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, 2017

☐ **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. 000-55364

HELIUS MEDICAL TECHNOLOGIES, INC.

(Exact name of registrant as specified in its charter)

WYOMING	**36-4787690**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

Suite 100, 642 Newtown Yardley Road
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	**Name of each exchange on which registered**
None	**None**

Securities registered pursuant to Section 12(g) of the Act: Class A Common Stock

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

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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

Large accelerated filer ☐ Accelerated filer ☒

Non-accelerated filer ☐ (Do not check if a smaller reporting company) Smaller reporting company ☒

Emerging growth company ☒

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

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. ☒

The aggregate market value of the common equity held by non-affiliates of the registrant on June 30, 2017, based on the closing price on that date of USD$7.80, was approximately $99,372,392. As of March 5, 2018, there were 20,241,135 shares of the registrant's common stock outstanding.

Documents Incorporated by Reference

Portions of the registrant's Definitive Proxy Statement to be filed with the Commission pursuant to Regulation 14A in connection with the registrant's 2018 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, 2017.

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

FORWARD-LOOKING STATEMENTS

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

The forward-looking statements in this Annual Report include but are not limited to statements relating to: clinical development plans, product development activities, other products not yet developed or acquired, our product candidate success, plans for U.S. Food and Drug Administration, or FDA, filings and their subsequent approvals, other foreign or domestic regulatory filings by us or our collaboration partners, including filings with Health Canada, CE Mark and the Therapeutic Goods Administration, our ability to commercialize the product(s), either independently or with collaboration partners, the safety and efficacy of our product candidate, the timeline for our improvement plans, our market awareness, our ability to compete effectively, the ability and limitation of our manufacturing source(s), our distribution network, the adequacy of our intellectual property protection, our future patent approvals, potential infringement of our intellectual property, future litigation waged against us and its outcome, any product liability we may incur, the sufficiency of our operating insurance, including sufficient product liability insurance, our limited operating history, our dependence on a small number of employees, employee conflicts of interest, our dependence on outside scientists and third party research institutions, our future expenses and cash flow, our ability to become profitable, our future financing arrangements, our ability to accurately report our financial position, our accountants' future perspective including any going concerns, our ability to maintain effective internal controls, any future stock price, the potential dilution of the stock, future sales of the Company's equity securities, any future Financial Industry Regulatory Authority sales practice requirements, future disclosure requirements, future regulatory risks, our relationship with the U.S. Army, our ability to build the necessary commercial infrastructure and to use existing reimbursement codes or receive reimbursement codes from the American Medical Association and the U.S. Department of Health and Human Services, and our ability to receive reimbursement coverage under Medicare, Medicaid or under other insurance plans. These and additional risks and uncertainties are more fully described in this Annual Report and our other public filings with the Securities and Exchange Commission or SEC.

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

INDUSTRY AND MARKET DATA

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

PART I

ITEM 1. BUSINESS

Overview

We are a medical technology company focused on the development of products for the treatment of neurological symptoms caused by disease or trauma. We seek to develop, license or acquire unique and noninvasive platform technologies that amplify the brain's ability to heal itself.

Many patients with brain injury or brain-related disease have disrupted neural networks that result in their brains being unable to correctly or efficiently carry neural impulses, which are responsible for directing bodily functions like movement control or sensory perception. Our first product in development, known as the portable neuromodulation stimulator or PoNS®, device, is designed to enhance the brain's ability to compensate for this damage. The PoNS Treatment is a combination of our PoNS device and functional, targeted physical or cognitive therapy, and is currently being developed for the treatment of movement, gait and balance disorders in patients with traumatic brain injury, or TBI, and other chronic neurological diseases.

We recently completed our registrational clinical trial of the PoNS Treatment for mild- to moderate TBI, in which we observed statistically and clinically significant increases in composite sensory observation test scores. Based on the safety and efficacy results from this clinical trial, we intend to submit a request for FDA marketing authorization for the treatment of chronic balance deficit due to mild- to moderate-TBI via the FDA's de novo classification process in the first half of 2018. In addition, we intend to submit applications for marketing authorizations in Canada, the European Union and Australia during the first half of 2018.

The PoNS Treatment

The PoNS Treatment consists of an investigational medical device that is comprised of two major components, an electric pulse generator and a replaceable mouthpiece combined with physical or cognitive therapy. The PoNS device delivers specially-patterned electrical stimulation developed to mirror nerve impulses to the brain through 143 gold-plated electrodes on the mouthpiece which is placed on the tongue. For 20 minutes the electrical stimulation, called translingual neurostimulation, is coupled with physical or cognitive therapy, which consists of condition specific physical, relaxation and cognitive exercises, based on the patient's functional deficits. Clinical research has shown that electrical stimulation of the tongue activates two major cranial nerves – the lingual nerve, a part of the trigeminal nerve, and the chorda tympani, a part of the facial nerve. Electrical stimulation of the cranial nerves creates a flow of neural impulses that are then delivered directly into the brain stem and cerebellum – the main control centers for multiple life functions including sensory perception and movement. From the brain stem, these impulses travel throughout the brain and activate or reactivate neurons and structures involved in human function such as the cortex, spinal cord and potentially the entire central nervous system. Researchers believe that sustained stimulation initiates a sequential cascade of changes in the actual interconnected nuclei, or neuronal network, the fundamental connections between the anatomical components of the brain. The PoNS device is also a smart device with built in technology to allow tracking of the patient use, including time and intensity of treatments.

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 that allows for technical data logging and communications. See Figure 1.

Figure 1
The portable neuromodulation stimulator, PoNS device

The mouthpiece of the PoNS device is held lightly in place by the lips and teeth around the neck of the tab that goes into the mouth and rests on the anterior and superior part of the tongue. 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 stimulus intensity can be adjusted by the user. The sensation produced by the array is similar to the feeling of drinking a carbonated beverage. The patented waveform is specifically designed to minimize the potential for tissue irritation.

Concurrent Use with Physical or Cognitive Rehabilitation

We have designed the PoNS Treatment whereby the PoNS device is used in conjunction with physical or cognitive rehabilitation, typically delivered for two weeks in the clinic followed by use by the patient at home. The PoNS device has a design feature that stops delivering treatment every 14 weeks, thus requiring the patient to return to their physician or physical therapy center, or PTC, for assessment of their progress, reestablishment of challenging physical therapy to achieve higher goals and download of utilization data, which we believe will be helpful for reimbursement and future research. We currently expect the PoNS device to be inspected visually by the physical therapist, reset for another 14 weeks of treatment if necessary, and the mouthpiece replaced with a new one to reduce the likelihood of degradation of the electrodes. We expect this business model feature to ensure proper support for patients in the early phase of their treatment.

We expect physicians will be informed to prescribe the PoNS Treatment, which includes both the PoNS device and a prescription to work with PTCs who are trained and PoNS-certified. We anticipate supporting the launch of the PoNS Treatment with the development and implementation of a hub services center with online and offline elements to help facilitate the healthcare transaction.

Upon completion of the in-clinic portion of the PoNS Treatment, which is normally two weeks, patients are expected to be monitored in their home treatment through the PTCs. At the end of their prescribed treatment, we expect patients to be directed back to their physician for assessment and then return to the PTC for additional treatment as necessary including replacement of the mouthpiece if continued treatment is deemed necessary.

PoNS Trials in TBI

During the third quarter of 2017, we completed our registrational clinical trial in mild- to moderate- TBI, which was a double-blind randomized, controlled study of the safety and effectiveness of the PoNS Treatment for translingual noninvasive neuromodulation stimulation training in subjects with chronic balance deficit due to mild- to moderate- TBI.

The study, which was launched in the third quarter of 2015 in conjunction with the U.S. Army Medical Research and Materiel Command, was conducted at seven sites in the United States and Canada. The trial evaluated a total of 122 randomized subjects, with ages between 18 and 65 years. Each subject received five weeks of treatment, two weeks in-clinic and three weeks at home with the treatment consisting of physical therapy with either a high-frequency pulse (25.7 million pulses per 20-minute treatment), or HFP, PoNS device or a low-frequency pulse (13,728 pulses per 20-minute treatment), or LFP, PoNS device. While the intensity of the pulses between the HFP and the LFP were identical, the frequency of the pulses was different between the two devices.

All subjects for the trial were at least one-year post injury to ensure spontaneous recovery was unlikely. To be considered for the study, all subjects had to have participated in a focused physical rehabilitation program for the TBI-related balance disorder and been deemed by the treating clinician to have reached a plateau and yet continued to have significant balance issues as they entered the trial.

An objective balance assessment is performed using the Composite Score from the NeuroCom Sensory Organization Test, or SOT, which measures balance using computerized sensors that measures participants' ability to maintain balance under six different conditions. This was used as the efficacy endpoint for the trial. The SOT is a widely used measurement tool for balance disorder associated with TBI. A responder was defined as a subject with an improvement of at least 15 points on the composite SOT score at five weeks of PoNS Treatment when compared to their baseline score. According to published, independent third-party data, patients receiving physical therapy alone to treat balance disorders related to TBI improve by 8-10 points on the composite SOT, and patients tend to drift back to their baseline disability when physical therapy is discontinued. It would be expected that if the PoNS Treatment was not effective that the improvement in SOT score in our patient population would be greater than 8-10 points compared with the patient score at the start of the trial.

The statistical analysis plan contemplated how to analyze the efficacy data based on the results of the comparison between the HFP and LFP PoNS device groups. There were three possible scenarios:

- The two devices would produce a response that was not statistically different from each other and neither device was effective at producing a 15-point SOT response (failed study).
- One device would be statistically superior to the other and produce a 15-point response in the SOT (positive study).
- The two devices would produce a response that was not statistically different from each other and both produced a significant response greater than 15 points (positive study). This third scenario is what happened in out trial.

Since scenario three was the outcome of the primary endpoint of the study, the statistical analysis plan prospectively dictated that the secondary endpoint would be calculated by combining the two groups and comparing the response to baseline at week two and week five.
Secondary effectiveness endpoints demonstrated statistically and clinically significant increases (at least 8 points) in composite SOT scores:

- The mean improvement at two weeks for combined-arms was 18.3 points, $p<0.0005$.
- The mean improvement at five weeks for combined-arms was 24.6 points, $p<0.0005$.

The primary safety endpoint was an improvement in the frequency of falls, as determined by daily event recording on the subject data case report form during the in-clinic phase of the study. The secondary safety endpoint was the frequency and severity of headaches, as measure 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 and headaches, in both treatment groups.
- There were no serious device related adverse events.

PoNS Long-Term Treatment Study

This study was performed to understand the durability of treatment response. This double-blind randomized controlled study in patients with mild- to moderate- TBI was completed in May 2017 at the Tactile Communication Neurorehabilitation Laboratory at University of Wisconsin-Madison and was sponsored by the U.S. Army. The study was conducted with 22 patients using the HFP PoNS device and 21 patients using the LFP PoNS device with 14 weeks of active treatment followed by a 12-week washout period after which final SOT scores were captured.

Highlights of the study results were as follows:

- There was no statistical difference between the HFP and LFP PoNS device groups in the trial supporting the results of the registrational clinical trial.
- On average, participants entered the study with an SOT score of approximately 40, which is a score that indicates profound disability due to impaired balance.
- At the end of 14 weeks of active treatment with the HFP PoNS device group, patients showed improvements on average of 29.7 points on the SOT score, which put the participants within the normal range of SOT score after 14 weeks of treatment.
- Participants then discontinued treatment and were told to resume normal lifestyle for another12 weeks and were monitored on a weekly basis. The participants, on average, maintained the benefit of the treatment throughout the 12-week withdrawal period.

Conclusion:

- The study demonstrated that the PoNS Treatment with the HFP PoNS device could, on average, make patients who were profoundly disabled at entry into the study, achieve a SOT score in the normal range from a balance perspective in 14 weeks and maintain that benefit after a 12-week washout period, supporting the durability of the response to the treatment and the potential restoration of the balance system.

With the completion of our registrational clinical trial, we expect to complete the verification and validation for device design and manufacturing to meet the requirements of the applications for commercial distribution, and submit applications for marketing authorizations for the treatment of balance disorder in mild- to moderate-TBI, with the FDA, Health Canada, CE Mark in Europe and the Therapeutic Goods Administration in Australia during 2018.

Planned Studies

Multiple Sclerosis

According to the National Multiple Sclerosis Society, there are approximately one million individuals in the United States living with MS, for an annual economic cost of MS in the United States of approximately $28 billion, many of whom experience balance problems. Studies from several countries estimate that 50% to 70% of MS patients had reported falls within the past two to six months.

The FDA has determined that we must obtain an investigational device exemption, or IDE, prior to commencing any clinical trial of the PoNS Treatment in MS patients in the United States. We intend to commence a registrational clinical trial of the PoNS Treatment in MS patients with balance and gait deficit in the second half of 2018, contingent on the availability of funding and the timing of our submission and approval of our IDE by the FDA.

Stroke

Stroke is the third leading cause of death in the United States, with approximately 795,000 annual episodes, resulting in approximately 140,000 deaths. The term “stroke” or “brain attack” implies brain tissue has been destroyed – because one of the vessels that provide oxygen and nutrients to the brain has ruptured or become blocked by atheromatous plaque or a blood clot traveling from elsewhere in the body, often due to an irregularly beating heart. Whichever mechanism leads to a stroke, the end result is the same; death of brain tissue and variable disability depending on what parts of the brain have been affected. This might be the inability to feel or move a part of the body, to speak, think, or many other symptoms. Acute treatment consists of maneuvers including drugs, interventional radiology or surgery to stop bleeding or remove blockages. Thereafter, therapy is focused on trying to help the patient recover use of disabled anatomy with physical therapy or learn to overcome disability with occupational therapy. We are determining next steps for our studies of the PoNS Treatment for stroke patients, which are subject to the availability of funding.

Cognition

In December 2016, we announced, based on preliminary, encouraging results, the expansion of our comprehensive study in healthy adults to measure the benefit of investigational PoNS Treatment on physiological improvements associated with cognition. The study was conducted at HealthTech Connex Inc, or HTC, in Surrey, BC. HTC also collaborated with us to explore whether a single, twenty-minute session of two PoNS stimulation waveforms - high frequency, or HF, and low frequency, or LF - impacted objective measures of brain activity recorded by high density 64-channel electroencephalography, or EEG, and whether there were differences between the two PoNS stimulation waveforms. The study in neurologically intact volunteers showed that:

- EEG results showed that translingual neurostimulation delivered through the PoNS device generated significant differences in brain activity.
- Statistically significant increases in alpha and theta frequency power were observed in the post-stimulation rest period for HF group, suggesting a lasting exposure effect.
- Statistically significant increases in alpha waveform power pre- to post-stimulation were present when both HF and LF groups were evaluated together.
- Significant increases in attentional microstate activity were seen in the HF group. The effects began during PoNS stimulation and continued to increase to the level of significantly greater than baseline following stimulation.

These findings confirmed several important assumptions about the PoNS technology, most importantly, being that a single PoNS stimulation session has an impact on brain activity, and the results also provide insights on the differences between PoNS waveforms and potential opportunities for research that will continue to drive improved and more effective patient experiences and results.

Further Studies

Given the likely mechanism of action of PoNS Treatment, we are exploring a range of other clinical applications including Parkinson's Disease, cognitive disorders, the treatment of addiction, xerostomia and other neurological conditions. We will require additional funding, in the form of grants and partnerships with collaborators, to expand our clinical development.

Our Partnership with the U.S. Army

In July 2015, we entered into a sole source cost sharing agreement, or the U.S. Army Agreement, with the U.S. Army for the commercial development of the PoNS Treatment for chronic balance deficits related to mild- to moderate-TBI. Pursuant to the U.S. Army Agreement, the laboratories of the U.S. Army Medical Material Agency, or USAMMA, and the U.S. Army Medical Research and Material Command, or USAMRMC, the "Army Laboratories," agreed to cooperate with NHC, our wholly-owned subsidiary, on clinical studies and regulatory responsibilities necessary to obtain FDA marketing authorization for this indication. Under the U.S. Army Agreement, NHC is the sole regulatory sponsor and will oversee and execute all required clinical studies. Further, the U.S. Army will reimburse NHC for the initially budgeted costs related to the registrational clinical trial of the safety and effectiveness of the PoNS Treatment for chronic balance deficits related to mild to moderate TBI, up to a maximum amount of $3.0 million. The U.S. Army Agreement terminates on December 31, 2018 unless the parties agree to extend the term.

We previously entered into a collaborative relationship with the U.S. Army, pursuant to a February 2013 cooperative research and development agreement as amended, or the CRADA, to determine if the PoNS Treatment could be developed for commercial use in the treatment of soldiers and others with a variety of military-relevant neurological manifestations of TBI, including tinnitus, post-traumatic stress disorder, pain and any subsequent indications identified by the parties. Under the CRADA, NHC is the sole regulatory sponsor of the PoNS Treatment, and the Army Laboratories provide support for the execution of clinical studies for FDA marketing authorization.

Based on our research and development work performed under the CRADA, we intend to initially seek FDA marketing authorization only for treatment of patients with chronic balance deficits due to mild- to moderate-TBI. Should we obtain FDA marketing authorization for this indication, we plan to develop the PoNS Treatment to treat other indications caused by neurological disorders. We would sponsor the regulatory process for these additional indications, but the Army Laboratories has agreed to support the execution of required studies. The amount of such support, if any, and the terms of such responsibility to support such studies are not yet negotiated, and we have no assurance that we can ultimately reach agreement with the Army Laboratories on such amount or terms of support. There can be no assurance that the Army Laboratories will not otherwise attempt to renegotiate its responsibilities under the U.S. Army Agreement or the CRADA.

The CRADA may be terminated by NHC or the Army Laboratories unilaterally at any time by providing the other party written notice at least 30 days prior to the desired termination date. The CRADA is subject to a four-year automatic extension as required for both FDA marketing authorization in the event that a pre-market approval application with the FDA is required, as well as for commercialization of the PoNS Treatment. The CRADA terminates on December 31, 2018 unless the parties agree to extend the term. We are required to commercialize the PoNS Treatment by December 31, 2021.

As of December 31, 2017, we have received a total of approximately $3.0 million with respect to reimbursements for expenses owed to the us for completion of development milestones, of which $0.2 million of the total received has been recorded as an advance against the fifth and final milestone. All reimbursement amounts received are credited directly to research and development expenses.

Manufacturing

We presently have relationships with three vendor partners on the design, development and manufacturing of the PoNS device: Cambridge Consulting, LLC, or Cambridge, Ximedica, LLC, or Ximedica and Key Tronic Corporation, or Key Tronic. Ximedica was our original design and development and clinic unit manufacturing partner. In January 2017, we entered into an agreement with Cambridge, pursuant to which Cambridge assumed responsibilities for the design and development, performance of the engineering and design verification testing of the PoNS device and documentation support for the FDA submission, and to assist in the identification of, and transition to, our commercial-scale manufacturer.

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

We place an emphasis on protecting our patented technology, trade secrets and know-how and only share confidential information on an as needed basis. Ximedica and Key Tronic are registered as medical device manufacturers 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. In addition, on November 30, 2016, NHC received our ISO 13485 certification.

Commercialization

We believe that, due to the lack of non-invasive devices currently on the market, if commercialized, the PoNS Treatment will be the first and only treatment that addresses the high unmet needs of brain injury patients with balance disorders.

PoNS in Civilian Population

In the United States, there are approximately five million patients suffering from chronic symptoms due to TBI, of which approximately 40% have balance and gait disorder as their primary complaint. By definition all TBIs are the result of an accident, with the patient's workers' compensation responsible for the medical and income replacement costs for those injured at work.

Our commercialization strategy is premised on leveraging workers' compensation, or WC, payers to drive early reimbursements and entice disability, Medicaid/Medicare and other commercial payers to study the experience in the WC market to help accelerate support for coverage under Medicaid/Medicare. As the PoNS Treatment has been deemed a non-significant risk device study for TBI, under Institutional Review Board, or IRB, supervision we intend to launch clinical experience programs for TBI patients to develop and test our commercialization strategy prior to FDA clearance and launch. Specifically, we intend to undertake the following:

- Engage with target WC payers to demonstrate the health economic benefit of a 14-week PoNS Treatment.
- Engage high visibility neurorehabilitation clinics to participate in clinical experience programs to accelerate commercial infrastructure at launch.
- Leverage new patients in hospital/clinic systems to build clinic revenues by providing other non-PoNS related services such as MRIs, sleep therapy or other complimentary services.

In addition, we intend to leverage high demand and hospital/clinic system savings to drive premium pricing for the PoNS Treatment, as well as target our marketing activity at physical therapy clinic systems to drive demand into their system, by negotiating exclusivity for a given territory and time-period. Further, we intend to leverage the clinic system equity to target physical therapy clinic referral base for an efficient deployment of our sales representatives.

Our clinical experience program contemplates identifying "clinical centers of excellence" around the country and conducting training with these centers in the use of the PoNS device along with the specific therapeutic protocol, with participants selected based on an established criterion. This would also be reinforced with patient, clinician and claim staff outreach and education.

PoNS in the U.S. Army

The U.S. Army's interest in the PoNS Treatment stems from the high incidence of TBI in soldiers and the fact that there are few proven, effective treatments available for those soldiers who suffer from chronic TBI symptoms. While the number of cases of TBI among active duty personnel may vary based on troop levels maintained by the federal government, our primary target market will be the large number of retired soldiers within the Veteran's Administration, or VA, system who suffer from chronic TBI symptoms as this population is less subject to material, year-to-year fluctuation. Based on the U.S. Army's indication of interest, we estimate that there is a sufficient potential market of active duty and retired soldiers who could potentially benefit from the PoNS treatment due to their chronic TBI symptoms. However, the U.S. Army is not under any obligation to purchase our product under the U.S. Army Agreement, the CRADA or any other agreement with us, and there is no assurance that the U.S. Army will ultimately purchase our product, even if we do demonstrate effectiveness and obtain FDA marketing authorization.

If it ultimately decides to purchase the PoNS Treatment from us, we expect that the U.S. Army would deploy the treatment to active duty personnel through their rehabilitation centers under orders from the central medical command. All personnel are expected to be certified PoNS therapists supported by live, paper and video-based training materials developed through this project by the U.S. Army. We also intend to pursue other military organizations in relevant countries based on need and size of potential deployment.

As part of our clinical experience program we intend to also focus on the nation's defense and veterans brain injury centers which is comprised of a network of eighteen centers, operating out of thirteen military treatment facilities and five Department of Veterans Affairs medical centers. We intend to establish pre-launch clinical experience programs in certain select centers.

PoNS Outside the United States

We intend to commercialize the PoNS device outside the United States, subject to approval by foreign regulatory authorities. We will evaluate the benefits of commercialization in certain territories either independently or with collaboration partners. For example, we intend to enter into a definitive exclusive license agreement with A&B (HK) Company Limited to commercialize the PoNS device in certain Asian countries.

Competition

The neurostimulation market is predominately comprised of invasive technologies that are growing but are not directly competitive with our technology. Our competitors in the industry are predominantly large, publicly-traded companies that have a history in the market, have significantly easier access to capital and other resources and have an established product pipeline. The combined clinical research and product development done by the industry, including by us and all of our competitors, is uncovering the secrets of neuro-modulation which now establishes neurostimulation as a legitimate and scientifically validated approach to the treatment of neurological conditions, and accordingly, we expect for competition in the non-invasive space to grow in the future. However, we believe that we will have the first-mover advantage in the non-invasive neurostimulation space.

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

Advantages of the PoNS Treatment

We believe that the PoNS Treatment offers the following benefits over existing neuro-stimulation technologies:

- The PoNS Treatment stimulates the trigeminal nerve which developing science has implicated to be beneficial in some neurological disorder models. The PoNS Treatment stimulates the lingual part of the nerve through the tongue, while other technologies stimulate other branches of the trigeminal nerve. It is the largest branch, having the highest amount of nerve fibers of the three branches. We believe this will be an advantage in 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 treatment.
- The tongue has an anatomically unique surface with a high density of receptors, a consistently moist and conductive environment, constant pH, constant temperature and a direct connection to the brain through at least two cranial nerves.
- We believe that the trigeminal and facial cranial nerves offer a high-bandwidth pathway for impulses to directly affect the central nervous system. The trigeminal and facial 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 allows impulses be sent through sites regulating dozens of functions.
- Unlike deep brain stimulation devices, implantable vagal nerve devices and other invasive forms of electrical stimulation, the tongue allows for neurostimulation to be delivered non-invasively and portably. This opens the door for integration of neurostimulation with a wide range of therapies previously unexplored for neurological rehabilitation.

Reimbursement

With the completion of our registrational clinical trials and should we obtain FDA marketing authorization for the treatment of balance disorder in mild- to moderate-TBI, and ultimately receive customer orders for the PoNS Treatment, we plan to submit applications for appropriate reimbursement codes so that insurers, including WC payers, disability payers, commercial payers, Medicare and Medicaid, are able to pay for the treatment. We plan to seek coverage and reimbursement of the PoNS Treatment as a whole, applying for reimbursement codes for the combination of stimulations and the associated physical or cognitive therapy. There are complex laws, regulations and guidance that set forth Medicare coverage and reimbursement policies. To help us navigate the regulatory complexities, we have engaged consultants to assist us with our reimbursement strategy.

From time to time, Congress enacts laws that impact Medicare coverage and reimbursement policy. In addition, the Centers for Medicare & Medicaid Services, or CMS, regularly engage in rulemaking activities and issues instructions and guidance that may affect Medicare coverage and reimbursement policy. Similarly, the federal and state governments may enact future laws or issue regulations or guidance that may impact Medicaid coverage and reimbursement policies, or the coverage and reimbursement policies of private insurers. We must ensure that we are in full compliance with all applicable requirements, and that we remain abreast of potential legislative or regulatory developments that could impact our business. For all payers, the PoNS Treatment must fit within an identifiable coverage category and fully meet the requirements of such category.

We initially intend to leverage what we learn from our clinical experience programs and seek coverage for the PoNS Treatment through workers' compensation and disability insurance, for those injured through work or leisure. We intend to contract with WC payers and third-party administrators for a 14-week PoNS Treatment unit and at the same time contract with some of the large rehabilitation centers in the United States who will provide the physical therapy. We believe that the WC case managers have the ability to identify potential patients for the treatment and refer those patients to physicians for a prescription to be generated and a PoNS certified physical therapy center identified. At the end of the 14-week treatment, patients will return to their physician for evaluation of their progress and future

needs. It is also possible that in some states the physical therapist would undertake the evaluation. We believe that this process should enable us to get reimbursement faster than the time experienced by other medical devices.

We understand that the process for obtaining coverage from commercial and public payers could be up to a 24-month process from the time a medical device receives marketing authorization. We intend to begin pursuing such coverage upon clearance and will be guided by our experiences in working through the WC process as there are many pathways to consider. As part of the coverage process, we may have to submit an application request to CMS, to revise the Healthcare Common Procedure Coding System, or HCPCS, level II national code set so that the PoNS Treatment becomes eligible to be covered and reimbursed, not only by Medicare, but by other public and private payers. The HCPCS Level II Code Set is a standardized coding set used for claims submitted to public and private payers that identifies products, supplies and services. At present, we do not believe that the PoNS Treatment would fit easily within an existing HCPCS code as the PoNS Treatment requires the combination of stimulation and targeted physical therapy. Thus, we are considering submitting a request to CMS for a new HCPCS code and are evaluating our options with our consultants. An applicant can request that (i) a new permanent code be added to the HCPCS level II national code set; (ii) the language used to describe an existing code be modified; or (iii) an existing code be deleted. However, prior to submitting the coding request application, we must satisfy several criteria, including but not limited to receiving documentation of the FDA's marketing authorization of the device and have sufficient claims activity or volume in the United States (evidenced by 3 months of marketing activity). The national codes are updated annually. Coding requests must be received by January 3 of the current year to be considered for the January update of the following year.

At launch, we will support our customers with hub services to aid in submitting the expense to private insurers as well as the communication between the patient, physician and physical therapist. The PoNS device is a smart-device with built in technology to allow tracking of patient use including time and intensity of treatments. We have also created a device management application which allows the physical therapist to gather the information from the device on the patient's usage to guide further treatment option discussions with the patient's physician. This data can also be used to support reimbursement and coverage decisions by insurance carriers.

In addition, Medicare and other insurers must find that the PoNS Treatment is medically reasonable and necessary for the treatment of patients' illness or injuries. If Medicare and other insurers find that the PoNS Treatment does not meet their medical necessity criteria, it will not be reimbursed. Medicare and commercial insurers must also develop a payment amount for the PoNS Treatment. If that amount is inadequate to cover the costs of the PoNS Treatment, healthcare providers will be unlikely to use this therapy.

Intellectual Property

Licensed Intellectual Property

Pursuant to the Second Amended and Restated Patent Sub-License agreement dated June 6, 2014 entered into between Advanced NeuroRehabilitation LLC, or ANR, and NHC, ANR has granted NHC 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	Utility patent covering 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
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; and 9,656,069 claim priority to U.S. Patent No. 8,849,407.

A U.S. provisional patent application provides the means to establish an early effective filing date for a later filed nonprovisional patent application. Therefore, though the two provisional applications have expired, they establish a priority date for U.S. Patent Nos. 8,849,407; 8,909,345; 9,020,612; 9,656,078; 9,597,501; 9,597,504; and 9,656,069, 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. Patent No. 8,849,407 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; and 9,656,069 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; and 9,656,069 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 NHC or ANR shall be owned by NHC, provided that if NHC decides not to patent such improvements, ANR may choose to pursue patent rights independently. Pursuant to the Sublicense Agreement, NHC has agreed to pay ANR royalties equal to 4% of NHC'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 NHC, 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, NHC 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 NeuroHabilitation Corporation 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, NHC 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 NHC's business and to produce and derive revenues from devices and services in connection with investigational uses of the PoNS device and related technology.

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

On April 17, 2017, we announced that the USPTO had issued two medical method patents (U.S. Patent Nos. 9,597,501 and 9,597,504) that together further protect the intellectual property rights for our core asset, the PoNS device therapeutic techniques. These patents bolster the current family of PoNS patents protecting various forms of physical and cognitive therapy combinations with both skin and oral cavity stimulation using the PoNS device or any equivalent neurostimulation device.

Company Owned Intellectual Property

On May 23, 2017, we announced that the USPTO had issued its first method patent (US Patent No. 9,656,069) that features claims directed to the use of the PoNS device for human performance improvement rather than rehabilitation therapy. This patent is the first member of the existing family of patents we have received for our PoNS device. We have filed 29 U. S. patent applications related to various technical and ornamental aspects of the PoNS device. We have also filed 13 non-provisional patent applications that describe various technical features in the current version device and 16 design patent applications describing various ornamental designs. We are the sole assignee for these 29 U.S. patent filings. Prior to issuance, once the USPTO determines that a patent application meets all of the statutory requirements for patentability it provides a notice of allowance. In addition to the first issued patent (U.S. Patent No.

9,072,889), the USPTO has issued nine utility patents, 16 design patents and provided notices of allowance for utility applications 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	Allowed	N/A	N/A	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	Pending	N/A	N/A	Utility patent covering the locators of the mouthpiece
14/559,118	12/3/2014	Issued	9,656,060	5/23/2017	Utility patent covering methods of manufacturing the mouthpiece
15/484,077	4/21/2017	Pending	N/A	N/A	Utility application covering overall system design, including controller and mechanical details of the mouthpiece
15/602,055	9/5/2017	Pending	N/A	N/A	Utility application covering methods of manufacturing the mouthpiece
29/510,741	12/3/2014	Issued	D750264	2/23/2016	Design patent covering an alternative version of the current PoNS device (over-ear double boom design)
29/510,742	12/3/2014	Issued	D749746	2/16/2016	Design patent covering an alternative version of the current PoNS device (overhead minimal interference design)
29/510,743	12/3/2014	Issued	D752236	3/22/2016	Design patent covering system design used in the current PoNS device
29/510,745	12/3/2014	Issued	D750265	2/23/2016	Design patent covering an alternative mouthpiece not used in the current PoNS device

U.S. Patent Application No.	Application Filing Date	Status	U.S. Patent No.	Issue Date	Subject Matter
29/510,754	12/3/2014	Issued	D750794	3/1/2016	Design patent covering the controller used in the PoNS device
29/510,755	12/3/2014	Issued	D751215	3/8/2016	Design patent covering an alternative controller not used in the current PoNS device
29/510,746	12/3/2014	Issued	D750266	2/23/2016	Design patent covering an alternative mouthpiece not used in the current PoNS device
29/510,749	12/3/2014	Issued	D750268	2/23/2016	Design patent covering an alternative mouthpiece not used in the current PoNS device
29/510,747	12/3/2014	Issued	D751213	3/8/2016	Design patent covering an alternative mouthpiece not used in the current PoNS device
29/510,748	12/3/2014	Issued	D750267	2/23/2016	Design patent covering an alternative mouthpiece not used in the current PoNS device
29/510,750	12/3/2014	Issued	D753315	4/5/2016	Design patent covering mouthpiece used in the current PoNS device
29/510,751	12/3/2014	Issued	D751722	3/15/2016	Design patent covering an alternative controller not used in the current PoNS device
29/510,752	12/3/2014	Issued	D752766	3/29/2016	Design patent covering an alternative controller not used in the current PoNS device
29/510,753	12/3/2014	Issued	D753316	4/5/2016	Design patent covering an alternative controller not used in the current PoNS device
29/510,744	12/3/2014	Issued	D760397	6/28/2016	Design patent covering alternative system design used in the current PoNS device
29/510,756	12/3/2014	Issued	D759830	6/21/2016	Design patent covering alternative system design used in the current PoNS device

In addition to its U.S. patents, We have been granted four foreign utility patents (three in Australia and one in Eurasia), and 11 foreign design patents (seven in Canada, three in Russia, and one community design in Europe), as detailed in the tables below.

Foreign Utility Patents

Australian Application No.	Application Filing Date	Status	Australian Patent No.	Issue Date	Subject Matter
2015355211	6/4/2017	Issued	2015355211	11/16/2017	Utility patent covering overall system design, including controller and mechanical details of the mouthpiece
2015355212	6/4/2017	Issued	2015355212	12/21/2017	Utility patent covering center of gravity of the mouthpiece
2017218934	8/19/2017	Issued	2017218934	1/3/2018	Utility patent covering overall system design, including controller and mechanical details of the mouthpiece

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

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	6/3/2015	Issued	002712026	9/4/2015	Design patent covering several aspects of the system design currently used in the PoNS device

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

Australian Application No.	Application Filing Date	Status	Australian Patent No.	Issue Date	Subject Matter
2017228517	9/11/2017	Pending	N/A	N/A	Utility application covering the shape of the mouthpiece

Canadian Application No.	Application Filing Date	Status	Canadian Patent No.	Issue Date	Subject Matter
2,969,729	6/2/2017	Pending	N/A	N/A	Utility application covering overall system design, including controller and mouthpiece, and authentication techniques
2,969,731	6/2/2017	Pending	N/A	N/A	Utility application covering various aspects of the mouthpiece such as shape, center of gravity, and the locators

European Application No.	Application Filing Date	Status	European Patent No.	Issue Date	Subject Matter
15813638.2	7/3/2017	Pending	N/A	N/A	Utility application covering overall system design, including controller and mouthpiece, and authentication technique
15812899.1	7/3/2017	Pending	N/A	N/A	Utility application covering various aspects of the mouthpiece such as shape, center of gravity, and the locators

Israeli Application No.	Application Filing Date	Status	Israeli Patent No.	Issue Date	Subject Matter
252648	6/4/2017	Pending	N/A	N/A	Utility application covering overall system design, including controller and mouthpiece
252649	6/4/2017	Pending	N/A	N/A	Utility application covering center of gravity of the mouthpiece

Russian Application No.	Application Filing Date	Status	Russian Patent No.	Issue Date	Subject Matter
2017123125	6/29/2017	Pending	N/A	N/A	Utility application covering overall system design, including controller and mouthpiece
2017123041	6/29/2017	Pending	N/A	N/A	Utility application covering center of gravity of the mouthpiece

Currently, we use four trademarks in connection with the operation of our business: PoNS, NeuroHabilitation, NHC 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 the sole owner of the rights in the NeuroHabilitation and NHC trademarks, and we are the owner of the rights in the Helius Medical Technologies mark. On October 31, 2014, we filed trademark applications in the USPTO for these four trademarks.

On January 7, 2015, we filed trademark applications with the Canada Intellectual Property Office, claiming priority to the corresponding U.S. applications filed on October 31, 2014. We are the owner of the rights in the NeuroHabilitation, NHC, and PoNS marks in Canada, and we are the owner of the rights in the Helius Medical Technologies mark in Canada. We have also applied for the PoNS trademark in Canada, Europe, Russia and China.

Government Regulation

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

FDA Regulation of Medical Devices

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

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

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

The FDA Review, Clearance and Approval Processes

Each medical device we seek to commercially distribute in the United States must first receive either clearance under Section 510(k) of the FD&C Act, receive *de novo* down-classification and 510(k) clearance, or pre-market approval application, or PMA, from the FDA, unless specifically exempted by the FDA. FDA review and approval is required for each intended use of a device, regardless of whether the device has been approved for other indications for use. The FDA classifies all medical devices into one of three classes. Devices deemed to pose the lower risk are categorized as either Class I or II, which requires the manufacturer to submit to the FDA a 510(k) pre-market notification application requesting clearance of the device for commercial distribution in the United States, unless the device is exempted from this requirement. 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 previously 510(k) cleared device are categorized as Class III and require submission and approval of a PMA.

In the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data may be required to support a determination of substantial equivalence. The PMA pathway requires an applicant to demonstrate the safety and effectiveness of the device based, in part, on extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. However, some devices are automatically assigned to Class III regardless of the level of risk they pose, because they have not previously been classified into a lower risk class by the FDA. Manufacturers of these devices may request that the FDA review such devices in accordance with the *de novo* classification procedure, which allows a manufacturer whose novel device would otherwise require the submission and approval of a PMA prior to marketing to request down-classification of the device on the basis that the device presents low or moderate risk. If the FDA agrees with the down-classification, the applicant will then receive clearance of a 510(k) to market the device. This cleared device can then be used as a predicate device for future 510(k) submissions by the manufacturer or a competitor.

We intend to utilize the *de novo* classification procedures to seek marketing authorization for the PoNS device, because there is currently no predicate cleared or approved by the FDA for commercial distribution and no existing classification decision by the FDA for such a device. The process of obtaining regulatory clearances or approvals, or completing 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.

If the FDA requires us to go through a lengthier, more rigorous examination for the PoNS device, introducing the product could be delayed or canceled, which could cause our launch to be delayed. In addition, the FDA may determine that the PoNS device requires the more costly, lengthy and uncertain PMA process. For example, if the FDA disagrees with our determination that the *de novo* classification procedures are the appropriate path to obtain marketing authorizations for the PoNS device, the FDA may require us to

submit a PMA application, which is generally more costly and uncertain and can take from one to three years, or longer, from the time the application is submitted to the FDA until an approval is obtained. Further, even with respect to those future products where a PMA may not be required, we cannot be certain that we will be able to obtain 510(k) clearances with respect to those products.

510(k) Clearance Process

To obtain 510(k) clearance, we must submit a pre-market notification to the FDA demonstrating that the proposed device is substantially equivalent to a previously-cleared 510(k) device or is a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of a PMA application. The FDA's 510(k) clearance process usually takes from three to 12 months from the date the application is submitted and filed with the FDA but may take significantly longer and clearance is never assured. Although many 510(k) pre-market notifications are cleared without clinical data, in some cases, the FDA requires clinical data to support substantial equivalence. In reviewing a pre-market notification submission, the FDA may request additional information, which may significantly prolong the review process.

After a device receives 510(k) clearance, any subsequent modification of the device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new 510(k) clearance or could require a PMA. The FDA requires each manufacturer to make this determination initially, but the FDA may review any such decision and may disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA may require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or PMA approval is obtained. Under these circumstances, the FDA may also subject a manufacturer to significant regulatory fines or other penalties. In addition, the FDA is currently evaluating the 510(k) process and may make substantial changes to industry requirements, including which devices are eligible for 510(k) clearance, the ability to rescind previously granted 510(k)s and additional requirements that may significantly impact the process.

De novo Classification Process

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

As previously discussed, we plan on utilizing the *de novo* classification process to obtain marketing authorization for the PoNS device for balance disorder in mild- to moderate- TBI, and we plan to seek Class II classification. In order to be placed in Class II, the FDA would need reasonable assurance of safety and effectiveness of the PoNS device. Under Class II, general controls (e.g., premarket notification) and special controls (e.g., specific performance testing) would be applicable. We are currently working to complete our device verification testing with our goal for submission of the *de novo* application and a 510(k) in the middle of 2018. To the extent the FDA completes its review in accordance with the goal of the medical device users fee amendments of 90 days, we anticipate marketing authorization in the second half of 2018.

Obtaining FDA marketing authorization, de novo down-classification, or approval for medical devices can be 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.

Pre-market Approval Process

A PMA must be submitted if the medical device is in Class III (although the FDA has the discretion to continue to allow certain pre-amendment Class III devices to use the 510(k) process) or cannot be cleared through the 510(k) process. A PMA must be supported by,

among other things, extensive technical, preclinical, clinical trial, manufacturing and labeling data to demonstrate to the FDA's satisfaction the safety and effectiveness of the device for its intended use.

After a PMA is submitted and filed, the FDA begins an in-depth review of the submitted information, which typically takes between one and three years, but may take significantly longer. During this review period, the FDA may request additional information or clarification of information already provided. Also, during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a pre-approval inspection of the manufacturing facility to ensure compliance with Quality System Regulations, or QSR, which may impose elaborate design development, testing, control, documentation and other quality assurance procedures in the design and manufacturing process. The FDA may approve a PMA with post-approval conditions intended to ensure the safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution and collection of long-term follow-up data from patients in the clinical study that supported approval. Failure to comply with the conditions of approval can result in materially adverse enforcement action, including the loss or withdrawal of the approval. New PMAs or supplements are required for significant modifications to the manufacturing process, labeling of the product and design of a device that is approved through the PMA process. PMA supplements often require submission of the same type of information as an original pre-market approval application, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require extensive clinical data or the convening of an advisory panel.

Clinical Trials

A clinical trial is typically required to support a PMA and is sometimes required for a 510(k) pre-market notification. FDA's regulations require submission and approval of an Investigational Device Exemption, or IDE, for all clinical investigations of significant risk medical devices to determine safety and effectiveness. Abbreviated requirements apply for non-significant risk device studies. After a clinical trial begins, the FDA may place it on hold or terminate it if, among other reasons, it concludes that the clinical subjects are exposed to an unacceptable health risk. Any clinical trials we conduct must be conducted in accordance with FDA regulations as well as other federal regulations and state laws concerning human subject protection and privacy. Moreover, the results of a clinical trial may not be sufficient to obtain clearance or approval of the product, and separate clinical trials may be necessary to obtain clearance for multiple uses of one device.

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

After a medical device is placed on the market, numerous FDA regulatory requirements apply, including, but not limited to the following:

- the QSR, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures during the manufacturing process;
- establishment registration, which requires establishments involved in the production and distribution of medical devices, intended for commercial distribution in the United States, to register with the FDA;
- medical device listing, which requires manufacturers to list the devices they have in commercial distribution with the FDA;
- correction and removal reporting regulations which require that manufacturers report to the FDA field corrections and product recalls or removals undertaken to reduce a risk to health posed by the device or remedy a violation of the FD&C Act that may present a risk to health;
- labeling regulations, which prohibit "misbranded" devices from entering the market, as well as prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling;
- clearance or approval of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use;
- post-market surveillance including Medical Device Reporting, which requires manufacturers report to the FDA 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.

Our Corporate History Highlights

Formation and Arrangement with Boomerang Oil, Inc.

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

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

Reincorporation in Wyoming

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

Acquisition of NeuroHabilitation Corporation and Concurrent Financing

On June 13, 2014, we completed the acquisition of NHC by way of an agreement and plan of merger. We refer to this transaction as the Reverse Merger. Pursuant to the agreement and plan of merger, HMT Mergersub, Inc., our wholly-owned subsidiary, merged with and into NHC with NHC as the surviving corporation. In connection with the Reverse Merger, we issued an aggregate of 7,060,016 shares of our Class A common stock, or our common stock, to the former shareholders of NHC. 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.

In connection with the Reverse Merger, we completed a non-brokered private placement financing of $7.02 million (CAD$7.62 million) by issuing 3,048,000 subscription receipts. Pursuant to its terms, each subscription receipt automatically converted into one unit upon satisfaction of certain escrow release conditions, which had been satisfied. Each unit consisted of one share of our common stock and one-half of one share purchase warrant with each whole warrant being exercisable at CAD$5.00 per share for a period of two years.

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

Following our Reverse Merger, we obtained approval of the listing of our common stock on the Canadian Securities Exchange, or CSE. On April 18, 2016, our common stock was listed on the Toronto Stock Exchange, or TSX, under the symbol "HSM." At the same time, we delisted our common stock from the CSE. Our Warrants were also approved for listing on the TSX on April 18, 2016. The Company's common stock also began trading on the OTC Markets, or OTCQB, under the ticker symbol "HSDT" on February 10, 2015.

Reverse Stock Split

Effective after the close of business on January 22, 2018, we completed a 1-for-5 reverse stock split of our Class A Common Stock. Since January 23, 2018, our Class A common stock has traded on a post-split basis on the OTCQB and Toronto Stock Exchange. All share and per share amounts in this Annual Report have been reflected on a post-split basis.

Corporate Information

Our principal executive offices are located at 642 Newtown Yardley Road, Suite 100 Newtown, PA 18940 and our telephone number is 215-944-6100. We maintain a corporate website at www.heliusmedical.com. We make available free of charge through our Internet website our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and any amendments to these reports, as soon as its reasonably practicable after we electronically file such material with, or furnish such material to the SEC. We are not including the information on our website as a part of, nor incorporating it by reference into this report. You may read and/or copy any materials we file at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for information on the Public Reference Room. Additionally, the SEC maintains a website that contains annual, quarterly, and current reports, proxy statements, and other information that issuers (including us) file electronically with the SEC. The SEC's website address is http://www.sec.gov.

Employees

As of December 31, 2017, we had ten full time employees and 40 full-time equivalent independent contractors. With the completion of our registrational clinical trial, we continue to work on completing certain activities required as part of our marketing application that we submit to FDA for clearance of the PoNS device. We intend to invest in our scale manufacturing capabilities, internal infrastructure for core functionality, as well as full commercialization resources.

Business Uncertainties and Going Concern Risk

To date we have not generated any revenue from the sales of products or services. There are a number of conditions that we must satisfy before we will be able to generate revenue, including but not limited to obtaining FDA, Health Canada, CE Mark in Europe and the TGA, in Australia, clearance of the PoNS Treatment for balance disorder associated with TBI, manufacturing of a commercially viable

version of the PoNS device, demonstration of safety and effectiveness sufficient to generate commercial orders by customers for our product and the creation of a national framework of PoNS-certified therapists. To date, we have not achieved many of these conditions, and the successful achievement of such conditions will require significant expenditures. Because we have not generated any revenues, we are dependent entirely on funding from outside investors. There is no guarantee that such funding will be available at all or in sufficient amounts to satisfy our required expenditures. Furthermore, even if we were able to raise sufficient capital to successfully design and manufacture a commercially viable version of the PoNS device and to receive FDA, CE Mark, Health Canada or TGA clearance, we do not currently have any contract or other arrangement to sell the PoNS Treatment. Accordingly, we cannot know for certain that we will ever be able to generate any revenue from the sales of products or services.

Additionally, based on management's assessment there is substantial doubt about the Company's ability to continue as a going concern. This means that there is substantial doubt that we can continue as an on-going business for the next twelve months. While we had $5.6 million of cash as of December 31, 2017, we do not currently have sufficient resources to accomplish all of the above conditions necessary for us to generate revenue. In reviewing this filing, you should carefully consider the risks described in the section entitled "Risk Factors" and other risks described throughout this Annual Report.

ITEM 1A. RISK FACTORS

RISK FACTORS

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

Risks Related to Our Financial Position and Need for Capital

We have a very limited operating history and 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 are a holding company and have no material assets other than cash and our ownership of all of the outstanding shares of NHC, which is our wholly owned subsidiary. NHC was incorporated in Delaware on January 22, 2013 and has had limited operations to date.

We have incurred substantial net losses since our inception. For the year ended December 31, 2017 and nine months ended December 31, 2016, we incurred a net loss of $28.0 million and $12.0 million, respectively, and used cash in operations of $19.3 million and $7.9 million respectively. We have an accumulated deficit of $66.4 million as of December 31, 2017. Our losses have resulted primarily from costs incurred in connection with our design, manufacturing and development, research and development activities, stock-based compensation, legal, advertising, marketing and investor relations, and general and administrative expenses associated with our operations. Even if we are successful in obtaining marketing authorization from the FDA in order to launch our PoNS Treatment in the United States or foreign regulatory authorities to launch outside of the United States, we expect to continue to incur substantial losses for the foreseeable future as we continue to research and develop and seek regulatory marketing authorization for our product candidate.

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

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

We currently have limited working capital and liquid assets. We held cash totaling $5.6 million at December 31, 2017. To date we have not generated any revenue from the sales of products or of services. There are a number of conditions that we must satisfy before we will be able to generate revenue, including but not limited to FDA marketing authorization of the PoNS device for mild- to moderate- TBI, manufacturing of a commercially-viable version of the PoNS device, obtaining favorable reimbursement from third party payers, and demonstration of effectiveness sufficient to generate commercial orders by customers for our product. While we are seeking additional funding, we do not currently have sufficient resources to accomplish all of these conditions necessary for us to generate revenue, and we do not expect to generate revenue in an amount sufficient to fund our operations for the foreseeable future. We will therefore require substantial additional funds in order to continue to conduct the research and development and regulatory authorization activities necessary to bring our product to market, to establish effective marketing and sales capabilities and to develop other product candidates. Our existing capital resources will not be sufficient to enable us to fund the completion of the development and commercialization of our current product and our product candidates. We cannot determine with certainty the duration and completion costs of the current or future development and commercialization of our product candidate or if, when, or to what extent we will generate revenues from the commercialization and sale of our current product candidate or potential future product candidates for which we obtain regulatory marketing authorization. We may never succeed in achieving regulatory authorization for our current product candidate and any potential future product candidates. We may be unable to raise the additional funding to finance our business on commercially reasonable terms, or at all. If we are unable to obtain additional financing as needed, we may be forced to reduce the scope of our operations and planned capital expenditures or sell certain assets, including intellectual property, and we may be forced to cease or wind down operations, seek protection under the provisions of the U.S. Bankruptcy Code, or liquidate and dissolve our company, which would have a material adverse effect on the value of our common stock..

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

To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of such securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through strategic partnerships with third parties, we may have to relinquish valuable rights to our technologies or product candidate, future revenue streams, research programs or product candidate, or otherwise grant licenses on terms that are not favorable to us. If we are unable to raise additional capital when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts for our product candidate or our preclinical product candidates, or grant rights to develop and market potential future product candidates that we would otherwise prefer to develop and market ourselves. Any of these events could adversely affect our ability to achieve our product development and commercialization goals and have a material adverse effect on our business, financial condition and results of operations.

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

In connection with our management's assessment, our report from our independent registered public accounting firm for the fiscal year ended December 31, 2017 includes an explanatory paragraph stating that our recurring losses from operations and net capital deficiency raise substantial doubt about our ability to continue as a going concern. If we are unable to obtain sufficient funding, our business, prospects, financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. For example, our existing capital resources will be insufficient to fund our operations beyond the first half of 2018. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our consolidated financial statements, and investors will likely lose all or a part of their investment. Future reports from our independent registered public accounting firm may also contain statements expressing substantial doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all.

Risks Related to the Development and Commercialization of our Product Candidate

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

We currently have no products authorized for commercial distribution. We are developing the PoNS Treatment for use in the neuromodulation market, but we cannot begin marketing and selling the device in the United States, Europe, Canada or Australia until we obtain authorizations from the FDA, EU, Health Canada or TGA, respectively. We have not yet submitted applications for regulatory authorization in any of these jurisdictions. The process of obtaining regulatory authorization is expensive and time-consuming and can vary substantially based upon, among other things, the type, complexity and novelty of a product. Changes in regulatory policy, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application may cause delays in the authorization of a product candidate or rejection of a regulatory application altogether. The FDA has substantial discretion in the *de novo* review and authorization processes and may refuse to accept any application or may decide that our data are insufficient for authorization and require additional pre-clinical, clinical, or other studies. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit, or prevent marketing authorization from the FDA or other regulatory authorities. Any marketing authorization from the FDA we ultimately obtain may be limited or subject to restrictions or post-market commitments that render the product candidate not commercially viable. If our attempts to obtain marketing authorization are unsuccessful, we may be unable to generate sufficient revenue to sustain and grow our business, and our business, financial condition, and results of operations will be materially adversely affected.

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

We may encounter substantial delays in our clinical trials, or our clinical trials may fail to demonstrate the safety and efficacy of the PoNS device to the satisfaction of applicable regulatory authorities.

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

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

Our deployment strategy in the civilian population depends on physicians prescribing the PoNS Treatment to patients with relevant neurological disorders and physical therapists being trained in the supervision of patients' use of our treatment. While the effectiveness of our PoNS technology to treat balance disorders related to TBI or any other neurological disorder has not been established in studies conducted in a controlled environment designed to produce scientifically significant results, it remains a new, "untested," and therefore unproven, treatment. Such technologies are usually more slowly adopted by the medical community as the medical community tends to be very conservative. Physicians may elect not to use our products for a variety of reasons, including:

- lack or perceived lack of evidence supporting the beneficial characteristics of our technology;
- limited long-term data on the use of PoNS technology for therapy;
- physicians' perception that there are insufficient advantages of our product relative to currently available products;
- our inability to effectively train physical therapists in the supervision of patients' use of the therapy;
- hospitals may choose not to purchase our product;
- group purchasing organizations may choose not to contract for our product, thus limiting availability of our products to hospital purchasers;
- lack of coverage or adequate payment from managed care plans and other third-party payers for our product;
- Medicare, Medicaid or other third-party payers may limit or not permit reimbursement for our product; and
- the development or improvement of competitive products.

If the medical community is slow to adopt, or declines to adopt our PoNS Treatment for neurostimulation therapy, we will not be able to generate significant revenues, if any, which would have a material adverse effect on our business.

There is limited market awareness of our product and the neuromodulation market is new and uncertain.

There is currently limited market awareness of our product. In order to succeed, we must, among other things, increase market awareness of our PoNS Treatment and implement a sales and marketing strategy. If we fail in any of these endeavors or experience delays in pursuing them, we will not generate revenues as planned and will need to curtail operations or seek additional financing earlier than otherwise anticipated. In addition, if the neuromodulation market fails to become more integrated in neurological therapy, it could have a materially adverse effect on our business and financial position.

We face significant competition in an environment of rapid technological change, and our competitors may develop devices or products that are more advanced or more effective than ours, 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 for 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. 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 Treatment uneconomical or obsolete.

Risks Related to our Reliance on Third Parties

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

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

Our subsidiary NHC is party to a sole source contract with the U.S. Army. Pursuant to the sole source contract, the U.S. Army has agreed to cooperate with NHC on research to determine if the PoNS Treatment can be developed for commercial use in assisting physical therapy in the treatment of soldiers and others with balance disorders resulting from mild- to moderate- TBI; however, NHC is solely responsible for sponsoring the registrational trial and the sole regulatory sponsor for the PoNS treatment for this indication. The Army Laboratories, the inventors and background patent owners of the PoNS device have agreed through a collaborative research and development agreement, or the CRADA to support the execution of clinical studies for the PoNS device as a treatment for other mutually agreed upon military-relevant neurological disorders, which could include tinnitus, PTSD and pain and any subsequent indications identified by the parties. The amount of such support, if any, and the terms of such responsibility to support such clinical studies are not yet negotiated and we have no assurance that we can ultimately reach agreement with the Army Laboratories on such amount or terms of support, and there can be no assurance that the U.S. Army or USAMRMC will not otherwise attempt to renegotiate its responsibilities under the CRADA or the sole-source contractual agreement, respectively. The Army Laboratories may terminate their obligations under the CRADA at any time upon 30 days prior written notice to us. If there are insufficient funds available to cover the necessary research and development costs for our product, the Army Laboratories could terminate the CRADA and cease research and development efforts, which could jeopardize our ability to commercialize our PoNS Treatment.

If we fail to obtain FDA authorization for commercialization of or otherwise fail to ensure that the PoNS device is available for purchase by the U.S. Government by December 31, 2018, we are subject to significant risk of loss of data and proprietary rights and to certain contractual penalties.

Under the CRADA, if we fail to obtain FDA marketing authorization of the PoNS device by December 31, 2018 or otherwise fail to ensure commercialization of the PoNS Treatment is available for purchase by the U.S. Government by December 31, 2021, we may forfeit the right to pursue commercialization on our own. Specifically, in either such case, we will be required to (i) transfer possession, ownership and sponsorship of any regulatory application, and correspondence supporting the PoNS technology to the USAMRMC and (ii) provide the U.S. Government with a non-exclusive, irrevocable license to any patent, copyright, data rights, proprietary information and regulatory information, in order to permit the U.S. Government to pursue commercialization on its own. Any such loss of our ability to exclusively market and sell the PoNS Treatment would have a material adverse effect on our business.

Additionally, under our Strategic Agreement with A&B (HK) Company Ltd., or A&B, if we fail to obtain FDA marketing authorization for commercialization, or otherwise fail to ensure that the PoNS device is available for purchase by the U.S. Government, by December 31, 2021, we may be required to pay a $2.0 million contract penalty to A&B.

We depend on third parties for the manufacture of our product and the loss of these third-party manufacturers could harm our business.

We will be dependent on our third-party scale manufacturing partner to manufacture and supply our PoNS device for clinical and commercial purposes. Our new contract manufacturer will manufacture the units for our engineering and device verification testing and will build the launch quantities for our early commercialization. This contract manufacturer also has the capability to warehouse and ship our products to customers and multiple locations to expand capacity and back-up capabilities. Our reliance on third-party manufacturers to supply us with our PoNS device to provide such other distribution and warranty services exposes us to risks that could delay our sales or result in higher costs or lost product revenues. In addition, our manufacturers could encounter difficulties in achieving volume production, quality control and quality assurance or suffer shortages of qualified personnel, which could result in their inability to manufacture sufficient quantities of our commercially available product to meet market demand. Our third-party manufacturer and distributor may also fail to follow and remain in compliance with the FDA-mandated Quality System Regulations, or QSR, compliance which is required for all

medical devices, or fail to document their compliance to QSRs, either of which could lead to significant delays in the availability of materials for our product and/or FDA enforcement actions against them and/or us.

If we are unable to obtain adequate supplies of our product that meet our specifications and quality standards, it will be difficult for us to compete effectively. While we have supply agreements in place with our manufacturer, and they may change the terms of our future orders or choose not to supply us with products in the future. Furthermore, if such manufacturer fails to perform their 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. We will also need to obtain FDA approval for any new manufacturers. 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.

If the U.S. Army terminates the sole-source cost sharing contract or decides in the future not to purchase our product candidate, we would be forced to find new partners or customers in order to continue advancing the PoNS device.

The U.S. Army is under no obligation to purchase the PoNS device from us. If the U.S. Army were to eventually decide not to purchase our product, we would need to find other buyers for our product. If the U.S. Army were to decline to purchase our product, we may have more difficulty persuading other third parties to purchase our product, which would materially harm our business.

In order to be successful, we must expand our products beyond our single product by commercializing new potential product candidates, but we may not be able to do so in a timely fashion and at expected costs, or at all.

In order to be successful, we will need to expand our product lines beyond our PoNS Treatment for mild- to moderate-TBI, which is currently our only indication for our only product candidate. To succeed in our commercialization efforts, we must effectively continue product development and testing, obtain regulatory authorizations, and enhance our sales and marketing 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. If we fail in bringing our product candidates to market, or experience delays in doing so, we will not generate revenues as planned and will need to curtail operations or seek additional financing earlier than otherwise anticipated.

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

Risks Related to Intellectual Property

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

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

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

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

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

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

Risks Related to Government Regulation

Before we can market and sell our products, we will be required to obtain marketing authorization from the FDA and foreign regulatory authorities. These authorizations will take significant time and require significant research, development, and clinical study expenditures, and ultimately may not succeed.

Before we begin to label and market the PoNS Treatment for use in the United States, we are required to obtain authorization from the FDA under Section 510(k) of the FD&C Act, approval of a de novo reclassification petition for our product, or approval of pre-market application from the FDA, unless an exemption from pre-market review applies. We intend to utilize the de novo classification procedures to seek marketing authorization for the PoNS device for the treatment of mild- to moderate- TBI, because there is currently no predicate cleared or approved by the FDA for commercial distribution and no existing classification decision by the FDA for such a device. We will also be required to comply with costly and more often time-consuming compliance by foreign regulatory authorities if we want to sell our products outside of the United States. The process of obtaining regulatory clearances or approvals, or completing 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.

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

Moreover, we are currently developing the PoNS device for other potential indications. At this time, we do not know what pathways FDA or other regulatory authorities will require us to utilize for these additional indications. We may be required to pursue marketing authorization via more rigorous pathways, such as a PMA application in the United States, which may require more development work than we are currently planning. This would delay the potential marketing authorization for such indications, potentially make marketing authorization more difficult to obtain, and increase our costs.

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

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

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

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

In addition, the FDA may change its authorization policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay marketing authorization of our products under development. For example, in response to industry and healthcare provider concerns regarding the predictability, consistency and rigor of the 510(k) regulatory pathway, the FDA initiated an evaluation of the program, and in January 2011, announced several proposed actions intended to reform the review process governing the clearance of medical devices. The FDA intends these reform actions to improve the efficiency and transparency of the clearance process, as well as bolster patient safety. In addition, as part of the FDASIA the U.S. Congress reauthorized the Medical Device User Fee Amendments with various FDA performance goal commitments and enacted several "Medical Device Regulatory Improvements" and miscellaneous reforms which are further intended to clarify and improve medical device regulation both pre- and post-approval. Any delay in, or failure to receive or maintain clearance or approval for our product candidate could prevent us from generating revenue from our product candidate and adversely affect our business operations and financial results.

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

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

Additionally, the FDA and other regulatory authorities have broad enforcement powers. Regulatory enforcement or inquiries, or other increased scrutiny on us, could affect the perceived safety and efficacy of our product candidate and dissuade our customers from using our product candidate, if and when it is authorized for marketing.

We expect to be required to conduct clinical trials to support regulatory marketing authorization of some of our potential future product candidates. We have limited experience in the clinical trials process, they may proceed more slowly than anticipated, and we cannot be certain that our product candidate will be shown to be safe and effective for human use.

In order to commercialize our product candidate in the United States, we may be required by the FDA to submit an application for PMA for review and approval by the FDA. A PMA application must be submitted to the FDA if our device cannot be cleared through the 510(k) clearance process, down-classified via the *de novo* process, or is not exempt from premarket review by the FDA. We could also be required to submit a PMA application for other 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. The FDA could also require us to provide the FDA with clinical trial data to support any 510(k) premarket notifications and we are required to submit clinical trial data to support the *de novo* down classification of our PoNS device. 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 and effective and otherwise meet the appropriate standards required for marketing authorization for specified indications.

Clinical trials are complex, expensive, time consuming, uncertain and are subject to substantial and unanticipated delays. Before we may begin clinical trials, 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 experience or 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 us or such third parties.

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

As we are required to conduct clinical trials to obtain FDA marketing authorization, we need to rely heavily on third parties over the course of our clinical trials, and as a result will have limited control over the clinical investigators and limited visibility into their day-to-day activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory, and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties 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 us or them 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 impact 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.

If we are unable to secure contracts with workers' compensation and third-party administrators or rehabilitation clinics who treat patients with balance and gait issues associated with TBI or to launch our clinical experience programs, 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 intend to launch clinical experience programs but there are no guarantees we will be able to get the contracts in place for the timely execution of the programs. Our clinical experience program also contemplates conducting training at certain clinical centers around the United States in the use of the PoNS Treatment along with the specific therapeutic protocol, with participants selected based on an established criterion and we may not be successful in reaching agreement at these centers in establishing our programs at their facilities. This could have the effect of delaying our sales and marketing strategy for the PoNS Treatment. In addition, our commercialization strategy is premised on leveraging workers' compensation 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 impact our financial conditions and operating results.

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 would have a negative impact on our intended sales and would have a material adverse effect on our business, financial condition and operating results.

We plan to submit an application to the U.S. Department of Health and Human Services for reimbursement code so that the PoNS Treatment is covered under Medicare and Medicaid. There can be no assurance that our application will be successful, or that we will be able to obtain a reimbursement code in a timely manner. In the event that we do not obtain a reimbursement code for the PoNS Treatment, our customers may be unable to obtain reimbursement for their purchases under private or government-sponsored insurance plans which would have a negative impact on 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 mild- to moderate-TBI or they will not pay for the treatment. In addition, there is a risk that the payment amount for the PoNS Treatment is either too low or too high to incentivize customer adoption.

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

In the United States, the commercial success of our existing product and any future products will depend, in part, on the extent to which governmental payers at the federal and state levels, including Medicare and Medicaid, private health insurers and other third-party payers provide coverage for and establish adequate reimbursement levels for procedures utilizing our products. Hospitals and other healthcare providers that purchase our product for treatment of their patients generally rely on third-party payers to pay for all or part of the costs and fees associated with our products as part of a "bundled" rate for the associated procedures. The existence of coverage and adequate reimbursement for our products and the procedures performed with them by government and private payers 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 United States belong to group purchasing organizations, which typically incentivize their hospital members to make a relatively large proportion of purchases from a limited number of vendors of similar products that have contracted to offer discounted prices. Accordingly, the commercial success of our products may also depend to some extent on our ability to either negotiate favorable purchase contracts with key group purchasing organizations and/or persuade hospitals and clinics to purchase our product "off contract."

The healthcare industry in the United States has experienced a trend toward cost containment as government and private payers seek to control healthcare costs by paying service providers lower rates. While we believe that hospitals will be able to obtain coverage for procedures using our products, the level of payment available to them for such procedures may change over time. State and federal healthcare programs, such as Medicare and Medicaid, closely regulate provider payment levels and have sought to contain, and sometimes reduce, payment levels. Private payers frequently follow government payment policies and are likewise interested in controlling increases in the cost of medical care. In addition, some payers are adopting pay-for-performance programs that differentiate

payments to healthcare providers based on the achievement of documented quality-of-care metrics, cost efficiencies, or patient outcomes. These programs are intended to provide incentives to providers to deliver the same or better results while consuming fewer resources. As a result 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 treatment 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 impact our ability to market and 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 impact market acceptance of our products in any international markets in which those approvals are being sought.

If we fail to comply with healthcare laws, we could face substantial penalties and financial exposure, and our business, operations and financial condition could be adversely affected.

We do not have a product candidate available for sale. If, however, we achieve this goal, the availability of payments from Medicare, Medicaid or other third-party payers would mean that many healthcare laws would place limitations and requirements on the manner in which we conduct our business, including our sales and promotional activities and interactions with healthcare professionals and facilities. In some instances, our interactions with healthcare professionals and facilities that occurred prior to commercialization (e.g., the granting of stock options) could have implications at a later date. The laws that may affect our ability to operate include, among others: (i) the federal healthcare programs Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as Medicare or Medicaid, (ii) federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent, and which may apply to entities like us if we provide coding and billing advice to customers, or under theories of "implied certification" where the government and *qui tam* relators may allege that device companies are liable where a product that was paid for by the government in whole or in part was promoted "off-label," lacked necessary marketing authorization, or failed to comply with good manufacturing practices or other laws; (iii) transparency laws and related reporting and/or disclosures such as the Sunshine Act; and/or (iv) state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, many of which differ from their federal counterparts in significant ways, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, exclusion from participation in government healthcare programs, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that their provisions are open to a variety of evolving interpretations and enforcement discretion. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

Our communications regarding products 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, 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.

Non-compliance with laws and requirements unique to our government contracts could subject us to substantial penalties and financial exposure, and our business, operations, and financial condition could be adversely affected by any non-compliance or the government's discretionary exercise of its rights under our government contracts.

We perform contracts awarded by federal governmental entities. Doing business in the public sector is very different than doing business in the commercial marketplace. For example, unlike commercial contracts, federal government contracts are governed by an array of statutes and regulations that define the way in which government contracts are conceived, structured, competed, awarded, performed, and ultimately completed. Due to the highly regulated nature of our business with the government, we have heightened responsibilities and compliance risks under those contracts. Non-compliance could result in significant civil liability and, in egregious cases, criminal prosecution.

In addition to presenting heightened compliance risks, our government contracts include terms that afford the government special rights that, if exercised at the government's discretion, could adversely affect our business, operations, and financial condition. For example, our sole source contract with the U.S. Army incorporates a clause allowing the government to terminate the contract for convenience of the government, in whole or in part, without any advance notice to us. A termination of this contract, or any other exercise of special governmental rights, could cause our business to suffer.

Risks Related to our Business Operations

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

We may find that the costs of carrying out our plan of operations are greater than we anticipate. Increased operating costs may cause the amount of financing that we require to increase. Investors may be more reluctant to provide additional financing if we cannot demonstrate that we can control our operating costs. There is no assurance that additional financing required as a result of our operating costs being greater than anticipated will be available to us. If we do not control our operating expenses, then we will have fewer funds with which to carry out our plan of operations with the result that our business may fail.

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

We currently have a very small management team and very limited other employees. Our success is dependent upon the ability, expertise, judgment, discretion and good faith of our senior management, and in particular Philippe Deschamps, our President and Chief Executive Officer. Currently, Mr. Deschamps is joined by Joyce LaViscount, our Chief Financial Officer and Chief Operating Officer, Jonathan Sackier, our Chief Medical Officer, and seven others as our only full-time employees. We also have engaged approximately 40 full-time equivalent persons as independent contractors. While employment agreements are customarily used as a primary method of retaining the services of key employees, these agreements cannot assure the continued services of such employees. Any loss of the services of such individuals could have a material adverse effect on our business, operating results or financial condition.

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

Under Section 382 of the Internal Revenue Code of 1986, as amended, 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 the way of exercising of warrants). We plan to undertake a study to analyze and determine if any historical ownership changes of us or our subsidiary NHC 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 products.

We currently have very few employees and will likely need to rely on third party distributors to sell our product. We cannot assure you that we will succeed in entering into and maintaining productive arrangements with an adequate number of distributors that are sufficiently committed to selling our products. The establishment of a distribution network is expensive and time consuming. As we launch new products and increase our marketing effort with respect to existing products, we will need to continue to hire, train, retain and motivate skilled independent distributors with significant technical knowledge. In addition, the commissions we pay our distributors could increase over time which would result in higher sales and marketing expenses. Furthermore, current and potential distributors may market and sell the products of our competitors. Even if the distributors market and sell our products, 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 products. The distributors may also help competitors solicit business from our existing customers. Some of our independent distributors will 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 products.

Outside of the United States, subject to approval by foreign regulatory authorities, we intend to evaluate the benefits of commercialization of the PoNS Therapy in certain territories either independently or with collaboration partners. For example, we intend to enter into a definitive exclusive license agreement with A&B to commercialize the PoNS device in certain Asian countries. However, to date, we have not entered into such a definitive agreement, and there can be no guarantee that we will be able to do so on commercially acceptable terms or at all.

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

The devices and products that we are developing 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 intend to 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 products. We cannot assure you that if and when we commence distribution of our product that we will be able to obtain or maintain adequate coverage on acceptable terms, or that such insurance will provide adequate coverage against all potential claims. Moreover, even if we maintain adequate insurance, any successful claim could materially and adversely affect our reputation and prospects and divert management's time and attention. If we are sued for any injury allegedly caused by our future products our liability could exceed our total assets and our ability to pay the liability.

We are an "emerging growth company" under the Jumpstart Our Business Startups Act of 2012, or JOBS Act, and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company" as defined in the JOBS Act. As an "emerging growth company", we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of section 404 of the Sarbanes-Oxley Act of 2002, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation, shareholder approval of any golden parachute payments not previously approved and presenting the relationship between executive compensation actually paid and our financial performance. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. Additionally, we have irrevocably elected to comply with new or revised accounting standards even though we are an emerging growth company.

We will remain an "emerging growth company" for up to five years after our first sale of common stock pursuant to a Securities Act of 1933, as amended, or the Securities Act, registration statement, although we will lose that status sooner if our revenues exceed $1 billion, if we issue more than $1 billion in non-convertible debt in a three year period, or if the market value of our common stock that is held by non-affiliates exceeds $700 million as of the end of our second quarter in any calendar year.

Our status as an "emerging growth company" under the JOBS Act may make it more difficult to raise capital as and when we need it. Because of the exemptions from various reporting requirements provided to us as an "emerging growth company", we may be less attractive to investors and it may be difficult for us to raise additional capital as and when we need it. If we are unable to raise additional capital as and when we need it, our financial condition and results of operations may be materially and adversely affected.

We have incurred increased costs and have become subject to additional regulations and requirements as a result of becoming a public company, which could lower our profits, if any, or make it more difficult to run our business.

As a public company, we have incurred significant legal, accounting and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. We will continue to incur costs associated with the rules implemented by the SEC, the TSX, the OTCQB, and any other exchange on which our common stock may become listed. The expenses incurred by public companies for reporting and corporate governance purposes have generally been increasing. These rules and regulations have increased our legal and financial compliance costs and have made some activities more time-consuming and costly. These laws and regulations also could make it more difficult or costly for us to obtain certain types of insurance, including director and

officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. These laws and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our Board of Directors, our board committees or as our executive officers. Furthermore, if we are unable to satisfy our obligations as a public company, we could be subject to delisting of our common stock, fines, sanctions and other regulatory action and potentially civil litigation.

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

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

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

During the third quarter of, 2017, we were the victim of a business email compromise, fraud which resulted in our incurring a loss of approximately $0.2 million. We are working with law enforcement authorities and the banks involved in the wire transfer to pursue recovery of the $0.2 million, but at this time we do not know whether we will be able to recover any of the funds, and we have been advised that it may take several months before we are better able to evaluate our recovery prospects. Enhancements have been made to our controls relating to electronic payments by or for us that we believe will reduce our risk of becoming a victim of future frauds related to our payments, including by wire transfers. However, cyber-related criminal activities continue to evolve and increase in sophistication, frequency and severity. As a result, the control enhancements that have been made, and any additional enhancements that may be made in the future, to our controls may not be successful in avoiding our becoming a victim to further cyber-related crimes.

Risks Related to Our Common Stock

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

A decline in the price of our common stock could result in a reduction in the liquidity of our common stock and a reduction in our ability to raise any required capital for our operations. Because our operations to date have been principally financed through the sale of equity securities, a decline in the price of our common stock could have an adverse effect upon our liquidity and our continued operations. A reduction in our ability to raise equity capital in the future may have a material adverse effect upon our business plan 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.

Our common stock does not have a well-established trading market in the United States. Trading of our common stock is 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 is currently periodically quoted on the OTCQB electronic quotation service operated by OTC Markets Group Inc. A well-established market for our common stock may never develop in the United States. Trading in stock quoted on the OTCQB is often thin and characterized by wide fluctuations in trading prices, due to many factors that may have little to do with our operations or business prospects. This volatility could depress the market price of our common stock for reasons unrelated to operating performance or the future prospect of our business. Moreover, the OTCQB is not a stock exchange, and trading of securities on the OTCQB is often more sporadic than the trading of securities listed on a quotation system like NASDAQ or a stock exchange like Amex. Accordingly, shareholders may have difficulty reselling any of the shares.

Our common stock has been listed on the TSX since April 18, 2016. Certain shares of our common stock are also restricted for immediate resale to U.S. persons or to anyone for the account or on behalf of any U.S. person, pursuant to the requirements of Regulation S. These shares are traded separately on the TSX under a separate ticker symbol. To date, trading on the TSX in our common stock has been extremely limited and sporadic.

Our warrants were also approved for listing on the TSX on April 18, 2016. However, because only the warrants issued in the offshore offering in transactions exempt from the registration requirements of the Securities Act were approved for listing on the TSX, the warrants listed on the TSX may not be purchased by or on behalf of a U.S. person, or by a person in the United States, unless in a registered transaction or pursuant to an applicable safe harbor or exemption from registration.

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, if it occurs at all, will likely be subject to

significant volatility since, among other reasons, we do not have nor, will we have in the foreseeable future an active trading market in our stock. These factors include macroeconomic developments in North America and globally and market perceptions of the attractiveness of particular industries. Factors unrelated to our performance that may affect the price of our common stock include the following: the extent of analytical coverage available to investors concerning our business may be limited if investment banks with research capabilities do not follow us, a reduction in trading volume and general market interest in our common stock may affect an investor's ability to trade significant numbers of shares of our common stock; the size of our public float may limit the ability of some institutions to invest in our common stock; and a substantial decline in the price of shares of our common stock that persists for a significant period of time could cause our common stock, if listed on an exchange, to be delisted from such exchange, further reducing market liquidity. As a result of any of these factors, the market price of our common stock at any given point in time may not accurately reflect our long-term value. The price of our common shares may increase or decrease in response to a number of events and factors, including: changes in financial estimates; our acquisitions and financings; quarterly variations in our operating results; the operating and share price performance of other companies that investors may deem comparable; and purchase or sale of blocks of our common stock. These factors, or any of them, may materially adversely affect the prices of our common shares regardless of our operating performance. We caution you as to the highly illiquid nature of an investment in our shares.

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.

Our shares are subject to potential delisting if we do not meet or continue to maintain the listing requirements of the TSX.

The TSX rules for continued listing include minimum market capitalization and other requirements. Failure to maintain our listing on the TSX or being de-listed from the TSX would make it more difficult for shareholders to dispose of our common stock and more difficult to obtain accurate quotations on our common stock. This could have an adverse effect on the price of our common stock. Our ability to issue additional securities for financing or other purposes, or to otherwise arrange for any financing we may need in the future, may also be materially and adversely affected if our common stock is not traded on a national securities exchange.

The market price of our common stock is likely to be highly volatile and subject to wide fluctuations, and you may be unable to resell your shares at or above the price at which you acquired them, or at all.

The market price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to a number of factors that are beyond our control, including, but not limited to:

- quarterly variations in our revenues and operating expenses;
- developments in the financial markets and worldwide or regional economies;
- announcements of innovations or new products or services by us or our competitors;
- announcements by the government relating to regulations that govern our industry;
- significant sales of our common stock or other securities in the open market;
- variations in interest rates;
- changes in the market valuations of other comparable companies; and
- changes in accounting principles.

In the past, stockholders have often instituted securities class action litigation after periods of volatility in the market price of a company's securities. If a stockholder were to file any such class action suit against us, we would incur substantial legal fees and our management's attention and resources would be diverted from operating our business to respond to the litigation, which could harm our business.

We are authorized to issue an unlimited number of Class A common stock, and we intend to issue significantly more shares to raise capital, which would result in substantial dilution to your investment in our shares.

Our Articles of Incorporation authorize the issuance of an unlimited number of Class A common shares that can be issued for such consideration and on such terms and conditions as are established by our board of directors without the approval of any of our shareholders. Any additional financings effected by us may result in the issuance of additional securities without stockholder approval and the substantial dilution in the percentage of common stock held by our then existing stockholders. Moreover, the common stock issued in any such transaction may be valued on an arbitrary or non-arm's-length basis by our management, resulting in an additional

reduction in the percentage of common stock held by our current stockholders. Moreover, in connection with any such financing, we may be required to issue warrants to the investors, which could result in additional dilution. Our board of directors has the power to issue any or all of such authorized but unissued shares without stockholder approval. To the extent that additional shares of common stock are issued in connection with a financing, dilution to the interests of our stockholders will occur and the rights of the holders of common stock might be materially and adversely affected. We may issue additional common shares in connection with a future financing or acquisition. The issuance of additional common shares may dilute an investor's investment in us and reduce cash available for distribution per common share, if any dividends are declared by the board of directors in the future.

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 significant portion of our outstanding common stock may be sold into the public market in the future, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur in the future. These sales, or the market perception that the holders of a large number of shares of our common stock intend to sell shares, could reduce the market price of our common stock.

FINRA sales practice requirements may limit a stockholder's ability to buy and sell our stock.

In addition to the "penny stock" rules promulgated by the SEC, the Financial Industry Regulatory Authority or FINRA, has adopted rules that require that in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending speculative low-priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives and other information. Under interpretations of these rules, FINRA believes that there is a high probability that speculative low-priced securities will not be suitable for at least some customers. The FINRA requirements make it more difficult for broker-dealers to recommend that their customers buy our common stock, which may limit your ability to buy and sell our stock.

Any future sales of our equity securities will dilute the ownership percentage of our existing stockholders and may decrease the market price for our common stock.

Future sales or issuances of equity securities could decrease the value of our common stock, dilute stockholders' voting power and reduce future potential earnings per share. We intend to sell additional equity securities in future offerings (including through the sale of securities convertible into shares of our common stock) and may issue additional equity securities to finance our operations, development, acquisitions or other projects. We cannot predict the size of future sales and issuances of equity securities or the effect, if any, that future sales and issuances of equity securities will have on the market price of our common stock. Sales or issuances of a substantial number of equity securities, or the perception that such sales could occur, may adversely affect prevailing market prices for our common stock. With any additional sale or issuance of equity securities, investors will suffer dilution of their voting power and may experience dilution in our earnings per share.

Anti-takeover provisions may limit the ability of another party to acquire us, which could cause our stock price to decline.

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

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

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

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

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

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

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

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our head office is located at 642 Newtown-Yardley Road, Suite 100, Newtown, PA 18940, with 10,444 square feet of lease office space. The lease terminates in January 2023, with an option to extend until January 2028. Monthly rent plus utilities is approximately $20 thousand per month, with a 3% annual increase. Our registered office and registered agent is located at CT Corporation System, 1712 Pioneer Ave., Ste. 120, Cheyenne, Wyoming 82001.

ITEM 3. LEGAL PROCEEDINGS

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

We are not aware of any legal proceedings contemplated by any governmental authority involving us or our properties. As of December 31, 2017, no director, officer or affiliate is: (i) a party adverse to us in any legal proceeding, or (ii) has an adverse interest to us in any legal proceedings.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market Information

Our shares of common stock commenced trading on the TSX under the symbol "HSM" on April 18, 2016. Our Warrants were also approved for listing on the TSX on April 18, 2016. See Part I Item 1, "Listing of our Common Stock on the CSE, TSX and OTCQB."

Our common stock is currently quoted on the OTCQB under the symbol "HSDT."

The following table sets forth, for the periods indicated, the high and low prices (on a post-split basis) relating to our common stock for the periods indicated, as provided by the CSE, the TSX and the OTCQB. The Company's common stock was delisted from the CSE concurrently with the TSX listing. These quotations reflect inter-dealer prices without retail mark-up, mark-down, or commissions, and may not reflect actual transactions.

	OTC (US$)		CSE / TSX (CAD$)	
Period	**High**	**Low**	**High**	**Low**
Year Ended December 31, 2016				
First Quarter	$ 4.30	$ 3.40	CAD$ 6.20	CAD$ 4.75
Second Quarter	$ 7.50	$ 3.50	CAD$ 9.75	CAD$ 5.05
Third Quarter	$ 5.67	$ 4.28	CAD$ 7.50	CAD$ 5.55
Fourth Quarter	$ 9.05	$ 5.18	CAD$ 11.75	CAD$ 6.75
Year Ended December 31, 2017				
First Quarter	$ 9.55	$ 7.10	CAD$ 12.95	CAD$ 8.80
Second Quarter	$ 8.00	$ 6.45	CAD$ 11.00	CAD$ 8.60
Third Quarter	$ 15.60	$ 7.65	CAD$ 19.05	CAD$ 9.75
Fourth Quarter	$ 20.70	$ 7.35	CAD$ 25.45	CAD$ 9.00

As of March 5, 2018, the last reported sales price of our common stock on the TSX was CAD$15.70 per share. As of March 5, 2018, the last reported sales price of our common stock on the OTCQB was US$12.09 per share.

The exchange rate in effect on March 5, 2018 as reported by Bank of Canada was US$1.00 = CAD$1.2977.

Holders

As of March 5, 2018, there were approximately 214 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.

In December 2017, we issued 646,016 units in a multi-tranche private placement with certain of our officers and directors and other accredited investors. Each unit consisted of one share of our Class A of common stock and one share purchase warrant and had a purchase price of $9.80 per share of our Class A common stock. Each warrant entitled the holder to acquire one additional share of our Class A common stock for a period of 36 months following the closing of the private placement at an exercise price of $12.25 per share. The issuance of these securities was exempt from registration under Section 4(a)(2) of the Securities Act and Rule 506 promulgated thereunder. We intend to use the net proceeds from the private placement to finance our near-term operations, satisfy accrued payables, fund our continued work towards our planned FDA de novo 510(k) submission and marketing applications in other jurisdictions and any remainder for working capital and other corporate purposes.

ITEM 6. SELECTED FINANCIAL DATA

As an accelerated filer in a transition period from a smaller reporting company, we have elected not to provide selected financial data in reliance **on** Item 301(c) of Regulation S-K.

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 on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this filing, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a medical technology company focused on the development of products for the treatment of neurological symptoms caused by disease or trauma. We seek to develop, license or acquire unique and noninvasive platform technologies that amplify the brain's ability to heal itself.

Many patients with brain injury or brain-related disease have disrupted neural networks that result in their brains being unable to correctly or efficiently carry neural impulses, which are responsible for directing bodily functions like movement control or sensory perception. Our first product in development, known as the portable neuromodulation stimulator or PoNS®, device, is designed to enhance the brain's ability to compensate for this damage. The PoNS Treatment is a combination of our PoNS device and functional, targeted physical therapy, and is currently being developed for the treatment of movement, gait and balance disorders in patients with traumatic brain injury, or TBI, and other chronic neurological diseases.

We recently completed our registrational clinical trial of the PoNS Treatment for mild- to moderate TBI, in which we observed statistically and clinically significant increases in composite sensory observation test scores. Based on the safety and efficacy results from this clinical trial, we intend to submit a request for FDA marketing authorization for the treatment of chronic balance deficit due to mild- to moderate-TBI via the FDA's de novo classification process in the first half of 2018. In addition, we intend to submit applications for marketing authorizations in Canada, the European Union and Australia during the first half of 2018.

Since our inception, we have incurred significant operating losses. Our net loss was $28.0 million for the year ended December 31, 2017 and $12.0 million for the nine months ended December 31, 2016. As of December 31, 2017, we had an accumulated deficit of $66.4 million. We expect to incur significant expenses and operating losses for the foreseeable future as we continue to advance the PoNS Treatment and seek regulatory clearance and pursue its commercialization. In addition, if we obtain marketing clearance, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Further, we may incur expenses in connection with the in-license or acquisition of other potential products.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings, or other capital sources, including potential collaborations with other companies or other strategic transactions. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements, as, and when, needed, we may have to reduce the scope of our operations and planned capital expenditures or sell certain assets, including intellectual property assets.

As of December 31, 2017, we had cash of $5.6 million. We intend to seek additional funding through the sale of equity or debt financing to continue to fund our operations. However, we do not currently have sufficient resources to accomplish all of the conditions necessary for us to generate revenue. For this reason, there is substantial doubt that we can continue as a going concern for the next 12 months unless we obtain additional capital to pay or reduce our expenditures.

Reverse Stock Split

Effective after the close of business on January 22, 2018, we completed a 1-for-5 reverse stock split of our Class A Common Stock. Since January 23, 2018, our Class A common stock has traded on a post-split basis on the OTCQB and Toronto Stock Exchange. All share and per share amounts in this Annual Report have been reflected on a post-split basis.

Components of Our Results of Operations

Revenue

We have not generated any revenue since our inception however, and will not generate revenue unless the PoNS device receives marketing authorization approval from the FDA or other foreign regulatory authorities.

Research and Development Expenses

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

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

R&D activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage registrational clinical trials. We expect our R&D expenses to increase over the next several years as we increase personnel costs, conduct feasibility and pilot studies and registrational clinical trials for additional indications, invest in our product development and manufacturing capabilities and prepare regulatory filings for our product candidates.

The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of, or when, if ever, material net cash inflows may commence from any of our product candidates. This uncertainty is due to the numerous risks and uncertainties associated with the duration and cost of clinical trials, which vary significantly over the life of a project as a result of many factors, including:

- the number of clinical sites included in the trials;
- the length of time required to enroll suitable patients;
- the number of patients that ultimately participate in the trials;
- the manufacturing costs of devices used in our clinical trials;
- the duration of patient follow-up; and
- the results of our clinical trials.

Our expenditures are subject to additional uncertainties, including those described in Item 1A. “Risk Factors” in this Annual Report.

General and Administrative Expenses

G&A expenses consist principally of salaries and related costs for personnel in executive, 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, and insurance costs.

We anticipate that our G&A expenses will increase as a result of increased personnel costs, including stock-based compensation, expanded infrastructure and higher consulting, legal and tax-related services associated with maintaining compliance with the TSX stock exchange listing and Securities and Exchange Commission, or SEC, requirements, accounting and investor relations costs, and director and officer insurance premiums associated with being a public company. Additionally, if and when we believe a regulatory approval of a drug candidate appears likely, we anticipate an increase in payroll and other expenses as a result of our preparation for commercial operations, especially as it relates to the sales and marketing and commercial infrastructure.

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: fair value of non-monetary transactions, fair value of stock options, warrants and derivative liabilities and valuation of income tax allowances and uncertain tax position.

Share-Based Payments

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

Share-based payments to non-employees are measured at the fair value of the consideration received, or the fair value of the equity instruments issued, or liabilities incurred, whichever is more reliably measurable. The fair value of share-based payments to non-employees is re-measured at each reporting period until the counterparty performance is complete, and any change therein is recognized over the vesting period of the award and in the same manner as if we had paid cash instead of paying with or using an equity-based instrument. The fair value of share-based payments to non-employees that is fully vested and non-forfeitable as at the grant date is measured and recognized at that date.

We account for the granting of stock options and restricted stock units to employees using the fair value method whereby all awards to employees are recorded 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 share 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 condition.

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. The expected term of our employee-related stock options is determined utilizing the “simplified” method for awards that qualify as “plain vanilla” options. The expected term of stock options granted to non-employees is equal to the contractual term of the option award. We lack historical and implied volatility information. Therefore, we estimate our expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expect to continue to do so until such time as we have adequate historical data regarding the volatility of our own traded stock price. The risk-free interest rate is determined by reference to the Bank of Canada Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that we have never paid cash dividends and do not expect to pay any cash dividends in the foreseeable future.

Derivative Financial Instruments

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

The classification of derivative financial instruments, including whether such instruments should be recorded as a liability or as equity, is re-assessed at the end of each reporting period. Derivative financial instruments that become subject to reclassification are reclassified at the fair value of the instrument on the reclassification date. Derivative financial instrument liabilities are classified in the consolidated balance sheet as current or non-current based on whether or not the right to exercise or settle the derivative financial instrument lies with the holder.

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

On January 4, 2017, our Board of Directors approved a change in our fiscal year end from March 31 to December 31. We believe that a reader’s understanding of our results of operations will be enhanced by review of a comparison between our audited results for the fiscal year ended December 31, 2017 and our unaudited results for the calendar year ended December 31, 2016. Accordingly we present our discussion and analysis under “Results of Operations” and “Statements of Cash Flows” below based on comparisons of the results for such periods.

Results of Operations

The following table summarizes our results of operations for the year ended December 31, 2017, the twelve months ended December 31, 2016 and the nine months ended December 31, 2016:

	Year Ended December 31, 2017	Twelve Months Ended December 31, 2016 (Unaudited)	Change	Nine Months Ended December 31, 2016
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	14,387	5,704	8,683	4,723
General and administrative	8,466	7,585	881	5,651
Total operating expenses	**22,853**	**13,289**	**9,564**	**10,374**
Operating loss	(22,853)	(13,289)	(9,564)	(10,374)
Other income (expense):				
Interest and other income	-	90	(90)	111
Change in fair value of derivative financial instruments	(3,443)	(2,511)	(932)	(2,480)
Foreign exchange loss	(1,728)	(161)	(1,567)	703
Total other expense	(5,171)	(2,582)	(2,589)	(1,666)
Net loss	**$ (28,024)**	**$ (15,871)**	**$ (12,153)**	**$ (12,040)**

Year Ended December 31, 2017 Compared to Unaudited Twelve Months Ended December 31, 2016

Revenue

During the year ended December 31, 2017 and the twelve months ended December 31, 2016 we did not generate any revenue.

Research and Development Expenses

Research and development, or R&D expenses were $14.4 million for the year ended December 31, 2017, compared to $5.7 million for the twelve months ended December 31, 2016. The increase of $8.7 million was primarily attributable to an increase in our activities with respect to the clinical development of our PoNS device, including our registrational clinical trial and device design and development and manufacturing activities.

Design and engineering verification and manufacturing of our PoNS device was $5.3 million higher for the year ended December 31, 2017 over the comparable period in 2016 as we prepared the required documentation for our FDA submission. In addition, expenses related to our registrational clinical trial for mild- to moderate- TBI increased by approximately $2.1 million for the year ended December 31, 2017 over the comparable period in 2016. This expense included start-up and operating costs which supported an increase in the number of our clinical sites as well expenses related to traditional and digital clinical trial recruitment activities. The increased spending during 2017 accelerated the completion of our registrational clinical trial, which we completed during the third quarter of 2017.

We also incurred $1.0 million for the year ended December 31, 2017, in expenses related to regulatory initiatives towards our FDA submission for marketing clearance of our PoNS device.

General and Administrative Expenses

General and administrative, or G&A, expenses were $8.5 million for the year ended December 31, 2017, compared to $7.6 million for the twelve months ended December 31, 2016.

The increase of $0.9 million was primarily attributable to higher legal expenses of $1.3 million and professional services fees of $0.2 million which were partially offset by lower stock-based compensation expense of $0.6 million, as a result of lower number of stock options granted in 2017.

Change in Fair Value of Derivative Financial Instruments

The change in fair value of derivative financial instruments was an expense of $3.4 million for the year ended December 31, 2017, compared to an expense of $2.5 million for the twelve months ended December 31, 2016.

The change in fair value of derivative financial instruments was primarily attributable a change in our stock price and volatility. The change in the fair value of derivative financial instruments is a non-cash item.

During the year ended December 31, 2017, derivative financial instruments increased by $3.0 million from the issuance of 646,016 warrants issued in our December 2017 financing, as these warrants were denominated in a currency other than our functional currency. This was partially offset by a $1.2 million decrease in derivative financial instruments as a result of the exercise of 208,333 warrants which were classified as derivative financial instruments (see Note 3).

Foreign Exchange Loss

Foreign exchange loss was $1.7 million during the year ended December 31, 2017, compared to a loss of $0.2 million during the twelve months ended December 31, 2016. 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.

Statements of Cash Flows

The following table summarizes our cash flows during the year ended December 31, 2017, the twelve months ended December 31, 2016 and the nine months ended December 31, 2016:

	Year Ended December 31, 2017	Twelve Months Ended December 31, 2016	Change	Nine Months Ended December 31, 2016
		(Unaudited)		
Net cash used in operating activities	$ (19,325)	$ (9,568)	$ (9,757)	$ (7,885)
Net cash used in investing activities	(190)	-	(190)	-
Net cash provided by financing activities	22,218	7,997	14,221	7,997
Effect of foreign exchange rate changes on cash	190	(110)	300	(87)
Net increase (decrease) in cash	$ 2,893	$ (1,682)	$ 4,575	$ 25

Year Ended December 31, 2017 Compared to the Twelve Months Ended December 31, 2016

Net Cash Used in Operating Activities

Net cash used in operating activities for the year ended December 31, 2017 was $19.3 million. This was comprised of a net loss of $28.0 million, adjusted for non-cash items including the change in the fair value of our derivative liabilities of $3.4 million, stock-based compensation expense of $1.8 million and unrealized foreign exchange loss of $1.6 million. In addition, changes in operating assets and liabilities was $1.8 million.

Net cash used in operating activities for the twelve months ended December 31, 2016 was $9.6 million. This was comprised of a net loss of $15.9 million, adjusted for non-cash items including the change in the fair value of our derivative liabilities of $2.5 million, stock-based compensation expense of $2.3 million and unrealized foreign exchange loss of $0.1 million. In addition, changes in operating assets and liabilities was $1.4 million.

Net Cash used in Investing Activities

Net cash used in investing activities for the year ended December 31, 2017 was $0.2 million, which was primarily related to leasehold improvements at our new office space.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the year ended December 31, 2017 was $22.2 million, which was primarily comprised of $20.9 million received from offerings of our common stock and warrants. In February 2017, we received approximately $9.2 million in a public offering from the sale of 1,311,000 shares of our Class A common stock. In June 2017, we received approximately $5.4 million from the sale of 800,000 of our Class A common stock in a private placement. In December 2017, we received approximately $6.3 million from the sale of 646,016 units which was comprised of one share of our Class A common stock and one share purchase warrant in a private placement. For the year ended December 31, 2017, we also received approximately $2.6 million in proceeds from the exercise of stock options and warrants. These proceeds were partially offset by $1.2 million in issuance costs primarily related to our public offering.

Net cash provided by financing activities for the twelve months ended December 31, 2016 was $8.0 million, which was primarily comprised of $7.9 million received from offerings of our Class A common stock conducted in April and May 2016, as well as $1.6 million received from the exercise of stock options and warrants. These amounts were partially offset by $1.5 million in share issuance costs incurred in connection with our offering.

Liquidity and Capital Resources

Our financial statements have been prepared assuming that we will continue as a going concern and, accordingly, do not include adjustments relating to the recoverability and realization of assets and classification of liabilities that might be necessary should we be unable to continue in operation.

The following table summarizes our cash and our working capital, which excludes non-cash items (derivative financial instruments) as of December 31, 2017 and 2016:

	December 31, 2017	December 31, 2016
Cash	$ 5,562	$ 2,669
Working capital	$ 1,897	$ 1,030

We currently have limited working capital and liquid assets. Our cash as of December 31, 2017 was $5.6 million. To date, we have not generated any revenue from the commercial sale of products or services. There are a number of conditions that we must satisfy before we will be able to generate revenue, including but not limited to FDA marketing authorization of the PoNS device for treating balance disorder associated with mild- to moderate-TBI, manufacturing of a commercially-viable version of the PoNS device and demonstration of effectiveness sufficient to generate commercial orders by customers for our product. While we are currently seeking additional funding, we do not currently have sufficient resources to accomplish any of these conditions necessary for us to generate revenue. We will therefore require substantial additional funds in order to continue to conduct the development of our PoNS device and regulatory clearance and approval activities necessary to bring our product to market, to establish effective marketing and sales capabilities and to develop other product candidates.

We will require additional funding to fund our ongoing activities. 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.

Off Balance Sheet Arrangements

To the best of management's knowledge, there are no off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our results of operations or financial condition.

Contractual Obligations

The following table summarizes, as of December 31, 2017, our obligations to make future payments pursuant to certain contracts or arrangements and provides an estimate of the fiscal years in which these obligations are expected to be satisfied:

	Payments due by Period				
	1 Year or Less	Greater than 1 Year to 3 Years	Greater than 3 Years to 5 Years	Greater than 5 Years	Total
Operating Lease	$ 231	$ 499	$ 527	$ 12	$ 1,269

Recently Issued Accounting Pronouncements

In March 2016, the FASB issued ASU 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*. The amendments in this update change existing guidance related to accounting for employee share-based payments affecting the income tax consequences of awards, classification of awards as equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 is effective for annual reporting periods beginning after December 15, 2016, including interim periods within those annual periods, with early adoption permitted. The updated accounting guidance was effective for us on January 1, 2017 and it did not have a material effect on our consolidated financial statements and any deferred tax benefits would be offset by a valuation allowance.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*. The new standard establishes a right-of-use, or ROU, model that requires a lessee to record a ROU asset and a lease liability on the consolidated balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the consolidated statement of operations. ASU 2016-02 is effective for annual periods beginning after December 15, 2018, including interim periods within those annual periods, with early adoption permitted. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the

condensed consolidated financial statements, with certain practical expedients available. We are currently evaluating the potential impact of the standard on our condensed consolidated financial statements.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which was further amended through various updates issued by the FASB thereafter. The amendments of Topic 606 completed the joint effort between the FASB and the IASB, to develop a common revenue standard for GAAP and IFRS, and to improve financial reporting. The guidance under Topic 606 provides that an entity should recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled to in exchange for the goods or services provided and establishes a five-step model to be applied by an entity in evaluating its contracts with customers. We do not have any revenues or contracts with customers and will need to evaluate the impact of Topic 606 on our results of operations, cash flows and financial position should a revenue generating transaction arise in the future. While we will adopt Topic 606 on January 1, 2018 (and will do so on a modified retrospective basis), the adoption will have no impact on our consolidated financial statements.

JOBS Act

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

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to foreign currency exchange risk from the transfer of funds between the United States and Canada to satisfy obligations as we do not hedge our foreign exchange exposure.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

See the Index to Financial Statements included in this Form 10-K.

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

On January 4, 2017, the Audit Committee of the Board of Directors approved BDO USA LLP to serve as our independent registered public accounting firm for the year ended December 31, 2016. Contemporaneous with the determination to appoint BDO USA LLP, we dismissed BDO Canada LLP from the role. The reports of BDO Canada LLP on our consolidated financial statements as of and for the fiscal years ended March 31, 2016 and 2015 did not contain an adverse opinion or a disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope or accounting principles, except that the reports for each such fiscal year included a paragraph stating that there was substantial doubt about our ability to continue as a going concern.

During the fiscal years ended March 31, 2016 and 2015, there were no disagreements between us and BDO Canada LLP on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure which, if not resolved to the satisfaction of BDO Canada LLP, would have caused BDO Canada LLP to make reference to the subject matter of the disagreements in connection with its reports for such fiscal years; and there were no reportable events as defined in Item 304(a)(1)(v) of Regulation S-K except for the material weakness in (i) our internal control over financial reporting disclosed in its Form 10-K/A for the fiscal year ended March 31, 2015 (filed January 11, 2016), related to the design of controls with respect to the calculation of the fair value of our share based compensation, and (ii) our Form 10-K for the fiscal year ended March 31, 2016 (filed June 28, 2016) related to our accounting staff having insufficient technical accounting knowledge relating to accounting for income taxes and complex U.S. GAAP matters. The Audit Committee discussed the subject matter of these reportable events with BDO Canada LLP. We have authorized BDO Canada LLP to respond fully and without limitation to all requests of BDO USA LLP concerning all matters related to the periods audited by BDO Canada LLP, including with respect to the subject matter of these reportable events.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(b) of 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 on Form 10-K.

Based on this evaluation, we have concluded that our disclosure controls and procedures were effective as of the end of the period covered by this 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, 2017. 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, 2017, our internal control over financial reporting was effective.

Because we qualify as an emerging growth company under the JOBS Act, this Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting as required by Section 404(b) of the Sarbanes Oxley Act of 2002.

Changes in Internal Control Over Financial Reporting

We monitor our internal control over financial reporting on a continuous basis. During the quarter ended September 30, 2017, we identified a material weakness in our internal control over financial reporting as a result of a business email compromise fraud. It involved the impersonation of our employees and fraudulent demands for wire transfers that targeted our finance department. We immediately responded to the criminal fraud. Despite our response, the fraud resulted in a transfer of approximately $0.2 million. To date, no funds have been recovered. The Company's investigation into this matter continues. During the third and fourth quarter of 2017, enhancements were made to our controls relating to electronic payments, including by wire transfer of funds. These enhancements included additional verification and documentation procedures to be followed prior to the initiation or approval of electronic payments by or for us. We believe these enhancements have increased the ability of our personnel to identify and block attempts by third parties to fraudulently initiate electronic payments from us. Our management believes that the foregoing actions will help to improve our internal controls over financial reporting. Other than the actions described above, there has not been any change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended December 31, 2017 have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item 10 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2018 Annual Meeting of Stockholders and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item 11 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2018 Annual Meeting of Stockholders and is incorporated herein by reference.

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

The information required by this Item 12 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2018 Annual Meeting of Stockholders and is incorporated herein by reference.

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

The information required by this Item 13 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2018 Annual Meeting of Stockholders and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item 14 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2018 Annual Meeting of Stockholders and is incorporated herein by reference.

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
2.2	Agreement and Plan of Merger among Helius Medical Technologies, Inc., HMT Mergersub, Inc. and NeuroHabilitation Corporation, dated June 6, 2014 (incorporated by reference to Exhibit 10.6 to the Form S-1 filed with the SEC on July 14, 2014)
3.1	Articles of Continuation (incorporated by reference to Exhibit 3.1 to the Form S-1 filed with the SEC on July 14, 2014)
3.2	Articles of Amendment filed with the Wyoming Secretary of State on July 3, 2014 (incorporated by reference to Exhibit 3.2 to the Form S-1 filed with the SEC on July 14, 2014)
3.3	Articles of Amendment filed with the Wyoming Secretary of State on April 27, 2015 (incorporated by reference to Exhibit 3.3 to amendment no. 1 to the Form 10 filed with the SEC on May 4, 2015)
3.4	Articles of Amendment filed with the Wyoming Secretary of State on January 22, 2018 (incorporated by reference to Exhibit 3.1 to the Form 8-K filed on January 23, 2018)
3.5	Bylaws as amended and restated (incorporated by reference to Exhibit 3.1 to the Form 8-K filed with the SEC on March 23, 2016)
4.1	Form of Warrant (included in Exhibit 4.2)
4.2	Warrant Indenture dated April 18, 2016 by and between Helius Medical Technologies, Inc. and Computershare Investor Services Inc. (incorporated by reference to Exhibit 4.1 to amendment no. 1 to the Form 8-K filed April 18, 2016 and amended on April 20, 2016)
4.3	Amended and Restated June 2014 Equity Incentive Plan (incorporated by reference to Exhibit 4.3 to the Form 10-Q filed with the SEC on November 9, 2017)
10.1†	Employment Agreement between Helius Medical Technologies, Inc. and Philippe Deschamps, dated June 13, 2014 (incorporated by reference to Exhibit 99.1 to the Form S-1 filed with the SEC on July 14, 2014)
10.2†	Amendment Agreement to the Employment Agreement between Helius Medical Technologies, Inc. and Philippe Deschamps, dated September 1, 2014 (incorporated by reference to Exhibit 99.5 to the Amendment to Form S-1 filed with the SEC on September 23, 2014)
10.3†	Employment Agreement between Helius Medical Technologies, Inc. and Jonathan Sackier, dated December 1, 2014 (incorporated by reference to Exhibit 10.4 to the Form 10-12G filed with the SEC on April 15, 2015)
10.4†	Consulting Agreement between NeuroHabilitation Corporation and Yuri Danilov, dated July 1, 2014 (incorporated by reference to Exhibit 99.4 to the Amendment to Form S-1 filed with the SEC on September 23, 2014)
10.5†	Consulting Agreement between NeuroHabilitation Corporation and Mitch Tyler, dated December 10, 2014 (incorporated by reference to Exhibit 10.5 to the Form 10-12G filed with the SEC on February 6, 2015)
10.6†	Advisory Agreement between Helius Medical Technologies, Inc. and V Baron Global Financial Canada Ltd., dated June 13, 2014 (incorporated by reference to Exhibit 99.2 to the Form S-1 filed with the SEC on July 14, 2014)
10.7	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)
10.8	Amended and Restated Patent Sub-License Agreement between Advanced NeuroRehabilitation, LLC and NeuroHabilitation Corporation, having an effective date of January 22, 2013 (incorporated by reference to Exhibit 10.1 to the Form S-1 filed with the SEC on July 14, 2014)

Exhibit Number	Exhibit
10.9	Second Amended and Restated Patent Sub-License Agreement between Advanced NeuroRehabilitation, LLC and NeuroHabilitation Corporation, 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)
10.10	Master Cooperative Research and Development Agreement between NeuroHabilitation Corporation, Advanced NeuroRehabilitation, LLC, Yuri Danilov, Mitchell Tyler, Kurt Kaczmarek and U.S. Army Medical Material Agency and U.S. Army Medical Material Development Activity, dated effective February 1, 2013 (incorporated by reference to Exhibit 10.2 to the Form S-1 filed with the SEC on July 14, 2014)
10.11	Notice of Modification No. 1 to Cooperative Research and Development Agreement between NeuroHabilitation Corporation, Advanced NeuroRehabilitation, LLC, Yuri Danilov, Mitchell Tyler, Kurt Kaczmarek and U.S. Army Medical Material Agency and U.S. Army Medical Material Development Activity, dated April 29, 2014 (incorporated by reference to Exhibit 10.5 to the Form S-1 filed with the SEC on July 14, 2014)
10.12	Notice of Modification No. 2 to Cooperative Research and Development Agreement between NeuroHabilitation Corporation, Advanced NeuroRehabilitation, LLC, Yuri Danilov, Mitchell Tyler, Kurt Kaczmarek and U.S. Army Medical Material Agency and U.S. Army Medical Material Development Activity, dated January 12, 2015 (incorporated by reference to Exhibit 10.12 to the Form 10-12G filed with the SEC on February 6, 2015)
10.13	Design and Manufacturing Consultant Agreement between NeuroHabilitation Corporation 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)
10.14	Commercial Development-to-Supply Program between NeuroHabilitation Corporation 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)
10.15	Amendment No. 1 to the Commercial Development-to-Supply Program between NeuroHabilitation Corporation and Ximedica, dated October 25, 2013, amended January 15, 2016 (incorporated by reference to Exhibit 10.15 to the Form S-1 filed with the SEC on May 4, 2016)
10.16†	Employment Agreement between Helius Medical Technologies, Inc. and Joyce LaViscount, dated October 19, 2015 (incorporated by reference to Exhibit 10.3 to the Form 10-Q filed with the SEC on February 16, 2016)
10.18‡	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)
10.19	Convertible Promissory Note between the Company and A&B (HK) Company Limited, dated as of October 9, 2015 (incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on October 16, 2015)
10.20	Notice of Modification No. 3 to Cooperative Research and Development Agreement between NeuroHabilitation Corporation, Advanced NeuroRehabilitation, LLC, Yuri Danilov, Mitchell Tyler, Kurt Kaczmarek and U.S. Army Medical Material Agency and U.S. Army Medical Material Development Activity, dated December 28, 2016 (incorporated by reference to Exhibit 2.1 to the Form 8-K filed with the SEC on December 31, 2015)
10.21	Agency Agreement between the Company and Mackie Research Capital Corporation, dated as of March 23, 2016 (incorporated by reference to Exhibit 10.21 to the Form S-1 filed with the SEC on May 4, 2016)
10.22	Sole-source cost sharing contract between NeuroHabilitation Corporation and the U.S. Army Medical Research and Materiel Command (USAMRMC) dated as of July 7, 2015 (incorporated by reference to Exhibit 10.22 to the Form S-1 filed with the SEC on May 4, 2016)
10.22.1	Amendment to Sole-Source Cost Sharing Contract between NeuroHabilitation Corporation and the U.S. Army Medical Research and Materiel Command (USAMRMC), dated November 7, 2016 (incorporated by reference to Exhibit 10.2 to the Form 8-K filed with the SEC on November 21, 2016)
10.23	2014 Stock Incentive Plan (incorporated by reference to Exhibit 4.1 to the Form S-1 filed with the SEC on July 14, 2014)
10.23.1	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)
10.24	Consulting Agreement between Helius Medical Technologies, Inc. and Montel Media, Inc., dated April 13, 2016 (incorporated by reference to Exhibit 10.24 to the Form S-1 filed with the SEC on May 4, 2016)
10.25	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)

Exhibit Number	Exhibit
10.25.1	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)
10.26	Commercial lease agreement dated March 29, 2017 between NeuroHabilitation Corporation and 660 Tudor Square, L.P. (incorporated by reference to Exhibit 10.26 to the Transition Report on Form 10-K filed with the SEC on April 3, 2017)
10.27	Modification No. 4 to the Amended Cooperative Research and Development Agreement, dated September 6, 2017 (incorporated by reference to Exhibit 2.1 to the Form 8-K filed September 12, 2017)
10.28	Amendment of Solicitation/Modification of Contract of Sole-Source Cost Sharing Agreement with the U.S. Army Medical Research and Materiel Command), dated November 7, 2017 (incorporated by reference to Exhibit 10.2 to the Form 10-Q filed with the SEC on November 9, 2017)
10. 29*+	Commercial contract manufacturing agreement dated December 29, 2017 between NeuroHabilitation Corporation and Key Tronic Corporation
16.1	Letter from BDO Canada LLP, dated January 10, 2017 (incorporated by reference to Exhibit 16.1 to the Form 8-K filed with the SEC on January 10, 2017)
21.1*	Subsidiaries of Helius Medical Technologies, Inc.
23.1*	Consent of BDO USA, LLP
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes – Oxley Act of 2002
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes – Oxley Act of 2002
32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes – Oxley Act of 2002
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document

* Filed herewith.
† Indicates a management contract or compensatory plan.
‡ Confidential information has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been granted with respect to this omitted information.
\+ Confidential information has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested 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") and subsidiaries as of December 31, 2017 and 2016, the related consolidated statements of operations and comprehensive loss, stockholders' deficit, and cash flows for the year ended December 31, 2017 and for the period from April 1, 2016 through December 31, 2016, 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 and subsidiaries at December 31, 2017 and 2016, and the results of their operations and their cash flows for the year ended December 31, 2017 and the period from April 1, 2016 through December 31, 2016**,** 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 approximate accumulated deficit of $66.4 million as of December 31, 2017 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 in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

/s/ BDO USA, LLP

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

Philadelphia, Pennsylvania
March 12, 2018

Helius Medical Technologies, Inc.
Consolidated Balance Sheets
(Except for share data, amounts in thousands and expressed in United States Dollars)

	December 31, 2017	December 31, 2016
ASSETS		
Current assets		
Cash	$ 5,562	$ 2,669
Receivables	704	225
Prepaid expenses and other current assets	352	556
Total current assets	6,618	3,450
Property, plant and equipment, net	173	—
Other assets	18	—
TOTAL ASSETS	$ 6,809	$ 3,450
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities		
Accounts payable	$ 3,479	$ 2,161
Accrued liabilities	1,242	259
Derivative financial instruments	9,578	4,474
Total current liabilities	14,299	6,894
TOTAL LIABILITIES	14,299	6,894
Commitments and contingencies (Note 7)		
STOCKHOLDERS' DEFICIT		
Common stock (Unlimited Class A common shares authorized); (20,178,226 shares issued and outstanding as of December 31, 2017 and 16,926,120 shares issued and outstanding as of December 31, 2016)	52,230	30,897
Additional paid-in capital	6,602	5,732
Accumulated other comprehensive income (loss)	47	(1,728)
Accumulated deficit	(66,369)	(38,345)
TOTAL STOCKHOLDERS' DEFICIT	(7,490)	(3,444)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$ 6,809	$ 3,450

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

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

	Year Ended December 31, 2017	Nine Months Ended December 31, 2016
Operating expenses:		
Research and development	$ 14,387	$ 4,723
General and administrative	8,466	5,651
Total operating expenses	22,853	10,374
Operating loss	(22,853)	(10,374)
Other income (expense):		
Interest and other income	—	111
Change in fair value of derivative financial instruments	(3,443)	(2,480)
Foreign exchange gain (loss)	(1,728)	703
Total other expense	(5,171)	(1,666)
Net loss	(28,024)	(12,040)
Other comprehensive (loss)		
Foreign currency translation adjustments	1,775	(728)
Comprehensive loss	$ (26,249)	$ (12,768)
Net loss per share		
Basic and diluted	$ (1.50)	$ (0.72)
Weighted average shares outstanding		
Basic and diluted	18,632,740	16,671,019

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

Helius Medical Technologies, Inc.
Consolidated Statements of Stockholders' Deficit
(Except shares data, amounts in thousands and expressed in United States Dollars)

	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
Balance as of April 1, 2016	**14,438,627**	**$ 24,348**	**$ 2,941**	**$ (26,305)**	**$ (999)**	**$ (15)**
Exercise of finder's warrants	365,120	1,549	(151)	—	—	1,398
Issuance of common stock in public offering and private placement	2,061,025	6,548	—	—	—	6,548
Issuance of warrants in public offering and private placement	—	—	1,504	—	—	1,504
Share issuance costs	—	(1,875)	366	—	—	(1,509)
Stock-based compensation expense	—	—	1,462	—	—	1,462
Fair value of non-employee vested options reallocated to derivative financial instruments	—	—	(268)	—	—	(268)
Agent compensation option exercise	150	1	—	—	—	1
Proceeds from the exercise of stock options and warrants	61,198	326	(122)	—	—	204
Net loss	—	—	—	(12,040)	—	(12,040)
Foreign currency translation adjustment	—	—	—	—	(729)	(729)
Balance as of December 31, 2016	**16,926,120**	**$ 30,897**	**$ 5,732**	**$ (38,345)**	**$ (1,728)**	**$ (3,444)**
Issuance of common stock in public offering	1,311,000	9,187	—	—	—	9,187
Issuance of common stock and warrants in private placement	1,446,016	11,691	—	—	—	11,691
Fair value of warrants issued in connection with the December 2017 financing classified as derivative financial instruments	—	(3,017)	—	—	—	(3,017)
Share issuance costs	—	(1,321)	—	—	—	(1,321)
Stock-based compensation expense	—	—	1,719	—	—	1,719
Proceeds from the exercise of stock options and warrants	492,826	2,588		—	—	2,588
Vesting of restricted stock units, net of taxes	2,264	—	—	—	—	—
Reclassification of exercised stock options and warrants from additional paid-in capital	—	849	(849)	—	—	—
Reclassification of liability classified warrants upon exercise	—	1,356	—	—	—	1,356
Net loss	—	—	—	(28,024)	—	(28,024)
Foreign currency translation adjustments	—	—	—	—	1,775	1,775
Balance as of December 31, 2017	**20,178,226**	**$ 52,230**	**$ 6,602**	**$ (66,369)**	**$ 47**	**$ (7,490)**

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

Helius Medical Technologies, Inc.
Consolidated Statements of Cash Flows
(Amounts in thousands and expressed in United States Dollars)

	Year Ended December 31, 2017	Nine Months Ended December 31, 2016
Cash flows from operating activities		
Net loss	$ (28,024)	$ (12,040)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	17	-
Change in fair value of derivative financial instruments	3,443	2,480
Stock-based compensation expense	1,818	1,462
Unrealized foreign exchange loss (gain)	1,585	(641)
Changes in operating assets and liabilities:		
Receivables	(479)	174
Prepaid expenses and other current assets	186	76
Account payable	1,318	345
Accrued liabilities	811	259
Net cash used in operating activities	(19,325)	(7,885)
Cash flows from investing activities		
Purchase of Property, plant & equipment	(190)	—
Net cash used in investing activities	(190)	—
Cash flows from financing activities		
Proceeds from the issuance of common stock and warrants	20,878	7,903
Share issuance costs	(1,248)	(1,509)
Proceeds from the exercise of stock options and warrants	2,588	1,603
Net cash provided by financing activities	22,218	7,997
Effect of foreign exchange rate changes on cash	190	(87)
Net increase in cash	2,893	25
Cash at beginning of period	2,669	2,644
Cash at end of period	$ 5,562	$ 2,669
Supplemental disclosure of non-cash cash activities		
Cash paid for interest	$ —	$ —
Cash paid for income taxes	—	—
Supplemental schedule of non-cash investing and financing activities		
Share issuance costs included in accounts payable	$ 73	$ -
Fair value of warrants issued to agent for services provided in conjunction with the April 2016 Offering	$ —	$ 366

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

1. DESCRIPTION OF BUSINESS

Helius Medical Technologies, Inc. (the "Company") is engaged primarily in the medical technology industry focused on neurological wellness. The Company's planned principal operations include the development, licensing and acquisition of unique and non-invasive platform technologies to amplify the brain's ability to heal itself.

Many patients with brain injury or brain-related disease have disrupted neural networks that result in their brains being unable to correctly or efficiently carry neural impulses, which are responsible for directing bodily functions like movement control or sensory perception. Our first product in development, known as the portable neuromodulation stimulator or PoNS, device, is designed to enhance the brain's ability to compensate for this damage. The PoNS Treatment is a combination of our PoNS device and functional, targeted physical or cognitive therapy, and is currently being developed for the treatment of movement, gait and balance disorders in patients with traumatic brain injury, or TBI, and other chronic neurological diseases.

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. The Company is headquartered in Newtown, Pennsylvania.

The Company has two wholly-owned subsidiaries, Neurohabilitation Corporation ("NHC") and Helius Medical Technologies (Canada), Inc. ("Helius Canada").

The Company's Class A common stock without par value ("common stock") is currently listed on the Toronto Stock Exchange (the "TSX"). The Company's common stock began trading on the Canadian Securities Exchange on June 23, 2014, under the ticker symbol "HSM", and trading of the common stock subsequently moved to the TSX on April 18, 2016. The Company's common stock also began trading on the OTC Markets ("OTCQB") under the ticker symbol "HSDT" on February 10, 2015. The financial information is presented in United States Dollars.

Reverse Stock Split

Effective after the close of business on January 22, 2018, we completed a 1-for-5 reverse stock split of our Class A Common Stock. Since January 23, 2018, our Class A common stock has traded on a post-split basis on the OTCQB and Toronto Stock Exchange. All share and per share amounts in this Annual Report have been reflected on a post-split basis.

Going Concern

As of December 31, 2017, the Company had cash of $5.6 million. For the year ended December 31, 2017, the Company incurred a net loss of $28.0 million and, as of December 31, 2017 its accumulated deficit was $66.4 million. The Company has not generated any product revenues and has not achieved profitable operations. The Company expects to continue to incur operating losses and net cash outflows until such time as it generates a level of revenue to support its cost structure. There is no assurance that the Company will achieve profitable operations, and, if achieved, whether it will be sustained on a continued basis. These factors raise substantial doubt about the Company's ability to continue as a going concern. The Company's consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and satisfaction of liabilities in the ordinary course of business.

The Company intends to fund ongoing activities by utilizing its current cash and by raising additional capital through equity or debt financings. There can be no assurance that the Company will be successful in raising additional capital or that such capital, if available, will be on terms that are acceptable to the Company. If the Company is unable to raise sufficient additional capital, the Company may be compelled to reduce the scope of its operations and planned capital expenditure or sell certain assets, including intellectual property assets.

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").

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 fair value pricing model for stock-based compensation 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. All intercompany balances and transactions have been eliminated.

Concentrations of Credit Risk

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

Receivables

Receivables are stated at their net realizable value. As of December 31, 2017, and 2016 receivables consisted primarily of Goods and Services Tax (“GST”) and Quebec Sales Tax (“QST) refunds related to the Company’s Canadian expenditures.

Property, Plant and Equipment

Property, plant and equipment are carried at cost, less accumulated depreciation. Depreciation is recognized using the straight-line method over the useful live of the related asset. 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 Company’s property, plant and equipment is comprised of leasehold improvements and software. The estimated useful life of its leasehold improvement is over the term of its lease of 5 years, while software has an estimated useful life of 3 to 5 years.

The following tables summarizes the Company property, plant and equipment as of December 31, 2017 (amounts in thousands). The Company had no property, plant and equipment as of December 31, 2016.

	As of December 31, 2017
Leasehold improvement	$ 173
Software	17
	190
Less accumulated depreciation	(17)
Total	$ 173

Share-Based Payments

The Company accounts for all share-based payments and awards under the fair value-based method. The Company recognizes its stock-based compensation expense using the straight-line method.

The Company accounts for the granting of stock options to employees using the fair value method whereby all awards to employees 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 share 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.

Share-based payment to non-employees are measured at the fair value of the consideration received, or the fair value of the equity instruments issued, or liabilities incurred, whichever is more reliably measurable. The fair value of stock-based payments to non-employees are re-measured at each reporting period until the counterparty performance is complete, and any change therein is recognized

over the vesting period of the award and in the same manner as if the Company had paid cash instead of paying with or using equity-based instruments. The fair value of the stock-based payments to non-employees that are fully vested and non-forfeitable as of the grant date are measured and recognized at that 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.

Foreign Currency

The functional currency of the Company and Helius Canada is the Canadian dollar ("CAD") and the functional currency of NHC is the U.S. dollar ("USD"). The Company's reporting currency is the U.S. dollar. 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 for the reporting period, but rather are accumulated and gains and losses are recorded in foreign exchange gain (loss) within the consolidated statements of operations and comprehensive loss. The foreign exchange adjustment in the books of NHC relating to intercompany advances from Helius that are denominated in Canadian dollars is recorded in the consolidated statements of operations.

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

Research and Development Expenses

Research and development ("R&D") expenses consist primarily of personnel costs, including salaries, benefits and stock-based compensation, clinical studies performed by contract research organizations, development and manufacturing of clinical trial devices and devices for manufacturing testing, materials and supplies as well as regulatory costs. 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 marked-to-market 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. The Company's derivative financial instruments are comprised of warrants and non-employee stock options. Upon settlement of a derivative financial

instrument, the instrument is marked to fair value at the settlement date and the fair value of the underlying instrument is reclassified to equity.

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

Fair Value Measurements

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

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

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

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

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

The Company's derivative financial instruments are classified as Level 3 within the fair value hierarchy and required to be recorded at fair value on a recurring basis. Unobservable inputs used in the valuation of these financial instruments include volatility of the underlying share price and the expected term. See Note 3 for the inputs used in the Black-Scholes option pricing model as of December 31, 2017 and 2016 and the roll forward of the derivative financial instruments related to the warrants and see Note 4 for the inputs used in the Black-Scholes option pricing model as of December 31, 2017 and 2016 for the roll forward of the derivative financial instruments related to the non-employee stock options.

The following table summarizes the Company's derivative financial instruments within the fair value hierarchy as of December 31, 2017 and 2016 (amounts in thousands):

	Fair Value	Level 1	Level 2	Level 3
December 31, 2017				
Liabilities:				
Non-employee stock options	$ 2,637	—	—	$ 2,637
Warrants	6,941	—	—	6,941
December 31, 2016				
Liabilities:				
Non-employee stock options	$ 1,617	—	—	$ 1,617
Warrants	2,857	—	—	2,857

There were no transfers between any of the levels during the year ended December 31, 2017 and the nine months ended December 31, 2016.

Basic and Diluted Income (Loss) per Share

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

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

EPS for convertible debt is calculated under the "if-converted" method. Under the if-converted method, EPS is calculated as the more dilutive of EPS (i) including all interest (both cash interest and non-cash discount amortization) and excluding all shares underlying the convertible debt or; (ii) excluding all interest and costs directly related to the convertible debt (both cash interest and non-cash discount amortization) and including all shares underlying the convertible debt.

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):

	Year Ended December 31, 2017	Nine Months Ended December 31, 2016
Basic and Diluted		
Numerator		
Net loss	$ (28,024)	$ (12,040)
Denominator		
Weighted-average common shares outstanding - basic and diluted	18,632,740	16,671,019
Basic and diluted net loss per share	$ (1.50)	$ (0.72)

The following outstanding securities have been excluded from the computation of diluted weighted shares outstanding for the periods noted below, as they would have been anti-dilutive:

	Year Ended December 31, 2017	Nine Months Ended December 31, 2016
Options outstanding	2,448,646	1,969,000
Warrants outstanding	2,379,919	2,017,252
Total	4,828,565	3,986,252

Reclassifications

Certain prior year amounts in the consolidated financial statements have been reclassified to conform to the current year presentation.

Recent Accounting Pronouncements

In March 2016, the FASB issued ASU 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*. The amendments in this update change existing guidance related to accounting for employee share-based payments affecting the income tax consequences of awards, classification of awards as equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 is effective for annual reporting periods beginning after December 15, 2016, including interim periods within those annual periods, with early adoption permitted. The updated accounting guidance was effective for the Company on January 1, 2017 and it did not have a material effect on our consolidated financial statements and any deferred tax benefits would be offset by a valuation allowance.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842).* The new standard establishes a right-of-use, or ROU, model that requires a lessee to record a ROU asset and a lease liability on the consolidated balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the consolidated statement of operations. ASU 2016-02 is effective for annual periods beginning after December 15, 2018, including interim periods within those annual periods, with early adoption permitted. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the consolidated financial statements, with certain practical expedients available. The Company is currently evaluating the potential impact of the standard on our consolidated financial statements.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which was further amended through various updates issued by the FASB thereafter. The amendments of Topic 606 completed the joint effort between the FASB and the IASB, to develop a common revenue standard for GAAP and IFRS, and to improve financial reporting. The guidance under Topic 606 provides that an entity should recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled to in exchange for the goods or services provided and establishes a five-step model to be applied by an entity in evaluating its contracts with customers. The Company does not have any revenues or contracts with customers and will need to evaluate the impact of Topic 606 on its results of operations, cash flows and financial position should a revenue generating transaction arise in the future. While the Company will adopt Topic 606 on January 1, 2018 (and will do so on a modified retrospective basis), the adoption will have no impact on the Company's consolidated financial statements.

3. COMMON STOCK AND WARRANTS

As of December 31, 2017, the Company's certificate of incorporation authorized the Company to issue unlimited Class A common shares without par value. Each Class A common share is entitled to have the right to vote at any shareholder meeting on the basis of one vote per share. Each Class A share held entitles the holder to receive dividends as declared by the directors. No dividends have been declared through December 31, 2017. In the event of a liquidation, dissolution or winding-up of the Company other distribution of assets of the Company among its shareholders for the purposes of winding-up its affairs or upon a reduction of capital the holders of the Class A common shares shall, share equally, share for share, in the remaining assets and property of the Company.

The Company is subject to a stockholders' agreement, which places certain restrictions on the Company's stock and its stockholders. These restrictions include approvals prior to sale or transfer of stock, a right of first refusal to purchase stock held by the Company and a secondary right of refusal to stockholders, right of co-sale whereby certain stockholders may be enabled to participate in a sale of other stockholders to obtain the same price, term and conditions on a pro-rata basis, rights of first offer of new security issuances to current stockholders on a pro-rata basis and certain other restrictions.

On October 9, 2015, the Company entered into a $7.0 million funding commitment with A&B (HK) Company Limited ("A&B"), in the form of a convertible promissory note consisting of an initial $2.0 million note and a $5.0 million funding commitment. On October 9, 2015, the Company received the conversion notice on the promissory note and in November 2015, the Company issued 416,666 shares of common stock at a price of $4.80 per share and 208,333 warrants exercisable at $7.20 for a period of three years from the date of issuance. The shares of common stock and the warrants were issued on November 10, 2015. On December 29, 2015, the Company drew down the $5.0 million funding commitment through the issuance of 1,111,111 shares of common stock at a price of $4.50 per share and 555,556 warrants exercisable at $6.75 for a period of three years from the date of issuance. The shares of common stock and the warrants were issued on January 7, 2016. In November 2017, A&B exercised 208,333 warrants at a price of $7.20 and the Company received gross cash proceeds of $1.5 million upon the exercise.

On April 18, 2016, the Company closed its short form prospectus offering in Canada and a concurrent U.S. private placement (the "April 2016 Offering") of units (the "Units") with gross proceeds to the Company of $7.2 million through the issuance of Units at a price of CAD$5.00 per Unit. Each Unit consists of one Class A common share in the capital of the Company (a "Common Share') and one half of one Common Share purchase warrant (each whole warrant, a "Warrant"). Each warrant entitles the holder thereof to acquire one additional Common Share at an exercise price of CAD$7.50 on or before April 18, 2019. Mackie Research Capital Corporation (the "Agent") acted as agent and sole bookrunner in connection with the April 2016 Offering. The Company paid the Agent a cash commission of $0.3 million and has granted to the Agent compensation options exercisable to purchase 87,210 Units at an exercise price of CAD$5.00 per Unit for a period of 24 months from the closing of the April 2016 Offering. The Company incurred other cash issuance costs of $1.1 million related to this offering.

On May 2, 2016, the Company closed the sale of the additional units issued pursuant to the exercise of the over-allotment option granted to the Agent in connection with the April 2016 Offering. The April 2016 Offering was made pursuant to a short form prospectus filed with the securities regulatory authorities in each of the provinces of Canada, except Québec. Pursuant to the exercise of the over-allotment option, the Company issued an additional 218,025 units at a price of CAD $5.00 per unit for additional gross proceeds to the Company of $0.9 million, bringing the total aggregate gross proceeds to the Company under the Offering to $8.1 million. Each over-allotment unit consisted of one Class A common share in the capital of the Company and one half of one Common Share purchase warrant. Each over-allotment warrant entitles the holder thereof to acquire one additional over-allotment Common Share at an exercise price of CAD $7.50 on or before April 18, 2019. In connection with the closing of the over-allotment option, the Company paid the Agent a cash commission of $0.1 million and granted to the Agent compensation options exercisable to purchase 13,081 over-allotment units at an exercise price of CAD $5.00 per unit for a period of 24 months from the closing of this Offering.

The warrants issued in each of the April 18, 2016 and May 2, 2016 closings are classified within equity. The proceeds from the Offering were allocated on a relative fair value basis between the Class A common shares and the warrants issued. The compensation options are accounted for as warrants. These warrants represent additional share issuance costs and are recorded within shareholders' deficit in the Company's consolidated balance sheets at their fair value.

The fair value of the warrants granted in the April 2016 Offering were estimated using the Black-Scholes option pricing model with the following weighted average assumptions:

Stock price	CAD$5.45
Exercise price	CAD$7.50
Warrant term	3.0 years
Expected volatility	83.83%
Risk-free interest rate	0.60%
Dividend rate	0.00%

The fair value of the compensation options granted during the April 2016 Offering were estimated using the Black-Scholes option pricing model with the following weighted average assumptions:

Stock price	CAD$6.80
Exercise price	CAD$5.00
Option term	2.0 years
Expected volatility	126.76%
Risk-free interest rate	0.61%
Dividend rate	0.00%

On June 6, 2016, the Company received proceeds of USD $1.4 million from the exercise of 365,120 outstanding warrants which were issued in connection with the Company's private placement of subscription receipts that closed on May 30, 2014. The remaining 1,320,880 warrants issued in this offering expired unexercised.

On February 16, 2017, the Company completed an underwritten registered public offering and issued an aggregate of 1,311,000 shares of common stock for gross proceeds of $9.2 million. The offering was made by means of written prospectuses and prospectus supplements, dated February 9, 2017, that form part of the Company's existing Canadian multi-jurisdictional disclosure system ("MJDS") short-form base shelf prospectus dated January 26, 2017, in Canada, and U.S. shelf registration statement on Form S-3 that became effective on January 6, 2017, in the U.S. The Company incurred cash issuance costs of $1.2 million in connection with this offering.

On June 28, 2017, the Company completed a non-brokered private placement of 800,000 shares of common stock for gross proceeds of $5.4 million. The Company incurred approximately $9 thousand in share issuance cost related to the private placement.

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

The fair value of the warrants granted in the December 2017 financing were estimated using the Black-Scholes option pricing model with the following weighted average assumptions:

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

Pursuant to the guidance of ASC 815 *Derivatives and Hedging*, the Company determined that certain warrants issued in 2015, warrants related to the funding commitment with A&B in 2016, as well as warrants issued in the December 2017 financing are accounted for as liabilities because they were not considered to be indexed to the Company's stock due to the exercise price being denominated in a currency other than the Company's functional currency. Consequently, the Company determined the fair value of each warrant issuance using the Black-Scholes option pricing model, with the remainder of the proceeds allocated to the common shares.

The following table summarizes warrants that the Company accounts for as liabilities for the year ended December 31, 2017 and nine months ended December 31, 2016 (amounts in thousands):

	Year Ended December 31, 2017	Nine Months Ended December 31, 2016
Fair value of warrants at beginning of period	$ 2,857	$ 1,205
Issuance of warrants	3,016	—
Exercise of warrants	(1,200)	—
Change in fair value of warrants during the period	2,268	1,652
Fair value of warrants at end of period	$ 6,941	$ 2,857

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

The fair value of warrants as of December 31, 2017 and 2016 were estimated using the Black-Scholes option pricing model with the following weighted average assumptions:

	December 31, 2017	December 31, 2016
Stock price	$ 12.32	$ 6.90
Exercise price	$ 10.25	$ 8.10
Warrant term	1.91 years	1.89 years
Expected volatility	62.20%	94.97%
Risk-free interest rate	1.83%	0.79%
Dividend rate	0.00%	0.00%

The following is a summary of warrant activity during the year ended December 31, 2017 and nine months ended December 31, 2016:

	Number of Warrants		Weighted-Average Exercise Price	
	CAD	US	CAD	US
Outstanding as of April 1, 2016	1,686,000	905,721	$ 5.00	$ 8.10
Granted	1,030,587	—	7.50	
Granted (Agent Compensation)	100,291	—	5.00	
Expired	(1,320,880)	—	5.00	
Exercised	(384,468)	—	5.10	
Outstanding as of December 31, 2016	1,111,530	905,721	7.30	8.10
Granted	25,063	646,016	7.50	12.25
Exercised	(125,088)	(208,333)	6.50	7.20
Outstanding and exercisable as of December 31, 2017	1,011,505	1,343,404	$ 7.38	$ 10.25

The following table summarizes the Company's warrants outstanding and exercisable as of December 31, 2017:

Number of Warrants Outstanding	Exercise Price	Expiration Date
90,406	US$15.00	April 30, 2018
33,546	US$15.00	June 26, 2018
3,795	US$10.75	June 26, 2020
12,576	US$15.00	July 17, 2018
1,509	US$10.75	July 17, 2020
555,556	US$6.75	December 29, 2018
961,489	CAD$7.50	April 18, 2019
50,015	CAD$5.00	April 18, 2018
270,915	US$12.25	December 22, 2020
171,020	US$12.25	December 28, 2020
204,081	US$12.25	December 29, 2020
2,354,908		

4. SHARE BASED PAYMENTS

On June 18, 2014, the Company's Board of Directors authorized and approved the adoption of the 2014 Stock Incentive Plan ("2014 Plan"), under which an aggregate of 2,421,603 shares of common stock may be issued. Pursuant to the terms of the 2014 Plan, the Company is authorized to grant stock options, as well as awards of stock appreciation rights, restricted stock, unrestricted shares, restricted stock units and deferred stock units. 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. On August 22, 2017, the Company's Board of Directors approved the amended and restated 2014 Plan to correct for a formulaic error included in the deemed net stock and cashless exercise equation within the 2014 Plan. This amendment had no impact on the Company's consolidated financial statements. As of December 31, 2017, the Company had 40,000 shares of common shares remaining available for grant under the 2014 Plan.

On August 8, 2016, the Company's Board of Directors authorized and approved the adoption of the 2016 Omnibus Incentive Plan ("2016 Plan"), under which an aggregate of 3,000,000 shares of common stock may be issued. Pursuant to the terms of the 2016 Plan, the Company is authorized to grant stock options, as well as awards of stock appreciation rights, restricted stock, unrestricted shares, restricted stock units, 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.

As of December 31, 2017, there were an aggregate of 2,693,614 shares of common stock remaining available for grant under the 2016 Plan.

The following is a summary of stock option activity for the year ended December 31, 2017 and nine months ended December 31, 2016:

	Number of Options	Weighted Average Exercise Price (CAD)	Aggregate Intrinsic Value (CAD)
Outstanding as of April 1, 2016	1,335,072	$ 5.40	$ 1,581
Granted	707,000	6.90	
Forfeited	(6,250)	3.00	
Cancelled	(24,822)	3.00	
Exercised	(42,000)	3.00	
Outstanding as of December 31, 2016	1,969,000	6.00	8,218
Granted	868,902	11.15	
Forfeited	(153,067)	11.45	
Cancelled	(62,689)	13.75	
Exercised (1)	(173,500)	5.15	
Outstanding as of December 31, 2017	2,448,646	$ 7.35	$ 21,089
Exercisable as of December 31, 2017	1,451,739	$ 5.70	$ 14,892

(1) For the year ended December 31, 2017, 20,000 stock options were exercised on a cashless basis resulting in 14,095 common shares being withheld.

The Company has adopted the simplified method prescribed by the SEC in SAB Topic 14 with respect to estimating the expected term of its stock options as its limited share purchase option history does not provide a reasonable basis to estimate the expected terms. Expected volatility was determined by reference to the average volatility rates of other companies in the same industry due to the Company's limited trading history. The aggregate intrinsic value of stock options exercised during the year ended December 31, 2017 and nine months ended December 31, 2016 was $1.3 million and $0.1 million, respectively.

The following table summarizes stock options outstanding and exercisable by employees and directors as of December 31, 2017:

Number of Options Outstanding	Expiration Date	Options Outstanding Remaining Contractual Life (In Years)	Exercise Price (CAD)	Grant Date Fair Value (CAD)	Number of Options Exercisable
360,000	June 18, 2019	1.46	$ 3.00	$ 1.00	360,000
80,000	June 18, 2019	1.46	$ 3.00	$ 1.32	80,000
20,000	December 8, 2019	1.94	$ 14.60	$ 6.55	20,000
80,000	December 8, 2019	1.94	$ 14.80	$ 6.46	80,000
20,000	March 16, 2020	2.21	$ 16.00	$ 7.09	20,000
8,500	August 14, 2020	2.62	$ 4.90	$ 1.94	8,500
150,000	October 21, 2020	2.81	$ 4.20	$ 1.80	112,500
20,000	December 31, 2020	3.00	$ 6.20	$ 2.49	20,000
595,000	July 13, 2020	2.53	$ 6.95	$ 3.23	396,666
20,000	August 8, 2020	2.61	$ 6.55	$ 3.23	10,000
617,000	April 17, 2027	9.30	$ 10.80	$ 7.76	-
6,146	May 18, 2027	9.38	$ 10.00	$ 5.23	3,073
10,000	May 18, 2027	9.38	$ 10.00	$ 7.63	-
30,000	August 8, 2027	9.61	$ 13.15	$ 8.86	-
2,016,646					1,110,739

As of December 31, 2017, and 2016, the unrecognized compensation cost related to non-vested stock options outstanding for employees and directors, was $4.9 million and $1.3 million, respectively, to be recognized over a weighted-average remaining vesting period of approximately 2.6 years and 1.41 years, respectively. The Company recognizes compensation expense for only the portion of awards that are expected to vest.

During the fourth quarter of 2017, upon a review of the Company's equity compensation awards granted under the 2016 Plan it determined that it had inadvertently exceeded the annual per-person sub-limits involving certain awards previously made to a current executive officer. The aggregate amount of common stock represented by this excess award, which consisted of stock options, was 60,000 shares. This excess award was deemed to have been granted outside of the 2016 Plan and as such the Company applied liability accounting to the awards. As a result, this excess award will be remeasured at each reporting period untill such time that the Company's shareholders approve the excess award at which time the liability will be reclassified to additional paid-in capital and the unrecognized fair value calculated for the excess award as of the date of shareholders' approval will be recognized as compensation expense ratably over the remaining requisite service period for the excess award.

For the year ended December 31, 2017 and the nine months ended December 2016, the Company granted 673,902 and 625,000 stock options, respectively, to employees and directors at a weighted average exercise price of CAD$10.87 and CAD$6.94, respectively. The fair value of employee and director stock options granted for the year ended December 31, 2017 and the nine months ended December 31, 2016 had a weighted average grant date fair value of CAD$4.34 and $2.60 per option, respectively, and they were estimated using the Black-Scholes option pricing model with the following weighted-average assumptions:

	Year Ended December 31, 2017	Nine Months Ended December 31, 2016
Stock price	CAD$10.40	CAD$6.95
Exercise price	CAD$10.85	CAD$6.95
Expected term	6.25 years	2.5 years
Expected volatility	90.84%	77.92%
Risk-free interest rate	1.06%	0.49%
Dividend rate	0.00%	0.00%

Non-Employee Stock Options

For the year ended December 31, 2017, the Company granted 195,000 stock options at a weighted average exercise price of CAD$12.20, of which 185,000 were either cancelled or forfeited to non-employees. For the nine months ended December 31, 2016, the Company granted 82,000 stock options to non-employees at a weighted average exercise price of CAD$6.70. The fair value of non-employee stock options granted for the year ended December 31, 2017 and the nine months ended December 31, 2016 had a weighted average grant date fair value of CAD$3.88 and $3.23 per option, respectively, and they were estimated using the Black-Scholes option pricing model with the following weighted-average assumptions:

	Year Ended December 31, 2017	Nine Months Ended December 31, 2016
Stock price	CAD$12.15	CAD$9.60
Exercise price	CAD$12.20	CAD$6.75
Option term	10 years	3.75 years
Expected volatility	91.02%	84.16%
Risk-free interest rate	1.60%	0.98%
Dividend rate	0.00%	0.00%

The following table summarizes stock options outstanding and exercisable by non-employees as of December 31, 2017:

Number of Options Outstanding	Expiration Date	Options Outstanding Remaining Contractual Life (In Years)	Exercise Price (CAD)	Grant Date Fair Value (CAD)	Number of Options Exercisable
160,000	June 18, 2019	1.46	$ 3.00	$ 1.32	160,000
30,000	December 8, 2019	1.94	$ 14.60	$ 8.25	30,000
82,000	October 3, 2020	2.76	$ 6.75	$ 4.00	41,000
110,000	October 28, 2020	2.83	$ 4.20	$ 2.20	110,000
20,000	May 18, 2027	9.38	$ 10.00	$ 8.69	-
15,000	August 8, 2027	9.61	$ 13.15	$ 11.70	-
15,000	November 6, 2027	9.85	$ 20.65	$ 19.93	-
432,000					341,000

As of December 31, 2017, the unrecognized compensation cost related to non-vested stock options outstanding for non- employees was $0.4 million to be recognized over a weighted-average remaining vesting period of approximately 1.93 years, respectively. As of December 31, 2016, the Company had no unrecognized compensation cost related to non-vested stock options outstanding for non-employees. The Company recognizes compensation expense for only the portion of awards that are expected to vest.

In accordance with the guidance of ASC 815-40-15, stock options awarded to non-employees that are performing services for NHC are required to be accounted for as derivative financial instruments once the services have been performed and the options have vested because they are considered not to be indexed to the Company's stock due to their exercise price being denominated in a currency other than NHC's functional currency. Stock options awarded to non-employees that have not vested are re-measured at their respective fair values at each reporting period and accounted for as equity awards until the terms associated with their vesting requirements have been met. The changes in fair value of the unvested non-employee awards are reflected in their respective operating expense classification in the Company's consolidated statements of operations and comprehensive loss.

The non-employee stock options that are accounted for as liabilities are summarized as follows (amounts in thousands):

	Year Ended December 31, 2017	Nine Months Ended December 31, 2016
Fair value of non-employee stock options at beginning of period	$ 1,617	$ 521
Reallocation of vested non-employee stock options	-	268
Exercised	(156)	-
Cancelled	(294)	-
Change in fair value of non-employee stock options during the period	1,470	828
Fair value of non-employee stock options at end of period	$ 2,637	$ 1,617

The non-employee stock options that have vested are required to be re-valued with the change in fair value recorded as a gain or loss in the change of fair value of derivative financial instruments and included in other income (expense) in the Company's consolidated statements of operations and comprehensive loss at the end of each reporting period. The fair value of the stock options will continue to be classified as a derivative financial instrument until such time as they are exercised, expire or there is an amendment to the respective agreements that renders these financial instruments to be no longer classified as such.

The fair value of non-employee liability classified awards as of December 31, 2017 and 2016 were estimated using the Black-Scholes option pricing model with the following weighted-average assumptions:

	December 31, 2017	December 31, 2016
Stock price	CAD$15.95	CAD$9.60
Exercise price	CAD$4.30	CAD$6.15
Expected life	1.51 years	2.59 years
Expected volatility	61.58%	87.61%
Risk-free interest rate	1.61%	0.79%
Dividend rate	0.00%	0.00%

Restricted Stock Units

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

The following is a summary of the Company's restricted stock unit activity for the year ended December 31, 2017:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value per Unit (CAD)
Outstanding as of January 1, 2017	-	$ -
Granted	8,097	10.00
Forfeited	(3,182)	
Outstanding as of December 31, 2017	4,915	$ 10.00
Vested as of December 31, 2017 (1)	2,987	$ 10.00

(1) includes 723 RSUs withheld for taxes

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

	Year Ended December 31, 2017	Nine Months Ended December 31, 2016
Research and development	$ 343	$ 107
General and administrative	1,475	1,355
	$ 1,818	$ 1,462

5. ACCRUED EXPENSES

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

	December 31, 2017	December 31, 2016
Employees benefits	$ 442	$ 259
Advance from U.S Army	233	-
Legal expense	343	-
Rent	97	-
Professional services	88	-
Severance	38	-
Other	1	-
	$ 1,242	$ 259

6. INCOME TAXES

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

	Year Ended December 31, 2017	Nine Months Ended December 31, 2016
U.S.	$ 24,980	$ 11,082
Non-U.S.	3,044	958
	$ 28,024	$ 12,040

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, 2017	Nine Months Ended December 31, 2016
Statutory tax rate	34.00%	34.00%
Net loss before income taxes	$ 28,024	$ 12,040
Expected income tax recovery	$ (9,528)	$ (4,094)
Increase (decrease) in income tax recovery resulting from:		
Derivative liability	1,171	843
Share based payments	453	467
Other permanent difference	(446)	(420)
Effect of change in statutory rate	5,938	—
State deferred change	(2,050)	—
Foreign income taxed at foreign rate	118	77
Increase in valuation allowance	4,344	3,127
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):

	December 31, 2017	December 31, 2016
Deferred income tax assets (liabilities)		
Operating losses carried forward	$ 11,382	$ 7,626
Tax credits	1,243	702
Stock compensation	1,414	1,726
Other	530	170
Valuation allowance	(14,569)	(10,224)
Net deferred income tax asset	$ —	$ —

As of December 31, 2017, the Company has accumulated non-capital losses totaling $6.0 million in Canada and net operating losses of $39.0 million in the U.S., which may be available to carry forward and offset future years' taxable income. The losses expire in various amounts starting in 2033.

Under the provisions of the Internal Revenue Code, 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 Internal Revenue Code, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years.

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

The Act reduces the corporate tax rate to 21%, effective January 1, 2018. The accounting for this portion of The Act has caused a reduction to the Company's net deferred tax assets before valuation allowance of $5.9 million for the year ended December 31,2017. However, the Company maintains a full valuation allowance against its deferred tax assets. As a result, the $5.9 million reduction to the Company's deferred tax assets is offset by a corresponding $5.9 million reduction in the Company's valuation allowance, resulting in no net impact to the Company's tax provision.

The Company has not completed its determination of the accounting implications of The Act on its tax accruals. However, the Company has reasonably estimated the effects of The Act as described above as of December 31, 2017, primarily comprised of the remeasurement of federal net deferred tax assets resulting from the permanent reduction in the U.S. statutory corporate tax rate to 21% from 34%. As the Company completes its analysis of The Act, collect and prepare necessary data, and interpret any additional guidance issued by the U.S. Treasury Department, the IRS, and other standard-setting bodies, the Company may make adjustments to the provisional amounts recorded as of December 31, 2017. However, those adjustments are not anticipated to have a material impact on the Company's tax provision.

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, 2017, the Company does not have an accrual relating to uncertain tax positions. It is not anticipated that unrecognized tax benefits would significantly increase or decrease within 12 months of the reporting date.

7. COMMITMENTS AND CONTINGENCIES

(a) On January 22, 2013, the Company entered into a license agreement with Advanced NeuroRehabilitation, LLC ("ANR") for an exclusive right on ANR's patent pending technology, claims and knowhow. In addition to the issuance of 3,207,005 shares of common stock, the Company agreed to pay a 4% royalty on net revenue on the sales of devices covered by the patent-pending technology and services related to the therapy or use of devices covered by the patent-pending technology. The Company has not made any royalty payments to date under this agreement.

(b) On October 30, 2017, NHC amended the Asset Purchase Agreement with A&B which specified that if the Company fails to obtain FDA marketing authorization for commercialization of or otherwise fails to ensure that the PoNS device is available for purchase by the U.S. Government by December 31, 2021, the Company would be subject to a $2.0 million contract penalty payable to A&B, unless the Company receives an exemption for the requirement of FDA marketing authorization from the US Army Medical Material Agency. Based on this amendment the Company has determined that the possibility of a payment under this contractual penalty is remote.

(c) In November 2014, the Company signed a development and distribution agreement with Altair LLC to apply for registration and distribution of the PoNS device in the territories of the former Soviet Union. The Company will receive 7% royalty on sales of the devices within the territories. However, there is no assurance that such commercialization will occur.

(d) In March 2017, the Company entered into a lease for office space in Newtown, Pennsylvania. The initial term of the lease is from July 1, 2017 through December 31, 2022, with an option to extend until 2027. In July 2017, the Company amended the contract to commence the lease on July 17, 2017 through January 16, 2023, with an option to extend until January 2028. Monthly rent plus utilities will be approximately $20,000 per month beginning in January 2018 with a 3% annual increase.

The future minimum lease payments related to the Company's non-cancellable operating lease commitments were as follows (amounts in thousands):

For the Year Ending December 31,	
2018	$ 231
2019	246
2020	253
2021	260
2022	267
Thereafter	12
	$ 1,269

(e) On December 29, 2017, NHC, a wholly owned subsidiary of the Company entered into a Manufacturing and Supply Agreement ("MSA") with Key Tronic Corporation ("Key Tronic"), for the manufacture and supply of the Company's PoNS device based upon the Company's product specifications as set forth in the MSA. Per the agreement, the Company shall provide to Key Tronic a rolling forecast for the procurement of parts and material and within normal lead times based on estimated delivery dates for the manufacture of the PoNS device. The term of the agreement will be for three-years and will automatically renew for additional consecutive terms of one year, unless cancelled by either party upon 180-day written notice to the other party prior to the end of the then current term. As of December 31, 2017, no initial forecast had been provided to Key Tronic by the Company.

8. RELATED PARTY TRANSACTIONS

For the year ended December 31, 2017, the Company paid approximately $16 thousand in consulting fee to a director of the Company. For the nine months ended December 31, 2016, the Company paid $0.1 million in consulting fees to certain directors of the Company.

During April 2016, the Company entered into a consulting agreement with Montel Media, Inc. ("Montel Media"), pursuant to which Montel Media provides consulting services for the promotion of the Company's clinical trials and ongoing media and marketing strategies. Under the agreement, Montel Media receives $15 thousand per month. For the year ended December 31, 2017 and the nine months ended December 31, 2016, the Company paid Montel Media $0.2 million and $0.1 million, respectively, pursuant to the consulting agreement. Montel Media is owned by Montel Williams, who beneficially owns greater than 5% of the Company's common stock.

For the year ended December 31, 2017 and nine months ended December 31, 2016, an expense of $0.4 million and $0.2 million, respectively, was included in the change in fair value of derivative financial instruments as the fair value of stock-based compensation attributed to the options granted to a director for consulting services rendered with respect to the design and development of the PoNS device.

The Company's Chief Medical Officer is a founding member of Clinvue LLC, a company that provides regulatory advisory services for the Company. During the year ended December 31, 2017, the Company paid Clinvue LLC approximately $0.1 million for consulting services. For the nine months ended December 31, 2016, the Company made no payment to Clinvue LLC.

In connection with the December 2017 private placement, the Company's Chief Executive Officer, its Chief Financial Officer/Chief Operating Officer, two directors and A&B, a greater than 5% owner of the Company's shares outstanding subscribed in the private placement. The following table summarizes their participation (subscription amount in thousands):

	Units Purchased	Subscription Amount
A&B (HK) Company Ltd.	204,081	$ 2,000
Director 1	76,530	750
Director 2	51,019	500
CEO	25,510	250
CFO/COO	15,816	155
	372,956	$ 3,655

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

In July 2015, the Company entered into a sole source cost sharing agreement with the U.S. Army Medical Research and Materiel Command ("USAMRMC"). Under the terms of the contract, the USAMRMC will reimburse the Company up to a maximum of $3.0 million to conduct a registrational trial investigating the safety and effectiveness of the PoNS device for the treatment of chronic balance deficits due to mild to moderate traumatic brain injury. Reimbursement of expenses under the agreement is based on a schedule of milestones related to the completion of subjects in the trial. The original contract expired on December 31, 2016; however, the Company extended the contract agreement through December 31, 2017. On November 7, 2017, the Company received another extension of the contract agreement to December 31, 2018. As of December 31, 2017, the Company has received a total of $3.0 million with respect to expenses reimbursed for amounts owed to the Company for completion of development milestones, of which $0.2 million of the total received has been recorded as an advance against the fifth and final milestone. All reimbursement amounts received are credited directly to the accounts in which the original expense is recorded, including research and development, wages and salaries, and legal expenses. In addition, during the third quarter of 2017, the Company announced the execution of an extension to its Cooperative Research and Development Agreement ("CRADA") with the USAMRMC through 2018 and extended the deadline for commercialization of the PoNS device to December 31, 2021.

10. SUBSEQUENT EVENTS

A&B Warrant Exercise and License Agreement

On February 28, 2018, A&B executed their notice to exercise 555,556 warrants issued on January 7, 2016, at an exercise price of $6.75 for gross proceeds to the Company of approximately $3.8 million.

On March 2, 2018, the Company, NHC and A&B entered into an agreement to negotiate an exclusive license agreement to grant A&B exclusive license rights to commercialize the PoNS device and components in additional territories in Asia.

SIGNATURES

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

HELIUS MEDICAL TECHNOLOGIES, INC.

Dated: March 12, 2018

By: /s/ Philippe Deschamps
Philippe Deschamps
President, Chief Executive Officer and Director

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

By /s/ Philippe Deschamps — Date: March 12, 2018
Philippe Deschamps
President, Chief Executive Officer and Director

By /s/ Joyce LaViscount — Date: March 12, 2018
Joyce LaViscount
Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer), and Corporate Secretary

By /s/ Blane Walter — Date: March 12, 2018
Blane Walter
Director

By /s/ Mitchell E. Tyler — Date: March 12, 2018
Mitchell E. Tyler
Director

By /s/ Edward M. Straw — Date: March 12, 2018
Edward M. Straw
Director

By /s/ Huaizheng Peng — Date: March 12, 2018
Huaizheng Peng
Director

By /s/ Thomas E. Griffin — Date: March 12, 2018
Thomas E. Griffin
Director

By /s/ Dane Andreeff — Date: March 12, 2018
Dane Andreeff
Director

MANUFACTURE AND SUPPLY AGREEMENT

This Manufacturing Agreement ("Agreement"), is entered into as of December 29, 2017 ("Effective Date") between **KEY TRONIC CORPORATION,** a Washington corporation, having its principal place of business at N. 4424 Sullivan Road, Spokane Valley, Washington 99216 ("Supplier") and NeuroHabilitation Corp., a Delaware corporation having its principal place of business at 642 Newtown Yardley Road, Suite 100, Newtown, PA 18940 ("Buyer").

1. SCOPE OF AGREEMENT

a. Supplier shall manufacture and supply to Buyer and Buyer shall purchase from Supplier under the terms and conditions of this Agreement Buyer's requirements for the Products listed on Exhibit A as ordered by Buyer, in accordance with the product specifications set forth thereon, or as may otherwise be provided by Buyer to Supplier in writing from time to time ("Product Specifications"), at the prices set forth in Exhibit B. For purposes of this Agreement, "Products" shall mean and be limited to those products manufactured for Buyer by Supplier as listed on Exhibit A and any mutually agreed upon modifications thereto. Unless otherwise specifically agreed to in writing, this Agreement prevails over any additional, conflicting or inconsistent terms and conditions appearing on any quotation, purchase order, acknowledgement, invoice or other form used by the parties in connection with this Agreement.

b. Supplier and Buyer may from time to time add Products to or delete Products from this Agreement. Such additions or deletions shall be accomplished by written addendum to this Agreement. Terms and conditions that may be specific to additional Products will be set forth in said addendum.

c. Unless otherwise specified herein or expressly consented to in writing by Buyer, as between the Parties, Supplier shall be solely responsible for performance of all procurement and manufacturing activities necessary for Supplier to be supplied with Product as contemplated hereunder. Unless provided otherwise herein, a party sublicensing, subcontracting or designating activities to be performed under this Agreement to an affiliate, third party or other permitted designee guarantees and warrants the related performance of any responsibilities so delegated, and assumes full vicarious liability for any such affiliate or third party sublicensee, subcontractor or permitted designee.

d. This Agreement shall not impose any obligation of exclusivity on Buyer and Buyer is free to have other parties (including, without limitation, itself) manufacture and sell the Products, or any similar products. However, if Buyer does not exclusively purchase Products from Supplier during the Initial Term, Buyer agrees to pay those actual, reasonable non-recurring engineering costs quoted by Supplier.

2. ORDERS FORECASTS AND AGED INVENTORY

a. Buyer shall provide Supplier at least once every month with a six month rolling forecast of Buyer's requirements for Products. The forecasts shall not be treated as authorization to manufacture Products. However, Supplier is authorized to rely on the forecasts to order, purchase and otherwise make available within normal lead times in existence from time to time as determined by Supplier in its reasonable judgment and based

on the estimated delivery dates set forth in the forecast all parts and materials for incorporation into forecasted Products including the parts and materials set forth on Exhibit C. If any parts and materials purchased by Supplier pursuant to this paragraph 2 in reliance on Buyer's forecast, including parts and materials set forth on Exhibit C, remain in Supplier's inventory for a period in excess of ninety (90) days (Aged Inventory) and Buyer has not made purchases in accordance with the forecast, then Buyer shall, at Supplier's option: (1) immediately pay Supplier a cash deposit in the amount of the Aged Inventory at Supplier's cost of the raw material plus ten percent (10%), and if Supplier is to retain possession of the Aged Inventory, Buyer shall pay Supplier an inventory storage fee equal to two percent (2%) of Supplier' s cost of Aged Inventory per month ; or (2) immediately purchase all such Aged Inventory at Supplier's cost plus ten percent (10%) and Buyer shall pay Supplier ' s costs to either package and ship Aged Inventory to Buyer or scrap Aged Inventory; or (3) immediately provide Supplier with a Purchase order to consume Aged Inventory in the next thirty (30) days. The parties will review Exhibit C once per month during the first three months of the term of this Agreement and once every three months thereafter and shall amend Exhibit C to add or delete parts and materials to reflect current usage.

b. Supplier will use commercially reasonable efforts to minimize Buyer's component liability for Aged Inventory, which shall include attempting to restock components with suppliers, attempting to cancel orders with suppliers, or attempting to consume components to meet the current demand of other Supplier customers, if possible. Buyer agrees to assist Supplier in such efforts if requested by Supplier. Buyer acknowledges that Supplier's mitigation efforts may result in cancellation, restocking, and similar charges imposed by suppliers. Supplier will obtain Buyer's written approval prior to incurring such charges. If so approved by Buyer, Buyer will pay Supplier for the charges imposed within thirty (30) days from the date of Supplier's invoice.

c. From time to time on its own initiative or upon Buyer's written request, Supplier will provide a written Aged Inventory report to Buyer detailing the amount of Aged Inventory at Supplier. Buyer will respond to Supplier in writing with twenty (20) days of receipt of the Aged Inventory report with details of any good faith disagreement. Buyer's failure to respond within such period will represent its acceptance of the Aged Inventory report. Should Buyer disagree with the Aged Inventory report, Buyer and Supplier will work in good faith to promptly resolve the disagreement, escalating such disagreement to executive management at the request of either party. Any undisputed portion of the Aged Inventory report shall be resolved pursuant to this Section.

d. From time to time, Buyer may order Products in accordance with the terms of this Agreement. Buyer will notify Supplier of its requirements for quantities of Products by submitting a purchase order [via electronic mail] to Supplier.

e. Supplier shall accept all purchase orders falling within Buyer's forecast within two (2) business days of receipt of each purchase order for forecasted Products. Supplier shall advise Buyer within seven (7) business days following receipt of each

purchase order for products which are in excess of forecast as to its ability to fulfill requirements as set forth in the purchase order provided, that Supplier shall use its commercially reasonably efforts to do so. This response shall include a schedule of anticipated deliveries against the purchase order. Supplier acknowledges that Buyer is not required to order any Products by virtue of this Agreement alone. Purchase orders issued by Buyer must be issued by an officer or authorized employee of Buyer in order to be valid.

If Buyer does not purchase and take delivery of any units of Products in accordance with the forecasts provided by Buyer pursuant to Section 2a during any continuous ninety (90) day period during the Term of this Agreement, then Supplier shall have the right to invoice Buyer and purchase from Supplier at Supplier's cost plus ten percent (10%) all parts and materials (including MOQs) on order or in transit purchased to Buyer's forecasts within lead times, all work in process at Supplier's cost plus quoted margin and all finished goods inventory of Products on hand at the applicable price; provided that such purchase by Buyer will be subject to the terms and conditions of Section 2a above. Buyer's payment shall be due in accordance with the payment terms set forth in Section 6 of this Agreement.

f. Flexibility

Rescheduling of Delivery Date:

Days to Scheduled Delivery Date	Maximum Purchase Order Quantity which May be Reschedule
0 – 30 days	No reschedule allowed
31 – 60 days	25%
61 – 90 days	50%
90+ days	100%

POs:

1) Non-Cancelable, Non-Reschedulable within 4 weeks of scheduled delivery date
2) Non-Cancelable, Reschedulable per percentages above not to exceed 60 day slide
3) Supplier will make reasonable efforts to accommodate P.O. order quantity increases based upon materials availability and Buyer provided equipment capacity
4) Buyer can only reschedule a P.O. one time

g. In the event that Supplier is aware or anticipates that it will be unable to meet any purchase order(s), either in whole or in part, for whatever reason, Supplier shall promptly notify Buyer in writing of such inability. In particular and without limiting the generality of the foregoing, Supplier shall promptly inform Buyer of any notice, written or oral, received from any materials supplier regarding a possible shortage or inability to supply. In the event that there is an actual or anticipated failure to substantially satisfy Buyer's orders for Products, then Supplier and Buyer will immediately work together, in good faith, to identify an appropriate alternative source of Product supply. In addition to all of Buyer's other rights and remedies, the price shall be reduced [***] that delivery of Products is delayed past the delivery dates specified in the applicable purchase order(s) as a result of any act or omission of Supplier under the Supplier's complete control.

3. LEAD TIMES

So long as Buyer performs its obligations set out in Section 2 above Supplier agrees that manufacturing lead times for Products shall be four (4) weeks. "Lead Time" means that length of time from the date of Supplier's receipt of Buyer's written purchase order !Q the date of Supplier's tender of the Products set forth in such accepted order to Buyer's carrier at Supplier's dock plus time required for acquisition of materials and components.

4. DELIVERY CHANGES

a. Buyer may, without penalty, but with Supplier's prior written consent, change the mix of Products requested within any forecast period provided however that, in the case of Products for which purchase orders have been accepted the Products incorporate only common components. Supplier will use commercially reasonable efforts to accommodate all such requests within material and capacity constraints.

b. If a purchase order has not yet been submitted for a forecast Product Buyer may, subject to the terms of Section 2, delay any forecast Product delivery beyond the scheduled delivery by giving Supplier at least two (2) weeks' notice.

c. Buyer may adjust the total units of Products forecasted for manufacture (but for which no purchase order has been received and accepted by Supplier) up or down in accordance with the terms of Section 2e. Such adjustments may be made no more than once every thirty (30) days.

5. DELIVERY, TITLE AND RISK OF LOSS

a. Delivery will be Ex Works Supplier's dock located in Oakdale, MN (Incoterms, 2010). Risk of loss and title to Products will pass to Buyer upon delivery to Buyer or Buyer's designated carrier at Supplier's dock.

b. Products, technology, and services of Supplier are subject to U.S. export controls under the applicable laws and regulations of the United States. Buyer agrees to abide by such laws and also abide with the provisions of the U.S. Export and Re-export requirements. Buyer agrees that it will not sell, license, or otherwise provide or ship to Supplier products or technical data (or the direct products thereof) for export or re-export to any country or nationals of the embargoed countries Cuba, Iran, Iraq, Libya, North Korea, Syria, Sudan, or other countries or persons as identified with the U.S. Expo1t Administration Regulations without prior authorization by the U.S. Government, Buyer agrees not to transfer, export or re-expo1t products, technology, or software to its customers or any intermediate entity who may be the subject of a U.S. Denial Order or other export restriction without proper U.S. Government authorizations.

c. Products sold by Supplier are sold as Ex Works (or FOB) Supplier's dock in Oakdale, MN.

d. Buyer is responsible for any import tariff (duty), VAT, tax or other governmental fee that is charged for the import of Buyer's finished Products.

e. Supplier will maintain an on time delivery performance of 98% to agreed upon delivery date. For purposes of this Agreement, on time delivery is defined as five (5) days early/five (5) days late to agreed upon delivery date at Supplier's dock.

*** CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

f. Failure to Supply. "Supply Delay" means, solely for purposes of this Section, Supplier's failure to deliver at least [***] ([***]) percent of the quantity of Product ordered in an accepted purchase order due to an act or omission of Supplier, or any other reasons under the control of the Supplier, within [***] of the delivery date. A Supply Delay will not be deemed to occur if (i) such failure is caused by a Force Majeure event, (ii) the volume ordered exceeds [***] of the volume set forth in the applicable forecast (but only in respect of the amount exceeding [***]% of the forecasted volume).

In the event of a Supply Delay, Supplier shall credit Buyer on Product invoices an amount equal to [***] ([***]) percent of the applicable price for the delayed Product for each [***] period (or portion thereof) beyond the delivery date in which the delivery is not made (e.g. [***] ([***]) percent) invoice reduction for any Product that is delivered [***] after the applicable delivery date and [***] ([***]) percent invoice reduction for any shipment that is delivered [***] after the delivery date, etc.). In no event, however, shall Supplier be required to credit Buyer on Product invoices an amount greater than [***] ([***]) percent of the supply Price for the Product subject to the Supply Delay.

6. PRICES AND PAYMENT/COST REDUCTION

a. The prices for Products shall be as set forth on Exhibit B. Supplier shall use good faith efforts to achieve cost reductions during the Term, and Buyer agrees that for Supplier-initiated efforts, Supplier and Buyer shall each be entitled to fifty percent (50%) of any resulting cost savings (i.e. savings less the costs required to achieve reduction of unit costs) ("Cost Savings"), and for Buyer-initiated efforts, Buyer shall be entitled to one-hundred percent (100%) of any Cost Savings after Supplier has recovered all costs associated with implementing the Cost Savings. The term "Cost Savings" shall include reductions in cost of raw materials, and components (but specifically excluding cost reductions resulting from volume increases). Supplier shall package the Products in accordance with packaging specifications approved in writing in advance by Buyer. Any applicable surcharges, including but not limited to surcharges on material, freight and fuel, shall be paid by Buyer.

b. Buyer shall pay all undisputed invoices for Products delivered within thirty (30) days of the date of invoice. Supplier shall invoice Buyer when Product is delivered to Supplier's dock.

c. Supplier warrants and agrees that the pricing payable by Buyer under this Agreement shall be equal to or better than the pricing offered by Supplier to any other customer of Supplier on substantially comparable terms and conditions, including any renewals thereof ("Most Favored Customer"). If Supplier shall enter into any arrangement with any other customer of Supplier providing for more favorable pricing than the pricing payable by Buyer hereunder on substantially similar terms and conditions, then this Agreement will be deemed to incorporate the more favorable pricing and Supplier will immediately apply such more favorable pricing to Buyer' s orders. Most Favored Customer pricing changes will apply to any Orders placed but not yet shipped to Buyer as soon as such pricing changes are effective. If Supplier's cost structure is adversely impacted by factors outside of its reasonable control such as but not limited to product changes, having to add post molding or assembly secondary process not quoted, or changes in the third party costs of parts and materials, Supplier and Buyer shall negotiate in good faith a reasonable price update, as the parties may be deem appropriate. Supplier will provide reasonable documentation to justify any such price change. Any such agreed upon changes shall be

documented by amending Exhibit B.

d. With respect to payments due from Buyer to Supplier hereunder, if full payment of undisputed amounts is not made by Buyer by the due date then Buyer shall be liable to Supplier for the lesser of interest at the rate of 1.0 % per month or the maximum interest allowed by law on all unpaid invoices. Such interest shall be computed on the unpaid balance for each day payment is not received after the date on which payment was originally due. If Buyer disputes any amount invoiced by Supplier, Buyer will notify Supplier in writing within fifteen (15) business days of such dispute together with an explanation of the basis for such dispute.

e. Payment terms to Buyer are subject to and Supplier reserves the following rights: the right to put any shipment on hold if outstanding receivables are more than thirty {30) days past due; and the right to hold both shipments and/or manufacturing if Buyer has failed to make any undisputed payment for more than forty-five (45) days from the due date.

f. All amounts due from Buyer to Supplier are net of any indebtedness of Supplier to Buyer, and mutually all amounts due from Supplier to Buyer are net of any indebtedness of Buyer to Supplier

f. Upon submission of the initial forecast hereunder, Buyer will pay Supplier a cash deposit equal to Supplier actual cost of (i) the material content of the forecast, including MOQs for material (provided that if any MOQ for any material is longer than a twelve (12) month supply based on Buyer's most recent forecast, Supplier will inform Buyer and Parties will discuss in good faith), (ii) material acquisition. The deposit will be reviewed monthly by the Parties to ensure it covers Supplier's actual material cost exposure and will be adjusted upward or downward as needed. Supplier will hold that deposit for Buyer and invoice for the full product amount as set fo11h above. Following twelve (12) months from the Effective Date, the Parties will discuss in good faith adjustment to the deposit terms based on Buyer's payment history.

7. REPRESENTATIONS AND WARRANTIES

a. "Manufacturing Activities" means the manufacturing, processing, testing, analytical, packaging, transport, handling, use, storage and other activities undertaken or required to be undertaken by Supplier or its suppliers or subcontractors in order to manufacture and supply Buyer with the Product meeting the Product Specifications.

b. "Manufacturing Facility" means any plant or other facility at which any Manufacturing Activities occur.

c. "Regulatory Approvals" means any and all approvals, licenses, permits, registrations or authorizations of any governmental authority required to market and sell the Product in a country or region as granted by a regulatory or governmental authority.

d. Supplier hereby represents and warrants to Buyer that that (i) each Product manufactured by Supplier under this Agreement will be free from defects in Supplier supplied materials (excluding materials supplied by Buyer ("Supplier Supplied Materials")) for a period of one (1) year from the date of shipment, (ii) each of the component parts of the Supplier Supplied Materials will meet Buyer's Specifications; (iii) each Product manufactured by Supplier under this Agreement will be free from defects in

Supplier supplied workmanship (excluding workmanship supplied by Buyer ("Supplier Workmanship")) and will conform to the Product Specifications for a period of one (1) year following manufacture, (iv) the operation of the Manufacturing Facilities shall be in material compliance with this Agreement, the Quality Agreement and all applicable Laws (including the receipt and possession of all applicable permits and authorizations), and all policies and procedures of Supplier, (v) Supplier shall manufacture, test, and supply the Products (and all components and materials used in the manufacture of such Products) in accordance with the Product Specifications, this Agreement, the Quality Agreement, and applicable laws, rules and regulations, including current Good Manufacturing Practices as required by the Federal Food, Drug, and Cosmetic Act, as amended, and the pertinent rules and regulations of the FDA, (vi) Supplier shall maintain all documents and records necessary for regulatory compliance throughout the useful life of each consumable product and a period of five (5) years thereafter, or if longer, as required under applicable laws and regulations, (vii) the manufacturing process used to produce the Product(s) by Supplier will not infringe or violate the patent, copyright, or other property or proprietary rights of any third party, except that the warranty in this subsection does not apply to the extent any such infringement or violation directly results from the Product Specifications or components or tools provided by Buyer; and (viii) Supplier will promptly notify Buyer if Supplier becomes aware of any facts leading it to believe that any Product shipped to Buyer hereunder fails or will fail to comply with the terms of this Agreement.

e. Mutual Representations and Warranties. Buyer and Supplier each represents and warrants to the other as of the Effective Date that:
It has full corporate right, power and authority to enter into this Agreement and to perform its respective obligations under this Agreement;
The execution and delivery of this Agreement by such party and the performance of such party's obligations hereunder (a) do not conflict with or violate any requirement of applicable laws or regulations existing as of the Effective Date and applicable to such party and (b) do not conflict with, violate, breach or constitute a default under, and are not prohibited or materially restricted by, any contractual obligations of such party or any of its affiliates existing as of the Effective Date; and Such party is duly authorized, by all requisite corporate action, to execute and deliver this Agreement and the execution, delivery and performance of this Agreement by such party does not require any shareholder action or approval or the approval or consent of any third party, and the person executing this Agreement on behalf of such party is duly authorized to do so by all requisite corporate action.

f. Supplier shall replace any Product that does not conform to the Product Specifications provided, (i) Supplier is notified of the non-conforming Product within thirty (30) days after discovery by Buyer that such item is non-conforming, and within the warranty period as stated above, whichever is earlier and (ii) the non-conforming Product is returned to Supplier at its factory, transportation prepaid, in accordance with Supplier's instructions. Transportation charges for Product returned to Supplier shall be at Buyer's expense. Transportation for shipment of the replacement Product to Buyer (or its designated location) shall also be at Supplier's expense. Buyer shall reimburse Supplier for all costs associated with returned Product which has no defects due to Supplier supplied material or Supplier supplied workmanship. In the event of any dispute regarding whether a Product conforms to the Product Specifications, such dispute shall be submitted to a mutually agreed expert who shall render a final and binding decision.

g. Buyer shall request and obtain a return material authorization number from Supplier for each defective Product prior to return of the Product.

g. Supplier agrees to replace defective Product within thirty (30) days of the date of notice of such defective Product, or if the replacement is not possible due to the lead time of components as soon as is possible thereafter.

h. With respect to Products sold outside the United States, Buyer shall replace defective Products and Supplier shall credit or reimburse Buyer for the cost of replacement. Supplier must pre-approve all proposed units for said replacement by Buyer in writing and Supplier must be given an opportunity to perform a failure analysis on such defective products.

i. Supplier represents and warrants that each Product sold to Buyer under this Agreement is and will be owned by Supplier, free and clear of any lien, claim or encumbrance.

j. Supplier shall have no responsibility or obligation to Buyer under warranty claims with respect to Products where the defect arose out of abuse, misuse, accident, alteration, neglect or unauthorized repair. All Warranties contained in this Section 8 are in lieu of, and Supplier expressly disclaims and Buyer waives all other representations and warranties, whether express, implied, statutory or arising by course of dealing or performance, custom, usage in the trade or otherwise, including without limitation, the implied warranties of merchantability, title and fitness for a particular use.

k. Buyer Representations and Warranties. Buyer represents and warrants to Supplier that as of the Effective Date, Buyer is not aware of any actions or other legal proceedings, against Buyer for infringement of any third party intellectual property or other rights related to the Product Specifications.

l. Exclusions from Warranty. This warranty does not include Products that have defects or failures resulting from (a) Buyer's design of Products, including but not limited to design functionality failures, or Product Specification inadequacies; (b) neglect, abuse, misuse, improper handling, testing, storage or installation, including improper handling in accordance with static sensitive electronic device handling requirements; or (c) alterations, modifications or repairs by Buyer or third parties) defective customer provided test equipment or test software.

8. PRODUCT CHANGES

a. Supplier shall not make any changes in the Product Specifications, the form, fit or function of the Products or materials used for manufacture of the Products without the prior written approval of Buyer. The costs of all changes approved in advance by Buyer shall be paid for by Buyer.

b. Buyer may request Supplier to incorporate changes to Products via engineering change orders or authorized red lined drawings. Supplier shall make every reasonable effort to incorporate requested changes within the time frame requested by Buyer. Buyer understands and agrees that additional charges may be incurred for incorporation of requested changes and delivery dates may be changed for incorporation of requested changes.

9. TOOLING

a. Buyer shall provide to Supplier the tools and equipment listed on Exhibit D ("Tools") for Supplier's use in manufacture of the Products. All Tools shall remain the property of Buyer and Supplier shall not permit any liens or encumbrances to attach to the Tools.

b. Supplier agrees to keep Buyer owned Tools in good working condition as it pertains to routine use, calibration and maintenance. Buyer agrees to furnish or fund all required replacements and upgrades and perform any major repairs required to the Tools unless replacements or repairs are required as a result of the negligent acts or omissions of Supplier.

c. Buyer represents and warrants that Buyer has the right to grant the rights to the Tools furnished by Buyer to Supplier hereunder.

d. All Tools supplied to Supplier by Buyer shall be in good working condition when delivered to Supplier and Buyer warrants that all periodic maintenance with respect thereto has been performed to schedule. Supplier shall perform an inspection on all Tools upon delivery and notify Buyer of any defects or required maintenance or repairs and Buyer shall furnish or fund any required replacement, maintenance or repairs within 10 days of receipt of notice from Supplier. Buyer acknowledges and agrees that delays in furnishing or funding required replacement, maintenance and/or repairs may require Supplier to set back production schedules for Buyer's Products.

10. [***]

11. PROPERTY RIGHTS

a. Supplier acknowledges that Buyer owns all right, title, and interest in and to the Products, the Product Specifications, tests or methods relating specifically to Products and any improvements or modifications thereto ("Buyer Technology"). Supplier shall assign and hereby does assign to Buyer any and all right, title and interest it may have or hereinafter obtain in, to or under the Buyer Technology, or any other intellectual property relating to the manufacture of the Products developed by Supplier or its employees, consultants or agents. Upon the termination or expiration of this Agreement or upon Buyer's written request at any time (and subject to payment by Buyer of all amounts due under this Agreement), Supplier agrees to deliver to Company any and all documents, data and information relating to the Buyer Technology. Supplier shall assist Buyer, at Buyer's expense, with the execution of all papers, including patent applications, invention assignment sand copyright, and as reasonably required to perfect the rights, title and other interest held by Buyer under this Agreement.

b. Subject to the terms and conditions of this Agreement, Buyer grants Supplier a nonexclusive, nontransferable, worldwide license, without the right to sublicense, to use all designs, materials, information, know-how and documentation including the Product Specifications, provided by Buyer to Supplier, solely in connection with manufacturing the Product(s) hereunder for Buyer. This license shall not include the right to modify, make derivative works of or improvements to the Product(s) or the Product Specifications, unless approved in writing by Buyer.

c. Buyer acknowledges that Supplier possesses certain technology, inventions,

processes, know-how, trade secrets, improvements, discoveries, ideas, other intellectual properties and other assets, including but not limited to procedures and techniques, computer technical expertise, software, and certain technical expertise and conceptual expertise in the area of manufacturing which have been independently developed by Supplier or its affiliates without the benefit of any information provided by Buyer{collectively "Supplier Technology"). Buyer and Supplier agree that any Supplier Technology or improvements thereto which are used, improved, modified or developed by Supplier under or during the term of this Agreement (but excluding those relating specifically to the Products) are the sole and exclusive property of Supplier or its affiliates, as the case may be; provided, however, Supplier agrees it will not use or disclose any Buyer Technology or Buyer's Confidential Information in connection with the use of any Supplier Technology except as expressly permitted herein.

d. Each of the parties shall not: (a) take any action that interferes with the other party's intellectual property rights, including such other party's ownership or exercise thereof; (b) challenge any right, title or interest of the other party in such other party's intellectual property rights; (c) make any claim or take any action adverse to such other party's ownership of its intellectual property rights; (d) register or apply for registrations, anywhere in the world, the other party's trademarks or any other trademark that is similar to such other party's trademarks or that incorporates such trademarks in whole or in confusingly similar part; use any mark, anywhere, that is confusingly similar to the other party's trademarks; (e) misappropriate any of the other party's trademarks for use as a domain name without such other party's prior written consent; or (f) alter, obscure or remove any of the other party's trademarks or trademark or copyright notices or any other proprietary rights notices placed on the Products, or related marketing or other materials.

12. INDEMNIFICATION

Unless otherwise stated in this Agreement, each party shall defend, indemnify and hold harmless the other party from and against all third-party damages, claims, liabilities and expenses ("Third Party Claims") arising out of or resulting from such party's negligence or willful misconduct.

a. Supplier shall further indemnify Buyer from and against Third-Party Claims arising out of (i) a defect in Supplier supplied materials or workmanship, (ii) Supplier's non-compliance with the Product Specifications; (iii) Supplier's breach of any of the provisions of this Agreement, or (d) Supplier's violation of laws, rules, or regulations applicable to Supplier's activities and/or obligations under this Agreement. Buyer shall further indemnify Supplier from and against Third Party Claims arising out of (A) any Product Specifications or designs as provided by Buyer to Supplier under this Agreement; (B) any claim that the Product infringes any third party rights of any kind, including without limitation any patent, trade secret, copyright or trademark rights; (c) Buyer's breach of any of the provisions of this Agreement; (B) Buyer' s violation of laws, rules, or regulations applicable to Buyer's activities and/or obligations under this Agreement.

b.The indemnified party shall notify the indemnifying party of such claim as soon as practicable upon receipt of knowledge of same; provided, however, that no failure to so notify the indemnifying party shall relieve the indemnifying party of its obligations under this Agreement except to the extent that the indemnifying party can demonstrate material prejudice attributable to such failure. The indemnified party may participate in the defense or settlement of such claim at its own expense and with its own choice of

counsel. The indemnifying party shall not settle any claim unless prior written approval and consent is obtained from indemnified party, which approval and consent will not be unreasonably withheld or delayed.

13. TAXES

Unless Buyer furnishes a valid exemption certificate, Buyer will bear all sales and use taxes properly imposed by federal, state, municipal or other local authorities with respect to purchases under this Agreement.

14. CONFIDENTIALITY AND PUBLICITY

a. Confidentiality Obligation. During the Term, and for three (3) years thereafter, each party shall maintain in confidence any and all Confidential Information, except as set forth in Section 14b. below. Each party shall not use the Confidential Information of the other party for any purpose other than the purposes expressly contemplated under this Agreement and shall not disclose to any third party the Confidential Information of the other party, except that either party may disclose Confidential Information under a similar obligation of confidentiality and non-use and on a need-to-know basis to its directors, officers, employees, consultants, or agents.

b. Exceptions. The obligations of confidentiality and non-use contained in Section O do not apply to any Confidential Information the extent that it can be established by the party receiving the Confidential Information (the "Receiving party") that such Confidential Information: (a) was already known to the Receiving party, other than under an obligation of confidentiality, at the time of disclosure by the other party, as evidenced in writing; (b) was part of the public domain at the time of its disclosure to the Receiving party or became part of the public domain after its disclosure to the Receiving party through no fault of the Receiving party; (c) was disclosed to the Receiving party, other than under an obligation of confidentiality to a third party, by a third party who had no obligation to the disclosing party not to disclose such information to others; or (d) was independently discovered or developed by the Receiving party without the use of Confidential Information belonging to the disclosing party, as evidenced in writing.

c. Authorized Disclosure. Each party may disclose Confidential Information of the other party to the extent such disclosure is reasonably necessary in complying with applicable laws, including securities laws, governmental regulations or court orders, obtaining regulatory or other government approvals, provided that a party making any such disclosure uses its reasonable efforts to secure confidential treatment of such Confidential Information required to be disclosed and to minimize the extent of such disclosure. Buyer may disclose the existence of this Agreement and the terms herein (a) to bona fide potential and actual investors, acquirors or other business partners on a need-to-know basis under appropriate confidentiality restrictions and (b) to comply with any applicable governmental regulations and legal requirements, including filings required in connection with the public sale of securities, provided that Buyer notifies Supplier prior to disclosure and uses reasonable efforts to seek confidential treatment of such information in connection with such filing.

d. Return of Confidential Information. Upon termination or expiration of this Agreement, or upon written request of the disc losing party, a Receiving party will promptly return to the disclosing party or destroy all documents, notes and other tangible materials comprising or containing the disclosing party's Confidential Information and all copies

*** CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

thereof; provided, that each party may retain a single archival copy of the other party' s Confidential Information for the sole purpose of facilitating compliance with the surviving provisions of this Agreement or as required by applicable laws or regulations.

e. Publicity.Supplier and Buyer shall not disclose to any third party any pricing or product information relating to this Agreement. Both parties agree not to publicize or otherwise make known to any third party any information relating to this Agreement without prior written consent of the other party.

15. LIMITATION OF LIABILITY

OTHER THAN WITH RESPECT TO LIABILITY ARISING FROM A PARTY'S INDEMNIFICATION CLAIMS, A BREACH OF CONFIDENTIALITY OBLIGATIONS, A VIOLATION OF THE OTHER PARTY'S INTELLECTUAL PROPERTY RIGHTS, OR GROSS NEGLIGENCE OR WILLFUL MISCONDUCT, (A) NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, PUNITIVE OR SPECIAL DAMAGES OR ANY DAMAGES WHATSOEVER RESULTING FROM LOSS OF USE OR OPPORTUNITY, DATA OR PROFITS OR LOST BUSINESS RESULTING IN ANY WAY FROM THIS AGREEMENT EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES; AND (B) EACH PARTY'S AGGREGATE, CUMULATIVE LIABILITY UNDER THIS AGREEMENT SHALL NOT EXCEED THE GREATER OF (1) [***] U.S. DOLLARS ($[***]), OR (2) THE AMOUNTS PAID BY BUYER TO SUPPLIER IN THE [***] DIRECTLY PRECEDING THE EVENT GIVING RISE TO LIABILITY. THIS CLAUSE SHALL SURVIVE ANY TERMINATION OR EXPIRATION OF THIS AGREEMENT.

16. TERM AND TERMINATION

a. This Agreement shall commence on the Effective Date and shall remain in effect until the third-year anniversary of the Effective Date ("Initial Term") and will automatically renew for additional consecutive terms of one (1) year, unless cancelled by either party upon at least 180 days written notice to the other party prior to the end of the then current term.

b. Either party may terminate this Agreement immediately upon written notice if the other party (i) fails to comply with any material term or condition of this Agreement, (ii) becomes insolvent or makes a general assignment for the benefit of creditors or (iii) has a petition under the Bankruptcy Act filed by or against it and such petition is not dismissed within sixty (60) days of the filing date.

c. Neither party may terminate this Agreement during the initial term other than for cause. Buyer may terminate this Agreement at any time during any renewal term, without cause, upon at least one-hundred eighty (180) days' written notice to Supplier. Supplier may terminate this Agreement at any time during any renewal term, without cause, upon at least twelve (12) months prior written notice to Buyer.

d. Either party may, without prejudice to any other remedies available to it at law or in equity, terminate this Agreement in the event that the other party (as used in this subsection, the "Breaching Party") shall have materially breached or defaulted in the performance of any of its obligations. The Breaching Party shall have thirty (30) days after

written notice thereof was provided to the Breaching Party by the non-breaching Party to remedy such default (or, if such default cannot be cured within such 30-day period, if the Breaching Party must commence and diligently continue actions to cure such default during such 30-day period). Any such termination shall become effective at the end of such 30-day period unless the Breaching Party has cured any such breach or default prior to the expiration of such 30-day period (or, if such default cannot be cured within such 30-day period, if the Breaching Party has commenced and diligently continued actions to cure such default).

e. Buyer may terminate this Agreement upon [***] days' prior written notice in the event of an [***] that is not corrected to Buyer's satisfaction.

f. Notwithstanding anything to the contrary contained in this Agreement, in the event a Force Majeure Event shall have occurred and be continuing for ninety (90) consecutive days, the party not suffering such Force Majeure Event shall be entitled to terminate this Agreement effective immediately upon written notice to the party suffering such Force Majeure Event.

f. Upon termination of this Agreement, in whole or in part, for any reason the Supplier shall remain obligated to deliver Products ordered by Buyer and acknowledged by Supplier prior to termination and Buyer shall pay for all such Products on the invoice due date or the termination date, whichever occurs first. After termination and after Buyer has paid all amounts due to Supplier pursuant to this Agreement, Supplier shall return all Tools, all Buyer furnished equipment and any other material provided by or owned by Buyer. On the termination date Buyer shall purchase from Supplier at Supplier's cost all inventory of parts and materials on hand, on order or in transit purchased to Buyer's forecasts within lead times or purchased as a result of minimum order quantity requirements of parts and materials vendors. On the termination date, Buyer shall also purchase from Supplier all work in process at Supplier's cost and all finished goods inventory of Products on hand at the applicable price. Payment shall be due upon receipt of Supplier's invoice.

17. GOVERNMENT APPROVALS; REGULATORY.

a. Supplier shall, [***], obtain any and all necessary governmental approvals and other authorizations and approvals which are appropriate or necessary to carry out the proposed activities contemplated herein. Supplier shall obtain all necessary governmental and regulatory approvals to sell the Products to Buyer.

b. Supplier shall permit Buyer to inspect and audit: (i) those portions of each Manufacturing Facility at which any Manufacturing Activities are performed and (ii) any of Supplier's manufacturing and quality control records and other documentation relating to the Manufacturing Activities (including any internal quality control audits or reviews conducted by Supplier). Such inspections and audits shall be for the purpose of ascertaining compliance with applicable laws, rules, and regulations, as well as Supplier's obligations under the Quality Agreement and this Agreement, reviewing correspondence, reports, filings and other documents from or to governmental or regulatory to the extent related to the Manufacturing Activities, and approving all variances from applicable requirements hereunder or under the Quality Agreement. Any information obtained by Buyer through such inspections and audits shall be treated as Confidential Information of Supplier. Such audits and inspections shall be conducted at Buyer's expense during normal

business hours, and no more than once per year per Manufacturing Facility (or more frequently for cause), with more frequent audits upon agreement of the Parties and upon reasonable advance written notice, and in a manner that does not unreasonably interfere with ongoing operations.

c. Supplier shall advise Buyer of any information arising out of its Manufacturing Activities that has adverse regulatory compliance and/or reporting consequences concerning the Product. Supplier will notify Buyer promptly of any warning (including any FDA Form 483), citation, indictment, claim, lawsuit, or proceeding issued or instituted by any federal, state, or local governmental entity or agency against Supplier if, and only to the extent that, the manufacture of Product hereunder is or may be affected, or of any revocation of any license or permit issued to Supplier, but only to the extent that such license or permit relates to Supplier's performance of its obligations hereunder.

d. Governmental Authorities. Supplier shall provide to Buyer any information reasonably requested by Buyer, and shall consult with Buyer before providing any information to any governmental or regulatory authority, to the extent directly related to the Product. Supplier shall immediately advise Buyer of any requests by any governmental or regulatory authority for inspections of any Manufacturing Facilities to the extent directly related to the Product. In the event Supplier is inspected by the FDA or any similar or related governmental authority relating to the Product, Supplier will use its commercially reasonable efforts to ensure that Buyer shall have the right to be present during such inspection. Supplier shall promptly notify Buyer of any alleged violations or deficiencies relating to a Manufacturing Facility, and shall promptly disclose to Buyer all relevant portions of any notice of observations or potential violations, as well as a copy of Supplier's response thereto.

e. Review of Technical Records. Buyer shall have the right, subject to any third party confidentiality obligations and prior advance notice to Supplier of at least ten (10) Business Days, during normal business hours, to examine those technical records made or kept by Supplier that relate to the Product.

f. Quality Agreement. Buyer and Supplier shall enter into a quality agreement (the "Quality Agreement"). To the extent there are any inconsistencies or conflicts between this Agreement and the Quality Agreement, the terms and conditions of this Agreement shall control unless otherwise agreed to in writing by the Parties.

g. Adverse Event and Product Compliant Reporting. Supplier shall promptly notify Buyer of all information reported to Supplier relating to serious and non-serious adverse events, whether expected or unexpected, relating to the use of the Product as well as all product complaints.

h. Regulatory Cooperation. Supplier shall cooperate, at Buyer's cost, with any reasonable requests for assistance from Buyer with respect to obtaining and maintaining any and all Regulatory Approvals for the Products.

i. Product Recall. [***]

18. QUALITY CONTROL AND TESTING. Supplier shall assure that all of its

processes and procedures comply with the quality control and testing requirements set forth in Exhibit E and that the completed Products conform to the finished product quality requirements set forth in Exhibit E.

19. COMPLIANCE WITH ROHS AND WEEE LAWS AND REGULATIONS.

a. Buyer RoHS Responsibilities. Buyer shall be responsible for Product compliance with applicable RoHS laws and regulations for Products, and/or for components, subassemblies or materials of or used in Products, sourced by Supplier from suppliers selected or designed by Buyer ("Buyer Sourced Parts"). Upon Buyer request, Supplier will certify to Buyer that it procured and/or used only Buyer Sourced Parts in the assembly or manufacture of the Products.

b. Supplier RoHS Responsibilities. Supplier shall be responsible to compliance with applicable RoHS laws and regulations for those components, subassemblies and materials used in the Product which Supplier sourced or procured from suppliers selected by Supplier ("Supplier Sourced Parts"). Upon Buyer request, Supplier shall certify such compliance to Buyer.

c. Buyer WEEE Responsibilities. Buyer shall be responsible for compliance by Buyer and the Products with applicable WEEE laws and regulations.

d. RoHS and WEEE Definitions. For purposes of this Section: "RoHS laws and regulations" means laws and regulations in any country, state, municipality or jurisdiction regulating or restricting the use of certain hazardous substances in electrical and electronic equipment, including, by way of example only. EC Directive 2002/95/EC; "WEEE laws and regulations" means laws and regulations in any country, state, municipality or jurisdiction regulating or restricting the design, disposal and recycling of electrical and electronic equipment, including, by way of example only, EC Directive 2002/96/EC.

20. GENERAL PROVISIONS

a. Parent Guaranty.

Medical Technologies, Inc., the parent company of Buyer, hereby guarantees the performance by Buyer of Buyer's obligations under this Agreement. If Buyer should breach its obligations under this Agreement, prior to pursuing any right, power or remedy against Helius Medical Technologies, Inc., Supplier shall first reasonably pursue such right, power or remedy against Buyer.

b. Entire Agreement Amendment.

This document and its Exhibits contain the entire Agreement between the parties relating to the subject matter contained herein. All prior or contemporaneous agreements, written or oral, between the parties regarding the Products are superseded by this Agreement. This Agreement may not be modified except by written document signed by an authorized representative of each party.

c. Force Majeure.

Neither pa11y shall be liable for delays or defaults due to fire, windstorm, riot, civil unrest, act of God, act of the public enemy, shortages of parts and materials, or other similar unforeseeable cause beyond the reasonable control and without the fault or negligence of

the party incurring such delay.

d. Waiver.

No term of this Agreement shall be considered waived and no breach excused by either party unless made in writing by the other party. No consent, waiver, or excuse by either party, express or implied, shall constitute a subsequent consent, waiver or excuse.

e. Non-assignment.

Neither party shall assign this Agreement or its rights hereunder without the prior written consent of the other party, such agreement not to be unreasonably withheld, except that Buyer shall have the right to assign this Agreement in connection with a merger, acquisition, or sale of all or substantially all of its assets. In the event of any merger, acquisition, or sale of all or substantially all of Buyer's assets, Supplier shall have the right to run a credit check on the successor entity, and depending on the result of such credit check, Supplier shall have the right to adjust the amount of the deposit set forth in Section 6f, as may be necessary.

f. Controlling Law.

This Agreement and its formation, operation and performance and the terms of all sales of Product hereunder, shall be governed, construed, performed and enforced in accordance within the laws of the State of Delaware without regard to its conflict of laws principles Each party irrevocably agrees that the state and federal courts of Delaware shall have exclusive jurisdiction to hear and determine any suit action or proceedings which may arise out of or in connection with this Agreement and, for such purposes, irrevocably submits to the jurisdiction of those courts.

g. Severability.

If any provision of this Agreement is held invalid, illegal or unenforceable, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired.

h. Surviving Clauses.

Any provision of this Agreement having its performance period beyond the Term of this Agreement shall survive the termination or expiration of this Agreement.

i. Notices.

All notices or other communications (except for services of process) required or permitted to be given pursuant to this Agreement shall be in writing and shall be conclusively deemed to have been received by a party hereto on the day on which such notice or communication was delivered by hand, prepaid telegram, facsimile, express overnight courier service to the address set forth below (or such other address as such party may specify to the other party from time to time), or, if sent postage prepaid by certified or registered mail, on the third business day after the day on which such notice or communication was mailed.

If to Supplier:

Key Tronic Corporation
N. 4424 Sullivan Road
Spokane Valley, WA 99216
Attention: Craig D. Gates, President & CEO

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If to Buyer:

NeuroHabilitation Corporation
642 Newtown Yardley Road, Suite 100
Newtown, PA 18940
Attention: Joyce LaViscount, CFO/COO

i. Relationship of Parties.
The relationship of the parties established by this Agreement is that of independent contractors and nothing contained herein shall be construed to constitute either party as the agent of the other party or as partners, joint ventures, co-owners or otherwise as participants in a joint or common undertaking.

j. Precedence.
Buyer and Supplier agree that this Agreement takes precedence over any and all terms and conditions on Buyer's purchase order.

k. Minimum Insurance Requirements.
Supplier and Buyer Shall, at their own expense, maintain all insurance appropriate to ensure proper performance of their obligations hereunder. Coverage limits may be satisfied through a combination of primary and/or excess umbrella coverage. Supplier and Buyer shall provide to each other a certificate of insurance showing the types and amounts of insurance in force. Coverage shall include, at a minimum, the following for Supplier and Buyer.

1. **Commercial General Liability.** Commercial General Liability insurance covering bodily injury, death, property damage, personal injury, broad form property damage and contractual liability with limits not less than One Million U.S. Dollars ($1,000,000) per occurrence and Two Million Dollars ($2,000,000) General Aggregate. Each party must name the other party as Additional Insured. Coverage will be considered primary without right of Contribution of the party's insurance policies and will include a blanket waiver of subrogation;
2. **Automobile Liability.** Automobile Liability insurance covering owned, non-owned and hired vehicles with limits not less than One Million Dollars ($1,000,000) per occurrence. Each party must name the other party as Additional Insured;
3. **Workers Compensation and Employer's Liability.** Workers Compensation insurance as required by the law(s) of the jurisdiction in which the Agreement is to be performed. Employer's Liability must be provided in a limit not less than One Million Dollars ($1,000,000). A waiver of subrogation must apply in favor of the other party;
4. **Umbrella Liability.** Umbrella Liability excess of General Commercial Liability, Auto Liability and Employer's Liability in a limit not less than Five Million Dollars ($5,000,000) per occurrence and in the aggregate;
5. **Employee Dishonesty.** Employee Dishonesty coverage, including third party client coverage for limits not less than One Million Dollars ($1,000,000) per occurrence and in the aggregate.

Buyer shall, in addition to the insurance requirements set forth above, maintain Errors and

Omissions (E&O) insurance and Product Liability insurance with limits of each not less than Five Million Dollars ($5,000,000) per occurrence, each. Buyer must name Supplier as an Additional Insured.

l. **Counterparts.** This Agreement may be executed in counterparts, each of which shall be considered an original, and all of which together shall constitute one instrument. A signed copy of this Agreement delivered by facsimile, e-mail or other means of electronic transmission is deemed to have the same legal effect as delivery of an original signed copy of this Agreement[, if the party sending such facsimile, e-mail or other means of electronic transmission has received express confirmation that the recipient party received the Agreement (not merely an electronic facsimile confirmation or automatic email reply).

The Parties have caused this Agreement to be executed as of the Effective Date.

KEY TRONIC CORPORATION

_____

Name: Brett R. Larsen

Title: EVP Admin & CFO

NEUROHABILITA TION CORP.

_____

Name: Joyce LaViscount

Title: CFO/COO

EXHIBITS

The following documents are attached to and made a part of this Agreement:

Exhibit A	Products and Product Specifications Prices
Exhibit B	Parts Lead Times and Unique Materials
Exhibit C	Tooling To be Supplied by Buyer
Exhibit D	Quality Control and Testing
Exhibit E	

*** CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

Exhibit 10.29

EXHIBIT A

PRODUCTS AND PRODUCTS SPECIFICATIONS

Part Description	Specifications
	*

*To be agreed to in writing between the parties prior to startup of production of Products

EXHIBIT B

PRICES

Product Description	Unit Price*	Minimum Order Quantity

*Prices are subject to change from time to time to reflect changes in the costs of parts and materials and components.

EXIDBIT C

PARTS LEAD TIMES AND UNIQUE MATERIALS*

*To be agreed upon as Bill of Materials Finalized

EXHIBIT D

TOOLING TO BE SUPPLIED BY BUYER*

*Tobe agreed upon as manufacturing design specifications are finalized

EXHIBIT E

QUALITY CONTROL AND TESTING*

* To be agreed upon by parties as plans are finalized

EXHIBIT 21.1

SUBSIDIARIES OF HELIUS MEDICAL TECHNOLOGIES, INC

ENTITY NAME	**JURISDICTION**
Neurohabilitation Corporation	Delaware
Helius Medical Technologies (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. 333-215286) and Form S-8 (No. 333-204155 and 333-218095) of Helius Medical Technologies, Inc., of our report dated March 12, 2018, relating to the consolidated financial statements which appears in this Form 10-K. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ BDO USA, LLP

Philadelphia, Pennsylvania
March 12, 2018

Exhibit 31.1

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

I, Philippe Deschamps, certify that:

1. I have reviewed this transition 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: March 12, 2018

/s/ Philippe Deschamps
Philippe Deschamps
President, Chief
Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

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

I, Joyce LaViscount, certify that:

1. I have reviewed this transition 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: March 12, 2018

/s/ Joyce LaViscount
Joyce LaViscount
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

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

In connection with the Annual Report on Form 10-K of Helius Medical Technologies, Inc. (the "Company") for the year ended December 31, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Philippe Deschamps, as Chief Executive Officer of the Company, and Joyce LaViscount, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge:

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

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

Date: March 12, 2018

/s/ Philippe Deschamps

Philippe Deschamps
President, Chief Executive
Officer and Director
(Principal Executive Officer)

/s/ Joyce LaViscount

Joyce LaViscount
Chief Financial Officer
(Principal Financial officer and Principal Accounting Officer)

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