictions, changes in tax laws and the applicable tax rates in these jurisdictions (including future tax laws that may become material), tax treaties between countries, our eligibility for benefits under those tax treaties and the valuation of deferred tax assets and liabilities. Such changes could result in an increase in the effective tax rate applicable to all or a portion of our income, impose new limitations on deductions, credits or other tax benefits or make other changes that may adversely affect our business, cash flows or financial performance. For example, if we are unable to fully realize the benefit of interest expense incurred in future periods as a result of recent tax law changes (as discussed below), we may need to recognize a valuation allowance on any related deferred tax assets, which would impact our annual effective income tax rate.

In particular, on December 22, 2017, the Tax Cuts & Jobs Act, or TCJA, was signed into law. That legislation, as modified by the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, significantly changed U.S. tax law by, among other things, lowering the U.S. federal corporate income tax rate from 35% to 21%, implementing a modified territorial tax system and imposing a transition tax on deemed repatriated earnings of foreign subsidiaries, or the Section 965 Transition Tax. Certain changes established by the TCJA increased our effective tax rate in prior years, including a new income inclusion item for global intangible low-taxed income, or GILTI, and the Section 965 Transition Tax on our accumulated offshore earnings held in cash and illiquid assets. Additional changes have impacted the timing of our recognition of certain items of loss and deduction, including a new limitation on the Company's deduction for business interest expense, a new limitation of the deduction for NOLs to 80% of current year taxable income (other than as temporarily modified by the CARES Act), elimination of NOL carrybacks for NOLs arising after December 31, 2017 (other than as permitted under the CARES Act with respect to NOLs arising in 2018, 2019, and 2020) and the allowance of the indefinite carryforward of such NOLs, and increased bonus depreciation from 50% to 100% for certain qualified property.

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

The cumulative impact of these and other changes in tax law is uncertain and our business and financial condition could be adversely affected. The impact of these changes on holders of our securities is also uncertain and could be adverse.

Risks Related to Our Common Stock

We could be delisted from The Nasdaq Capital Market, which could seriously harm the liquidity of our stock and our ability to raise capital.
Our common stock is listed on the Nasdaq Capital Market under the symbol "HSDT". In order to maintain that listing, we must satisfy minimum financial and other requirements including, without limitation, the minimum stockholders equity requirement and the

minimum bid price requirement. There can be no assurances that we will be successful in maintaining, or if we fall out of compliance, in regaining compliance with the continued listing requirements and maintaining the listing of our common stock on the Nasdaq Capital Market. Delisting from Nasdaq could adversely affect our ability to raise additional financing through the public or private sale of equity securities and we would incur additional costs under requirements of state "blue sky" laws in connection with any sales of our securities. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities.

If our common stock is delisted by Nasdaq, the price of our common stock may decline and our common stock may be eligible to be quoted on the OTC Bulletin Board, another over-the-counter quotation system, or on the pink sheets, which would negatively affect the liquidity of our common stock and an investor may find it more difficult to dispose of their common stock or obtain accurate quotations as to the market value of our common stock.

In addition, if our common stock is delisted from the Nasdaq Capital Market and the trading price remains below $5.00 per share, trading in our common stock might also become subject to the requirements of certain rules promulgated under the Exchange Act, which require additional disclosure by broker-dealers in connection with any trade involving a stock defined as a "penny stock" (generally, any equity security not listed on a national securities exchange or quoted on NASDAQ that has a market price of less than $5.00 per share, subject to certain exceptions).

On December 31, 2020, we effected a 1-for-35 reverse stock split of our outstanding common stock. If we seek to implement a reverse stock split in the future to remain listed on the Nasdaq Capital Market, the announcement or implementation of a reverse stock split could significantly negatively affect the price of our common stock. Additionally, in 2020, the SEC approved a Nasdaq rule change to expedite delisting of securities of companies that have had one or more reverse stock splits with a cumulative ratio of one for 250 or more shares over the prior two-year period. Under the new rules, if a company falls out of compliance with the $1.00 minimum bid price after completing reverse stock splits over the immediately preceding two years that cumulatively result in a ratio one for 250 shares, the company will not be able to avail itself of any compliance periods and Nasdaq will instead require the issuance of a Staff delisting determination, which is appealable to a hearings panel. Our ability to remain listed on the Nasdaq Capital Market may be negatively impacted by this new Nasdaq rule.

We continue to actively monitor our performance with respect to the listing standards and will consider available options to resolve any deficiency and maintain compliance with the Nasdaq rules. There can be no assurance that we will be able to maintain compliance or, if we fall out of compliance, regain compliance with any deficiency, or if we implement an option that regains our compliance, maintain compliance thereafter.

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

Although our common stock is listed on The Nasdaq Capital Market, we cannot assure you that an active trading market for our common stock will continue to develop or be sustained. If an active market for our common stock does not continue to develop or is not sustained, it may be difficult for investors in our common stock to sell their shares of our common stock without depressing the market price for the shares or to sell the shares at all.

Trading of our common stock could be sporadic, and the price of our common stock may be volatile; we caution you as to the highly illiquid nature of an investment in our shares.

Our common stock was listed on the TSX between April 18, 2016 and September 9, 2021 and has been listed on The Nasdaq Capital Market since April 11, 2018. Securities of microcap and small-cap companies have experienced substantial volatility in the past, often based on factors unrelated to the companies' financial performance or prospects. We believe that trading in our stock has been and will likely continue to be subject to significant volatility. These factors include macroeconomic developments in North America and globally and market perceptions of the attractiveness of particular industries. Factors unrelated to our performance that may affect the price of our common stock include the following: the extent of analytical coverage available to investors concerning our business may be limited if investment banks with research capabilities do not follow us, a reduction in trading volume and general market interest in our common stock may affect an investor's ability to trade significant numbers of shares of our common stock; the size of our public float may limit the ability of some institutions to invest in our common stock. As a result of any of these factors, the market price of our common stock at any given point in time may not accurately reflect our long-term value. The price of our common stock may increase or decrease in response to a number of events and factors, including: changes in financial estimates; our acquisitions and financings; quarterly variations in our operating results; the operating and share price performance of other companies that investors may deem comparable; and purchase or sale of blocks of our common stock. These factors, or any of them, may materially adversely affect the prices of our common shares regardless of our operating performance.

The market price of our common stock is affected by many other variables which are not directly related to our success and are, therefore, not within our control. These include other developments that affect the breadth of the public market for shares of our common stock

and the attractiveness of alternative investments. The effect of these and other factors on the market price of our common stock is expected to make our common stock price volatile in the future, which may result in losses to investors.

Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our common stock may be lower as a result.

There are provisions in our certificate of incorporation and bylaws that may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change of control was considered favorable by you and other stockholders. For example, our board of directors has the authority to issue up to 10,000,000 shares of preferred stock. The board of directors can fix the price, rights, preferences, privileges, and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change of control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

Our charter documents also contain other provisions that could have an anti-takeover effect, including:

- stockholders are not entitled to remove directors other than by a 66 ⅔% vote and only for cause;
- stockholders are not be permitted to take actions by written consent;
- stockholders cannot call a special meeting of stockholders; and
- stockholders must give advance notice to nominate directors or submit proposals for consideration at stockholder meetings.

In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions by prohibiting Delaware corporations from engaging in specified business combinations with particular stockholders of those companies. These provisions could discourage potential acquisition proposals and could delay or prevent a change of control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware and, to the extent enforceable, the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim for breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws or (iv) any action asserting a claim governed by the internal affairs doctrine. Our certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, subject to and contingent upon a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision. These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. For example, stockholders who do bring a claim in the Court of Chancery could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near the State of Delaware. The Court of Chancery and federal district courts may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our stockholders. Some companies that adopted a similar federal district court forum selection provision are currently subject to a suit in the Chancery Court of Delaware by stockholders who assert that the provision is not enforceable. If a court were to find either choice of forum provision contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition. For example, the Court of Chancery of the State of Delaware recently determined that the exclusive forum provision of federal district courts of the United States of America for resolving any complaint asserting a cause of action arising under the Securities Act is not enforceable. As a result of this decision, we do not currently intend to enforce the federal forum selection provision in our certificate of incorporation, unless the decision is reversed on appeal. However, if the decision is reviewed on appeal and ultimately overturned by the Delaware Supreme Court, we would enforce the federal district court exclusive forum provision.

If securities or industry analysts do not publish or cease publishing research or reports about us, our business or our market, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts may publish about us, our business, our market or our competitors. If any of the analysts who may cover us change their recommendation regarding our stock adversely, or provide more favorable relative recommendations about our competitors, our stock price would likely decline. If any analyst who may cover us were to cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

General Risks

We have not paid any dividends and do not foresee paying dividends in the future.

We intend to retain earnings, if any, to finance the growth and development of our business and do not intend to pay cash dividends on shares of our common stock in the foreseeable future. The payment of future cash dividends, if any, will be reviewed periodically by the board of directors and will depend upon, among other things, conditions then existing including earnings, financial condition and capital requirements, restrictions in financing agreements, business opportunities and other factors.

A decline in the price of our common stock could affect our ability to raise any required working capital and adversely affect our operations.

A decline in the price of our common stock could result in a reduction in the liquidity of our common stock and a reduction in our ability to raise any required capital for our operations. Because our operations to date have been principally financed through public and private offerings of our common stock and warrants and exercises of options and warrants, a decline in the price of our common stock could have an adverse effect upon our liquidity and our continued operations. A reduction in our ability to raise equity capital in the future may have a material adverse effect upon our business plans and operations. If our stock price declines, we may not be able to raise additional capital or generate funds from operations sufficient to meet our obligations.

We are heavily dependent upon the ability and expertise of our management team and a very limited number of employees and the loss of such individuals could have a material adverse effect on our business, operating results or financial condition.

We currently have a very small management team. Our success is dependent upon the ability, expertise and judgment of our senior management. While employment agreements are customarily used as a primary method of retaining the services of key employees, these agreements cannot assure the continued services of such employees. Any loss of the services of such individuals could have a material adverse effect on our business, operating results or financial condition.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

Our head office is located at 642 Newtown-Yardley Road, Suite 100, Newtown, PA 18940, with 1,780 square feet of lease office space. In May 2020, we terminated our lease and entered into a new lease (the “Lease Amendment”) for a smaller footprint of the current office space in Newtown, Pennsylvania. Lease payments under the original contract were made through December 31, 2020. In January 2021, we signed a Lease Amendment extending the lease term from July 1, 2021 through September 30, 2021, which could then be extended on a month-to-month basis thereafter. In November 2021, we entered into a new lease with a lease term commencing January 1, 2022 and terminating March 31, 2025. Monthly rent plus utilities is approximately $4 thousand per month, with a 3% annual increase. We believe our current facilities are adequate for our needs.

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market Information

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

Holders

As of March 4, 2022, there were approximately 45 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. [Reserved]

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this Annual Report. Further, you should read the following discussion and analysis of our financial condition and results of operations together with the "Item 1A. Risk Factors" included elsewhere in this Annual Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. See also "Forward-Looking Statements". All information is stated in U.S. dollars unless otherwise specified.

Overview

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

Our product, known as the PoNS, is an innovative non-implanted medical device, inclusive of a controller and mouthpiece, which delivers mild electrical stimulation to the surface of the tongue to provide treatment of gait deficit and is indicated for use in the U.S. as a short term treatment of gait deficit due to mild-to-moderate symptoms from MS and is to be used as an adjunct to a supervised therapeutic exercise program in patients 22 years of age and over by prescription only. We are currently accepting prescriptions for PoNS in the U.S. and we anticipate our first commercial sales to occur in the near term. PoNS is authorized for sale in Canada for two indications: (i) for use as a short term treatment (14 weeks) of chronic balance deficit due to mmTBI and is to be used in conjunction with physical therapy (PoNS Therapy); and (ii) for use as a short term treatment (14 weeks) of gait deficit due to mild and moderate symptoms from MS and it is to be used in conjunction with physical therapy. It has been commercially available in Canada since March 2019. PoNS is authorized for sale as a Class IIa medical device in Australia and we are currently seeking a business partner to commercialize and distribute PoNS in Australia.

Since our inception, we have incurred significant operating losses. Our net loss was $18.1 million and $14.1 million for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021, we had an accumulated deficit of $137.0 million. We expect to incur significant expenses and operating losses for the foreseeable future as we continue to advance the PoNS Therapy and seek regulatory clearance and pursue its commercialization. There are a number of conditions that we must satisfy before we will be able to generate sufficient revenue to fund our operations, including but not limited to the successful commercialization of PoNS Therapy in the U.S., as we expect that the revenue opportunity in the U.S. is significantly greater than in Canada. Further, we may incur expenses in connection with the in-license or acquisition of other potential products. See "—Liquidity and Capital Resources" below for additional information.

Business Update

U.S. Regulatory Status: MS

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

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

In September 2021, we initiated activities to setup and implement a new study as part of a Therapeutic Experience Program, or TEP, with NYU Langone Health as our first Center of Excellence clinical site.

U.S. Regulatory Status: Stroke

In August 2021, we received Breakthrough Designation for the PoNS device as a potential treatment for dynamic gait and balance deficits due to symptoms from stroke, to be used as an adjunct to a supervised therapeutic exercise program in patients 22 years of age and over. With Breakthrough Designation received, a clinical trial of PoNS therapy in stroke patients in collaboration with Medical University of South Carolina is planned to commence in the second quarter of 2022 with initial patient enrollments beginning in the second half of 2022.

U.S. Regulatory Status: mmTBI

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

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

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

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

Based on the receipt of the FDA's final minutes from the pre-submission meeting, we are assessing the feasibility of a clinical program to advance the development of a study aimed to obtain clearance for gait and balance deficits in mmTBI if nondilutive financing to fund the program becomes available.

European Regulatory Status

In December 2018, we submitted an application for 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 will reconsider submitting to the EU when conditions stabilize.

Australian Regulatory Status

In the third quarter of 2019, we initiated the submission of our application to the TGA. We supplemented our submission with additional data based on questions supplied to date and provided responses to additional questions during the third quarter of 2020. In November 2021, we received market authorization from the TGA for the sale of PoNS as a Class IIa medical device. In Australia, the PoNS device is indicated for short term use by healthcare professionals as an adjunct to a therapeutic exercise program to improve balance and gait. PoNS is not intended to be used alone without an exercise program. We are working to establish a distribution partner for Australia but currently do not expect to have commercial sales of PoNS in Australia in 2022.

Canadian Commercialization Efforts

Following in-depth market analysis and field intelligence, our Canadian commercial team began an expansion plan to increase the number of authorized PoNS clinics. During the year ended December 31, 2021, we authorized 6 new clinical locations to have 37 clinic locations across Canada as of December 31, 2021. In addition to continuing to increase the number of clinic locations, we have shifted our focus to driving patient throughput to these clinics. Sales performance in Canada continues to be impacted by the COVID-19 pandemic due to space restrictions that the provincial governments have imposed as well as the risk tolerance of patients and therapists.

In collaboration with Toronto Rehabilitation Institute (part of University Health Network) we are continuing our clinical experience program, the results of which we will look to publish in 2022.

We continue to refine our go-to-market pricing model. In 2020, we implemented a modified pricing approach which is focused on reducing the need for clinics and patients to pay large, upfront costs at the start of treatment. We have also experimented with various promotional pricing programs resulting in lower unit prices for both PoNS system purchases and mouthpieces in order to increase access to the PoNS Therapy and drive market awareness which we believe resulted in an increase in the volume of units sold, beginning in the second half of 2020. We extended the promotional pricing through the end of 2021 including any order placed but not fulfilled before December 31, 2021. The promotional pricing was discontinued in 2022 with new pricing established.

The value dossiers for mmTBI and MS that were created in mid-2020 to fully demonstrate in both scientific and financial terms, the merits of PoNS Therapy for claimants are now being utilized along with submissions from clinics on behalf of their patients. The dossiers are provided to our clinics across Canada to submit as part of treatment plans with reimbursement applications to the payer community. Our reimbursement strategy for mmTBI is focused initially on the auto collision insurance and workers' compensation, or WC, market as well as long-term disability cases. Our reimbursement strategy for MS is focused on commercial insurers/extended health benefits.

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

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

U.S. Commercialization Efforts

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

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

We are currently accepting prescriptions for PoNS in the United States, and we anticipate our first commercial sales in the near term. We have targeted specific Key Opinion Leaders (i.e., neurologists and physiatrists) and their associated neurorehabilitation centers, where selected physical therapists will be trained to deliver the PoNS Therapy. Importantly, this focused strategy will also allow us to measure patient outcomes to determine if they are similar to those observed in our clinical trials. To further develop and implement the PoNS commercialization strategy, we have hired a Vice President of Sales and Marketing, North America, have identified the initial launch areas within the U.S., and we have continued to build out our commercial team, including field sales, reimbursement specialists, and marketing and operational support commensurate with PoNS sales activity.

Material Trends and Uncertainties

COVID-19 Pandemic

On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 as a global pandemic, which has spread throughout the U.S. and around the world. The Company's business, results of operations and financial condition have been and may continue to be adversely impacted by the COVID-19 pandemic and global economic conditions. The outbreak and spread of COVID-19 has significantly increased economic uncertainty. Authorities implemented, and continue to implement, numerous measures to try to contain the virus, such as travel bans and restrictions, quarantines, shelter in place orders, and business shutdowns. The COVID-19 pandemic initially led to the closure of PoNS authorized clinic locations across Canada from March until June 2020. Patients who completed their initial training in the clinics prior to the closures were able to continue working independently in the at-home portion of the treatment, with remote check-ins with their certified therapists. While all clinics have re-opened, as of December 31, 2021, they were all operating at reduced capacity, which limited operations to 50% capacity during the second half of 2021. Some patients have begun to return to these clinics for treatment, but patients have been and may continue to be less willing to return to the clinics due to COVID-19, impacting our commercial activities and our customer engagement efforts. This was especially true in the first half of 2021, as cases of COVID-19 increased significantly in Canada and additional restrictions, shelter in place orders, and business shutdowns were imposed. The rate of vaccination increased throughout all provinces throughout 2021, facilitating the lifting of some of the previously imposed restrictions. Thus far during the first quarter of 2022, capacity has remained at the 50% threshold with the expectation that the capacity limit will increase as provinces continue to lift restrictions. We continue to monitor the impact of COVID-19 and adjust our operations as the circumstances change.

We have expanded our services to include remote training and treatment, but the long-term viability of these remote programs is still being assessed. Additionally, current and planned clinical experience programs and clinical trials have experienced and may continue to experience delays in the programs as trial participant attendance has generally decreased as a result of the pandemic, and clinics and clinical research sites have experienced delays and difficulties in recruiting and re-hiring clinical site staff.

The COVID-19 pandemic has and may continue to cause delays in or the suspension of our business partners manufacturing operations, our research and product development activities, our regulatory workstreams, our research and development activities and other important commercial functions. We are also dependent upon our suppliers for the manufacture of our PoNS device. In the second quarter of 2020, two of our business partners diverted resources towards other activities related to COVID-19, resulting in delays in our product development activities. Such diversion of suppliers' resources may occur again in the future, and the pandemic could limit our suppliers' ability to travel or ship materials or force temporary closure of facilities that we rely upon. Manufacturing delays have occurred and may also occur as the result of labor shortages. Two of our suppliers experienced significant labor shortages as a result of COVID-19 from the end of November 2021 through early January 2022 which reduced the available resources needed to build and test product resulting in production delays of the PoNS devices. Disruptions in business operations or governmental operations due to COVID-19 may delay the timing for the submission and approval of our marketing applications with regulatory agencies. Further, the economic impact of the COVID-19 pandemic could affect our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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

Other Trends and Uncertainties

Beginning in late 2021, production delays began to negatively impact the ability of our contract manufacturer to successfully ramp up production during 2022 to fulfill orders for both commercial sales and clinical trials, which has been exacerbated by both labor and supply chain shortages currently being experienced by many industries in the U.S.

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

In response to the aforementioned challenges and trends, we have supplemented our personnel including quality resources at our contract manufacturer. Additionally, we continue to actively recruit and source candidates to fill positions as we build out our team to support our anticipated growth.

Financings

See "—Liquidity and Capital Resources" below for information regarding our financing activities in 2021.

Components of Our Results of Operations

Revenue

We have three categories of revenue: Product Sales, Fee Revenue and License Revenue. Product Sales is derived from the sale of the PoNS device. Fee Revenue was derived from franchise fees from new neuroplasticity clinics engaged in providing the PoNS Therapy. This practice ended during the first quarter of 2020. License Revenue is recognized ratably over the ten-year term as the performance obligation is met in connection with the Co-Promotion Agreement as a result of the Heuro acquisition. We expect our revenue will increase substantially over historical levels throughout 2022 as a result of the commercialization of PoNS Therapy in the U.S.

Cost of Sales

Cost of product sales includes the cost to manufacture the PoNS device, royalty expense, freight charges, customs duties as well as wages and salaries of employees involved in the management of the supply chain and logistics of fulfilling sales orders. We expect cost of sales to increase as a result of increased sales of PoNS devices in the U.S.

Research and Development Expenses

Research and development, or R&D, expenses consist of expenses incurred in connection with the discovery and development of our product. 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. Products 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 continue to increase over the next several years as we increase personnel costs, conduct feasibility and pilot studies and registrational clinical trials for our existing and additional indications, invest in our product development and manufacturing-related expenses and prepare regulatory filings for our products in additional indications. Our expenditures are subject to certain uncertainties, including those described in Item 1A. “Risk Factors” in this Annual Report.

Selling, General and Administrative Expenses

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

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

Amortization Expense

Amortization expense consists of the periodic amortization of intangible assets, including customer relationships and proprietary software recognized in connection with the acquisition of Heuro on October 30, 2019 and internally developed software. The customer relationships, proprietary software and reacquired rights recognized in connection with the acquisition of Heuro had remaining useful lives at acquisition of 1.25 years, 5 years and 3.87 years, respectively. They are amortized using the straight-line method. The customer relationships intangible asset became fully amortized and was written off during the first quarter of 2021. The internally developed software has a useful life of 3 years and is amortized using the straight-line method.

Critical Accounting Policies and Estimates

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

Revenue Recognition

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

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

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

Product Sales

Product sales were derived from the sale of the PoNS device to clinics in Canada. 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. Our payment terms are defined within each customer's supply agreement and are all 30 days or less. For the year ended December 31, 2020, we recorded $0.6 million in product sales. As of December 31, 2020, the control of 21 of the 55 PoNS devices included as consideration in the Heuro acquisition had been transferred resulting in revenue of $0.1 million being recognized which is included in the aforementioned $0.6 million in product sales for the year ended December 31, 2020. For the year ended December 31, 2021, we recorded $0.5 million in product sales. During the year ended December 31, 2021, the control of an additional 18 of the 55 PoNS devices included as consideration in the Heuro acquisition had been transferred resulting in revenue of $0.1 million being recognized which is included in the aforementioned $0.5 million in product sales for the year ended December 31, 2021. The fair value of the remaining 16 devices is recorded as deferred revenue of $0.1 million on the consolidated balance sheet. Revenue will be recognized for these devices as control is transferred. The only returns during 2021 were the result of warranty returns for defective products. These returns were insignificant during the year and any future replacements are expected to be insignificant.

Fee Revenue

During the first half of 2020, we earned fee revenue for engaging new neuroplasticity clinics to provide the PoNS Therapy. These agreements were terminated in the second quarter of 2020.

License Revenue

As described above, in connection with the Heuro acquisition, we entered into a Clinical Research and Co-Promotion Agreement with HTC (the "Co-Promotion Agreement"). The Co-Promotion Agreement had a fair value of CAD$360 thousand at the time of acquisition and a ten-year term. License revenue has been recognized ratably over the ten-year term of the Co-Promotion Agreement as the performance obligation is met.

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. Compensation cost is not adjusted for estimated forfeitures, but instead is adjusted upon an actual forfeiture of a stock option.

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, while the par value of the shares received is reclassified from additional paid in capital. 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 is recognized over the requisite service period following the measurement of the fair value on the grant date.

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.

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, (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.

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 derivative is re-measured at each balance sheet date and recorded as a liability or asset and the change in fair value is recorded in the consolidated statements of operations and comprehensive loss. Upon settlement of a derivative financial instrument, the instrument is re-measured at the settlement date and then that fair value of the underlying instrument is reclassified to equity.

The classification of derivative financial instruments, including whether such instruments should be recorded as liabilities/assets or as equity, is 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 if 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.*

As of December 31, 2020, our derivative financial instruments accounted for in accordance with ASC 815 were comprised of warrants issued in connection with public securities offerings. The last of the warrants accounted for in accordance with ASC 815 expired in April 2021, and as such, as of December 31, 2021, we do not hold any derivative financial instruments accounted for in accordance with ASC 815.

Accounting for Warrants

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

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

Goodwill and Other Intangible Assets

Goodwill represents the excess of purchase price over the fair values underlying net assets acquired in an acquisition. All of our goodwill as of December 31, 2020 and December 31, 2021 is the result of the Heuro acquisition. Goodwill is not amortized, but rather will be tested annually for impairment or more frequently if events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. We will test goodwill for impairment annually in the fourth quarter of each year using data as of October 1 of that year.

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

If the estimated fair value exceeds the carrying value, no further evaluation is required, and no impairment loss is recognized. If the carrying amount of a reporting unit, including goodwill, exceeds the estimated fair value, the excess of the carrying value over the

estimated fair value is recorded as an impairment loss, the amount of which is not to exceed the total amount of goodwill allocated to the reporting unit.

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

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

Income Taxes

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

We have adopted the provisions of ASC 740 *Income Taxes* regarding accounting for uncertainty in income taxes. We initially recognize 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. We consider 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, we classify penalties and interest associated with uncertain tax positions as a component of income tax expense in its consolidated statements of operations and comprehensive loss.

Going Concern

From our inception through December 31, 2021, we have generated approximately $2.6 million in revenue from the commercial sale of products or services. Because we have generated limited revenues from commercialization, our operations to date have been principally financed through public and private offerings of our common stock and convertible debt and exercises of options and warrants. There are a number of conditions that we must satisfy before we will be able to generate sufficient revenue to fund our operations, including but not limited to the successful commercialization of the PoNS device in the U.S.

These factors raise substantial doubt about our ability to continue as a going concern through at least 12 months from the date of this Annual Report. While we had $11.0 million of cash as of December 31, 2021, we do not currently have sufficient resources to accomplish all of the above conditions necessary for us to generate sufficient revenues to achieve profitability, and we expect that we will require additional financing to continue to fund our operations. There is no guarantee that such funding will be available at all or in sufficient amounts to satisfy our required expenditures. In reviewing this filing, you should carefully consider this uncertainty, the risks described in the section entitled “Item 1A. Risk Factors” and other risks described throughout this Annual Report.

Results of Operations

The following table summarizes our results of operations for the years ended December 31, 2021 and 2020 (amounts in thousands):

	Year Ended December 31,		
	2021	2020	Change
Revenue:			
Product sales	$ 493	$ 625	$ (132)
Fee revenue	-	9	(9)
License revenue	29	27	2
Total operating revenue	**522**	**661**	**(139)**
Cost of sales:			
Cost of product sales	298	388	(90)
Gross profit	**224**	**273**	**(49)**
Operating expenses:			
Research and development	5,990	4,582	1,408
Selling, general and administrative	12,176	9,714	2,462
Amortization expense	200	363	(163)
Total operating expenses	**18,366**	**14,659**	**3,707**
Operating loss	(18,142)	(14,386)	(3,756)
Other income:			
Other income	-	63	(63)
Change in fair value of derivative financial instruments	-	4	(4)
Foreign exchange gain	10	189	(179)
Total other income	10	256	(246)
Net loss	**$ (18,132)**	**$ (14,130)**	**$ (4,002)**

Year Ended December 31, 2021 Compared to Year Ended December 31, 2020

Revenue

For the year ended December 31, 2021, we recognized revenue of $0.5 million, of which $0.5 million was generated through product sales of our PoNS device in Canada pursuant to our executed supply agreements with neuroplasticity clinics in Canada and $29 thousand was generated from license fee revenue related to our co-promotion agreement with HTC. For the year ended December 31, 2020, we recognized revenue of $0.7 million, of which $0.6 million was generated through product sales of our PoNS device in Canada pursuant to our executed supply agreements with neuroplasticity clinics in Canada and $27 thousand was generated from license fee revenue related to our co-promotion agreement with HTC. The decrease year-over-year in revenue generated through product sales of our PoNS device in Canada is the result of the adverse impact of the COVID-19 pandemic on our product sales beginning in March 2020 as well as the impact of price changes focused on reducing the need for clinics and patients to pay large, upfront costs at the start of treatment.

Cost of Sales

For the year ended December 31, 2021, we incurred $0.3 million in cost of sales, compared to $0.4 million for the year ended December 31, 2020, a decrease of approximately $0.1 million. The decrease is attributable to a decrease in sales during 2021 compared to 2020 combined with an inventory reserve of $0.2 million recorded in 2020, partially offset by an increase in overhead costs including wages and salaries of employees involved in the management of the supply chain.

Research and Development Expenses

Research and development, or R&D, expenses were $6.0 million for the year ended December 31, 2021, compared to $4.6 million for the year ended December 31, 2020, an increase of approximately $1.4 million. The increase was primarily driven by a $0.8 million increase in product development expenses, a $0.5 million increase in professional expenses and a $0.5 million increase in clinical trial expenses. These increases were partially offset by a $0.2 million decrease in stock-based compensation expense and a $0.2 million decrease in legal expenses compared to those incurred during 2020 as a result of the submission of our request to the FDA for de novo classification and clearance of the PoNS device for the treatment of gait deficit due to symptoms from MS.

Selling, General and Administrative Expenses

Selling, general and administrative, or SG&A, expenses were $12.2 million for the year ended December 31, 2021, compared to $9.7 million for the year ended December 31, 2020, an increase of $2.5 million. The increase was primarily due to a $1.9 million increase in our stock-based compensation expense and a $0.8 million increase in wages and salaries, both resulting primarily from the addition of key management and sales executives in the second and third quarters of 2021 preparing for the commercial launch of PoNS in the U.S. Approximately $1.0 million of the stock-based compensation expense during the year ended December 31, 2021 related to the June 2021 one-time fully vested stock option grant to our then Interim President and Chief Executive Office in recognition of his service since August 2020 and election to take no additional compensation and continue to be compensated as a non-employee director of the Company while serving in that capacity. These increases were partially offset by a $0.3 million decrease in other operating expenses primarily as the result of the $0.2 million impairment of customer relationship intangible assets in the first quarter of 2020 and a $0.1 million loss as the result of the disposal of furniture and fixtures and leasehold improvements in the second quarter of 2020.

Amortization Expense

Amortization expense was $0.2 million for the year ended December 31, 2021, compared to $0.4 million for the year ended December 31, 2020, a decrease of $0.2 million. The decrease is primarily the result of the customer relationships intangible asset becoming fully amortized during the first quarter of 2021.

Change in Fair Value of Derivative Financial Instruments

There was no change in fair value of derivative financial instruments for the year ended December 31, 2021 because the warrants that qualified as derivatives required to be accounted for in accordance with ASC 815 (requiring the re-measurement of fair value at each balance sheet date) expired in April 2021 and had been valueless during the period. This compared to a gain of $4 thousand for the year ended December 31, 2020.

The change in fair value of our derivative financial instruments for the year ended December 31, 2020 was primarily attributable the change in our stock price, volatility and the number of derivative financial instruments being measured during the period (see Note 3 to our consolidated financial statements elsewhere in this Annual Report on Form 10-K). The change in the fair value of derivative financial instruments is a non-cash item.

Foreign Exchange Gain

Foreign exchange gain was $10 thousand for the year ended December 31, 2021, compared to a gain of $189 thousand for the year ended December 31, 2020. This was primarily due to fluctuations in the foreign exchange rate as it relates to the amount of Canadian dollars held at the end of each reporting period.

Liquidity and Capital Resources

We currently have limited working capital and liquid assets. The following table summarizes our cash and working capital (which we define as current assets less current liabilities excluding derivative financial instruments) as of December 31, 2021 and 2020 (amounts in thousands):

	As of December 31,	
	2021	2020
Cash	$ 11,005	$ 3,331
Working capital	$ 9,941	$ 2,261

From our inception through December 31, 2021, we have generated approximately $2.6 million in revenue from the commercial sale of products or services. Because we have generated limited revenues from commercialization, our operations to date have been principally financed through public and private offerings of our common stock and convertible debt and exercises of options and warrants. There are a number of conditions that we must satisfy before we will be able to generate sufficient revenue to fund our operations, including but not limited to the successful commercialization of PoNS Therapy in the U.S.

To date, our major sources of cash have been proceeds from various public and private offerings of our common stock and exercises of options and warrants. From June 2014 through December 31, 2021, we raised approximately $130.6 million in gross proceeds from various public and private offerings of our securities as well as the exercise of options and warrants, including during 2021, $21.3 million

in aggregate net proceeds from two public offerings, the exercise of options and warrants and the use of the Lincoln Park Purchase Agreement.

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

On February 1, 2021, in an underwritten public offering (the "February 2021 Offering"), we issued 744,936 shares of common stock and warrants to purchase up to an aggregate of 372,468 shares of common stock at a purchase price of $14.82 per unit, consisting of one share and a warrant to purchase 0.50 shares of common stock. The warrants have an initial exercise price of $16.302 per share and are exercisable for five years from the date of issuance. We also issued warrants to the underwriter to purchase 25,910 shares of common stock, with an exercise price of $18.525 per share. Net proceeds from the February 2021 Offering after underwriter's discounts and commissions and offering expenses paid by us were approximately $9.6 million. Affiliates of one of our officers and directors participated in the February 2021 Offering on the same terms and conditions as all other purchasers. During the second quarter of 2021, 262 warrants had been exercised for proceeds of $4 thousand.

During the second quarter of 2021, employees exercised 214 stock options for proceeds of $2 thousand.

On September 1, 2021, we entered into a purchase agreement (the "LPC Purchase Agreement") and a registration rights agreement with Lincoln Park, pursuant to which, under the terms and subject to the conditions of the LPC Purchase Agreement, we have the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase, up to $15.0 million of our common stock. Such sales of common stock by us, if any, will be subject to certain limitations, and may occur from time to time, at our sole discretion, over the 36-month period commencing September 15, 2021, subject to satisfaction of certain conditions.

Actual sales of shares of common stock to Lincoln Park will depend on a variety of factors to be determined by us from time to time, including, among others, market conditions, the trading price of the common stock and determinations by us as to the appropriate sources of funding for us and our operations. The net proceeds under the LPC Purchase Agreement will depend on the frequency and prices at which we sell shares of our common stock to Lincoln Park. We expect that any proceeds received from such sales to Lincoln Park will be used for working capital and general corporate purposes.

Under the LPC Purchase Agreement, on any business day on which the closing sale price of the common stock is not below the "floor price" stated in the LPC Purchase Agreement, we may, by written notice delivered by us to Lincoln Park, direct Lincoln Park to purchase up to 20,000 shares of common stock on such business day, at a purchase price per share that will be determined and fixed in accordance with the Purchase Agreement at the time we deliver such written notice to Lincoln Park (each, a "Regular Purchase"), provided that the maximum number of shares we may sell to Lincoln Park in a Regular Purchase may be increased to (i) up to 25,000 shares, provided that the closing sale price of the common stock on the applicable purchase date is not below $20.00 and (ii) up to 30,000 shares, provided that the closing sale price of the common stock on the applicable purchase date is not below $25.00, in each case, subject to adjustment for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction as provided in the LPC Purchase Agreement and provided that Lincoln Park's maximum purchase commitment in any single Regular Purchase may not exceed $2.0 million. The purchase price per share of common stock sold in each such Regular Purchase, if any, will be based on prevailing market prices of the common stock immediately preceding the time of sale as computed under the LPC Purchase Agreement. In addition to Regular Purchases, we may also direct Lincoln Park to purchase other amounts as accelerated purchases or as additional accelerated purchases on the terms and subject to the conditions set forth in the LPC Purchase Agreement.

We have agreed with Lincoln Park that we will not enter into an additional "equity line" or a substantially similar transaction whereby a specific investor is irrevocably bound pursuant to an agreement with us to purchase securities over a period of time from us at a price based on the market price of the common stock at the time of such purchase for a period defined in the LPC Purchase Agreement. Lincoln Park has covenanted not to cause or engage in any manner whatsoever, any direct or indirect short selling or hedging of our shares.

As part of the LPC Purchase Agreement, we issued 31,958 shares of our common stock to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the LPC Purchase Agreement. During the year ended December 31, 2021, we issued 40,000 shares, excluding the 31,958 shares issued as the commitment fee, under the LPC Purchase Agreement for net proceeds of approximately $0.6 million.

In November 2021, in an underwritten public offering (the "November 2021 Offering"), we issued 1,385,031 shares of common stock at a purchase price of $8.00 per share. Net proceeds from the November 2021 Offering after underwriter's discounts and commissions and offering expenses paid by us were approximately $9.9 million. Affiliates of one of our officers and directors participated in the November 2021 Offering on the same terms and conditions as all other purchasers.

Statements of Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2021 and 2020 (amounts in thousands):

	Year Ended December 31,		
	2021	2020	Change
Net cash used in operating activities	$ (13,388)	$ (11,738)	$ (1,650)
Net cash used in investing activities	(56)	(9)	(47)
Net cash provided by financing activities	21,126	9,638	11,488
Effect of foreign exchange rate changes on cash	(8)	(19)	11
Net increase (decrease) in cash	$ 7,674	$ (2,128)	$ 9,802

Year Ended December 31, 2021 Compared to the Year Ended December 31, 2020

Net Cash Used in Operating Activities

Net cash used in operating activities for the year ended December 31, 2021 was $13.4 million. This was comprised primarily of a net loss of $18.1 million, partially offset by $127 thousand net cash provided by operating activities resulting from changes in operating assets and liabilities, certain adjustments for non-cash items comprised primarily of stock-based compensation expense of $4.3 million and depreciation and amortization of $0.3 million.

Net cash used in operating activities for the year ended December 31, 2020 was $11.7 million. This was comprised primarily of a net loss of $14.1 million, unrealized foreign exchange gains of $0.2 million, gain on lease modification of $0.1 million and $1.2 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 $2.5 million, depreciation and amortization of $0.5 million, non-cash lease expense of $0.2 million, provision for inventory reserve of $0.2 million, impairment loss on intangible assets of $0.2 million (related to the customer relationships from the Heuro acquisition), provision for doubtful accounts of $0.1 million, and loss on disposal of office furniture and leasehold improvements of $0.1 million.

Net Cash used in Investing Activities

Net cash used in investing activities for the year ended December 31, 2021 was nominal and primarily related to the purchase of equipment and computer software and hardware.

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

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the year ended December 31, 2021 was $21.1 million, which was primarily comprised of $11.1 million in gross proceeds received from the November 2021 Offering, $11.0 million in gross proceeds received from the February 2021 Offering, $1.3 million in proceeds from the exercise of warrants and $0.6 million in gross proceeds from the sale of common stock pursuant to the LPC Purchase Agreement. These proceeds were partially offset by $2.9 million in issuance costs primarily related to the aforementioned offerings.

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

Cash Requirements

Funding Requirements

Our ability to generate product revenues sufficient to achieve profitability will depend heavily on the successful commercialization of PoNS Therapy in the U.S. Our net loss was $18.1 million and $14.1 million for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021, we had an accumulated deficit of $137.0 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We intend to use our available capital resources primarily to expand our U.S.

commercialization efforts; fund manufacturing activities for the PoNS device; conduct clinical trials; and for working capital and general corporate purposes.

We believe that our existing capital resources will be sufficient to fund our operations into the third quarter of 2022, but we will be required to seek additional funding through the sale of equity or debt financing to continue to fund our operations thereafter. We will need additional funding for our planned clinical trial for stroke. The amount required to fund operations thereafter will depend on various factors, including timing of approval of clinical trials, duration and result of clinical trials and other factors that affect the cost of the clinical trial, manufacturing costs of product, development of our product for new indications and demand for our authorized products in the market.

There can be no assurance that we will be successful in raising additional capital or that such capital, if available, will be on terms that are acceptable to us. If we are unable to raise sufficient additional capital, we may be compelled to reduce the scope of our operations and planned capital expenditure or sell certain assets, including intellectual property, and we may be forced to cease or wind down operations, seek protection under the provisions of the U.S. Bankruptcy Code, or liquidate and dissolve our company.

Contractual and Other Obligations

We have entered into arrangements that contractually obligate us to make payments that will affect our liquidity and cash flows in future periods. Such arrangements include those related to our lease commitments.

Lease Commitments

Our cash requirements greater than twelve months from various contractual obligations and commitments include operating lease liabilities. Our lease commitments reflect payments due for our lease arrangement for office space at our head office located in Newtown, Pennsylvania. As of December 31, 2021, our contractual commitment for our lease was $0.1 million. The amount of lease commitments reflects payments due for the new lease in Newtown, Pennsylvania that had not commenced under ASC Topic 842, *Leases*, as of December 31, 2021, and as a result, these leases are not reflected within our consolidated balance sheets. The new lease commenced on January 1, 2022 and is contracted to terminate on March 31, 2025. Refer to Note 7 in the Notes to Consolidated Financial Statements, included in Item 8 of Part II of this Annual Report on Form 10-K for further detail of our lease obligations and the timing of expected future payments.

Other Obligations

We enter into contracts in the normal course of business with various third parties for clinical trials, testing and manufacturing, and other services and products for operating purposes. These contracts provide for termination upon notice. Payments due upon cancellation generally consist only of payments for services provided or expenses incurred, including non-cancellable obligations of our service providers, up to the date of cancellation. These payments have not been separately included within these contractual and other obligations disclosures.

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

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

In November 2018, FASB issued ASU 2018-18, C*ollaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606*, which, among other things, provides guidance on how to assess whether certain collaborative arrangement transactions should be accounted for under Topic 606. The amendments in this ASU are effective for fiscal years, and interim periods

within those fiscal years, beginning after December 15, 2019, with early adoption permitted. We adopted this standard on January 1, 2020 and the adoption did not have a material impact on our consolidated financial statements.

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

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(b) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, under the direction of the Chief Executive Officer and the Chief Financial Officer, we have evaluated our disclosure controls and procedures as 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, 2021. 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, 2021, our internal control over financial reporting was effective.

This Annual Report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting as required by Section 404(b) of the Sarbanes Oxley Act of 2002. As a non-accelerated filer, our management's report was not subject to attestation by our registered public accounting firm pursuant to rules of the SEC that permit us to provide only management's report in this Annual Report.

Changes in Internal Control over Financial Reporting

We monitor our internal control over financial reporting on a continuous basis. There has not been any change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) under the Exchange Act that occurred during the quarter ended December 31, 2021 which have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

We will file a definitive Proxy Statement for our 2022 Annual Meeting of Stockholders (the “2022 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 2022 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 2022 Proxy Statement under the captions "Information Regarding the Board of Directors and Corporate Governance," "Proposal 1 - Election of Directors," "Executive Officers", and “Delinquent Section 16(a) Reports”.

ITEM 11. EXECUTIVE COMPENSATION

The information required by Item 11 is hereby incorporated by reference to the sections of the 2022 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 2022 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 2022 Proxy Statement under the captions "Certain Relationships and Related Transactions" and "Information Regarding the Board of Directors and Corporate Governance - Independence of the Board of Directors."

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by Item 14 is hereby incorporated by reference to the sections of the 2022 Proxy Statement under the caption "Proposal 2 - Ratification of Independent Registered Public Accounting Firm."

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

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

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

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

3. Exhibits.

Exhibit Number	Exhibit
3.1	Certificate of Conversion filed with the Delaware Secretary of State on July 18, 2018 (incorporated by reference to Exhibit 3.1 to the Form 10-Q filed August 9, 2018)
3.2	Certificate of Incorporation, as corrected (incorporated by reference to Exhibit 3.1 to the Form 8-K filed October 30, 2018)
3.3	Certificate of Amendment to Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Form 8-K filed on December 31, 2020)
3.4	Bylaws as amended and restated (incorporated by reference to Exhibit 3.3 to the Form 10-Q filed August 9, 2018)
4.1	Form of Warrant (incorporated by reference to Exhibit 4.1 to the Form 8-K filed October 26, 2020)
4.2	Form of Warrant (incorporated by reference to Exhibit 4.1 to the Form S-1/A filed January 20, 2021)
4.3	Warrant Agency Agreement (incorporated by reference to Exhibit 4.2 to the Form S-1/A filed January 20, 2021)
4.4	Description of Registrant's Securities (incorporated by reference to Exhibit 4.7 to the Form 10-K filed March 10, 2021)
4.5	Warrant Agency Agreement dated as of February 1, 2021 by and between Helius Medical Technologies, Inc. and American Stock Transfer & Trust Company, LLC (incorporated by reference to Exhibit 4.2 to the Form 8-K filed February 1, 2021)
10.1	License Agreement between Advanced NeuroRehabilitation, LLC and Yuri Danilov, Mitchell Tyler, Kurt Kaczmarek and John Klus, dated June 29, 2011 (incorporated by reference to Exhibit 10.8 to the Amendment to Form S-1 filed with the SEC on September 23, 2014)
10.2	Amended and Restated Patent Sub-License Agreement between Advanced NeuroRehabilitation, LLC and Helius Medical, Inc, having an effective date of January 22, 2013 (incorporated by reference to Exhibit 10.1 to the Form S-1 filed with the SEC on July 14, 2014)
10.3	Second Amended and Restated Patent Sub-License Agreement between Advanced NeuroRehabilitation, LLC and Helius Medical, Inc, dated June 6, 2014, but having an effective date of January 22, 2013 (incorporated by reference to Exhibit 10.7 to the Form S-1 filed with the SEC on July 14, 2014)
10.4	Design and Manufacturing Consultant Agreement between Helius Medical, Inc and Clinvue, LLC, dated January 30, 2013 (incorporated by reference to Exhibit 10.3 to the Form S-1 filed with the SEC on July 14, 2014)
10.5	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)
10.6‡	Asset Purchase Agreement between the Company and A&B (HK) Company Limited, dated as of October 9, 2015 (incorporated by reference to Exhibit 2.1 to the Form 8-K filed with the SEC on October 16, 2015)
10.6.1	Amendment to Asset Purchase Agreement between the Company and A&B (HK) Company Limited, dated as of October 30, 2017 (incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on November 2, 2017)
10.6.2	Supplemental Agreement to Asset Purchase Agreement dated October 9, 2015, between Helius Medical, Inc. and A&B (HK) Company Limited, dated as of August 15, 2018 (incorporated by reference to Exhibit 10.27 to the Form 10-K filed March 14, 2019)
10.7†	Amended and Restated June 2014 Equity Incentive Plan (incorporated by reference to Exhibit 4.3 to the Form 10-Q filed with the SEC on November 9, 2017)

Exhibit Number	Exhibit
10.7.1†	2014 Stock Incentive Plan Form of Option Grant Agreement (incorporated by reference to Exhibit 10.23.1 to the Transition Report on Form 10-K filed with the SEC on April 3, 2017)
10.8†	2016 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.25 to the Transition Report on Form 10-K filed with the SEC on April 3, 2017)
10.8.1†	Amendment Number 1 to the 2016 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.25.1 to the Transition Report on Form 10-K filed with the SEC on April 3, 2017)
10.8.2†	Amendment Number 2 to the 2016 Omnibus Incentive Plan (incorporated by reference to Exhibit 4.7 to the Registration Statement on Form S-8 filed with the SEC on May 18, 2017)
10.8.3†	2016 Omnibus Incentive Plan Form of U.S. Option Grant Agreement (incorporated by reference to Exhibit 4.8 to the Registration Statement on Form S-8 filed with the SEC on May 18, 2017)
10.8.4†	2016 Omnibus Incentive Plan Form of Canada Option Grant Agreement (incorporated by reference to Exhibit 4.9 to the Registration Statement on Form S-8 filed with the SEC on May 18, 2017)
10.9†	2018 Omnibus Incentive Plan, as amended (incorporated by reference to Exhibit 10.2 to the Form 10-Q filed November 8, 2018)
10.9.1†	2018 Omnibus Incentive Plan Form of Option Grant Agreement (incorporated by reference to Exhibit 10.3 to the Form 10-Q filed November 8, 2018)
10.9.2†	2018 Omnibus Incentive Plan Form of Restricted Stock Unit Grant Agreement (incorporated by reference to Exhibit 10.4 to the Form 10-Q filed November 8, 2018)
10.9.3†	2018 Omnibus Incentive Plan Form of Option Grant Agreement – 2020 Retention Grant (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on October 7, 2020)
10.9.4†	2018 Omnibus Incentive Plan Form of Stock Grant Notice and Award Agreement (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on April 7, 2021)
10.9.5†	Amendment to the Helius Medical Technologies, Inc. 2018 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on May 27, 2021)
10.9.6†	2018 Omnibus Incentive Plan Form of Option Grant Agreement – Initial Grants to Dane C. Andreeff and Jeffrey S. Mathiesen (incorporated by reference to Exhibit 10.3 to the Form 8-K filed on June 15, 2021)
10.10†	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.24 to the Form 10-K filed March 10, 2021)
10.11	Non-employee Director Compensation Policy (incorporated by reference to Exhibit 10.7 to the Form 10-Q filed on May 17, 2021)
10.12†	Employment Agreement between Helius Medical Technologies, Inc. and Dane C. Andreeff, dated June 14, 2021 (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on June 15, 2021)
10.13†	Employment Agreement between Helius Medical Technologies, Inc. and Jeffrey S. Mathiesen, dated June 14, 2021 (incorporated by reference to Exhibit 10.2 to the Form 8-K filed on June 15, 2021)
10.14†	Helius Medical Technologies, Inc. 2021 Inducement Plan (incorporated by reference to Exhibit 4.6 to the Form S-8 filed July 7, 2021)
10.14.1†	Form of Stock Option Grant Notice, Option Agreement and Notice of Exercise under the Helius Medical Technologies, Inc. 2021 Inducement Plan (incorporated by reference to Exhibit 4.5 to the Form S-8 filed July 7, 2021)
10.15†	Separation and Release Agreement between Helius Medical Technologies, Inc. and Joyce LaViscount, dated August 17, 2021 (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on August 19, 2021)
10.16	Purchase Agreement between Helius Medical Technologies, Inc. and Lincoln Park Capital Fund, LLC dated September 1, 2021 (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on September 2, 2021)
10.17	Registration Rights Agreement between Helius Medical Technologies, Inc. and Lincoln Park Capital Fund, LLC, dated September 1, 2021 (incorporated by reference to Exhibit 10.2 to the Form 8-K filed on September 2, 2021)
10.18†	Employment Agreement between Helius Medical Technologies, Inc. and Antonella Favit-Van Pelt, dated July 7, 2021 (incorporated by reference to Exhibit 10.31 to the Form S-1 filed on September 3, 2021)

Exhibit Number	Exhibit
10.19†	Helius Medical Technologies, Inc. 2022 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on February 18, 2022)
10.19.1†	Helius Medical Technologies, Inc. 2022 Equity Incentive Plan Form of Stock Option Agreement (incorporated by reference to Exhibit 10.3 to the Form 8-K filed on February 18, 2022)
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*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Filed herewith.
† Indicates a management contract or compensatory plan.
‡ Confidential information has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been granted with respect to this omitted information.

ITEM 16. FORM 10-K SUMMARY

None

INDEX TO 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, 2021 and 2020, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of 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, 2021 and 2020, 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 $137.0 million as of December 31, 2021 and the Company expects to incur further net losses in the development of its business. These conditions raise substantial doubt about its ability to continue as a going concern. Management's plans concerning these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

Critical Audit Matter

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

Accounting for Warrants Issued as part of Equity Offering

As described in Note 3 to the consolidated financial statements, the Company closed on a public offering in February 2021 that included the issuance of common stock and warrants to purchase common stock. The warrants were evaluated for proper classification on the balance sheet and it was determined that the warrants issued in this equity offering should be classified within stockholders' equity.

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

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

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

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

/s/ BDO USA, LLP

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

Philadelphia, Pennsylvania
March 14, 2022

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

	As of December 31,	
	2021	**2020**
ASSETS		
Current assets		
Cash	$ 11,005	$ 3,331
Accounts receivable, net	66	74
Other receivables	185	156
Inventory, net	476	389
Prepaid expenses	862	735
Total current assets	12,594	4,685
Property and equipment, net	409	486
Other assets		
Goodwill	763	759
Intangible assets, net	333	527
Operating lease right-of-use asset, net	3	90
Total other assets	1,099	1,376
TOTAL ASSETS	**$ 14,102**	**$ 6,547**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 1,069	$ 747
Accrued liabilities	1,433	1,337
Operating lease liability	3	59
Deferred revenue	148	281
Total current liabilities	2,653	2,424
Non-current liabilities		
Operating lease liability	—	32
Deferred revenue	193	220
TOTAL LIABILITIES	**2,846**	**2,676**
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, 2021 and December 31, 2020	—	—
Class A Common stock, $0.001 par value; 150,000,000 shares authorized; 3,780,674 and 1,484,362 shares issued and outstanding as of December 31, 2021 and December 31, 2020, respectively	4	1
Additional paid-in capital	149,412	123,872
Accumulated deficit	(137,035)	(118,903)
Accumulated other comprehensive loss	(1,125)	(1,099)
TOTAL STOCKHOLDERS' EQUITY	**11,256**	**3,871**
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 14,102**	**$ 6,547**

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

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

	Year Ended December 31,	
	2021	**2020**
Revenue:		
Product sales	$ 493	$ 625
Fee revenue	—	9
License revenue	29	27
Total operating revenue	**522**	**661**
Cost of sales:		
Cost of product sales	298	388
Gross profit	**224**	**273**
Operating expenses:		
Research and development	5,990	4,582
Selling, general and administrative	12,176	9,714
Amortization expense	200	363
Total operating expenses	**18,366**	**14,659**
Operating loss	**(18,142)**	**(14,386)**
Other income:		
Other income	—	63
Change in fair value of derivative financial instruments	—	4
Foreign exchange gain	10	189
Total other income	**10**	**256**
Net loss	**(18,132)**	**(14,130)**
Other comprehensive loss:		
Foreign currency translation adjustments	(26)	(197)
Comprehensive loss	**$ (18,158)**	**$ (14,327)**
Net loss per share		
Basic	**$ (7.38)**	**$ (11.80)**
Diluted	**$ (7.38)**	**$ (11.80)**
Weighted average shares outstanding		
Basic	**2,456,782**	**1,197,774**
Diluted	**2,456,782**	**1,197,774**

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

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

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

	Common Stock, $0.001 par value		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Shares	Amount				
Balance as of December 31, 2020	**1,484,362**	**$ 1**	**$ 123,872**	**$ (118,903)**	**$ (1,099)**	**$ 3,871**
Proceeds from the issuance of common stock from the February 2021 Offering	744,936	1	8,398	—	—	8,399
Warrant issuance from the February 2021 Offering	—	—	2,638	—	—	2,638
Proceeds from issuance of common stock pursuant to the LPC Purchase Agreement	40,000	—	577	—	—	577
Proceeds from issuance of common stock from the November 2021 Offering	1,385,031	2	11,079	—	—	11,081
Share issuance costs	31,958	—	(2,744)	—	—	(2,744)
Proceeds from the exercise of warrants	81,895	—	1,318	—	—	1,318
Proceeds from the exercise of stock options	214	—	2	—	—	2
Settlement of restricted stock units	5,012	—	—	—	—	—
Issuance of shares to a consultant for services	1,929	—	20	—	—	20
Stock-based compensation	5,337	—	4,252	—	—	4,252
Foreign currency translation adjustments	—	—	—	—	(26)	(26)
Net loss	—	—	—	(18,132)	—	(18,132)
Balance as of December 31, 2021	**3,780,674**	**$ 4**	**$ 149,412**	**$ (137,035)**	**$ (1,125)**	**$ 11,256**

(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,	
	2021	**2020**
Cash flows from operating activities		
Net loss	$ (18,132)	$ (14,130)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of derivative financial instruments	—	(4)
Stock-based compensation expense	4,252	2,529
Common shares issued to a consultant for services	20	—
Unrealized foreign exchange gain	(25)	(182)
Depreciation expense	112	119
Amortization expense	200	363
(Recovery of) provision for doubtful accounts	(22)	140
Provision for inventory reserve	—	205
Non-cash lease expense	62	225
Intangible asset impairment	—	184
Loss from disposal of property and equipment	18	110
Gain on lease modification	—	(56)
Changes in operating assets and liabilities:		
Accounts receivable	30	(4)
Other receivables	(29)	226
Inventory	(87)	4
Prepaid expenses	(127)	(125)
Operating lease liability	(63)	(253)
Account payable	369	(635)
Accrued liabilities	194	(280)
Deferred revenue	(160)	(174)
Net cash used in operating activities	**(13,388)**	**(11,738)**
Cash flows from investing activities		
Purchase of property and equipment	(54)	(63)
Proceeds from sale of property and equipment	—	61
Internally developed software	(2)	(7)
Net cash used in investing activities	**(56)**	**(9)**
Cash flows from financing activities		
Proceeds from the issuances of common stock and warrants	22,695	10,653
Share issuance costs	(2,889)	(1,015)
Proceeds from the exercise of stock options and warrants	1,320	—
Proceeds from Paycheck Protection Program Loan	—	323
Repayment of Paycheck Protection Program Loan	—	(323)
Net cash provided by financing activities	**21,126**	**9,638**
Effect of foreign exchange rate changes on cash	(8)	(19)
Net increase (decrease) in cash	7,674	(2,128)
Cash at beginning of year	3,331	5,459
Cash at end of year	**$ 11,005**	**$ 3,331**
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		
Non-cash share issuance costs	$ 476	$ —
Share issuance costs included in accounts payable and accrued liabilities	17	$ 162

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

1. DESCRIPTION OF BUSINESS

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

The Company's product, known as the Portable Neuromodulation Stimulator ("PoNS®"), is an innovative non-surgical medical device, inclusive of a controller and mouthpiece, which delivers mild electrical stimulation to the surface of the tongue to provide treatment of gait deficit and is indicated for use in the U.S. as a short term treatment of gait deficit due to mild-to-moderate symptoms from multiple sclerosis ("MS"), and is to be used as an adjunct to a supervised therapeutic exercise program in patients 22 years of age and over by prescription only. The Company is currently accepting prescriptions for PoNS in the U.S., and expects the first commercial sales to occur in the near term. PoNS is authorized for sale in Canada for two indications: (i) PoNS is authorized 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 ("PoNS Therapy™"); and (ii) PoNS is authorized for use as a short term treatment (14 weeks) of gait deficit due to mild and moderate symptoms from MS and is to be used in conjunction with physical therapy. It has been commercially available in Canada since March 2019. PoNS is authorized for sale as a Class IIa medical device in Australia. The Company is working to establish a distribution partner for Australia but currently does not expect to have commercial sales of PoNS in Australia in 2022.

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

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

The Company's Class A common stock, par value $0.001 per share ("common stock") is listed on the Nasdaq Capital Market ("Nasdaq"). 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 Toronto Stock Exchange (the "TSX") on April 18, 2016. The Company voluntarily delisted from the TSX effective as of the close of trading on September 9, 2021. On April 11, 2018, the common stock began trading on Nasdaq under the ticker symbol "HSDT" after having traded on the OTCQB in the United States under the ticker symbol "HSDT" since February 10, 2015.

Reverse Stock Split

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

Going Concern Uncertainty

As of December 31, 2021, the Company had cash of $11.0 million. For the year ended December 31, 2021, the Company incurred a net loss of $18.1 million and, as of December 31, 2021, its accumulated deficit was $137.0 million. For the year ended December 31, 2021, the Company had $0.5 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 indicate substantial doubt about the Company's ability to continue as a going concern within one year after the date the financial statements are filed. The Company's consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and satisfaction of liabilities in the ordinary course of business; no adjustments have been made relating to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company not continue as a going concern.

The Company intends to fund ongoing activities by utilizing its current cash on hand, cash received from the sale of its PoNS device in Canada and the U.S. and by raising additional capital through equity or debt financings as well as by using its equity line facility entered

into on September 1, 2021 with Lincoln Park Capital Fund, LLC ("Lincoln Park"), which is subject to certain limitations and conditions. There can be no assurance that the Company will be successful in raising that additional capital or that such capital, if available, will be on terms that are acceptable to the Company. If the Company is unable to raise sufficient additional capital, the Company may be compelled to reduce the scope of its operations and planned capital expenditures.

Risks and Uncertainties

COVID-19

On March 11, 2020, the World Health Organization declared the outbreak of a novel coronavirus ("COVID-19") as a global pandemic, which has spread throughout the U.S. and around the world. The Company's business, results of operations and financial condition have been and may continue to be adversely impacted by the COVID-19 pandemic and global economic conditions. The outbreak and spread of COVID-19 has significantly increased economic uncertainty. Authorities implemented, and continue to implement, numerous measures to try to contain COVID-19, such as travel bans and restrictions, quarantines, shelter in place orders, and business shutdowns. The COVID-19 pandemic initially led to the closure of PoNS Authorized clinic locations across Canada. While all clinics have re-opened, as of December 31, 2021, they were all operating at reduced capacity, and patients have been and may continue to be less willing to return to these clinics, impacting our commercial activities and our customer engagement efforts. In addition, the resurgence of COVID-19 cases across Canada in the fourth quarter of 2020 and first half of 2021 led to further restrictions on clinic activities. However, the rate of vaccination increased throughout all provinces throughout 2021 facilitating the lifting of some of the previously imposed restrictions. Moreover, the Company's ability to conduct its ongoing clinical experience programs and clinical trials has been and may be impaired due to trial participants' attendance being adversely affected by COVID-19. In addition, the COVID-19 pandemic has and may continue to cause delays in the Company's suppliers' ability to ship materials that the Company relies upon as well as manufacturing delays as the result of labor shortages. Two of the Company's suppliers experienced significant labor shortages as a result of COVID-19 from the end of November 2021 through early January 2022 which reduced the available resources needed to build and test product resulting in production delays of the PoNS devices. Disruptions in business or governmental operations due to COVID-19 may delay the timing for the submission and approval of the Company's marketing applications with regulatory agencies. Further, the economic impact of the COVID-19 pandemic could affect the Company's ability to access the public markets and obtain necessary capital in order to properly capitalize and continue its operations.

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

2. SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

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

Use of Estimates

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

Principles of Consolidation

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

Concentrations of Credit Risk

The Company is subject to credit risk with respect to its cash. Amounts invested in such instruments are limited by credit rating, maturity, industry group, investment type and issuer. The Company maintains cash in excess of federally insured limits in certain banks. However, the Company has not experienced any losses in such accounts and believes it is not exposed to any significant credit risk related to cash. The Company seeks to maintain safety and preservation of principal and diversification of risk, liquidity of investments sufficient to meet cash flow requirements and a competitive after-tax rate of return.

Receivables

Accounts receivables are stated at their net realizable value. In determining the appropriate allowance for doubtful accounts, the Company considers a combination of factors, such as the aging of trade receivables, its customers' financial strength, and payment history. Changes in these factors, among others, may lead to adjustments in the Company's allowance for doubtful accounts. The calculation of the allowance requires judgment by Company management. As of December 31, 2021, the Company's accounts receivable of $0.1 million, is net of an allowance for doubtful accounts of $0.4 million and is the result of revenue from product sales. As of December 31, 2020, the Company's accounts receivable of $0.1 million, is net of an allowance for doubtful accounts of $0.4 million and is the result of revenue from product sales.

Other receivables included Goods and Services Tax ("GST"), Quebec Sales Tax ("QST") refunds related to the Company's Canadian expenditures of $0.2 million, and refunds from research and development ("R&D") tax credits of $1 thousand as of December 31, 2021. Other receivables included and GST and QST refunds related to the Company's Canadian expenditures of $0.1 million refunds, from rent deposits of $18 thousand and receivable from R&D tax credits of $1 thousand as of December 31, 2020.

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. No inventory markdowns to net realizable value were recorded during the year ended December 31, 2021. Inventory markdowns to net realizable value of $205 thousand were recorded during the year ended December 31, 2020.

As of December 31, 2021 and 2020, inventory consisted of the following (amounts in thousands):

	As of December 31, 2021	As of December 31, 2020
Raw materials	$ 171	$ 160
Work-in-process	528	440
Finished goods	32	44
Inventory	**$ 731**	**$ 644**
Inventory reserve	(255)	(255)
Total inventory, net of reserve	**$ 476**	**$ 389**

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, 2021 and 2020 (amounts in thousands):

	As of December 31,	
	2021	2020
Leasehold improvement	$ —	$ 64
Furniture and fixtures	65	93
Equipment	373	335
Computer hardware and software	212	197
Property and equipment	650	689
Less accumulated depreciation	(241)	(203)
Property and equipment, net	$ 409	$ 486

Depreciation expense was $112 thousand and $119 thousand for the years ended December 31, 2021 and 2020, respectively.

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

During the fourth quarter of 2021, the Company abandoned leasehold improvements with a net book value of $7 thousand and wrote down furniture and fixtures with a net book value of $17 thousand to $6 thousand. The loss on the disposal of the leasehold improvements and furniture and fixtures of $18 thousand was recorded as selling, general and administrative expense in the consolidated statements of operations and comprehensive loss.

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, 2021 is the result of the acquisition of Heuro in October 2019. Goodwill is not amortized, but rather is 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 tests goodwill for impairment annually in the fourth quarter of each year using data as of October 1 of that year.

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

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

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

The COVID-19 pandemic and its continuing impact was considered a triggering event for testing whether goodwill is impaired throughout 2020 and the first half of 2021. The Company performed quantitative assessments at each quarter end in 2020 and at March 31, 2021 and June 30, 2021. As a result of these assessments, the Company determined that the estimated fair value of the reporting unit exceeded the carrying value of the reporting unit. Therefore, the Company concluded that goodwill was not impaired as of any of the aforementioned periods. The Company will continue to monitor the impacts of the COVID-19 pandemic in future periods.

The Company performed a qualitative assessment for its annual impairment analysis as of October 1, 2021. Qualitative factors included in the assessment included, but were not limited to, economic conditions, industry and market conditions, cost factors, overall financial

performance of the reporting unit and reporting unit specific events. Based on that assessment, the Company determined that it was not "more likely than not" that the fair value of its reporting unit was less than its carrying amount and therefore goodwill was not impaired.

The following is a summary of the activity for the years ended December 31, 2021 and December 31, 2020 for goodwill:

Carrying amount at December 31, 2019	$	1,242
Business acquisition fair value allocation adjustment		(503)
Foreign currency translation		20
Carrying amount at December 31, 2020	$	759
Foreign currency translation		4
Carrying amount at December 31, 2021	$	763

Definite-lived intangibles consist principally of acquired customer relationships, proprietary software and reacquired rights as well as internally developed software. All are amortized straight-line over their estimated useful lives. Amortization expense related to intangible assets was $0.2 million and $0.4 million during the year ended December 31, 2021 and the year ended December 31, 2020, respectively. During the year ended December 31, 2020, the Company incurred an intangible asset impairment loss of $0.2 million related to the customer relationships, all of which was incurred during the first quarter of 2020, which is included in selling, general and administrative expenses in the accompanying consolidated statement of operations and comprehensive loss.

Intangible assets as of December 31, 2021 and December 31, 2020 consist of the following:

		As of December 31, 2021			As of December 31, 2020		
	Useful Life	Gross Carrying Amount	Accumulated Amortization	Net Carrying Value	Gross Carrying Amount	Accumulated Amortization	Net Carrying Value
Customer relationships (1)	1.25 years	$ —	$ —	$ -	$ 237	$ (228)	$ 9
Acquired proprietary software	5 years	151	(66)	85	150	(35)	115
Reacquired rights	3.87 years	505	(283)	222	503	(152)	351
Internally developed software	3 years	84	(58)	26	82	(30)	52
Total intangible assets		$ 740	$ (407)	$ 333	$ 972	$ (445)	$ 527

(1) During the year ended December 31, 2021, the Company wrote off $0.2 million of fully amortized customer relationships, all of which occurred during the first quarter of 2021.

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

For the Year Ending December 31,	
2022	$ 185
2023	123
2024	25
	$ 333

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

The Company accounts for its leases under ASU No. 2016-02, *Leases*. 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, 2021 and 2020, the Company had only one operating lease, which was for its headquarters office in Newtown, Pennsylvania. As of December 31, 2021, the Company modified the existing lease arrangement and in November 2021 entered into a new lease with an initial term commencing January 1, 2022. As the new Lease Agreement is not effective until January 1, 2022, there is no impact to the Company's financial statements as of December 31, 2021. Operating lease ROU assets and operating lease liabilities are recognized based on the present value of lease payments over the lease term. The Company does not have a public credit rating and as such used a corporate yield with a "CCC" rating by S&P Capital IQ with a term commensurate with the term of its lease as its incremental borrowing rate in determining the present value of lease payments. Lease expense is recognized on a straight-line basis over the lease term. The Company's lease arrangement does not have lease and non-lease components which are to be accounted for separately (see Note 7).

Foreign Currency

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

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

Stock-Based Compensation

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

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

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

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

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

Revenue Recognition

In accordance with FASB's ASC 606, *Revenue from Contracts with Customers*, ("ASC 606"), the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to

be entitled in exchange for those goods or services, in an amount that reflects the consideration which the Company expects to be entitled in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, it performs the following five steps:

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

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

Product Sales

Product sales were derived from the sale of the PoNS to clinics in Canada. 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. The Company's payment terms are defined within each customer's supply agreement and are all 30 days or less. For the year ended December 31, 2020, the Company recorded $0.6 million in product sales. As of December 31, 2020, the control of 21 of the 55 PoNS devices included as consideration in the Heuro acquisition had been transferred resulting in revenue of $0.1 million being recognized which is included in the aforementioned $0.6 million in product sales for the year ended December 31, 2020. For the year ended December 31, 2021, the Company recorded $0.5 million in product sales. During the year ended December 31, 2021, control of 18 of the 55 PoNS devices included as consideration in the Heuro acquisition had been transferred resulting in revenue of $0.1 million being recognized which is included in the aforementioned $0.5 million in product sales for the year ended December 31, 2021. The fair value of the remaining 16 devices is recorded as deferred revenue of $0.1 million on the consolidated balance sheet. The returns during 2021 were the result of warranty returns for defective products. These returns were insignificant during the year and any future replacements are expected to be insignificant.

Fee Revenue

During the first half of 2020, the Company earned fee revenue of $9 thousand for engaging new neuroplasticity clinics to provide the PoNS Therapy, before terminating these agreements in the second quarter of 2020.

License Revenue

In connection with the Heuro acquisition, the Company entered into a Clinical Research and Co-Promotion Agreement with HTC (the "Co-Promotion Agreement"). Under the Co-Promotion Agreement, subject to certain terms and conditions, the Company granted to HTC the exclusive right to provide the PoNS Therapy in the Fraser Valley and Vancouver metro regions of British Columbia, where HTC has operated a PoNS authorized clinic since February 2019. HTC 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. The Co-Promotion Agreement had a fair value of CAD$360 thousand at the time of acquisition and a ten-year term. License revenue has been recognized ratably over the ten-year term as the performance obligation is met. During the year ended December 31, 2020, the Company recognized revenues of $27 thousand in license fees associated with the Co-Promotion Agreement. For the year ended December 31, 2021, the Company recognized revenues of $29 thousand in license fees associated with the Co-Promotion Agreement. Revenue not yet recognized of $0.2 million is recorded as deferred revenue on the consolidated balance sheet as of December 31, 2021.

As of December 31, 2021, the Company had recorded $0.1 million in current receivables, net and had no contract assets or liabilities on its consolidated balance sheets related to the supply agreements with each clinic. As of December 31, 2020, the Company has recorded $0.1 million in current receivables, net and had no contract assets or liabilities on its consolidated balance sheets related to the supply agreements with each clinic.

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.

Income Taxes

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

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

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

Research and Development Expenses

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

Segment Information

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

Derivative Financial Instruments

The Company evaluates its financial instruments and other contracts to determine if those contracts or embedded components of those contracts qualify as derivatives to be separately accounted for in accordance with ASC 815, *Derivatives and Hedging*. The result of this accounting treatment is that the fair value of the derivative is re-measured at each balance sheet date and recorded as a liability or asset and the change in fair value is recorded in the consolidated statements of operations and comprehensive loss. As of December 31, 2020, the Company's derivative financial instruments accounted for in accordance with ASC 815 were comprised of warrants issued in connection with public securities offerings. Upon settlement of a derivative financial instrument, the instrument is re-measured at the settlement date and the fair value of the underlying instrument is reclassified to equity (see Note 3).

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

The last of the warrants accounted for in accordance with ASC 815 expired in April 2021, and as such, as of December 31, 2021, the Company does not hold any derivative financial instruments accounted for in accordance with ASC 815.

Fair Value Measurements

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

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

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

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

The Company's financial instruments recorded in its consolidated balance sheets consist primarily of cash, accounts receivable, other current receivables, operating lease ROU asset, accounts payable, accrued liabilities, operating lease liability and derivative financial instruments. The book values of these instruments, with the exception of derivative financial instruments, non-current lease liability, and operating lease ROU asset, 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 are required to be recorded at fair value on a recurring basis. Unobservable inputs used in the valuation of these financial instruments include volatility of the underlying share price and the expected term. See Note 3 for the inputs used in the Black-Scholes option-pricing model as of December 31, 2020 and the roll forward of the derivative financial instruments. The Company's derivative financial instruments are comprised of warrants which are classified as liabilities. The fair value of the derivative financial instruments as of December 31, 2020 was zero. The warrants classified as liabilities expired in April 2021 and as such, as of December 31, 2021, the Company does not hold any derivative financial instruments accounted for in accordance with ASC 815.

There were no transfers between any of the levels during the years ended December 31, 2021 and 2020.

In addition to assets and liabilities that are recorded at fair value on a recurring basis, the Company's assets and liabilities are also subject to nonrecurring fair value measurements. Generally, assets are recorded at fair value on a nonrecurring basis as a result of impairment charges. Due to the COVID-19 pandemic and the related risks and uncertainties, the Company's customer relationship intangible asset incurred an impairment loss during the year ended December 31, 2020 of $0.2 million, all of which was recorded during the first quarter of 2020, and had a remaining net book value of $9 thousand as of December 31, 2020. The fair value of this intangible asset was determined based on Level 3 measurements within the fair value hierarchy. Inputs to these fair value measurements included estimates of the amount and timing of the asset's net future discounted cash flows based on historical data, current trends and market conditions. As of December 31, 2021, the Company's customer relationship intangible asset had been fully amortized and written off.

Basic and Diluted Net Income (Loss) per Share

Earnings or loss per share ("EPS") is computed by dividing net income (loss) by the weighted average number of shares of common stock 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,	
	2021	2020
Basic and Diluted		
Numerator		
Net loss	$ (18,132)	$ (14,130)
Denominator		
Weighted-average shares of common stock outstanding - basic and diluted	2,456,782	1,197,774
Basic and diluted net loss per share	$ (7.38)	$ (11.80)

No incremental common stock equivalents, consisting of outstanding stock options, warrants and restricted stock units, were included in calculating diluted loss per share because such inclusion would be anti-dilutive given the net loss reported for the years ended December 31, 2021 and 2020. Dilutive common stock equivalents excluded from the computation of diluted weighted average shares outstanding were 1,265,400 and 455,631 for the years ended December 31, 2021 and 2020, respectively.

Recent Accounting Pronouncements

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

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

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

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

3. COMMON STOCK AND WARRANTS

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

No dividends have been declared since inception of the Company through December 31, 2021. 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.

April 2018 Offering

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

Each warrant issued in connection with the April 2018 Offering entitles the holder to acquire one additional share of common stock at an exercise price of CAD$428.75 per share on or before April 10, 2021. Pursuant to the guidance of ASC 815 *Derivatives and Hedging*, the Company has determined that warrants issued in connection with the April 2018 Offering should be accounted for as liabilities as the ability to maintain an effective registration is outside of the Company's control and that it may be required to settle the exercise of the warrants in cash and because the exercise prices of these warrants are in a currency other than the Company's functional currency. Consequently, the Company determined the fair value of each warrant issuance using the Black-Scholes option-pricing model, with the remainder of the proceeds allocated to the shares of common stock. As of December 31, 2021, 2,025 warrants had been exercised, all during 2018, for gross proceeds of CAD$0.9 million. The remaining 68,351 warrants expired in April 2021.

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.

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

2020 At The Market Offering

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

March 2020 Offering

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

Each warrant issued in connection with the March 2020 Offering entitles the holder to acquire one additional share of common stock at an exercise price of $16.10 per share, which became exercisable on September 20, 2020 and will expire on March 20, 2025. Pursuant to the guidance of ASC 480 *Distinguishing Liabilities from Equity* and ASC 815 *Derivatives and Hedging*, the Company has determined that warrants issued in connection with the March 2020 Offering should be classified as equity as partial cash settlement under certain circumstances, charges of transfer taxes and fees and provisions related to market volatility did not preclude equity classification. The relative fair value of these warrants at issuance was approximately $0.8 million and was included in additional paid-in capital. As of December 31, 2021, 81,633 warrants had been exercised, all during the first quarter of 2021, for gross proceeds of $1.3 million.

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

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

October 2020 Offering

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

Pursuant to the securities purchase agreement for the October 2020 Offering, if the Company issues any shares of common stock or common stock equivalents for cash consideration, indebtedness or a combination thereof, with certain exceptions, within twelve months of the closing of the October 2020 Offering, each purchaser who subscribed for at least $250,000 had the right to participate in up to such purchaser's pro rata portion of 30% of the such subsequent financing on the same terms, conditions and price provided for in the subsequent financing. These participation rights expired on October 26, 2021.

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

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

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

February 2021 Offering

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

Pursuant to the guidance of ASC 480 *Distinguishing Liabilities from Equity* and ASC 815 *Derivatives and Hedging*, the Company has determined that warrants issued in connection with the February 2021 Offering should be classified as equity as partial cash settlement under certain circumstances, charges of transfer taxes and fees and provisions related to market volatility did not preclude equity classification. The relative fair value of these warrants at issuance was approximately $2.6 million and was included in additional paid-in capital. As of December 31, 2021, 262 warrants had been exercised, all during the second quarter of 2021, for gross proceeds of $4 thousand.

The following table summarizes the weighted average assumptions used in estimating the fair value of the warrants granted in the February 2021 Offering using the Black-Scholes option pricing model as of the date of the closing of the offering on February 1, 2021.

	February 1, 2021
Stock price	$ 14.82
Exercise price	16.47
Warrant term	5.00 years
Expected volatility	75.02%
Risk-free interest rate	0.42%
Dividend rate	0.00%

Lincoln Park Purchase Agreement

On September 1, 2021, the Company entered into a purchase agreement (the "LPC Purchase Agreement") and a registration rights agreement with Lincoln Park. The LPC Purchase Agreement provides that, subject to the terms and conditions therein, the Company has the right, but not the obligation, to sell from time to time, at its sole discretion, to Lincoln Park up to $15.0 million of shares of its common stock over a 36-month period commencing on September 15, 2021. In addition, under the LPC Purchase Agreement, during the third quarter of 2021, the Company issued 31,958 shares of common stock to Lincoln Park as consideration for Lincoln Park's commitment to purchase shares of the Company's common stock. The $0.5 million fair value of the commitment fee shares was recorded as share issuance costs as of September 30, 2021 upon execution of the agreement.

Lincoln Park has no right to require the Company to sell any shares of common stock to Lincoln Park, but Lincoln Park is obligated to make purchases as the Company directs, subject to certain conditions.

The number of shares the Company may sell to Lincoln Park on any single business day (provided that the closing sale price of the common stock is not below the "floor price" stated in the LPC Purchase Agreement) in a regular purchase is 20,000, but that amount may be increased to (i) up to 25,000 shares, provided that the closing sale price of the common stock on the applicable purchase date is not below $20.00 and (ii) up to 30,000 shares, provided that the closing sale price of the common stock on the applicable purchase date is not below $25.00, in each case, subject to a maximum limit of $2.0 million per regular purchase. The purchase price per share for each such regular purchase will be based on prevailing market prices of the Company's common stock immediately preceding the time of sale as computed under the LPC Purchase Agreement. In addition to regular purchases, the Company may also direct Lincoln Park to purchase other amounts as accelerated purchases or as additional accelerated purchases as set forth in the LPC Purchase Agreement.

Under applicable rules of the Nasdaq Capital Market, the Company may not issue or sell to Lincoln Park under the LPC Purchase Agreement more than 19.99% of the shares of the common stock outstanding immediately prior to the execution of the LPC Purchase Agreement unless (i) the Company obtains stockholder approval to issue shares of Common Stock in excess of such amount to Lincoln Park under the LPC Purchase Agreement in accordance with applicable Nasdaq rules or (ii) the average price of all applicable sales of common stock to Lincoln Park under the LPC Purchase Agreement equals or exceeds $15.1661 per share, such that issuances of common

stock to Lincoln Park under the LPC Purchase Agreement will not be subject to such limitation under applicable Nasdaq rules. In any event, the LPC Purchase Agreement specifically provides that the Company may not issue or sell any shares of its common stock under the LPC Purchase Agreement if such issuance or sale would breach any applicable Nasdaq rules.

In all instances, the LPC Purchase Agreement prohibits the Company from directing Lincoln Park to purchase any shares of its common stock if those shares, when aggregated with all other shares of common stock then beneficially owned by Lincoln Park, would result in Lincoln Park beneficially owning more than 9.99% of the outstanding shares of the Company's common stock.

The Company has agreed with Lincoln Park that it will not enter into an additional "equity line" or a substantially similar transaction whereby a specific investor is irrevocably bound pursuant to an agreement with the Company to purchase securities over a period of time from the Company at a price based on the market price of the common stock at the time of such purchase for a period defined in the LPC Purchase Agreement. Lincoln Park has covenanted not to cause or engage in any manner whatsoever, any direct or indirect short selling or hedging of the Company's shares.

Actual sales of common stock to Lincoln Park will depend on a variety of factors to be determined by the Company from time to time, including, among others, market conditions, the trading price of the common stock and determinations by the Company as to the appropriate sources of funding for the Company and its operations. The net proceeds under the LPC Purchase Agreement to the Company will depend on the frequency and prices at which the Company sells shares of its common stock to Lincoln Park.

During the year ended December 31, 2021, all of which occurred during the third quarter of 2021, the Company sold and issued 40,000 shares under the LPC Purchase Agreement, excluding the 31,958 shares issued for the commitment fee, for net proceeds of $0.6 million.

November 2021 Offering

On November 12, 2021, in an underwritten public offering (the "November 2021 Offering"), the Company issued 1,385,031 shares of common stock at a purchase price of $8.00 per share. Net proceeds from the November 2021 Offering after underwriter's discounts and commission and offering expenses paid by us were approximately $9.9 million. Affiliates of an officer and director participated in the November 2021 Offering on the same terms and conditions as all other purchasers.

Warrants

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, 2021 and 2020 (amounts in thousands):

	Year Ended December 31,	
	2021	2020
Fair value of warrants at beginning of year	**$ —**	$ 5
Exercise of warrants	—	—
Foreign exchange losses	—	(1)
Change in fair value of warrants during the year	—	(4)
Fair value of warrants at end of year	$ —	$ —

These warrants, which expired in April 2021, were classified as derivative financial instruments in the Company's consolidated balance sheets and were required to be re-measured at each reporting period, with the change in fair value recorded as a gain or loss in the change of fair value of derivative financial instruments, included in other income in the Company's consolidated statements of operations and comprehensive loss.

The warrants classified as liabilities expired in April 2021 and as such, as of December 31, 2021, the Company does not hold any derivative financial instruments accounted for in accordance with ASC 815. The fair value of all warrants classified as derivative

financial instruments outstanding as of December 31, 2020 were estimated using the Black-Scholes option-pricing model with the following weighted average assumptions:

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

The following is a summary of warrant activity during the years ended December 31, 2021 and 2020:

	Number of Warrants (by currency denomination of exercise price)		Weighted-Average Exercise Price	
	CAD$	USD$	CAD$	USD$
Outstanding as of December 31, 2019	68,351	18,607	$ 428.75	$ 428.32
Granted	—	273,554	—	16.04
Cancelled/Expired	—	(18,607)	—	428.32
Exercised	—	—	—	—
Outstanding as of December 31, 2020	68,351	273,554	$ 428.75	$ 16.04
Granted	—	402,265	—	16.47
Cancelled/Expired	(68,351)	—	428.75	—
Exercised	—	(81,895)	—	16.10
Outstanding and exercisable as of December 31, 2021	—	593,924	$ —	$ 16.32

The following table summarizes the Company's warrants outstanding and exercisable as of December 31, 2021:

Number of Warrants Outstanding	Exercise Price	Expiration Date
97,143	US$16.10	March 20, 2025
17,431	US$16.1665	October 26, 2023
76,386	US$15.82	October 26, 2023
961	US$19.775	October 26, 2023
372,206	US$16.302	February 1, 2026
29,797	US$18.525	February 1, 2026
593,924		

4. SHARE BASED PAYMENTS

2018 Omnibus Incentive Plan

On May 15, 2018, the Company's Board of Directors authorized and approved the adoption of the 2018 Omnibus Incentive Plan (as amended, the "2018 Plan"), which was effective upon approval by the stockholders of the Company on June 28, 2018 and under which an aggregate of 153,031 shares could be issued. This share reserve is the sum of 85,714 new shares, plus the 67,317 shares that remained available for issuance under the Company's 2016 Omnibus Incentive Plan, the predecessor incentive plan (the "2016 Plan") at the time of the adoption of the 2018 Plan. On April 20, 2021, the Company's Board of Directors authorized and approved an amendment, which was effective upon approval by the stockholders of the Company on May 25, 2021, authorizing an additional 565,000 shares of common stock to be issued under the 2018 Plan. Pursuant to the terms of the 2018 Plan, the Company is authorized to grant stock options, as well as awards of stock appreciation rights, restricted stock, unrestricted shares, restricted stock units ("RSUs"), stock equivalent units and performance-based cash awards. These awards may be granted to directors, officers, employees and eligible consultants. Vesting and the term of an option is determined at the discretion of the Company's Board of Directors. Subsequent to the adoption of the 2018 Plan, the Company ceased granting awards under the 2016 Plan, the predecessor incentive plan. However, outstanding stock options granted prior to the effective date of the 2018 Plan are still governed by the 2016 Plan or the Company's 2014 Stock Incentive Plan, which preceded the 2016 Plan.

As of December 31, 2021, there were an aggregate of 138,745 shares of common stock remaining available for issuance under the 2018 Plan.

2021 Inducement Plan

On July 2, 2021, the Company adopted the Helius Medical Technologies, Inc. 2021 Inducement Plan (the "Inducement Plan"), pursuant to which the Company reserved 100,000 shares of its common stock to be used exclusively for grants of awards to individuals who were not previously employees or directors of the Company, as an inducement material to the individuals' entry into employment with the Company within the meaning of Rule 5635(c)(4) of the Nasdaq Listing Rules. The Inducement Plan was approved by the Company's Board of Directors without stockholder approval pursuant to Rule 5635(c)(4) of the Nasdaq Listing Rules.

The Inducement Plan permits the grant of non-statutory stock options, stock appreciation rights, restricted stock, restricted stock units, performance stock and cash awards, and other share-based awards.

As of December 31, 2021, there was an aggregate of 50,500 shares of common stock remaining available for grant under the Company's Inducement Plan.

Stock Options For the year ended December 31, 2021, the Company issued 584,115 stock options to employees and directors of which 14,200 were forfeited. The Company issued 1,000 stock options to consultants during the same period.

The following is a summary of stock option activity for the year ended December 31, 2021 and 2020:

	Number of Options	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price in USD$	Aggregate Intrinsic Value in USD$
Outstanding as of December 31, 2019	99,018	7.78	$ 236.63	$ —
Granted	42,988		15.20	
Forfeited	(28,448)		210.57	
Exercised	—		—	
Outstanding as of December 31, 2020	113,558	7.75	$ 159.33	$ —
Granted	585,115		$ 14.89	
Forfeited/Cancelled	(29,342)		61.55	
Exercised	(214)		10.50	$ 1
Outstanding as of December 31, 2021	669,117	9.03	$ 37.36	$ —
Exercisable as of December 31, 2021	281,435	8.50	$ 65.23	$ —

Employee and Director Stock Options

As of December 31, 2021, the unrecognized compensation cost related to non-vested stock options outstanding for employees and directors was $2.9 million which will be recognized over a weighted-average remaining vesting period of approximately 3.3 years. Compensation cost is not adjusted for estimated forfeitures, but instead is adjusted upon an actual forfeiture of a stock option.

For the years ended December 31, 2021 and 2020, the Company granted 584,115 and 42,417 stock options, respectively, to employees and directors at a weighted average exercise price of $14.89 and $15.23, respectively. The expected term represents the period of time the stock options are expected to be outstanding and is based on the "simplified method." Under the "simplified method," the expected term of an option is presumed to be the mid-point between the vesting date and the end of the contractual term. For the years ended December 31, 2021 and 2020, the Company used the "simplified method" for the expected term of employee and director stock options due to lack of sufficient historical exercise data to provide a reasonable basis upon which to otherwise estimate the expected term of the stock options. The employee and director stock options granted for the years ended December 31, 2021 and 2020 had a weighted average grant date fair value of $10.53 and $9.71 per option, respectively, and they were estimated using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	Year Ended December 31,	
	2021	2020
Stock price	$14.98	$15.23
Exercise price	$14.89	$15.23
Expected term	6.99 years	5.32 years
Expected volatility	78.03%	75.35%
Risk-free interest rate	1.18%	0.52%
Dividend rate	0.00%	0.00%

Consultant Stock Options

For the years ended December 31, 2021 and 2020, the Company granted 1,000 and 571 stock options, respectively, to consultants at a weighted average exercise price of $14.20 and $13.58, respectively. Stock options granted to the Company's consultants for the years ended December 31, 2021 and 2020 had a weighted average grant date fair value of $11.80 and $8.18 per share, respectively, and they were estimated using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	Year Ended December 31,	
	2021	2020
Stock price	$14.20	$13.58
Exercise price	$14.20	$13.58
Option term	10.0 years	5.27 years
Expected volatility	84.26%	73.15%
Risk-free interest rate	1.57%	0.33%
Dividend rate	0.00%	0.00%

As of December 31, 2021, the unrecognized compensation cost related to non-vested stock options outstanding for consultants was $10 thousand which will be recognized over a weighted-average remaining vesting period of 0.8 years. Compensation cost is not adjusted for estimated forfeitures, but instead is adjusted upon an actual forfeiture of a stock option.

Restricted Stock Units

Beginning in the fourth quarter of 2019, certain members of the Company's executive management team elected to receive RSUs in lieu of cash compensation under the 2018 Plan that vested upon issuance. The fair value of the RSUs was based on the closing price of the Company's common stock on the day of the grant. Subsequent to the March 31, 2021 pay period, no members of the Company's executive management team continued to elect to receive RSUs in lieu of cash compensation.

During the second quarter of 2021, the Company granted 2,668 RSUs to an officer of the Company under the 2018 Plan that were scheduled to vest on October 2, 2021. The fair value of the RSUs was based on the closing price of the Company's common stock on the Nasdaq Capital Market on the day of the grant. These RSUs were forfeited during the third quarter of 2021.

During the year ended December 31, 2021, the Company granted 6,343 RSUs to members of the Company's Board of Directors pursuant to the Non-Employee Director Compensation Policy which vest in twelve monthly installments on the last day of each month. The fair value of the RSUs is based on the closing price of the Company's common stock on the Nasdaq Capital Market on the day of the grant.

The following is a summary of the Company's RSU activity for the years ended December 31, 2021 and 2020:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value per Unit
Outstanding as of December 31, 2019	788	$ 21.17
Granted	7,172	15.25
Settled	(7,792)	17.81
Outstanding as of December 31, 2020	168	$ 13.20
Granted	9,871	15.41
Forfeited	(2,668)	14.50
Settled	(5,012)	15.66
Outstanding as of December 31, 2021	2,359	$ 15.76

Unrestricted Stock

On April 1, 2021, the Company granted 5,337 shares of unrestricted common stock to an officer of the Company under the 2018 Plan.

During the year ended December 31, 2021, all of which occurred during the fourth quarter of 2021, the Company granted 1,929 shares of unrestricted common stock to a consultant of the Company under the 2018 Plan.

Stock-Based Compensation Expense

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

	2021	2020
Research and development	$ 693	$ 933
Cost of sales	$ 7	$ (1)
General and administrative	3,552	1,597
Total	$ 4,252	$ 2,529

Stock-based compensation expense for the year ended December 31, 2020, was reduced by $0.1 million related to the forfeiture of stock options as a result of the departure of our former chief executive officer. Stock-based compensation expense for the year ended December 31, 2021 included $0.5 million in expense related to the accelerated vesting of stock options as a result of the departure of our former chief operating officer in July 2021.

5. ACCRUED EXPENSES

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

	As of December 31,	
	2021	2020
Employees benefits	$ 712	$ 496
Professional services	174	292
Legal expense	23	133
Royalty fees	10	12
Franchise fees	193	—
Severance	258	347
Other	63	57
	$ 1,433	$ 1,337

Accrued severance expenses as of December 31, 2021 included $0.3 million in severance costs related to the departure of our former chief operating officer in July 2021.

6. INCOME TAXES

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

	Year Ended December 31,	
	2021	2020
U.S.	$ 16,589	$ 12,362
Non-U.S.	1,543	1,768
	$ 18,132	$ 14,130

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,	
	2021	2020
Statutory tax rate	21.00%	21.00%
Net loss before income taxes	$ 18,132	$ 14,130
Expected income tax recovery	$ (3,808)	$ (2,967)
Increase (decrease) in income tax recovery resulting from:		
Derivative liability	—	(1)
Share based payments	810	415
Other permanent difference	(103)	(21)
Foreign income taxed at foreign rate	(85)	(97)
Increase in valuation allowance	3,186	2,671
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,	
	2021	2020
Deferred income tax assets (liabilities)		
Operating losses carried forward	$ 27,514	$ 24,576
Tax credits	987	882
Stock compensation	1,715	1,616
Other	1,006	1,099
Valuation allowance	(31,222)	(28,173)
Net deferred income tax asset	$ —	$ —

As of December 31, 2021, the Company has accumulated non-capital losses totaling $6.7 million in Canada, Federal net operating losses of $98.2 million in the U.S., and State net operating losses of $64.9 million in the U.S. which may be available to carry forward and offset future years' taxable income. Federal net operating losses of $39.6 million and all State net operating losses of $64.9 million begin to expire starting in 2033 through 2041. The remaining $58.6 million of the Federal net operating losses are available to be carried forward indefinitely.

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. The Company believes it is possible an ownership change has occurred and that Federal

net operating losses of $39.6 million and State net operating losses of $64.9 million may be materially limited and expire prior to being utilized.

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, 2021, the Company does not have an accrual relating to uncertain tax positions. It is not anticipated that unrecognized tax benefits would significantly increase or decrease within 12 months of the reporting date.

7. COMMITMENTS AND CONTINGENCIES

(a) On January 22, 2013, the Company entered into a license agreement with Advanced NeuroRehabilitation, LLC (“ANR”) for an exclusive right on ANR’s patent pending technology, claims and knowhow. In addition to the issuance of 91,628 shares of common stock to ANR, the Company agreed to pay a 4% royalty on net revenue on the sales of devices covered by the patent-pending technology and services related to the therapy or use of devices covered by the patent-pending technology. For the years ended December 31, 2021 and 2020, the Company recorded approximately $20 thousand and $22 thousand, respectively, in royalty expenses in its consolidated statement of operations.

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

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

In January 2021, the lease term of the Lease Amendment was amended to go through September 30, 2021, with options to extend monthly thereafter. The expected lease termination date remained June 30, 2021. The Company extended month to month commencing October 1, 2021.

In November 2021, the Company entered into a new lease (the "Lease Agreement") for 1,780 square feet of dedicated office space to serve as the Company's headquarters in Newtown, Pennsylvania. The initial term of the lease is from January 1, 2022 through March 31, 2025. Monthly rent plus utilities is approximately $4 thousand per month with a 3% annual increase. As a result of entering into the Lease Agreement, the Company's assessment of the lease term of the Lease Amendment changed from terminating on June 30, 2022 to terminating on January 15, 2022. The termination was determined to be a remeasurement of the existing Lease Amendment due to the change in term assessment. As such, the ROU assets and operating lease liabilities were remeasured using an incremental borrowing rate at the date of modification. The carrying value of the ROU asset decreased on a basis proportionate basis by approximately $29 thousand and the related lease liability decreased by approximately $29 thousand. The Company recorded a gain of less than $1 thousand resulting from the difference between the reduction in the lease liability and the proportionate reduction of the ROU asset. This amount is recorded as a component of other income in the consolidated statement of operations and comprehensive loss for the year ended December 31, 2021. As the new Lease Agreement is not effective until January 1, 2022, there is no impact to the Company's financial statements as of December 31, 2021.

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

For the Year Ending December 31,	**2021**	**2020**
Operating lease cost	$ 8	$ 107
Operating lease - operating cash flows	$ 63	$ 253
Weighted average remaining lease term	0.04 years	1.50 years
Weighted average discount rate	3.3%	7.2%
Future minimum lease payments under non-cancellable lease as of December 31, 2021 were as follows:		
For the Period Ending December 31,		
2021	$ 3	
Total future minimum lease payments	**3**	
Less imputed interest	—	
Total liability	**$ 3**	

Reported as of December 31,	**2021**	**2020**
Current operating lease liability	3	59
Non-current operating lease liability	—	32
Total	**$ 3**	**$ 91**

(c) On December 29, 2017, HMI (formerly known as NeuroHabilitation Corporation) entered into a Manufacturing and Supply Agreement ("MSA") with Keytronic Corporation ("Keytronic"), 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 Keytronic a rolling forecast for the procurement of parts and material and within normal lead times based on estimated delivery dates for the manufacture of the PoNS device. The term of the agreement is for three years and the agreement will automatically

renew for additional consecutive terms of one year, unless cancelled by either party upon 180-day written notice to the other party prior to the end of the then current term. On June 1, 2020, HMI extended the existing manufacturing agreement with Keytronic for a second three year term from December 29, 2020 until December 31, 2023. As of December 31, 2021, the Company did not have any outstanding commitments to Keytronic to complete the Company's forecast for the procurement of materials necessary for the delivery of PoNS devices.

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

8. RELATED PARTY TRANSACTIONS

For the year ended December 31, 2020, the Company paid approximately $5 thousand in consulting fees to a director of the Company. No consulting fees were paid to this director during the year ended December 31, 2021.

An officer of the Company and affiliates of an officer and director subscribed for units in the Company's October 2020 Offering (see Note 3).

Affiliates of an officer and director participated in the February 2021 Offering and the November 2021 Offering on the same terms and conditions as all other purchasers.

SIGNATURES

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

HELIUS MEDICAL TECHNOLOGIES, INC.

Dated: March 14, 2022

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

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

By /s/ Dane C. Andreeff — Date: March 14, 2022
Dane C. Andreeff
President, Chief Executive Officer and Director

By /s/ Jeffrey S. Mathiesen — Date: March 14, 2022
Jeffrey S. Mathiesen
Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)

By /s/ Blane Walter — Date: March 14, 2022
Blane Walter
Director

By /s/ Mitchell E. Tyler — Date: March 14, 2022
Mitchell E. Tyler
Director

By /s/ Edward M. Straw — Date: March 14, 2022
Edward M. Straw
Director

By /s/ Sherrie Perkins — Date: March 14, 2022
Sherrie Perkins
Director

By /s/ Paul Buckman — Date: March 14, 2022
Paul Buckman
Director

Exhibit 21.1

SUBSIDIARIES OF HELIUS MEDICAL TECHNOLOGIES, INC

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

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

Helius Medical Technologies, Inc.
Newtown, Pennsylvania

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-236101), Form S-1 (No. 333-248824, 333-250974 and 333-259334), and Form S-8 (No. 333-204155, 333-218095, 333-229724, 333-256680 and 333-257749) of Helius Medical Technologies, Inc., of our report dated March 14, 2022, 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, 2021. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ BDO USA, LLP

Philadelphia, Pennsylvania
March 14, 2022

Exhibit 31.1

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

I, Dane C. Andreeff, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 14, 2022

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

Exhibit 31.2

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

I, Jeffrey S. Mathiesen, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 14, 2022

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

Exhibit 32.1

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

In connection with the Annual Report on Form 10-K of Helius Medical Technologies, Inc. (the "Company") for the year ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Dane C. Andreeff, as Chief Executive Officer of the Company, and Jeffrey S. Mathiesen, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of their knowledge:

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

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

Date: March 14, 2022

/s/ Dane C. Andreeff

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

/s/ Jeffrey S. Mathiesen

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

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