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

FORM 10-K/T

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

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

For the transition period from April 1, 2016 to December 31, 2016

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 400, 41 University Drive
Newtown, Pennsylvania, 18940
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (215) 809-2018

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 ☒

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

The aggregate market value of the common equity held by non-affiliates of the registrant on June 30, 2016, based on the closing price on that date of USD$1.11, was approximately $49,022,798. As of March 15, 2017, there were 91,246,676 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 2017 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 nine-month period ended December 31, 2016.

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In this transition report on Form 10-K, unless otherwise specified, references to "we," "us," "our," "Helius" or "the Company" mean Helius Medical Technologies, Inc. (formerly known as "0996445 B.C. Ltd.") 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 transition report on Form 10-K ("Transition Report") includes certain statements that may constitute "forward-looking statements." All statements contained in this Transition 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 transition report include but are not limited to statements relating to: enrollment and future plans for our clinical trials, progress of and reports of results from clinical studies, 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 ("FDA") filings and their subsequent approvals, other foreign or domestic regulatory filings by us or our collaboration partners, our ability to commercialize the product(s), 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, the ability of a limited number of shareholders to take shareholder action without the involvement of the management or the Company's other shareholders, future disclosure requirements, future regulatory risks, our relationship with the U.S. Army, our ability 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 Transition Report and our other public filings with the Securities and Exchange Commission ("SEC").

Although the Company believes 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 financing, 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, the Company undertakes 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 Transition 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, the portable neuromodulation stimulator ("PoNS™") device, is designed to enhance the brain's ability to compensate for this damage. The PoNS™ device is an electrical pulse generator that delivers controlled electrical stimulation to the tongue, which alters cranial nerve activity in order to intentionally change and regulate the electrochemical environment of the brain in a process called neuromodulation. When combined with physical or cognitive rehabilitation, we believe that the neuromodulation induced by PoNS™ therapy enhances neuroplasticity, or the brain's ability to reorganize its operation in response to new information sources, new functional needs, or new communication pathways, and may benefit patients experiencing balance and gait disorders or other movement and sensory challenges associated with neurologic diseases and disorders including traumatic brain injury ("TBI"), multiple sclerosis ("MS"), cerebral palsy ("CP"), stroke and Parkinson's disease. We are currently conducting registrational trials of the effectiveness of the PoNS™ therapy in balance disorders related to mild- to moderate-TBI and are planning our MS registrational trial. A registrational trial is a study of safety and effectiveness intended to support a marketing application. We are also studying the effectiveness of the PoNS™ therapy in the improvement of cognitive function in healthy subjects. We intend to use the cognitive study as a precursor to evaluating potential indications in age-related dementia, Alzheimer's diseases, depression, attention deficit hyperactivity disorder and autism, among others. We must submit an Investigation Device Exemption ("IDE") for clinical trials of the PoNS™ therapy in neurodegenerative diseases. Subject to the approval by the FDA of our IDE, we also intend to commence a registrational trial of the PoNS™ therapy in MS patients with chronic balance and gait deficit. We also intend to study the effectiveness of the PoNS™ therapy in balance and movement control-related symptoms in CP and the rehabilitation of balance and gait disorder in patients who have had a stroke, subject to the approval of the IDE and the availability of additional funding.

According to a study by GBI Research, the neurostimulation market is expected to grow at a compounded annual growth rate of 15.3% from 2011 to 2018, with a forecasted U.S. revenue of $4 billion in 2018. We believe that, due to the lack of non-invasive devices currently on the market, non-invasive stimulation addresses only approximately 3% of the overall neurostimulation market today, and, if commercialized, the PoNS™ device will be the first device that addresses the high unmet needs of brain injury patients with balance and gait disorders.

The PoNS™ device has not yet received authorization from the U.S. Food and Drug Administration ("FDA") for commercialization. As further described in "—Current Studies—Traumatic Brain Injury," we are conducting safety and effectiveness clinical trials of the use of the PoNS™ therapy for the treatment of TBI-related balance disorders with the U.S. Army. The PoNS™ device has been deemed by the FDA through the pre-submission process a non-significant risk device in the context of the mild- to moderate-TBI clinical trials for chronic balance deficit and thus do not need to submit an IDE application to the FDA or obtain FDA approval of an IDE application to complete such trials. Such trials are subject to abbreviated requirements under the FDA's IDE regulations, which include, among other things, oversight of an Institutional Review Board ("IRB"), the conduct of the clinical trials in accordance with current Good Clinical Practices ("cGCP") and compliance with human subjects' protection requirements such as informed consent. Subject to the availability of additional funding and the timing of our validation and device verification activities described in "—Manufacturing," we intend to submit a request for FDA classification as a Class II device and marketing authorization for the treatment of chronic balance deficit due to mild- tomoderate-TBI via the FDA's de novo classification process following the completion of these trials, which is anticipated in the second half of 2017. We intend to concurrently submit applications for the clearance of the PoNS™ device for a CE Mark in Europe and to Health Canada and the Therapeutic Goods Administration ("TGA") in Australia, and we anticipate regulatory clearance in the first half of 2018. We are required to produce the PoNS™ device in accordance with the FDA's Quality System Regulation ("QSR"), and in compliance with European, Canadian and Australian regulatory requirements.

The PoNS™ Device

The PoNS™ device is an electrical pulse generator that delivers controlled electrical stimulation to the tongue through a replaceable hygienic mouthpiece. When the mouthpiece of the PoNS™ device is placed into and held in the patient's mouth, it stimulates the trigeminal and facial nerves that innervate the anterior two-thirds of the human tongue using a sequenced pattern of superficial electrical stimulation. This stimulation excites a natural flow of neural impulses to the brainstem and cerebellum that is designed to effect changes in the function of these targeted brain structures. Pilot studies and prior anecdotal studies suggest that prolonged

activation of 20 minutes or more of neuronal circuits, when combined with physical or cognitive therapy, initiate a durable neuronal reorganization with a variety of positive results, including the correction of gait/balance impairments resulting from TBI.

The predecessor to the current PoNS™ device was developed in 2008 at the Tactile Communication and Neurorehabilitation Laboratory (the "TCNL") at the University of Wisconsin-Madison. Since then, we have conducted a significant amount of experimentation, research and development to arrive at the present-day PoNS™ device.

Design

The PoNS™ device is ergonomically designed for patient comfort, is relatively light, contains a replaceable hygienic mouthpiece, a rechargeable battery and allows for technical data logging and communications. See Figure 1.

Figure 1
The portable neuromodulation stimulator, or PoNS™ device.

The 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

The paddle-shaped tab of the mouthpiece has a hexagonally patterned array of 143 gold-plated circular electrodes (1.50 mm diameter, on 2.34 mm centers) that is created by a photolithographic process used to make printed circuit boards. It is designed to use low-level electrical current to stimulate the lingual branch projections of at least two cranial nerves in the anterior tongue through the gold-plated electrodes. Device function is controlled by three buttons: On/Off, Intensity Up, and Intensity Down. Pulses are generated and organized by a counter, timer, and wave-shaping electronic components.

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 waveform is specifically designed to minimize the potential for tissue irritation.

When the PoNS™ device is turned off, the intensity setting automatically resets to zero. Upon first introduction to the device stimulation, subjects are instructed to press the "Up" intensity button and hold it for approximately 4-5 seconds to reach sensation threshold. Subjects will frequently notice that the sensation intensity decreases 2-4 minutes after stimulation onset. Subjects are instructed to simply increase the sensation level to return to the predetermined perceptual midpoint of their individual perceptual dynamic range.

Concurrent Use with Physical or Cognitive Rehabilitation

We have designed the PoNS device for use in connection with physical or cognitive rehabilitation. The PoNS™ device has a design feature that stops delivering therapy every 14 weeks. This is expected to require patients to return to their physician or physical therapy center ("PTC") for assessment of their progress and reestablishment of challenging physical therapy to achieve higher goals. We currently expect the device to be inspected visually by the physical therapist, reset for another 14 weeks of treatment, and the mouthpiece would be replaced by 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 therapy.

We expect physicians will be informed to prescribe the PoNS™ therapy, which includes both the PoNS™ device itself and work with PTCs with PoNS™-certified training. We anticipate supporting the launch of the PoNS™ therapy with the development and implementation of a hub services center to help facilitate the healthcare transaction.

Upon discharge from the PTC, patients are expected to be monitored in their home therapy 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 well as replacement of the mouthpiece if the fourteen weeks have expired.

Ongoing and Planned Studies

Traumatic Brain Injury

According to the Center for Disease Control and Prevention ("CDC"), an estimated 1.7 million people in the United States sustain a TBI annually. The CDC estimated in 2015 that approximately 3.2 million to 5.3 million people in the United States were living with a TBI-related disability, based on extrapolations from limited data from 1999. In addition, the Department of Defense estimates that almost 30,000 active duty soldiers are diagnosed with TBI annually and, according to the U.S. Department of Veterans Affairs, over 200,000 U.S. former military personnel suffer from chronic symptoms of TBI. We estimate that approximately 20-30% of newly-diagnosed TBI injuries result in chronic symptoms, and the Brain Injury Association of America estimates that 40% of TBI patients complain of balance disturbances.

In partnership with the U.S. Army pursuant to a sole source cost-sharing agreement described in "—Our Partnership with the U.S. Army," we are currently conducting a clinical trial of our PoNS™ therapy for the treatment of balance disorder in patients with mild- to moderate- TBI. Assuming 3.2 to 5.3 million people in the United States are living with a TBI-related disability and 40% of them have balance disturbances, we estimate that our PoNS™ therapy could assist up to 2.1 million individuals.

We launched a registrational clinical trial of the PoNS™ therapy, with concurrent physiotherapy, investigating the safety and effectiveness of the device for the treatment of balance disorders resulting from mild- to moderate-TBI in August 2015, with the support of the U.S. Army. This double-blind, sham-controlled trial is enrolling 120 patients at multiple study sites. We expect to complete the trial in the second quarter of 2017. The primary endpoint of this trial is improvement in chronic balance deficit at five weeks in the active group compared to the sham group, as measured by the sensory organization test. We intend to use the results of this trial to support our application to the FDA (via the (510K) de novo process) for marketing authorization in the United States. Additionally, the U.S. Army, through a collaborative research and development agreement with the University of Wisconsin-Madison (the "UW-M"), is also sponsoring a double-blind, sham-controlled non-registrational clinical trial of the PoNS™ therapy, with concurrent physiotherapy, for the treatment of chronic balance deficits due to TBI. This trial is fully enrolled with 44 patients and is designed to assess the durability of response of the PoNS™ therapy. The primary endpoint of this non-registrational trial is an improvement in balance at 14 weeks of treatment as measured by the sensory organization test. We expect this trial will be completed in the second quarter of 2017. We intend to include data from the UW-M study as supportive information as part of our regulatory submission for TBI.

To further characterize the effect on the brain resulting from stimulation of an active PoNS™ versus a sham PoNS™ device, we are conducting two comparative studies between the active device and the sham device at the Montreal Neurological Institute and the Surrey Medical Center, BC, Canada respectively. These studies will use electroencephalogram (EEG) to document passage of electricity in the brain in response to hearing specific words, as well as positron emission tomography (PET) scans to verify and quantify the relative effect of the different levels of stimulation. We are also conducting a randomized, controlled study in Montreal (Concordia University's Perform Center) and Surrey, BC comparing the efficacy of physical therapy alone versus physical therapy with the concurrent use of the PoNS™ device, to further characterize the independent effect of the PoNS™ device versus physical

therapy alone. These studies were not mandated by FDA, and were designed by us and are solely sponsored by us. The results of these studies will be presented to the FDA and other regulatory authorities to support our applications for marketing authorization.

Multiple Sclerosis

According to the National Multiple Sclerosis Society, there are approximately 400,000 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.

In 2015, we completed a pilot study that evaluated the effect of the use of the PoNS™ device, with concurrent physiotherapy, in 14 patients (7 active, 7 sham) with MS while performing working memory and mental imagery tasks. Patients who used the PoNS™ therapy showed statistically significant differences in neurostimulation (left Primary motor cortex) from baseline, as measured by functional MRI (i.e., via BOLD signals indicating activity). Moreover, patients who used the PoNS™ therapy showed a statistically significant improvement in balance from baseline, as measured by the sensory organization test. The sham group, in contrast, did not reach statistical significance. The active and sham group were not compared head-to-head. The PoNS™ therapy also demonstrated a favorable safety profile in the study. Based on these results we believe a larger study is warranted to explore these findings further.

The FDA has determined that we must obtain an IDE prior to commencing any clinical trial of the PoNS™ therapy in MS patients. Subject to the FDA's approval of our IDE, we intend to commence a registrational trial of the PoNS™ therapy in MS patients with chronic balance and gait deficit.

Cerebral Palsy

In September 2016, we announced results from a pilot study conducted in Russia of the effectiveness of the PoNS™ device, with concurrent physiotherapy, in treating movement control-related symptoms of CP. In the study, 45 of the 65 patients received neurostimulation via the PoNS™ therapy. The study found a statistically significant difference between active and control groups in spasticity of the lower limbs and gross motor function. Positive changes in quality of life, cognitive function and social status were also observed. The FDA has determined that we must obtain an IDE prior to commencing any clinical trial of the PoNS™ therapy in CP patients. Subject to the availability of additional funding and upon the receipt of an IDE by the FDA, we intend to develop a registrational trial of the PoNS™ device in CP patients with movement control-related symptoms.

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™ therapy on physiological improvements associated with cognition. The study is being conducted at HealthTech Connex Inc ("HTC") in Surrey, BC. We chose HTC as the site of this study because of HTC's experience in measuring and quantifying physiological changes in brain function. This study will further test the hypothesis, in healthy subjects, that use of the PoNS™ device may contribute to improved cognitive function. We expect that this study will be completed in the second quarter of 2017.

Earlier Studies of First Generation PoNS™ Device

The inventors of the PoNS™ device conducted a series of IRB-sanctioned feasibility studies, case studies, and one placebo-controlled study. In total, these studies involved approximately 260 patients using the first generation PoNS™ device in conjunction with physical or cognitive therapy at the TCNL at the University of Wisconsin-Madison. These studies generated encouraging anecdotal results. A third-party retrospective review of this early data concluded that the use of the PoNS™ therapy led to statistically better outcomes in patients with resistant neurological conditions.

Our Partnership with the U.S. Army

As described above in "—Current Studies—Traumatic Brain Injury," in July 2015 we have entered into a sole source cost sharing agreement (the "U.S. Army Agreement") with the U.S. Army for the commercial development of the PoNS™ device for the treatment of 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 ("USAMMA") and the U.S. Army Medical Research and Material Command ("USAMRMC" and, together with USAMMA, the "Army Laboratories") have agreed to cooperate with NeuroHabilitation Corporation ("NHC"), our wholly-owned subsidiary, on clinical studies and regulatory responsibilities necessary to obtain FDA marketing authorization of the PoNS™ device for this indication. Under the U.S. Army Agreement, NHC is the sole regulatory sponsor of the PoNS™ device 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 trial of the safety and effectiveness of the PoNS™ device for the treatment of chronic balance deficits related to mild- to

moderate-TBI, up to a maximum amount of $2,996,244. As of December 31, 2016, we have been reimbursed $1.8 million in reimbursements pursuant to the U.S. Army Agreement. The U.S. Army Agreement expires December 31, 2017, but the U.S. Army may extend the term of the agreement at its discretion.

We previously entered into a collaborative relationship with the U.S. Army, pursuant to a February 2013 cooperative research and development agreement (as amended, the "CRADA"), to determine if the PoNS™ device could be developed for commercial use, with concurrent physical therapy, 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™ therapy, 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 will initially seek FDA marketing authorization only for treatment of patients with chronic balance deficits due to mild- to moderate-TBI. If we are able to complete development of the PoNS™ therapy and obtain FDA marketing authorization of the PoNS™ therapy for this indication, we plan to develop the PoNS™ therapy 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. In addition, the CRADA automatically expires on December 31, 2017 unless modified in writing by the parties, provided that 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 for the PoNS™ device for the treatment of chronic balance deficits resulting from TBI, as well as for commercialization of the PoNS™ device.

Manufacturing

We presently have relationships with two contract manufacturers for the PoNS™ device, Cambridge Consulting, LLC ("Cambridge") and Ximedica, LLC ("Ximedica"). Ximedica, which was our sole manufacturer until January 2017, has agreed to manufacture the PoNS™ device for use in our ongoing clinical trials and design verification testing and may assist in manufacturing early commercialization devices. In January 2017, we entered into an agreement with Cambridge, pursuant to which Cambridge agreed to assume responsibilities for the 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. We believe the addition of a second development partner will mitigate our risk by adding back-up capabilities for our manufacturing process and improve the quality of our planned FDA submission. We will, however, 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 a need to know basis, even with our manufacturers. We expect that the PoNS™ device will require some light assembly and labeling that will be performed by our commercial manufacturer or distribution partner. Both Cambridge and Ximedica are registered as medical device manufacturers in good standing with the FDA, and are certified in accordance with International Organization for Standardization (ISO) 13485, a comprehensive quality management system for the design and manufacture of medical devices. On November 30, 2016, we received our ISO 13485 certification.

With the assistance of Cambridge, we are currently evaluating commercial-scale manufacturers for the PoNS™ device with the goal of building sufficient stock to warehouse and ship the product to our distributor, who will in turn manage customer distribution, if we receive marketing authorization.

Commercialization

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

PoNS™ in Civilian Population

We believe that a key to deployment success in the civilian population will be to create a national framework of PoNS™-trained physical therapists ("PTs") or physical therapy centers ("PTCs"). We have developed a training certification program for use if we obtain marketing authorization where PTs can become certified PoNS™ therapists after on-line and in-person training. We expect there to be a strong financial incentive for the PT community to partner with us because PoNS™ training offers substantial opportunity for business growth for the PTs and PTCs. We anticipate that PTs and PTCs will be able to use existing reimbursement

codes for the physical therapy portion of the therapy. As discussed below, we plan to apply for reimbursement codes for the PoNS™ therapy, which we refer to as the concurrent use of the PoNS™ device and physical therapy.

We will concentrate our efforts in the United States, Canada, United Kingdom and Australia as first launch markets. We are currently uncertain which of these three markets will launch first, primarily due to the relative speed of the regulatory process, and there is no assurance that any will launch at all. Following the initial launch of marketplaces, we intend to commercialize the PoNS™ therapy in the rest of Europe and Japan as second phase countries and Brazil, India and other markets as third phase countries.

In November 2014, we signed a development and distribution agreement with Altair, LLC, a Russian company, to apply for registration and distribution of the PoNS™ device in the territories of the former Soviet Union. Altair sponsored the pilot study of the PoNS™ device in the treatment of movement control-related symptoms of CP, as described in "—Current and Planned Studies—Cerebral Palsy." Thus far the device has received a letter of conformity as an adjunct to physical therapy in Russia and full regulatory approval in Uzbekistan following regulatory applications to the health authorities of these two countries. The full scale launch of the technology in those markets will follow the completion of our manufacturing development process.

PoNS™ in the U.S. Army

As mentioned above in "—Current Studies—Traumatic Brain Injury," we have partnered with the U.S. Army pursuant to the U.S. Army Agreement and a CRADA for the development of the PoNS™ therapy for the treatment of mild- to moderate-TBI. The U.S. Army's interest in the PoNS™ therapy stemmed from the very high incidence of TBI in soldiers and the fact that there are very 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 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™ therapy 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 PoNS™ devices from us, we expect that the U.S. Army would deploy the device to active duty personnel through their rehabilitation centers under orders from the central medical command. All personnel are expected to be certified PoNS™ trainers 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.

Competition

The neurostimulation market is competitive and growing. Our competitors in the industry are predominantly large, publicly-traded companies that have a history in the market, have significantly easier access to 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 foundational, and neurostimulation has slowly become integrated into neurological therapy. This foundation has allowed for new and innovative neurostimulation companies to enter the market.

We believe that the PoNS™ device introduces an innovative target and method of stimulation because targeting the tongue for neurostimulation provides several clear advantages, which are discussed below. While we believe that the factors described below competitively distinguish our technologies and provide the PoNS™ therapy a competitive advantage for non-invasive neuromodulation therapy, we note that these factors are only supported by published pilot studies in MS and CP, in addition to anecdotal evidence of efficacy from the preclinical studies at TCNL. However, these results must be confirmed by a larger well-controlled, independently reviewed scientific studies, such as our ongoing registrational trial of the PoNS™ device in balance disorders related to TBI.

Advantages of the PoNS™ Therapy

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

- Other technologies stimulate other branches of the trigeminal nerve. We target the lowest branch of the trigeminal nerve, which is found in the tongue. It is also the largest branch, having the highest amount of nerve fibers of the three branches.
- 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 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

If we complete our clinical trials and obtain FDA marketing authorization, and ultimately receive customer orders for the PoNS™ device, we plan to submit applications for appropriate reimbursement codes so that insurers, including Medicare and Medicaid, are able to pay for the device. We plan to seek coverage and reimbursement of the PoNS™ therapy from public payers, such as Medicare and Medicaid, as well as private payers. 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 its business. For all payers, the PoNS™ therapy must fit within an identifiable coverage category and fully meet the requirements of such category.

Once we complete our clinical trials and obtain FDA marketing authorization, and ultimately receive customer orders for the PoNS™ device, we intend to seek coverage for the PoNS™ device under the Medicare part B durable medical equipment benefit. This will involve ensuring that the PoNS™ device meets all of the criteria for coverage under that benefit. In addition, 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™ device 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 particular products, supplies and services. At present, we do not believe that the PoNS™ device would fit easily within an existing HCPCS code. 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 (1) a new permanent code be added to the HCPCS level II national code set; (2) the language used to describe an existing code be modified; or (3) an existing code be deleted. However, prior to submitting its 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 having 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.

If we do submit such a request for a new HCPCS code, it will be reviewed by the CMS HCPCS Workgroup, which is comprised of representatives of CMS, Medicaid state agencies, and the Pricing, Data Analysis and Coding contractor. The HCPCS Workgroup meets monthly and determines whether each coding request warrants a change to the HCPCS national coding set.

We intend to perform a health economic study to confirm the potential value of our therapy to the healthcare system. We anticipate this report to be completed prior to regulatory approval so that we are in a position to use it, should it be positive, in support of coverage through private insurers prior to potential CMS reimbursement.

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.

In addition, Medicare and other insurers must find that the PoNS™ therapy is medically reasonable and necessary for the treatment of patients' illness or injuries. If Medicare and other insurers find that the PoNS™ therapy 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™ therapy. If that amount is inadequate to cover the costs of the PoNS™ therapy, 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 as of June 6, 2014 entered into between ANR and NHC (the "Sublicense Agreement"), 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 TM 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 the trigeminal nerve, the facial nerve or both:

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	Pending	N/A	N/A	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	Pending	N/A	N/A	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	Pending	N/A	N/A	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
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 and 9,020,612 and U.S. Patent Application Nos. 14/615,766, 14/689,462 and 14/815,171 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, and U.S. Patent Application Nos. 14/615,766, 14/689,462, 14/815,171 and any future filings that claim priority. We intend to file additional continuation applications in the USPTO claiming priority to U.S. Patent Application Nos. 14/615,766, 14/689,462, and 14/815,171 to protect other aspects of the PoNS ™ device and related non- invasive neurostimulation techniques.

ANR, which is one of Helius' significant shareholders, holds an interest in the Patent Pending Rights pursuant to an exclusive license from the inventors. U.S. Patent Application Nos. 14/615,766, 14/689,462, 14/815,171 are included in the exclusive license as the exclusive license agreement covers (i) U.S. Patent Application No. 12/348,301 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 Application Nos. 14/615,766, 14/689,462, 14/815,171 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 are 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 Helius is not willing or is unable to commercialize the PoNS ™ technology within four years from the expiration of the CRADA, the Company is required to transfer possession, ownership and sponsorship/holdership of the regulation application, regulatory correspondence and supporting regulatory information related technology to USAMRMC and grant the U.S. Government a non-exclusive, irrevocable license to any patent, copyright, data rights, proprietary information or regulatory information for the U.S. Government to commercialize the technology.

Company Owned Intellectual Property

On July 17, 2015, the Company announced that the USPTO issued the Company its first patent related to the design of the current PoNS ™ device. U.S. Patent No. 9,072,889, "Systems for Providing Non-Invasive Neurorehabilitation of a Patient," issued on July 7, 2015, is the first patent Helius has received related specifically to the new device design.

The Company filed 27 U. S. patent applications related to various technical and ornamental aspects of the PoNS ™ device. The Company filed eleven non-provisional patent applications that describe various technical features in the current version device and 16 design patent applications describing various ornamental designs. Helius is the sole assignee for these 27 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 three 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 application covering overall system design, including controller and mouthpiece
14/559,123	12/3/2014	Issued	9,272,133	3/1/2016	Utility application 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 application covering shape of the mouthpiece
14/558,789	12/3/2014	Issued	9,283,377	3/15/2016	Utility application covering center of gravity of the mouthpiece
14/559,080	12/3/2014	Allowed	TBD	TBD	Utility application covering structural support of the mouthpiece
14/559,105	12/3/2014	Allowed	TBD	TBD	Utility application covering glue wells of the mouthpiece
29/510,741	12/3/2014	Issued	D750264	2/23/2016	Design application 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 application 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 application covering system design used in the current PoNS™ device
29/510,745	12/3/2014	Issued	D750265	2/23/2016	Design application 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 application covering the controller used in the PoNS™ device
29/510,755	12/3/2014	Issued	D751215	3/8/2016	Design application covering an alternative controller not used in the current PoNS™ device
29/510,746	12/3/2014	Issued	D750266	2/23/2016	Design application covering an alternative mouthpiece not used in the current PoNS™ device
29/510,749	12/3/2014	Issued	D750268	2/23/2016	Design application covering an alternative mouthpiece not used in the current PoNS™ device
29/510,747	12/3/2014	Issued	D751213	3/8/2016	Design application covering an alternative mouthpiece not used in the current PoNS™ device
29/510,748	12/3/2014	Issued	D750267	2/23/2016	Design application covering an alternative mouthpiece not used in the current PoNS™ device
29/510,750	12/3/2014	Issued	D753315	4/5/2016	Design application covering mouthpiece used in the current PoNS™ device
29/510,751	12/3/2014	Issued	D751722	3/15/2016	Design application covering an alternative controller not used in the current PoNS™ device
29/510,752	12/3/2014	Issued	D752766	3/29/2016	Design application covering an alternative controller not used in the current PoNS™ device
29/510,753	12/3/2014	Issued	D753316	4/5/2016	Design application covering an alternative controller not used in the current PoNS™ device
29/510,744	12/3/2014	Issued	D760397	6/28/2016	Design application covering system design used in the current PoNS™ device
29/510,756	12/3/2014	Issued	D759830	6/21/2016	Design application covering system design used in the current PoNS™ device

Additionally, Helius has filed three international applications, and 14 foreign design applications: seven in Canada, three in China, three in Russia, and one community design in Europe. The following three applications filed in China, which have been assigned to China Medical Systems Holdings LTD. pursuant to an asset purchase agreement (the "Strategic Agreement") dated effective October 9, 2015 with A&B have issued:

Chinese Patent Application No.	Application Filing Date	Status	Chinese Patent No.	Issue Date	Subject Matter
201530177804.4	6/3/2015	Issued	CN303597712S	2/24/2016	Design application covering the system design currently used in the PoNS ™ 4.0 device
201530178171.9	6/3/2015	Issued	CN303597713S	2/24/2016	Design application covering the mouthpiece design currently used in the PoNS ™ 4.0 device
201530177398.1	6/3/2015	Issued	CN303597711S	2/24/2016	Design application covering the controller design currently used in the PoNS ™ 4.0 device

Further, the three design applications filed in Russia have been allowed, and the Canadian Design applications and European community design have issued:

Russian Design Application No.	Application Filing Date	Status	Russian Patent No.	Issue Date	Subject Matter
2015501883	6/3/2015	Allowed	TBD	TBD	Design application covering the system design currently used in the PoNS ™ 4.0 device
2015501882	6/3/2015	Allowed	TBD	TBD	Design application covering the mouthpiece design currently used in the PoNS ™ 4.0 device
2015501881	6/3/2015	Allowed	TBD	TBD	Design application covering the controller design currently used in the PoNS ™ 4.0 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 application covering system design used in the current PoNS ™ device
162672	6/2/2015	Issued	162672	2/29/2016	Design application covering an alternative mouthpiece not used in the current PoNS ™ device
162671	6/2/2015	Issued	162671	2/29/2016	Design application covering an alternative mouthpiece not used in the current PoNS ™ device
162674	6/2/2015	Issued	162674	2/29/2016	Design application covering mouthpiece used in the current PoNS ™ device
162675	6/2/2015	Issued	162675	2/29/2016	Design application covering an alternative controller not used in the current PoNS ™ device
162670	6/2/2015	Issued	162670	2/29/2016	Design application covering the controller used in the PoNS ™ device
162673	6/2/2015	Issued	162673	2/29/2016	Design application 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 application covering several aspects of the system design currently used in the PoNS ™ 4.0 device

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

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

We take precautions to safeguard our intellectual property, and it has been and may be the subject of lawsuits. See Part I Item 3, "Legal Proceedings."

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 FD&C Act and the FDA's implementing regulations, among others.

The FDA Review, Clearance and Approval Process

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, or pre-market approval, or PMA, from the FDA, unless specifically exempted by the FDA. FDA review and approval is required for each application of a device, regardless of whether the device has been approved for other applications. The FDA classifies all medical devices into one of three classes. Devices deemed to pose the lowest risk are categorized as either Class I or II, which requires the manufacturer to submit to the FDA a 510(k) pre-market notification submission 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 application.

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 is sometimes 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 subject to the PMA pathway 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 approval to market the device. This device type can then be used as a predicate device for future 510(k) submissions.

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 is not 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 PMA applications. 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 significant clinical data to support substantial equivalence. In reviewing a pre-market notification submission, the FDA may request additional information, including clinical data, 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 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 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 found, the device is automatically classified Class III regardless of the level of risk it poses. 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 application. 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. The 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 the 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. In addition, the FDA may reject the reclassification petition if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk or that general controls would be inadequate to control the risks and special controls cannot be developed.

We plan to utilize the *de novo* classification process to obtain marketing authorization for the PoNS™ device under development, 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. Our goal would be to complete a safety and effectiveness clinical trial using the PoNS™ device, initially only for the treatment of balance disorder in patients with mild- to moderate-TBI. Our overall goal for submission of the *de novo* application and FDA marketing authorization of a 510(k) would be in 2018. The application to the FDA will be made after the completion of the registration trial, which we anticipate will be completed in the second quarter of calendar year 2017. Originally, we anticipated that the registration trial would be completed at the end of 2015, but that timing was revised due to slower than expected enrollment. We have invested resources to expand recruiting to recoup for time lost. We thus anticipate that we will be applying for marketing authorization in the second half of calendar year 2017. To the extent the FDA completes its review in 90 days, we anticipate clearance by the first half of calendar year 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 application 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 application 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 application 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 impose elaborate design development, testing, control, documentation and other quality assurance procedures in the design and manufacturing process. The FDA may approve a PMA application 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 PMA applications 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 application, and may not require as extensive clinical data or the convening of an advisory panel.

Clinical Trials

A clinical trial is typically required to support a PMA application and is sometimes required for a 510(k) pre-market notification. After a 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 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 will be necessary to obtain clearance for multiple uses of one device.

Risks of Delay from the FDA Marketing Authorization Process and Regulatory Compliance Risks

The FDA can delay, limit or deny clearance or approval 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, sensitive and specific diagnostic tests, for its intended users;
- the data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required; and
- the manufacturing process or facilities we use may not meet applicable requirements.

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under development or impact our ability to

modify our currently approved or cleared products on a timely basis. 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 that 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 we obtain FDA marketing authorization for our PoNS™ device, we will still be required to pursue a 510(k) clearance, *de novo* down-classification, or PMA for any future product which will delay future product launches and would likely place substantial restrictions on how our device is manufactured, marketed and sold. For example, the manufacture of medical devices must comply with the FDA's QSR. In addition, manufacturers must register their manufacturing facilities, list the products with the FDA, and comply with requirements relating to labeling, marketing, complaint handling, adverse event and medical device reporting, reporting of corrections and removals, and import and export. The FDA monitors compliance with the QSR and these other requirements through periodic inspections. If our facilities or those of our manufacturers or suppliers are found to be in violation of applicable laws and regulations, or if we or our manufacturers or suppliers fail to take satisfactory corrective action in response to an adverse inspection, the regulatory authority could take enforcement action, including any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications or repair, replacement, refunds, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) marketing clearance or pre-market approvals of new products or modified products;
- withdrawing 510(k) marketing clearances or pre-market approvals 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 they are authorized for marketing.

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 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 35,300,083 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 NeuroHabilitation Corporation whereby NeuroHabilitation Corporation 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 $7.016 million (CAD$7.62 million) by issuing 15.24 million 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$1.00 per share for a period of two years. In connection with the concurrent private placement financing, we paid aggregate finders' fees of $379,806 (CAD $412,200) and issued 824,000 finder's warrants. Each finder warrant is exercisable at CAD$1.00 per share for a period of two years.

General Development of the Business of NeuroHabilitation Corporation

Our primary operations are conducted through our wholly-owned subsidiary NHC. On January 22, 2013, NHC entered into a patent sub-license agreement whereby ANR granted NHC exclusive worldwide rights to ANR's trade secrets, knowhow, and patent pending technology for a non-invasive means for delivering neurostimulation through the oral cavity, or the PoNS™ device. NHC obtained these rights in exchange for 50% of the outstanding equity in NHC and an obligation to pay ANR a royalty equal to 4% of any revenue collected by NHC from (1) the sale of products covered by any claim of the patent rights to end users and (2) services related to the therapy or use of such products in therapy services. This agreement was subsequently amended by the Amended and Restated Patent Sub-License and again by the Sublicense Agreement described above.

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 (the "CSE").

On April 18, 2016, our common stock was listed on the Toronto Stock Exchange ("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.

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

Our shares of Class A common stock were approved for listing on the TSX on April 18, 2016. However, some of our shares of common stock were issued in an offshore offering in April and May of 2016 (the "Offshore Offering") in transactions exempt from the registration requirements of the Securities Act of 1933, as amended (the "Securities Act") and are listed under a separate ticker symbol for trading on the TSX. These shares of common stock are subject to restrictions on their resale to a U.S. person (as that term is defined in Regulation S), or to a person in the United States, unless in a registered transaction or pursuant to an applicable safe harbor or exemption from registration. Certain of our warrants were also approved for listing on the TSX on April 18, 2016. However, because only 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.

Employees

As of December 31, 2016, we have seven full time employees and 20 full-time equivalent independent contractors. Upon completion of our TBI clinical trial and submission to FDA of our application for clearance, we intend to invest in our 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 successful completion of the TBI trial and obtaining FDA, CE Mark or Health Canada clearance of the PoNS™ therapy 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 PTs and PTCs who are PoNS-certified. 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 or Health Canada clearance, we do not currently have any contract or other arrangement to sell the PoNS™ device. 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 $2,668,655 of cash as of December 31, 2016 and in February 2017 we raised an additional $9,518,878 (CAD$12,454,500) before underwriting commissions and expenses in a public offering of 6,555,000 shares of Class A Common Stock, 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 Transition 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 Transition 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 cash equivalents 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 nine months ended December 31, 2016 and the fiscal year ended March 31, 2016, we incurred a net loss of $12,039,971 and $6,881,812, respectively, and used cash in operations of $7,243,640 and $7,937,412 respectively. We have an accumulated deficit of $38,345,234 as of December 31, 2016. 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 and launching our PoNS™ device into the market, 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 candidates.

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 and cash equivalents totaling $2,668,655 at December 31, 2016. 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 completion of our registrational trial of the PoNS™ device for the treatment of balance disorder in subjects with mild- to moderate-TBI, FDA marketing authorization of the PoNS™ device for this indication, manufacturing of a commercially-viable version of the PoNS™ device, obtaining favorable reimbursement from third party payors, 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 required to reduce the scope of our operations and pursue only those projects that can be funded through cash flows generated from its existing operations, if any.

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, 2016 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 end of 2017. 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, from 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™ therapy 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, CE Mark, 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 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 to treat 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 would 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™ device, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidate. Clinical testing is expensive, time consuming and uncertain as to outcome. We cannot guarantee that clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of testing. Delays can be costly and could negatively affect our ability to complete a clinical trial and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize the PoNS™ device. If we are unable to complete 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 and prospects.

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

Our deployment strategy in the civilian population depends on physicians prescribing the PoNS™ therapy to patients with relevant neurological disorders and physical therapists being trained in the supervision of patients' use of our therapy. 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. Accordingly, our PoNS™ technology is a new, "untested," and therefore unproven, therapy. 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™ device for neurostimulation therapy, we will not be able to generate significant revenues, if any, which would have a material adverse effect on our business.

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

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

We face significant competition in an environment of rapid technological change, and our competitors may develop devices or products that are more advanced or more effective than ours, 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 a longer operating history than us, with significantly easier access to resources and an established product pipeline. 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™ device uneconomical or obsolete.

Risks Related to our Reliance on Third Parties

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

We currently have a limited number of employees and resources available to perform the research and development necessary to commercialize our PoNS™ therapy and potential future product candidates. We therefore rely, and will continue to rely, on third-party research institution collaborators 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™ therapy 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 remains solely responsible for sponsoring the registrational trial and the sole regulatory sponsor for the PoNS™ device 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 (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™ device.

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, 2017, 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 authorization of the PoNS™ device or otherwise fail to ensure that the PoNS™ device is available for purchase by the U.S. Government, in each case by the expiration date under the CRADA of December 31, 2017, 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™ therapy would have a material adverse effect on our business.

Additionally, under our Strategic Agreement with A&B (HK) Company Ltd. ("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, 2017, we may be required to pay a $2,000,000 contract penalty to A&B.

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

We will be dependent on two third parties to manufacture and supply our PoNS™ device. One of these manufacturers will be manufacturing our clinical units, design verification units and potentially the early commercialization inventory. The second manufacturer will be performing the engineering and device verification and will coordinate the manufacturing information for our FDA submission. This vendor will also support the company with the identification of and transfer to our commercial scale manufacturer. Initially, the manufacturer of the early commercialization devices will also hold some inventory and ship our products to our distribution center, which will hold the bulk of our inventory, warehouse and ship our products to customers as well as handle customer service related tasks. Our reliance on third-party manufacturers to supply us with our PoNS™ device and a separate vendor 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 particular, 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, or they could experience similar problems that result in the manufacture of insufficient quantities of our product candidate, which would delay our clinical trials. Our third party manufacturers and distributors may fail to follow and remain in compliance with the FDA-mandated Quality System Regulations, or QSRs, 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. We have no supply agreements in place with our manufacturers, and they may change the terms of our future orders or choose not to supply us with products in the future. Furthermore, if such manufacturers fail 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. Given the importance of the U.S. Army to our commercial plans, 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. More immediately, NHC is party to a sole source cost sharing contract with the USAMRMC, pursuant to which the USAMRMC has agreed to reimburse the Company for costs related to our registrational trial of the PoNS™ device for the treatment of balance disorders relating to mild- to moderate-TBI. If the USAMRMC terminates this agreement, we would need to seek additional funding to complete this registrational trial, which may not be available on commercially favorable terms to us, or at all.

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™ therapy 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 its 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, or 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 term. 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™ device 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 approval 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 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™ device 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 authorizations 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 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 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.

A number of events or factors, including any of the following, could delay and/or prevent the completion of our clinical trials in the future and negatively impact our ability to obtain FDA marketing authorization for, and to introduce our product candidate:

- failure to obtain financing necessary to bear the cost of designing and conducting clinical trials;
- failure to obtain and maintain approval from the FDA or foreign regulatory authorities to commence investigational studies;
- conditions imposed on us by the FDA or foreign regulatory authorities regarding the scope or design of our clinical trials;
- failure to find a qualified CRO to conduct our clinical trials or to negotiate a CRO services agreement on favorable terms;
- delays in obtaining or in our maintaining required approvals from institutional review boards or other reviewing entities at clinical sites selected for participation in our clinical trials;
- insufficient supply of our product candidate or other materials necessary to conduct our clinical trials;
- difficulties in enrolling or retaining patients in our clinical trials;
- negative or inconclusive results from clinical trials, or results that are inconsistent with earlier results, that necessitate additional clinical studies;
- failure on the part of the CRO to conduct the clinical trial in accordance with regulatory requirements;
- our failure to maintain a successful relationship with the CRO or termination of our contractual relationship with the CRO before completion of the clinical trials;
- serious or unexpected side effects experienced by patients;
- refusal of FDA to accept data from foreign clinical trial sites; or
- failure by any of our third-party contractors or investigators to comply with regulatory requirements, protocols, or meet other contractual obligations in a timely manner.

Our clinical trials may need to be redesigned or may not be completed on schedule, if at all. Delays in our clinical trials may result in increased development costs for our product candidate, which could cause our stock price to decline and limit our ability to obtain additional financing. In addition, if one or more of our clinical trials are delayed, competitors may be able to bring products to market before we do, and the commercial viability of our product candidate could be significantly reduced.

We will be substantially dependent on third parties to conduct 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 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™ device is covered under Medicare and Medicaid. There can be no assurance that our application will be successful, or that we will be able to obtain a reimbursement code in a timely manner. In the event that we do not obtain a reimbursement code for the PoNS™ device, our customers may be unable to obtain reimbursement for their purchases under private or government-sponsored insurance plans which 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 or they will not pay for the device. In addition, there is a risk that the payment amount for the PoNS™ device is too low 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. Such contracts often include exceptions for purchasing certain innovative new technologies, however. 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 implants 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 products 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 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 payors 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 payors 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 payor, 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 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 almost no 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 four others as our only full-time employees. We also have engaged 20 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 ("NOL"s) 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.

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.

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 future prospects 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. Trading in our common stock on the CSE was also extremely limited.

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.

We have not voluntarily implemented various corporate governance measures, in the absence of which, shareholders may have more limited protections against interested director transactions, conflicts of interest and similar matters.

Federal legislation, including the Sarbanes-Oxley Act of 2002, has resulted in the adoption of various corporate governance measures designed to promote the integrity of the corporate management and the securities markets. Some of these measures have been adopted in response to legal requirements. Others have been adopted by companies in response to the requirements of national securities exchanges, such as the NYSE or the Nasdaq Stock Market, on which their securities are listed. Among the corporate governance measures that are required under the rules of national securities exchanges are those that address board of directors' independence, and audit committee oversight. We have not yet adopted many of these corporate governance measures, including the requirement that we have a nominating and corporate governance committee, a compensation committee and an audit committee composed entirely of independent directors, with written charters addressing the committees' purpose and responsibilities.

It is possible that if we were to adopt some or all of these corporate governance measures, stockholders would benefit from somewhat greater assurances that internal corporate decisions were being made by disinterested directors and that policies had been implemented to define responsible conduct. Investors should bear in mind our current lack of corporate governance measures in formulating their investment decisions.

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.

Our two major shareholders have the ability to take shareholder action without the involvement of our other shareholders.

In accordance with our governing documents, any action required to be taken at a shareholders' meeting may be taken without a meeting if consents in writing setting forth the action so taken are signed by the holders of our outstanding shares having not less than the minimum number of votes that would be required to authorize or take the action at a meeting at which all shares entitled to vote on the action were present and voted. Currently, our two major shareholders, MPJ Healthcare, LLC ("MPJ") and Advanced Neuro-Rehabilitation LLC ("ANR") hold approximately 35% of our outstanding shares of common stock. Philippe Deschamps, our Chief Executive Officer, and Jonathan Sackier, our Chief Medical Officer, are co-owners of MPJ along with a third individual and each serve on the board of members of MPJ. Mitch Tyler, a member of our board of directors, is co-owner of ANR.

Our two major shareholders may have the ability to take shareholder action at a shareholders' meeting even if they do not hold a majority of our outstanding common stock.

As long as our two major shareholders, MPJ and ANR, collectively hold at least 33 1/3% of our outstanding common stock, they may be able to effect a vote requiring shareholder approval. In accordance with our governing documents, shareholders holding at least five percent of all the votes entitled to be cast on a proposal may call a special meeting to vote on the proposal. Also in accordance with our governing documents, quorum for a shareholders' meeting is at least 33 1/3% of our outstanding common stock entitled to vote and, where quorum is present, shareholder action may be taken by the affirmative vote of a majority of the shares represented at the meeting and entitled to vote. Accordingly, if our two major shareholders call a meeting and establish quorum, they can effect shareholder approval on a proposal unless other shareholders holding a greater number of shares than our two major shareholders were present at the meeting, either in person or by proxy, and vote against the proposal. There is no guarantee that such other shareholders will be present at any such meeting or, even if they were present at such meeting, will vote against the proposal.

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. 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 or preferred 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.

Our stock is a penny stock. Trading of our stock may be restricted by the SEC's penny stock regulations which may limit a stockholder's ability to buy and sell our stock.

Our stock is a penny stock. The SEC has adopted Rule 15g-9 which generally defines "penny stock" to be any equity security that has a market price (as defined) less than $5.00 per share or an exercise price of less than $5.00 per share, subject to certain exceptions. Our securities are covered by the penny stock rules, which impose additional sales practice requirements on broker-dealers who sell to persons other than established customers and "accredited investors". The term "accredited investor" refers generally to institutions with assets in excess of $5,000,000 or individuals with a net worth in excess of $1,000,000, not including any equity in that person's or person's spouse's primary residence, or annual income exceeding $200,000 or $300,000 jointly with their spouse. The penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document in a form prepared by the SEC which provides information about penny stocks and the nature and level of risks in the penny stock market. The broker-dealer also must provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and its salesperson in the transaction and monthly account statements showing the market value of each penny stock held in the customer's account. The bid and offer quotations, and the broker-dealer and salesperson compensation information, must be given to the customer orally or in writing prior to effecting the transaction and must be given to the customer in writing before or with the customer's confirmation. In addition, the penny stock rules require that prior to a transaction in a penny stock not otherwise exempt from these rules, the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written agreement to the transaction. These disclosure requirements may have the effect of reducing the level of trading activity in the secondary market for the stock that is subject to these penny stock rules. Consequently, these penny stock rules may affect the ability of broker-dealers to trade our securities. We believe that the penny stock rules discourage investor interest in and limit the marketability 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 ("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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our head office is located at 41 University Drive, Suite 400, Newtown, PA 18940. We currently lease six office rooms from Regus Management Group, LLC for approximately $8,513 per month. The lease expires on July 31, 2017. On March 29, 2017, we entered into a lease for 10,444 square feet of dedicated office space at 642 Newtown-Yardley Road, Suite 100, Newtown, PA 18940. The lease commences on July 1, 2017 and terminates on December 31, 2022 with an option to extend until 2027. Monthly rent plus utilities is approximately $20,018 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.

On February 14, 2017, Mackie Research Capital Corporation ("Mackie"), a Canadian investment banking firm, filed a statement of claim in the Ontario Superior Court of Justice naming us as defendant. The claim alleges that we breached a term of the agency agreement dated March 23, 2016 between us and Mackie in connection with our public offering of Class A Common Stock, which

closed on February 16, 2017, by not complying with Mackie's right of first refusal to serve as the lead underwriter in the offering. We believe that we fully complied with our obligations under the agency agreement by offering Mackie the opportunity to serve as lead underwriter in the offering. The claim seeks damages totaling $1,400,000 and equitable relief. As the matter is at a preliminary stage, we have not been able to make a full assessment on the merits of the claim. We intend to defend against this claim vigorously.

Except as described above, we are not aware of any legal proceedings contemplated by any governmental authority or any other party involving us or our properties. As of December 31, 2016, 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. We are not aware of any other legal proceedings pending or that have been threatened against us or our properties.

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 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
Fiscal Year Ended March 31, 2016				
First Quarter	$ 2.60	$ 1.90	CAD$ 3.28	CAD$ 2.30
Second Quarter	$ 2.10	$ 0.62	CAD$ 2.55	CAD$ 0.80
Third Quarter	$ 1.15	$ 0.58	CAD$ 1.55	CAD$ 0.75
Fourth Quarter	$ 0.86	$ 0.68	CAD$ 1.24	CAD$ 0.95
Nine Months Ended December 31, 2016				
April 1, 2016 - June 30, 2016	$ 1.50	$ 0.70	CAD$ 1.95	CAD$ 1.01
July 1, 2016 - September 30, 2016	$ 1.13	$ 0.86	CAD$ 1.50	CAD$ 1.11
October 1, 2016 - December 31, 2016	$ 1.81	$ 1.04	CAD$ 2.35	CAD$ 1.35

As of March 15, 2017, the last reported sales price of our common stock on the TSX was CAD$2.10 per share. As of March 15, 2017, the last reported sales price of our common stock on the OTCQB was US$1.57 per share.

The exchange rate in effect on March 15, 2017 as reported by Bank of Canada was US$1.00 = CAD$1.34.

Holders

As of March 15, 2017, there were approximately 200 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.

Other than as previously disclosed in our Quarterly Reports on Form 10-Q, as amended, and our Current Reports on Form 8-K, there were no sales of equity securities by the Company that were not registered under the Securities Act during the nine months ended December 31, 2016.

ITEM 6. SELECTED FINANCIAL DATA

As 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 Transition Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Transition 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, the portable neuromodulation stimulator ("PoNS™") device, is designed to enhance the brain's ability to compensate for this damage. We are currently conducting registrational trials of the effectiveness of the PoNS™ therapy in balance disorders related to mild-to moderate-TBI.

Since our inception, we have incurred significant operating losses. Our net loss was $12,039,971 and $3,051,492 during the nine months ended December 31, 2016 and 2015, respectively. As of December 31, 2016, we had an accumulated deficit of $38,345,234. We expect to incur significant expenses and operating losses for the foreseeable future as we continue to advance the PoNS™ device through clinical trials, and seek regulatory clearance and pursue commercialization of such products. In addition, if we obtain marketing clearance for the PoNS™ device, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. In addition, 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, 2016, we had cash and cash equivalents of $2,668,655. As discussed in more detail below, we recently raised additional capital in a registered public offering of common stock and we intend to seek additional funding. 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 our expenditures.

Components of Our Results of Operations

Revenue

We have not generated any revenue since our inception and do not expect to generate any revenue from the sale of products in the near future.

Research and Development Expenses

Research and development expenses consists of expenses incurred in connection with the discovery and development of our product candidates. We expense research and development 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.

Research and development 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 research and development expenses to increase significantly over the next several years as we increase personnel costs, conduct feasibility and pilot studies and registrational clinical trials 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 Transition Report.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, finance and legal functions, including stock-based compensation, and travel expenses. Other general and administrative expenses include facility related costs, professional fees for legal, auditing and tax services, consulting, and insurance costs.

We anticipate that our general and administrative 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 expense as a result of our preparation for commercial operations, especially as it relates to the sales and marketing and commercial infrastructure of that drug candidate.

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: valuation of non-monetary transactions, stock-based compensation, valuation of options and valuation of income taxes.

Stock-Based Compensation

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

Stock-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 stock-based payments to non-employees is periodically re-measured 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 equity based instruments. The fair value of the stock-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 to employees using the fair value method whereby all awards to employees will be recorded at fair value on the date of the grant. The fair value of all stock options are expensed over their vesting 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 stock options has been 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 U.S. 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 Liabilities

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

We use the Black-Scholes option pricing model to value derivative 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.

Results of Operations

The following table summarizes our results of operations for the nine months ended December 31, 2016 and 2015:

	Nine Months Ended December 31,		
	2016	2015	Change
Revenue	$ —	$ —	$ —
Operating expenses:			
Research and development	4,722,584	2,664,063	2,058,521
General and administrative	5,651,218	3,738,041	1,913,177
Total operating expenses	**10,373,802**	**6,402,104**	3,971,698
Operating loss	(10,373,802)	(6,402,104)	(3,971,698)
Other income (expense):			
Interest and other income	110,611	123,741	(13,130)
Change in fair value of derivative liability	(2,479,905)	2,113,391	(4,593,296)
Foreign exchange gain	703,125	845,146	(142,021)
Gain on extinguishment of debt	—	268,334	(268,334)
Total other income (expense)	(1,666,169)	3,350,612	(5,016,781)
Net loss	**$(12,039,971)**	**$ (3,051,492)**	$ (8,988,479)

Nine Months Ended December 31, 2016 Compared to Nine Months Ended December 31, 2015

Revenue

During the nine months ended December 31, 2016 and 2015 we did not generate any revenue.

Research and Development Expenses

Research and development expenses were $4,722,584 during the nine months ended December 31, 2016, compared to $2,664,063 during the nine months ended December 31, 2015. The increase of $2,058,521 was primarily attributable to an increase in our activities as we recruit for, and perform our clinical trials. Due to challenges in clinical trial recruiting, we increased the number of sites from three to six and incurred additional costs in start-up and on-going operations of the sites and launched a comprehensive radio, print and social media campaign. In addition, we continued to invest in the development and manufacturing of our clinical trial devices and devices used for our testing for our FDA submission.

General and Administrative Expenses

General and administrative expenses were $5,651,218 during the nine months ended December 31, 2016, compared to $3,738,041 during the nine months ended December 31, 2015. The increase of $1,913,177 was primarily attributable to an increase in stock-based compensation expense and payroll expenses resulting from an increase in headcount. Our stock-based compensation expense increased by $980,278 due to the issuance of 3,535,000 stock options during the nine months ended December 31, 2016. Additionally, during the nine months ended December 31, 2016, we had an increase in consulting and other professional fees.

Interest and Other Income

Interest and other income was $110,611 during the nine months ended December 31, 2016, compared to $123,741 during the nine months ended December 31, 2015. Other income during the nine months ended December 31, 2016 related to the distribution of prototype devices into approved territories in Russia through the Altair distribution agreement.

Change in Fair Value of Derivative Liability

The change in fair value of derivative liability was an expense of $2,479,905 during the nine months ended December 31, 2016, compared to a benefit of ($2,113,391) during the nine months ended December 31, 2015. The change in fair value of derivative liability was primarily attributable to the change in our stock price during the period. Our derivative liabilities do not represent cash liabilities.

Foreign Exchange Gain

Foreign exchange gain was $703,125 during the nine months ended December 31, 2016, compared to $845,146 during the nine months ended December 31, 2015. This is primarily due to fluctuations in the foreign exchange rate as related to the amount of Canadian dollars held at the end of each reporting period.

Gain on Extinguishment of Debt

Gain on extinguishment of debt relating to the A&B promissory note was $268,334 during the nine months ended December 31, 2015. As a result of the bifurcation of the embedded conversion option, for accounting purposes, two instruments were considered outstanding and, upon exercise of the contractual conversion option, extinguishment accounting has been applied. Consequently, the shares issued pursuant to the conversion are recorded at their fair value on the date of issuance, determined with reference to their quoted market price on the date of conversion. The resulting difference between the fair value of the shares issued, less the fair value of the related conversion feature and the carrying value of the related debt, is recorded as a gain or loss on the consolidated statement of operations.

Statements of Cash Flows

The following table summarizes our cash flows during the nine months ended December 31, 2016 and 2015:

	Nine Months Ended December 31,	
	2016	2015
Net cash used in operating activities	$ (7,885,125)	$ (6,254,529)
Net cash provided by investing activities	—	378,000
Net cash provided by financing activities	7,996,593	9,691,336
Net increase in cash and cash equivalents	24,718	3,931,457

Nine Months Ended December 31, 2016 Compared to the Nine Months Ended December 31, 2015

Net Cash Used in Operating Activities

Net cash used in operating activities during the nine months ended December 31, 2016 was $7,243,640. This was comprised of a net loss of $12,039,971, adjusted for non-cash items including the change in the fair value of our derivative liabilities of $2,479,905, and stock-based compensation expense of $1,461,646.

Net cash used in operating activities during the nine months ended December 31, 2015 was $6,254,529. This was comprised of a net loss of $3,051,492, adjusted for non-cash items including the change in fair value of our derivative liabilities of $(2,113,391) and stock-based compensation expense of $431,986.

Net Cash Provided by Investing Activities

Net cash provided by investing activities during the nine months ended December 31, 2015 was $378,000, which consisted of the receipt of funds from a short-term investment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities during the nine months ended December 31, 2016 was $7,996,593 which was comprised of $7,902,912 received from offerings of our common stock conducted in April and May, 2016, as well as $1,602,600 received from the exercise of stock options and warrants. These amounts were partially offset by $1,508,919 in share issuance costs incurred in connection with our offering.

Net cash provided by financing activities during the nine months ended December 31, 2015 was $9,691,336 which was comprised of $7,832,436 received from the issuance of common stock and warrants, which was partially offset by $141,100 in share issuance costs. Additionally, during the nine months ended December 31, 2015, we received $2,000,000 in proceeds from convertible debt and a credit facility.

Liquidity and Capital Resources

Our financial statements have been prepared assuming that we will continue as a going concern and, accordingly, does 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 cash equivalents and our working capital as of December 31, 2016 and March 31, 2016:

	December 31, 2016	March 31, 2016
Cash and cash equivalents	$ 2,668,655	$ 2,643,937
Working capital (deficit)	$ (3,444,295)	$ (16,192)

We currently have limited working capital and liquid assets. Our cash and cash equivalents as of December 31, 2016 were $2,668,655. To date, we have not generated any revenue from the commercial 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 successful completion of the clinical trial, 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 research and development 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.

In February 2017, we issued and sold 6,555,000 shares of common stock for an aggregate of CAD$12,454,500, net of issuance costs through an underwritten registered public offering. The Company intends to use the net proceeds from this offering to fund investment in PoNS™ research and development, including the completion of its ongoing registrational trial in non-severe traumatic brain injury, the launch of a registrational clinical trial in multiple sclerosis and an additional clinical trial in cognition, research and development activities to complete the Company's FDA submission and for working capital and general corporate purposes.

We will require additional funding in order 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 assets.

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.

Tabular Disclosure of Contractual Obligations

As of December 31, 2016, we did not have any contractual obligations required to be disclosed by Item 303(a)(5) of Regulation S-K during the nine months ended December 31, 2016.

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. We are currently evaluating the potential impact of the adoption of this standard.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*. The new standard establishes a right-of-use ("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 income statement. 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

financial statements, with certain practical expedients available. We are currently evaluating the potential impact of the adoption of this standard.

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements - Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* , which is intended to define management's responsibility to evaluate whether there is substantial doubt about an organization's ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable) and to provide related footnote disclosures. The ASU provides guidance to an organization's management, with principles and definitions that are intended to reduce diversity in the timing and content of disclosures that are commonly provided by organizations today in the financial statement footnotes. The ASU is effective for annual periods ending after December 15, 2016. The updated accounting guidance was effective for us on December 31, 2016 and we have implemented this new accounting standard and updated our liquidity disclosures as necessary.

JOBS Act

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

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

See the Index to Financial Statements included in this Transition Report.

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 Transition Report.

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, 2016. 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, 2016, our internal control over financial reporting was effective at the reasonable assurance level based on those criteria.

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

Changes in Internal Control Over Financial Reporting

We monitor our internal control over financial reporting on a continuous basis. During the year ended March 31, 2016, we identified a material weakness in our internal control over financial reporting. Subsequent to March 31, 2016, we have taken a number of steps to ensure that our disclosure controls and procedures were effective. We have added personnel experienced in U.S. GAAP as well as SEC rules and regulations to our internal accounting staff. Additionally, we have engaged an independent consulting firm with expertise in U.S. GAAP and technical accounting matters to assist us with complex technical matters. These changes 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 year ended December 31, 2016 have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

On March 29, 2017, we entered into a lease for 10,444 square feet of dedicated office space at 642 Newtown-Yardley Road, Suite 100, Newtown, PA 18940. The lease commences on July 1, 2017 and terminates on December 31, 2022, with an option to extend until 2027. Monthly rent plus utilities is approximately $20,018 per month with a 3% annual increase.

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 2017 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 2017 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 2017 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 2017 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 2017 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 Transition 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	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)
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)
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)

Exhibit Number	Exhibit
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 13, 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 13, 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
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
10.25.1*	Amendment Number 1 to the 2016 Omnibus Incentive Plan
10.26*	Commercial lease agreement dated March 29, 2017 between NeuroHabilitation Corporation and 660 Tudor Square, L.P.
16.1	Letter from Davidson & Company LLP, dated April 15, 2015 (incorporated by reference to Exhibit 16.1 to the Form 10-12G filed with the SEC on April 15, 2015)

Exhibit Number	Exhibit
16.2	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.:
	1. NeuroHabilitation Corporation is a wholly owned subsidiary of Helius Medical Technologies, Inc.
	2. Helius Medical Technologies (Canada), Inc. is a wholly owned subsidiary of Helius Medical Technologies, Inc.
23.1*	Consent of BDO Canada LLP
23.2*	Consent of BDO USA, LLP
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes – Oxley Act of 2002
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes – Oxley Act of 2002
32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes – Oxley Act of 2002
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document

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

ITEM 16. FORM 10-K SUMMARY

None

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

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

We have audited the accompanying consolidated balance sheet of Helius Medical Technologies, Inc. as of December 31, 2016 and the related consolidated statements of operations and comprehensive loss, stockholders' deficit, and cash flows for the period April 1, 2016 through December 31, 2016. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Helius Medical Technologies, Inc. at December 31, 2016, and the results of its operations and its cash flows for the period April 1, 2016 through December 31, 2016, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As described in Note 1 to the consolidated financial statements, the Company incurred a net loss of $12,039,971 for the period April 1, 2016 through December 31, 2016, had an accumulated deficit of $38,345,234 at December 31, 2016 and the Company expects to incur further 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.

/s/ BDO USA, LLP

Philadelphia, Pennsylvania
April 3, 2017

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BDO Canada LLP
600 Cathedral Place
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Vancouver BC V6C 3L2 Canada

Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors
Helius Medical Technologies Inc.

We have audited the accompanying consolidated balance sheet of Helius Medical Technologies Inc. as of March 31, 2016 and the related consolidated statements of operations and comprehensive loss, stockholders' deficit, and cash flows for the year then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Helius Medical Technologies Inc. at March 31, 2016, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

The previously filed consolidated financial statements as of and for year ended March 31, 2016 have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the previously filed consolidated financial statements, the Company incurred a net loss of $6,881,812 for the year ended March 31, 2016, had an accumulated deficit of $26,305,263 at March 31, 2016 and the Company expected to incur further losses in the development of its business. These conditions raised substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1 to the previously filed consolidated financial statements as of and for the year ended March 31, 2016. The consolidated financial statements did not include any adjustments that might result from the outcome of this uncertainty.

/s/BDO Canada, LLP

Chartered Professional Accountants

Vancouver, Canada
June 27, 2016

Helius Medical Technologies, Inc.
Consolidated Balance Sheets
(Expressed in United States Dollars)

	December 31, 2016	March 31, 2016
ASSETS		
Current assets		
Cash and cash equivalents	$ 2,668,655	$ 2,643,937
Receivables	225,155	399,106
Prepaid expenses and other current assets	556,456	997,679
Total current assets	3,450,266	4,040,722
TOTAL ASSETS	$ 3,450,266	$ 4,040,722
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities		
Accounts payable and accrued liabilities	$ 2,420,761	$ 2,181,154
Shares to be issued	—	150,000
Derivative liability	4,473,800	1,725,760
Total current liabilities	6,894,561	4,056,914
TOTAL LIABILITIES	6,894,561	4,056,914
Commitments and contingencies (Note 8)		
STOCKHOLDERS' DEFICIT		
Common stock (Unlimited Class A common shares authorized); (84,630,676 shares issued and outstanding as of December 31, 2016 and 72,193,209 shares issued and outstanding as of March 31, 2016)	30,897,064	24,347,930
Additional paid-in capital	5,731,508	2,940,539
Accumulated other comprehensive loss	(1,727,633)	(999,398)
Accumulated deficit	(38,345,234)	(26,305,263)
TOTAL STOCKHOLDERS' DEFICIT	(3,444,295)	(16,192)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$ 3,450,266	$ 4,040,722

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

Helius Medical Technologies, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(Expressed in United States Dollars)

	Nine Months Ended December 31, 2016	Year Ended March 31, 2016	Nine Months Ended December 31, 2015 (Unaudited)
Operating expenses:			
Research and development	$ 4,722,584	$ 3,645,796	$ 2,664,063
General and administrative	5,651,218	5,671,598	3,738,041
Total operating expenses	10,373,802	9,317,394	6,402,104
Operating loss	(10,373,802)	(9,317,394)	(6,402,104)
Other income (expense):			
Interest and other income	110,611	103,330	123,741
Change in fair value of derivative liability	(2,479,905)	2,082,703	2,113,391
Foreign exchange gain (loss)	703,125	(18,785)	845,146
Gain on extinguishment of debt	—	268,334	268,334
Total other income (expense)	(1,666,169)	2,435,582	3,350,612
Net loss	(12,039,971)	(6,881,812)	(3,051,492)
Other comprehensive income (loss)			
Foreign currency translation adjustments	(728,235)	(27,758)	(890,689)
Comprehensive loss	$ (12,768,206)	$ (6,909,570)	$ (3,942,181)
Net loss per share			
Basic	$ (0.14)	$ (0.10)	$ (0.05)
Diluted	$ (0.14)	$ (0.12)	$ (0.06)
Weighted average shares outstanding			
Basic	83,355,095	66,522,564	64,646,096
Diluted	83,355,095	67,026,544	65,180,918

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

Helius Medical Technologies, Inc.
Consolidated Statements of Stockholders' Deficit - Unaudited
(Expressed in United States Dollars)

	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Shares to be Issued	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
Balance as of April 1, 2015	**63,104,788**	**$16,358,093**	**$2,434,552**	**$ 39,545**	**$(19,423,451)**	**$ (971,640)**	**$(1,562,901)**
Exercise of finders' warrants	14,400	11,926	—	—	—	—	11,926
Issuance of common stock for private placement	849,273	1,465,524	—	—	—	—	1,465,524
Issuance of common stock for private placement	335,463	585,702	—	(39,545)	—	—	546,157
Issuance of common stock for private placement	125,756	233,806	—	—	—	—	233,806
Stock option exercise	94,640	42,500	—	—	—	—	42,500
Fair value of options exercised	—	20,454	(20,454)	—	—	—	—
Issuance of common stock as bonus shares	30,000	23,959	—	—	—	—	23,959
Issuance of common stock for convertible note	2,083,333	1,525,000	—	—	—	—	1,525,000
Share issuance costs	—	(141,100)	—	—	—	—	(141,100)
Stock-based compensation	—	—	431,986	—	—	—	431,986
Fair value of non-employee vested options reallocated to derivative liability	—	—	(690,885)	—	—	—	(690,885)
Net loss	—	—	—	—	(3,051,492)		(3,051,492)
Foreign currency translation adjustments	—	—	—	—		(890,689)	(890,689)
Balance as of December 31, 2015	**66,637,653**	**$20,125,864**	**$2,155,199**	**$ —**	**$(22,474,943)**	**$ (1,862,329)**	**$(2,056,209)**

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

Helius Medical Technologies, Inc.
Consolidated Statements of Stockholders' Deficit
(Expressed in United States Dollars)

	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Shares to be Issued	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
Balance as of April 1, 2015	**63,104,788**	**$ 16,358,093**	**$ 2,434,552**	**$ 39,545**	**$ (19,423,451)**	**$ (971,640)**	**$ (1,562,901)**
Exercise of finder's warrants	14,400	11,926	—	—	—	—	11,926
Issuance of common stock for private placement	849,273	1,825,937	—	—	—	—	1,825,937
Fair value of warrants issued in connection with private placement, classified to derivative liability	—	(360,413)	—	—	—	—	(360,413)
Issuance of common stock for private placement	335,463	721,243	—	(39,545)	—	—	681,698
Fair value of warrants issued in connection with private placement, classified to derivative liability	—	(135,540)	—	—	—	—	(135,540)
Issuance of common stock for private placement	125,756	270,375	—	—	—	—	270,375
Fair value of warrants issued in connection with private placement, classified to derivative liability	—	(36,569)	—	—	—	—	(36,569)
Stock option exercise	94,640	42,500	—	—	—	—	42,500
Fair value of options exercised	—	34,378	(34,378)	—	—	—	—
Shares issued as a debt discount	30,000	29,045	—	—	—	—	29,045
Issuance of common stock upon conversion of convertible note	2,083,333	1,731,667	—	—	—	—	1,731,667
Fair value of warrants issued in connection with initial borrowing under credit facility, classified to derivative liability	—	(206,667)	—	—	—	—	(206,667)
Issuance of common stock for draw down of remaining credit facility	5,555,556	5,000,000	—	—	—	—	5,000,000
Fair value of warrants issued in connection with draw down of remaining credit facility, classified to derivative liability	—	(796,945)	—	—	—	—	(796,945)
Share issuance cost	—	(141,100)	—	—	—	—	(141,100)
Stock-based compensation expense	—	—	1,231,250	—	—	—	1,231,250
Fair value of non-employee vested options reallocated to derivative liability	—	—	(690,885)	—	—	—	(690,885)
Net loss	—	—	—	—	(6,881,812)	—	(6,881,812)
Foreign currency translation adjustment	—	—	—	—	—	(27,758)	(27,758)
Balance as of March 31, 2016	**72,193,209**	**$ 24,347,930**	**$ 2,940,539**	**$ —**	**$ (26,305,263)**	**$ (999,398)**	**$ (16,192)**

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

Helius Medical Technologies, Inc.
Consolidated Statements of Stockholders' Deficit
(Expressed in United States Dollars)

	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
Balance as of April 1, 2016	**72,193,209**	**$ 24,347,930**	**$ 2,940,539**	**$ (26,305,263)**	**$ (999,398)**	**$ (16,192)**
Exercise of finder's warrants	1,825,600	1,548,863	(151,184)	—	—	1,397,679
Issuance of common stock in public offering and private placement	10,305,125	6,547,997	—	—	—	6,547,997
Issuance of warrants in public offering and private placement	—	—	1,504,914	—	—	1,504,914
Share issuance costs	—	(1,875,190)	366,271	—	—	(1,508,919)
Stock-based compensation expense	—	—	1,461,646	—	—	1,461,646
Fair value of non-employee vested options reallocated to derivative liability	—	—	(268,135)	—	—	(268,135)
Agent compensation option exercise	750	1,129	(548)	—	—	581
Proceeds from the exercise of stock options and warrants	305,992	326,335	(121,995)	—	—	204,340
Net loss	—	—	—	(12,039,971)	—	(12,039,971)
Foreign currency translation adjustment	—	—	—	—	(728,235)	(728,235)
Balance as of December 31, 2016	**84,630,676**	**$ 30,897,064**	**$ 5,731,508**	**$ (38,345,234)**	**$ (1,727,633)**	**$ (3,444,295)**

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

Helius Medical Technologies, Inc.
Consolidated Statements of Cash Flows
(Expressed in United States Dollars)

	Nine Months Ended December 31, 2016	Year Ended March 31, 2016	Nine Months Ended December 31, 2015 (Unaudited)
Cash flows from operating activities			
Net loss	$ (12,039,971)	$ (6,881,812)	$ (3,051,492)
Adjustments to reconcile net loss to net cash used in operating activities:			
Change in fair value of derivative liability	2,479,905	(2,082,703)	(2,113,391)
Interest accretion	—	29,045	23,959
Stock-based compensation expense	1,461,646	1,231,250	431,986
Gain on extinguishment of debt	—	(268,334)	(268,334)
Unrealized foreign exchange loss (gain)	(641,485)	(120,876)	(901,518)
Changes in operating assets and liabilities:			
Receivables	173,951	(390,273)	(119,567)
Prepaid expenses and other current assets	76,601	(91,644)	(384,629)
Accounts payable and accrued liabilities	604,228	487,935	128,457
Shares to be issued	—	150,000	—
Net cash used in operating activities	(7,885,125)	(7,937,412)	(6,254,529)
Cash flows from investing activities			
Proceeds from the sale of short term investment	—	378,000	378,000
Net cash provided by investing activities	—	378,000	378,000
Cash flows from financing activities			
Proceeds from the issuance of common stock and warrants	7,902,912	7,777,910	7,832,436
Share issuance costs	(1,508,919)	(141,000)	(141,100)
Proceeds from the exercise of stock options and warrants	1,602,600	54,426	—
Proceeds from issuance of convertible debt	—	2,000,000	2,000,000
Proceeds from issuance of promissory note	—	200,000	—
Repayment of promissory note	—	(200,000)	—
Net cash provided by financing activities	7,996,593	9,691,336	9,691,336
Effect of foreign exchange rate changes on cash	(86,750)	93,120	116,650
Net increase in cash and cash equivalents	24,718	2,225,044	3,931,457
Cash and cash equivalents at beginning of period	2,643,937	418,893	418,893
Cash and cash equivalents at end of period	$ 2,668,655	$ 2,643,937	$ 4,350,350
Supplemental disclosure of non-cash cash activities			
Cash paid for interest	$ —	$ 1,651	$ 1,644
Cash paid for income taxes	—	—	—

(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. To date, the Company has not generated any revenue.

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 based in Newtown, Pennsylvania.

The Company is currently listed on the Toronto Stock Exchange (the "TSX"). The Company began trading on the Canadian Securities Exchange on June 23, 2014, under the ticker symbol "HSM", and subsequently moved to the TSX on April 18, 2016. The Company also began trading on the OTCQB under the ticker symbol "HSDT" on February 10, 2015.

On June 13, 2014, the Company completed its acquisition of 100% of the issued and outstanding shares of Neurohabilitation Corporation ("Neuro"), a private company incorporated in Delaware, USA, on January 22, 2013. Prior to the transaction, the Company was a non-operating public shell company. Accordingly, for financial reporting purposes, this transaction was deemed to be a capital transaction in substance and recorded as a reverse recapitalization of Neuro whereby Neuro is deemed to be the continuing, surviving entity for accounting purposes, but through reorganization, has deemed to have adopted the capital structure of the Company. Because the acquisition was considered a reverse recapitalization for accounting purposes, the combined historical financial statements of Neuro became the historical financial statements and from the completion of the acquisition on June 13, 2014, the financial statements have been prepared on a consolidated basis. The assets and liabilities of Neuro have been brought forward at their book value and no goodwill has been recognized in connection with the transaction.

On December 17, 2014, Neuro incorporated a wholly-owned subsidiary, Helius Medical Technologies (Canada), Inc. ("Helius Canada"). The financial information is presented in United States Dollars.

Going Concern

As of December 31, 2016, the Company had cash and cash equivalents of $2,668,655. During the nine months ended December 31, 2016, the Company incurred a net loss of $12,039,971 and, as of December 31, 2016 its accumulated deficit was $38,345,234. 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 profitable operations will ever be achieved, and, if achieved, will be sustained on a continuing 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 current cash and cash equivalents 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 allowances. 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.

Cash and Cash Equivalents

Cash and cash equivalents comprise cash at banks and on hand, and short-term highly liquid investments that have an original maturity of three months or less.

Concentrations of Credit Risk

The Company is subject to credit risk in respect of 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

Receivable are stated at their net realizable value. As of December 31, 2016 and March 31, 2016 receivables consisted primarily of Goods and Services Tax ("GST") and Quebec Sales Tax ("QST) refunds related to the Company's Canadian expenditures.

Stock-Based Compensation

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

The Company accounts for the granting of stock options to employees using the fair value method whereby all awards to employees will be measured at fair value on the date of the grant. The fair value of all stock options are expensed over their vesting 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.

Stock-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 stock-based payments to non-employees is periodically re-measured 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 at 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 Neuro is the U.S. dollar ("USD"). The Company's reporting currency is the U.S. dollar. Transactions in foreign currencies are remeasured 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. Resulting 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 Neuro relating to intercompany advances from Helius that are denominated in Canadian dollars is recorded in the consolidated statements of operations and comprehensive loss.

Income Taxes

The Company accounts for income taxes using the asset and liability method. The asset and liability method provides 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 materials and supplies. 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 views their operations and manages their business in one segment.

Derivative Liabilities

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 and the change in fair value is recorded in the consolidated statements of operations and comprehensive loss. Upon conversion or exercise of a derivative 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 instruments, including whether such instruments should be recorded as liabilities or as equity, is re-assessed at the end of each reporting period. Derivative instruments that become subject to reclassification are reclassified at the fair value of the instrument on the reclassification date. Derivative instrument liabilities will be classified in the balance sheet as current if the right to exercise or settle the derivative instrument lies with the holder.

Fair Value Measurements

The Company's financial instruments consist primarily of cash and cash equivalents, receivables, accounts payable and accrued liabilities. The book values of these instruments approximate their fair values due to the immediate or short-term nature of those instruments.

ASC 820 establishes a fair value hierarchy based on the level of independent, objective evidence surrounding the inputs used to measure fair value. A financial instrument's categorization within the fair value hierarchy is based upon the lowest level of input that is significant to the fair value measurement. ASC 820 prioritizes the inputs into three levels that may be used to measure fair value:

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

Level 2 – Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; and

Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the

determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The Company had certain Level 3 derivative liabilities required to be recorded at fair value on a recurring basis. Unobservable inputs used in the valuation of these liabilities includes volatility of the underlying share price and the expected term. See Note 5 for the inputs used in the Black-Scholes option pricing model as of December 31, 2016 and March 31, 2016 and the roll forward of the warrant liability and see Note 6 for the inputs used in the Black-Scholes option pricing model as of December 31, 2016 and March 31, 2016 for the roll forward of the derivative liability for non-employee stock options.

	Fair Value	Level 1	Level 2	Level 3
December 31, 2016				
Liabilities:				
Non-employee stock options	$ 1,616,739	—	—	$ 1,616,739
Warrants	2,857,061	—	—	2,857,061
March 31, 2016				
Liabilities:				
Non-employee stock options	$ 521,179	—	—	$ 521,179
Warrants	1,204,581	—	—	1,204,581

There were no transfers between any of the levels during the nine months ended December 31, 2016 or the year ended March 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:

	Nine Months Ended December 31, 2016	Year Ended March 31, 2016
Basic		
Numerator		
Net loss	$ (12,039,971)	$ (6,881,812)
Denominator		
Weighted-average common shares outstanding	83,355,095	66,522,564
Basic net loss per share	$ (0.14)	$ (0.10)
Diluted		
Numerator		
Net loss, basic	$ (12,039,971)	$ (6,881,812)
Effect of dilutive securities: change in fair value of derivative liability	—	(1,156,002)
Net loss, diluted	$ (12,039,971)	$ (8,037,814)
Denominator		
Weighted average common shares outstanding	83,355,095	66,522,564
Effect of dilutive securities: stock options and warrants	—	503,980
Weighted average common shares outstanding	83,355,095	67,026,544
Diluted net loss per share	$ (0.14)	$ (0.12)

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:

	Nine Months Ended December 31, 2016	Year Ended March 31, 2016
Options outstanding	9,845,000	5,875,360
Warrants outstanding	10,086,262	12,973,009
Total	19,931,262	18,848,369

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 Company is currently evaluating the potential impact of the adoption of this standard.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*. The new standard establishes a right-of-use ("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 income statement. 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 financial statements, with certain practical expedients available. The Company is currently evaluating the potential impact of the adoption of this standard.

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements - Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* , which is intended to define management's responsibility to evaluate whether there is substantial doubt about an organization's ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable) and to provide related footnote disclosures. The ASU provides guidance to an organization's management, with principles and

definitions that are intended to reduce diversity in the timing and content of disclosures that are commonly provided by organizations today in the financial statement footnotes. The ASU is effective for annual periods ending after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. The updated accounting guidance was effective for the Company on December 31, 2016 and the Company has implemented this new accounting standard and updated its liquidity disclosures as necessary.

3. PROMISSORY NOTE

On August 25, 2015, the Company received $200,000 in exchange for the issuance of a promissory note. The promissory note was to be repaid six months from the date of issuance with interest accruing at the rate of 6% per annum. In addition, the lender was entitled to receive 30,000 common shares of the Company's common stock on the date of the promissory note and an additional 30,000 common shares every three months thereafter as long as the principal of the loan remained outstanding.

On October 28, 2015, the Company repaid the loan in its entirety and issued 30,000 common shares that were owed the lender in accordance with the terms of the promissory note.

4. CONVERTIBLE NOTE

On October 9, 2015, in connection with an Asset Purchase Agreement, under which the Company licensed the use of its intellectual property in the People's Republic of China, Taiwan, Singapore, Hong Kong, and the Macau Special Administrative Region, the Company entered into a US$7.0 million funding commitment with A&B Company Limited ("A&B") in the form of a convertible promissory note. The funding commitment consisted of (i) an initial $2.0 million under the Note ("$2.0 million note" and (ii) an additional $5.0 million funding commitment, upon which the Company could draw down at any time or from time to time during the six-month period beginning on the issuance date of the promissory note. The $2.0 million note would accrue interest at a rate equal to 6% per annum, payable in cash on the due date of April 9, 2016. The $2.0 million note was unsecured and was convertible at the option of the holder into units of the Company at $0.96 per unit. Each unit would consist of one share of common stock and one half share purchase warrant exercisable at $1.44 for a period of three years from the date of issuance.

Pursuant to the guidance of ASC 815 *Derivatives and Hedging*, the Company determined that the conversion feature embedded in the $2.0 Million Note was required to be bifurcated from the Note and accounted for as a derivative liability because it was considered not to be indexed to the Company's stock due to its exercise price being denominated in a currency other than the Company's functional currency. Therefore, pursuant to the guidance of ASC 815-15, the Company allocated the proceeds from the issuance of the $2.0 million note first to the fair value of the embedded conversion feature, with a corresponding discount allocated to the Note. This resulted in a debt discount of $425,208. This debt discount would be amortized using the effective interest method over the term of the $2.0 million note. During the year ended March 31, 2016, the Company did not record any accretion in respect of this discount, because the $2.0 million note was immediately converted, as noted below.

On October 9, 2015, the Company received the conversion notice and on November 10th, 2015, the Company issued 2,083,333 shares of common stock at a price of $0.96 per share and 1,041,667 warrants exercisable at $1.44 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. Pursuant to the guidance of ASC 815 *Derivatives and Hedging*, the Company determined that the warrants are required to be accounted for as liabilities because they are considered not 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. The fair value of these warrants was determined to be $206,667 using the Black-Scholes option pricing model. See Note 5. for the derivative liability roll forward.

As a result of the bifurcation of the embedded conversion option, for accounting purposes, two instruments were considered outstanding and, upon exercise of the contractual conversion option, extinguishment accounting has been applied. Consequently, the shares issued pursuant to the conversion are recorded at their fair value on the date of issuance, determined with reference to their quoted market price on the date of conversion. The resulting difference between the fair value of the shares issued, less the fair value of the related conversion feature and the carrying value of the related debt, is recorded as a gain or loss on the consolidated statement of operations. During the year ended March 31, 2016, the Company recorded a gain on extinguishment of debt of $268,334 in connection with the conversion of the Note.

The Company could elect to draw down on the additional $5.0 million funding through the issuance of units of the Company at a price based on the volume weighted average closing price of the Company's shares of common stock on the date the Company elects to draw down from the commitment (the "Draw Down Price"). Each unit would consist of one shares of common stock of the Company and one half share purchase warrant. The warrant would be exercisable at the price representing a fifty percent (50%) premium to the Draw Down Price.

On December 29, 2015, the Company drew down the remaining $5.0 million commitment through the issuance of 5,555,556 shares of common stock at a price of $0.90 per share and 2,777,778 warrants exercisable at $1.35 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.

Pursuant to the guidance of ASC 815 *Derivatives and Hedging*, the Company determined that the warrants are required to be accounted for as liabilities because they are considered not 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 allocated the proceeds from the $5.0 million funding initially to the warrants at their fair value, with the remainder allocated to the common shares. The fair value of these warrants was determined to be $796,945 using the Black Scholes option pricing model. See Note 5. for the derivative liability roll-forward relating to these warrants.

5. COMMON STOCK AND WARRANTS

As of December 31, 2016, 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, 2016. In the event of the 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.

Upon completion of the Recapitalization on June 13, 2014, the Company issued a total of 35,300,083 shares to the shareholders of Neuro. In connection with the Recapitalization, the Company also closed a non-brokered private placement (the "Private Placement") at CAD $0.50 per unit of 15,240,000 units raising $7,016,002 on May 30, 2014. Each unit consists of one common stock of the Company and one half of a warrant of the Company where one full warrant is exercisable for 2 years at CAD $1.00 into one common stock. The fair value of the warrants issued was determined using the Black Scholes option-pricing model and the Company used the relative fair value method to allocate $578,961 of the gross proceeds to Additional Paid-in Capital to account for the warrants issued.

On April 30, 2015, the Company closed a non-brokered private placement (the "First Financing") raising gross proceeds of $1,825,937 by the issuance of 849,273 units (each a "First Financing Unit") at a price of $2.15 per First Financing Unit. Each First Financing Unit consists of one (1) common share and one half of one (1/2) common share purchase warrant (each a "First Financing Warrant"). Each whole First Financing Warrant entitles the holder thereof to purchase one additional common share of the Company at a price of $3.00 per share for a period of thirty-six (36) months from the closing date of the Financing. The Company paid a cash finder's fee of $84,074 in connection with this First Financing, as well as 27,396 finder's warrants (the "First Financing Finder's Warrants"). Each First Financing Finder's Warrant entitles the holder thereof to purchase one additional common share of the Company at a price of $3.00 per share for a period of thirty-six (36) months from the closing date of the First Financing.

On June 26, 2015, the Company closed a non-brokered private placement (the "Second Financing") raising gross proceeds of $721,243 by the issuance of 335,463 units (each a "Second Financing Unit") at a price of $2.15 per Second Financing Unit. Each Second Financing Unit consists of one (1) common share and one half of one (1/2) common share purchase warrant (each a "Second Financing Warrant"). Each whole Second Financing Warrant entitles the holder thereof to purchase one additional common share of the Company at a price of $3.00 per share for a period of thirty-six (36) months from the closing date of the Second Financing. The Company paid a cash finder's fee of $40,803 in connection with this Second Financing, as well as 18,978 finder's warrants (the "Second Financing Finder's Warrants"). Each Second Financing Finder's Warrant entitles the holder thereof to purchase one additional common share of the Company at a price of $2.15 per share for a period of sixty (60) months from the closing date of the Second Financing.

On July 17, 2015, the Company closed a non-brokered private placement (the "Third Financing") raising gross proceeds of $270,375 by the issuance of 125,756 units (each a "Third Financing Unit") at a price of $2.15 per Third Financing Unit. Each Third Financing Unit consists of one (1) common share and one half of one (1/2) common share purchase warrant (each a "Third Financing Warrant"). Each whole Third Financing Warrant entitles the holder thereof to purchase one additional common share of the Company at a price of $3.00 per share for a period of thirty-six (36) months from the closing date of the Third Financing. The Company paid a cash finder's fee of $16,223 in connection with this Third Financing, as well as 7,545 finder's warrants (the "Third Financing Finder's Warrants"). Each Third Financing Finder's Warrant entitles the holder thereof to purchase one additional common share of the Company at a price of $2.15 per share for a period of sixty (60) months from the closing date of the Third Financing.

On November 10, 2015, upon conversion of the $2.0 million Note, the Company issued 2,083,333 shares of common stock at a price of $0.96 per share and 1,041,667 warrants exercisable at $1.44 for a period of three years from the date of issuance.

On December 29, 2015, the Company drew down the remaining $5.0 million commitment through the issuance of 5,555,556 shares of common stock at a price of $0.90 per share and 2,777,778 warrants exercisable at $1.35 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.

On April 18, 2016, the Company closed its short form prospectus offering in Canada and a concurrent U.S. private placement (the "Offering") of units (the "Units") with gross proceeds to the Company of USD $7,184,190 through the issuance of Units at a price of CAD$1.00 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$1.50 on or before April 18, 2019. Mackie Research Capital Corporation (the "Agent") acted as agent and sole bookrunner in connection with the Offering. The Company paid the Agent a cash commission of USD $340,250 and has granted to the Agent compensation options exercisable to purchase 436,050 Units at an exercise price of CAD$1.00 per Unit for a period of 24 months from the closing of the Offering. The Company incurred other cash issuance costs of USD $1,116,545 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 ("Over-Allotment Option") granted to the Agent in connection with the Offering. The 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 1,090,125 Units (the "Over-Allotment Units") at a price of CAD $1.00 per Over-Allotment Unit for additional gross proceeds to the Company of USD $868,721, bringing the total aggregate gross proceeds to the Company under the Offering to USD $8,052,911. Each Over-Allotment Unit consists of one Class A common share in the capital of the Company (an "Over-Allotment Common Share") and one half of one Common Share purchase warrant (each whole warrant, an "Over-Allotment Warrant"). Each Over-Allotment Warrant entitles the holder thereof to acquire one additional Over-Allotment Common Share at an exercise price of CAD $1.50 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 USD $52,124 and granted to the Agent compensation options exercisable to purchase 65,407 Over-Allotment Units at an exercise price of CAD $1.00 per Over-Allotment 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 equity at their fair value.

The fair value of the warrants granted during the nine months ended December 31, 2016 was estimated using the Black-Scholes option pricing model with the following weighted average assumptions:

	December 31, 2016
Stock price	$1.09 CAD
Exercise price	$1.50 CAD
Expected life	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 nine months ended December 31, 2016 was estimated using the Black-Scholes option pricing model with the following weighted average assumptions:

	December 31, 2016
Stock price	$1.36 CAD
Exercise price	$1.00 CAD
Expected life	2.0 years
Expected volatility	126.76%
Risk-free interest rate	0.61%
Dividend rate	0.00%

The weighted average fair value of the warrants issued during the nine months ended December 31, 2016 was CAD$0.50 per share.

The weighted average fair value of the compensation options issued during the nine months ended December 31, 2016 was CAD$0.93 per share.

On June 6, 2016, the Company received proceeds of USD $1,397,679 from the exercise of 1,825,600 outstanding warrants which were issued in connection with the Company's private placement of subscription receipts that closed on May 30, 2014. The remaining 6,604,400 warrants issued in this offering expired unexercised.

Pursuant to the guidance of ASC 815 *Derivatives and Hedging*, the Company determined that all of the warrants issued during the year ended March 31, 2016 as described above are required to be accounted for as liabilities because they are considered not 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 warrants having an exercise price denominated in a currency other than the functional currency of the Company that are required to be accounted for as liabilities are summarized as follows for nine months ended December 31, 2016 and the year ended March 31, 2016:

	Nine Months Ended December 31, 2016	Year Ended March 31, 2016
Fair value of warrants at beginning of period	$ 1,204,581	$ —
Issuance of warrants	—	1,536,134
Change in fair value of warrants during the period	1,652,480	(331,553)
Fair value of warrants at end of period	$ 2,857,061	$ 1,204,581

The warrants are required to be re-valued with the change in fair value of the liability recorded as a gain or loss in the change of fair value of derivative liability, 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, 2016 and March 31, 2016 were estimated using the Black-Scholes option pricing model with the following weighted average assumptions:

	December 31, 2016	March 31, 2016
Stock price	$ 1.38	$ 0.78
Exercise price	$ 1.62	$ 1.62
Expected life	1.89 years	2.65 years
Expected volatility	94.97%	83.86%
Risk-free interest rate	0.79%	0.83%
Dividend rate	0.00%	0.00%

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

	Number of Warrants		Weighted-Average Exercise Price	
	CAD	US	CAD	US
Outstanding as of April 1, 2016	8,430,000	4,528,609	$ 1.00	$ 1.62
Granted	5,152,938	—	1.50	
Granted (Agent Compensation)	501,457	—	1.00	
Expired	(6,604,400)	—	1.00	
Exercised	(1,922,342)	—	1.02	
Outstanding as of December 31, 2016	5,557,653	4,528,609	$ 1.46	$ 1.62

The warrants outstanding and exercisable as of December 31, 2016 were as follows:

Number of Warrants Outstanding	Exercise Price	Expiration Date
452,032	US$3.00	April 30, 2018
167,731	US$3.00	June 26, 2018
18,978	US$2.15	June 26, 2020
62,878	US$3.00	July 17, 2018
7,545	US$2.15	July 17, 2020
1,041,667	US$1.44	November 10, 2018
2,777,778	US$1.35	December 29, 2018
5,056,946	CAD$1.50	April 18, 2019
500,707	CAD$1.00	April 18, 2018

6. 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 12,108,016 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 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 15,000,000 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, 2016, there were an aggregate of 16,958,376 shares of common stock remaining available for grant under the 2014 and the 2016 Plan.

The following is a summary of stock option activity during nine months ended December 31, 2016:

	Number of Options	Weighted Average Exercise Price (CAD)	Aggregate Intrinsic Value (CAD)
Outstanding as of April 1, 2016	6,675,360	$ 1.08	$ 1,580,883
Granted	3,535,000	1.38	
Forfeited	(31,250)	0.60	
Cancelled	(124,110)	0.60	
Exercised	(210,000)	0.60	
Outstanding as of December 31, 2016	9,845,000	1.20	8,218,150
Exercisable as of December 31, 2016	6,763,502	$ 1.16	$ 6,243,040

The aggregate intrinsic value of stock options exercised during the nine months ended December 31, 2016 and the year ended March 31, 2016 was $117,530 and $19,832, respectively.

The stock options outstanding and exercisable as of December 31, 2016 were as follows:

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
3,310,000	June 18, 2019	2.46	$ 0.60	$ 0.26	3,310,000
100,000	July 14, 2017	0.53	$ 2.52	$ 1.05	100,000
450,000	December 8, 2019	2.94	$ 2.92	$ 1.65	450,000
100,000	December 8, 2019	2.94	$ 2.92	$ 1.31	100,000
400,000	December 8, 2019	2.94	$ 2.96	$ 1.29	400,000
100,000	March 16, 2020	3.21	$ 3.20	$ 1.42	66,667
50,000	August 15, 2015	3.62	$ 0.98	$ 0.39	33,334
750,000	October 21, 2020	3.81	$ 0.87	$ 0.36	375,000
550,000	October 28, 2020	3.83	$ 0.84	$ 0.44	550,000
400,000	October 28, 2020	3.83	$ 0.84	$ 0.36	176,000
100,000	December 31, 2020	4.00	$ 1.24	$ 0.50	66,668
3,025,000	July 13, 2020	3.53	$ 1.39	$ 0.65	1,008,333
100,000	August 8, 2020	3.61	$ 1.31	$ 0.65	25,000
410,000	October 3, 2020	3.76	$ 1.35	$ 0.80	102,500
9,845,000					6,763,502

Included in the table above are non-employee awards that are subject to re-measurement each reporting period until vested. As a result, the grant date fair value is not representative of the total expense that will be recorded for these awards. As of December 31, 2016, the unrecognized compensation cost related to non-vested stock options outstanding, was $1,263,767 to be recognized over a weighted-average remaining vesting period of approximately 1.41 years. The Company recognizes compensation expense for only the portion of awards that are expected to vest. During the nine months ended December 31, 2016 and the year ended March 31, 2016, the Company applied an expected forfeiture rate of 0% based on its historical experience.

The fair value of the employee and director stock options granted during the nine months ended December 31, 2016 and the year ended March 31, 2016 were estimated using the Black-Scholes option pricing model with the following weighted-average assumptions:

	Nine Months Ended December 31, 2016	Year Ended March 31, 2016
Stock price	$1.39 CAD	$0.82 CAD
Exercise price	$1.39 CAD	$0.87 CAD
Expected life	2.5 years	3.75 years
Expected volatility	77.92%	67.85%
Risk-free interest rate	0.49%	0.63%
Dividend rate	0.00%	0.00%

The Company has adopted the simplified method prescribed by the SEC in SAB Topic 14 in respect of 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 Company recognizes stock-based compensation expense for only the portion of awards that are expected to vest. During the nine months ended December 31, 2016 and the year ended March 31, 2016, the Company applied an expected forfeiture rate of 0% based on its historical experience.

Non-Employee Stock Options

In accordance with the guidance of ASC 815-40-15, stock options awarded to non-employees that are performing services for Neuro are required to be accounted for as derivative liabilities once the services have been performed and the stock 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 Neuro's functional currency. Stock options awarded to non-employees that are 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:

	Nine Months Ended December 31, 2016	Year Ended March 31, 2016
Fair value of non-employee stock options at beginning of period	$ 521,179	$ 1,581,444
Reallocation of vested non-employee stock options	268,135	690,885
Change in fair value of non-employee stock options during the period	827,425	(1,751,150)
Fair value of non-employee stock options at end of period	$ 1,616,739	$ 521,179

The non-employee stock options that have vested are required to be re-valued with the change in fair value of the liability recorded as a gain or loss on the change of fair value of derivative liability and included in other items 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 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 non-employee liability classified awards as of December 31, 2016 and March 31, 2016 were estimated using the Black-Scholes option pricing model with the following weighted-average assumptions:

	December 31, 2016	March 31, 2016
Stock price	$1.92 CAD	$0.97 CAD
Exercise price	$1.23 CAD	$1.52 CAD
Expected life	2.59 years	3.23 years
Expected volatility	87.61%	84.62%
Risk-free interest rate	0.79%	0.53%
Dividend rate	0.00%	0.00%

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

	Nine Months Ended December 31, 2016	Year Ended March 31, 2016
Research and development	$ 106,932	$ 158,396
General and administrative	1,354,714	1,072,854
	$ 1,461,646	$ 1,231,250

7. INCOME TAXES

The components of net loss are as follows:

	Nine Months Ended December 31, 2016	Year Ended March 31, 2016
U.S	$ 11,081,757	$ 5,132,611
Non-U.S.	958,214	1,749,201
	$ 12,039,971	$ 6,881,812

A reconciliation of the income tax provision computed at statutory rates to the reported income tax provision is as follows:

	Nine Months Ended December 31, 2016	Year Ended March 31, 2016
Statutory tax rate	34.00%	34.00%
Net loss before income taxes	$ 12,039,971	$ (6,882,812)
Expected income tax recovery	$ (4,093,591)	$ (2,340,000)
Increase (decrease) in income tax recovery resulting from:		
Derivative liability	843,168	(708,000)
Share based payments	467,183	419,000
Other permanent difference	(419,782)	49,000
Effect of change in statutory rate	—	(147,000)
Effect of over provision in prior year	—	(2,164,000)
Foreign income taxed at foreign rate	76,654	100,000
Increase in valuation allowance	3,126,368	4,791,000
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:

	December 31, 2016	March 31, 2016
Deferred income tax assets (liabilities)		
Operating losses carried forward	$ 7,626,208	$ 4,915,000
Tax credits	702,153	—
Stock compensation	1,726,293	1,725,000
Other	169,968	609,000
Valuation allowance	(10,224,622)	(7,249,000)
Net deferred income tax asset	$ —	$ —

As of December 31, 2016, the Company has accumulated non-capital losses totaling $2,707,393 in Canada and net operating losses of $21,335,527 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.

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.

At December 31, 2016, 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.

8. 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 16,035,026 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 March 7, 2014, the Company entered into a commercial development-to-supply program with Ximedica, LLC ("Ximedica") where Ximedica will design, develop and produce the PoNS™ product solution suitable for clinical trial and commercial sale. The multi-phased development program contains total contracted amounts of $5,900,000, of which $6,959,784 was expensed as research and development expense since inception through December 31, 2016. Invoices are to be issued monthly for work in progress. The Company can cancel the project at any time with a written notice at least 30 days prior to the intended date of cancellation. During the nine months ended December 31, 2016 and the year ended March 31, 2016, the Company incurred R&D charges of $1,647,968 and $120,448 pursuant to this agreement. As the development agreement progresses, the Company expects to contract for additional phases.

(c) Under the Company's Asset Purchase Agreement with A&B, if the Company fails to obtain FDA marketing 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, 2017, the Company is subject to a $2,000,000 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. The Company has determined that the possibility of an economic outlay under this contractual penalty is remote.

(d) 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.

9. RELATED PARTY TRANSACTIONS

During the nine months ended December 31, 2016 and the year ended March 31, 2016, the Company paid $97,829 and $64,210 in consulting fees to certain directors of the Company, respectively. As of December 31, 2016 and March 31, 2016, the Company owed $2,550 and $3,450 to a director for consulting services, respectively.

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 $15,000 per month. During the nine months ended December 31, 2016, the Company paid Montel Media $135,000 pursuant to the consulting agreement. Montel Media is owned by Montel Williams, who serves on the board of MPJ Healthcare, LLC, which beneficially owns greater than 5% of the Company's common stock.

During the nine months ended December 31, 2016 and the year ended March 31, 2016, an expense of $648,208 and a benefit of $195,709, respectively. was included in the change in fair value of derivative liabilities as the fair value of stock-based compensation attributed to the options granted to two directors and a consultant for consulting services rendered with respect to the design and development of the PoNS™ device.

10. SOLE-SOURCE COST-SHARING AGREEMENT

During the year ended March 31, 2016, the Company entered into a sole source cost sharing contract executed with the U.S. Army Medical Research and Material Command ("USAMRMC"). Under the terms of the contract, the USAMRMC will reimburse the Company up to a maximum of $2,996,244 for the registrational trial ("the trial") investigating the safety and effectiveness of the PoNS™ device for mild- to moderate-traumatic brain injury. The original contract expired on December 31, 2016; however, the Company has extended the contract with the USAMRMC through December 31, 2017 with reimbursement of expenses based on a milestone schedule of subjects completing the trial based on the current trial forecast timelines. As of December 31, 2016, the Company has received a total of $1,818,249 in respect of expenses reimbursed. 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.

11. SUPPLEMENTAL CASH FLOW INFORMATION

Investing and financing activities that do not have a direct impact on current cash flows are excluded from the consolidated statements of cash flows.

During the nine months ended December 31, 2016:

i) Fair value of warrants issued to agent for services provided in conjunction with the Offering was $366,271.

ii) Proceeds from the issuance of common stock excludes $150,000 that was received prior to April 1, 2016.

During the year ended March 31, 2016:

i) Fair value of warrants issued in conjunction with private placements in April, June and July 2015 was $532,522.

ii) Fair value of warrants issued in conjunction with A&B credit facility (including upon conversion of $2.0 million convertible note and draw down of $5.0 million) was $1,003,612.

iii) The Company issued 30,000 shares of common stock having a fair value of $29,045 based on the quoted market price as a bonus in connection with the issuance of a promissory note;

iv) A gain on extinguishment of debt of $268,334 based on the difference between the fair value of the shares issued to settle the A&B credit facility and the fair value of the related conversion feature and the carrying value of the related debt.

During the nine months ended December 31, 2015:

i) The Company issued 30,000 shares of common stock having a fair value of $23,959 based on their quoted market price as a bonus in connection with the advance of a loan.

ii) The Company issued $2,083,333 common shares having a fair value of $1,525,000 based on their quoted market price upon the conversion of a convertible note payable in the amount of $2,000,000. Also, in connection with this debt conversion, the Company also issued 1,041,667 share purchase warrants having a fair value of $206,667 at their inception.

iii) The Company reallocated $690,885 from additional paid-in capital to derivative liability in respect of the fair value of non-employee share purchase options that had vested.

12. SUBSEQUENT EVENTS

In February 2017, the Company issued 6,555,000 shares of common stock and raised a total of CAD$12,454,500, net of issuance costs through an underwritten registered public offering. The Company intends to use the net proceeds from the offering to fund investment in PoNS™ research and development, including the completion of its ongoing registrational trial in mild- to moderate-traumatic brain injury, the launch of a registrational clinical trial in multiple sclerosis and an additional clinical trial in cognition, research and development activities to complete the Company's FDA submission and for working capital and general corporate purposes.

On February 14, 2017, Mackie Research Capital Corporation ("Mackie"), a Canadian investment banking firm, filed a statement of claim in the Ontario Superior Court of Justice naming the Company as defendant. The claim alleges that the Company breached a term of the agency agreement dated March 23, 2016 between the Company and Mackie in connection with its public offering of Class A Common Stock, which closed on February 16, 2017 by not complying with Mackie's right of first refusal to serve as the lead underwriter in the offering. The Company believes that it fully complied with its obligations under the agency agreement by offering Mackie the opportunity to serve as lead underwriter in the offering. The claim seeks damages totaling $1,400,000 and equitable relief. As the matter is at a preliminary stage, the Company has not been able to make a full assessment on the merits of the claim. The Company intends to defend itself vigorously.

In March 2017, the Company entered into a lease for 10,444 square feet of dedicated office space at 642 Newtown-Yardley Road, Suite 100, Newtown, PA 18940. The lease commences on July 1, 2017 and terminates on December 31, 2022 with an option to extend until 2027. Monthly rent plus utilities is approximately $20,018 per month with a 3% annual increase.

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: April 3, 2017

By: /s/ Philippe Deschamps
Philippe Deschamps
President, Chief Executive Officer and a 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: April 3, 2017
Philippe Deschamps
President, Chief Executive Officer and a Director

By /s/ Joyce LaViscount — Date: April 3, 2017
Joyce LaViscount
Chief Financial Officer (Principal Accounting Officer), and Corporate Secretary

By /s/ Blane Walter — Date: April 3, 2017
Blane Walter
Director

By /s/ Mitchell E. Tyler — Date: April 3, 2017
Mitchell E. Tyler
Director

By /s/ Edward M. Straw — Date: April 3, 2017
Edward M. Straw
Director

By /s/ Huaizheng Peng — Date: April 3, 2017
Huaizheng Peng
Director

By /s/ Thomas Griffin — Date: April 3, 2017
Thomas Griffin
Director