

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-K**

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended March 31, 2015

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File No. 000-55364

**HELIUS MEDICAL TECHNOLOGIES, INC.**

(Exact name of registrant as specified in its charter)

**WYOMING**  
(State or other jurisdiction of  
incorporation or organization)

**36-4787690**  
(I.R.S. Employer  
Identification No.)

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

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

**Securities registered pursuant to Section 12(b) of the Act:**

Title of each class  
None

Name of each exchange on which registered

**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

Smaller reporting company

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

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The aggregate market value of the common equity held by non-affiliates of the registrant on September 30, 2014, based on the closing price on that date of CAD \$2.40 (USD \$2.14), was approximately \$59,502,069. As of June 26, 2015 there were 63,968,461 shares of the registrant's common stock outstanding.

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# TABLE OF CONTENTS

	<u>Page</u>
<b><u>PART I</u></b>	
<a href="#"><u>ITEM 1. BUSINESS</u></a>	<a href="#"><u>3</u></a>
<a href="#"><u>ITEM 1A. RISK FACTORS</u></a>	<a href="#"><u>21</u></a>
<a href="#"><u>ITEM 1B. UNRESOLVED STAFF COMMENTS</u></a>	<a href="#"><u>36</u></a>
<a href="#"><u>ITEM 2. PROPERTIES</u></a>	<a href="#"><u>36</u></a>
<a href="#"><u>ITEM 3. LEGAL PROCEEDINGS</u></a>	<a href="#"><u>37</u></a>
<a href="#"><u>ITEM 4. MINE SAFETY DISCLOSURES</u></a>	<a href="#"><u>37</u></a>
<b><u>PART II</u></b>	
<a href="#"><u>ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES</u></a>	<a href="#"><u>38</u></a>
<a href="#"><u>ITEM 6. SELECTED FINANCIAL DATA</u></a>	<a href="#"><u>41</u></a>
<a href="#"><u>ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u></a>	<a href="#"><u>41</u></a>
<a href="#"><u>ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u></a>	<a href="#"><u>49</u></a>
<a href="#"><u>ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA (INCLUDED IN F-PAGES)</u></a>	<a href="#"><u>50</u></a>
<a href="#"><u>ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE</u></a>	<a href="#"><u>50</u></a>
<a href="#"><u>ITEM 9A. CONTROLS AND PROCEDURES</u></a>	<a href="#"><u>50</u></a>
<a href="#"><u>ITEM 9B. OTHER INFORMATION</u></a>	<a href="#"><u>51</u></a>
<b><u>PART III</u></b>	
<a href="#"><u>ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE</u></a>	<a href="#"><u>52</u></a>
<a href="#"><u>ITEM 11. EXECUTIVE COMPENSATION</u></a>	<a href="#"><u>55</u></a>
<a href="#"><u>ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS</u></a>	<a href="#"><u>58</u></a>
<a href="#"><u>ITEM 13. CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS, AND DIRECTOR INDEPENDENCE</u></a>	<a href="#"><u>59</u></a>
<a href="#"><u>ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES</u></a>	<a href="#"><u>60</u></a>
<b><u>PART IV</u></b>	
<a href="#"><u>ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES</u></a>	<a href="#"><u>62</u></a>
<b><u>SIGNATURES</u></b>	

In this annual report on Form 10-K, unless otherwise specified, references to “we”, “us” or “our” 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 annual report on Form 10-K contains forward-looking statements that involve risks and uncertainties, including statements regarding our market, strategy, competition, capital needs, business plans and expectations. Such forward-looking statements involve risks and uncertainties regarding the success of our business plan, availability of funds, government regulations, operating costs, our ability to achieve significant revenues and other factors. Forward-looking statements are made, without limitation, in relation to operating plans, availability of funds and operating costs. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “may”, “will”, “should”, “expect”, “plan”, “intend”, “anticipate”, “believe”, “estimate”, “predict”, “potential” or “continue”, the negative of such terms or other comparable terminology. Actual events or results may differ materially. In evaluating these statements, you should consider various factors, including the risks outlined in this annual report. These factors may cause our actual results to differ materially from any forward-looking statements. While these forward-looking statements, and any assumptions upon which they are based, are made in good faith, based on information available to us as of the date hereof, and reflect our current judgment regarding our business plans, our actual results will almost always vary, sometimes materially, from any estimates, predictions, projections, assumptions or other future performance suggested herein. We do not intend to update any of the forward-looking statements to conform these statements to actual results, except as required by applicable law, including the securities laws of the United States.

## INDUSTRY AND MARKET DATA

Within this annual report on Form 10-K, 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 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 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 these publications and reports.

ITEM 1. BUSINESS

**Our Business**

We are a medical technology company focused on neurological wellness. We seek to develop, license or acquire unique and non-invasive platform technologies that amplify the brain’s ability to heal itself.

The brain’s ability to reorganize its operation in response to new information sources, new functional needs, or new communication pathways is referred to as neuroplasticity. Neuroplasticity is a process underlying all cerebral learning, training, and rehabilitation. Neuromodulation is the use of various external stimulation to intentionally change and regulate the internal electrochemical environment of the brain.

Our mission is to develop, license and acquire non-invasive treatments designed to help patients affected by neurological symptoms caused by disease or trauma. Applying the principles of neuroplasticity, our portable neuromodulation stimulator, or PoNS™, device is designed to induce Cranial Nerve Non Invasive Neuromodulation that utilizes the brain’s innate ability to achieve neuroplastic change to aid persons with neurological, cognitive, sensory, and motor disorders when combined with the rehabilitation process.

Traditional rehabilitation interventions have typically involved medication and various forms of therapies, including physical therapy. Our patented PoNS™ device is being developed to enable the first non-invasive means for delivering neurostimulation through the oral cavity. With respect to many neurologic diseases and disorders such as Multiple Sclerosis (MS), Huntington’s, Muscular Dystrophy, Spina Bifida, Parkinson’s and Alzheimer’s diseases, Stroke, Epilepsy, and Traumatic Brain Injury (TBI), we believe that published studies in the field suggest that many such diseases may benefit from neurostimulation.

The PoNS™ device, which is placed into and held in the patient’s mouth, 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. A series of case studies and feasibility studies, which are further described below, suggest that prolonged activation (20 minutes or more) of neuronal circuits, when combined with physical therapy, may initiate long-lasting processes of neuronal reorganization with a variety of positive results, including the correction of gait/balance impairments resultant from TBI. However, these results represent what we refer to as anecdotal evidence only, which means that the results are not scientifically supported by a well-controlled, scientific study. Furthermore, such results may be suggestive but are not adequate to support FDA approval.

The inventors and background patent owners of the PoNS™ device conducted a series of Institutional Review Board sanctioned feasibility studies, case studies and one placebo-controlled study. In total, these studies involved approximately 200 patients using the PoNS™ 2.2 device in conjunction with physical or cognitive therapy at the University of Wisconsin-Madison. An Institutional Review Board is a scientific and patient advocacy board that reviews the validity and safety of clinical trials on behalf of patients. We use the term “feasibility study” to mean a study that allows for early clinical evaluation of devices to provide proof of principle and initial clinical safety data. A feasibility study may be appropriate early in device development when clinical experience is necessary because nonclinical testing methods are not available or adequate to provide the information needed to advance the developmental process. We use the term “case study” to mean a study of one patient that may support at most anecdotal evidence of efficacy. By “placebo-controlled study”, we mean a way of testing a medical therapy in which, in addition to a group of subjects that receives the treatment to be evaluated, a separate control group receives an artificial “placebo” treatment which is specifically designed to have no real effect. These studies were conducted primarily at the Tactile Communication and Neurorehabilitation Laboratory, or TCNL, at the University of Wisconsin-Madison with the approval and oversight by the university’s Institutional Review Board, which is required for scientific studies involving human subjects. The results for a number of individual test subjects from these studies suggest that usage of the PoNS™ 2.2 device resulted in positive relief in rehabilitating symptoms caused by neurological disorders or injury for such individual patients. While such case and feasibility studies qualify only as anecdotal evidence, and the placebo-controlled study qualifies only as directional evidence, we believe that relief achieved by these patients suggests that the PoNS™ device, when combined with physical or cognitive therapy, improves and sustains functional rehabilitation of the symptoms from brain dysfunction from traumatic, degenerative, developmental, chemical, or unknown origins. We use the term “directional evidence” to mean in respect of such placebo-controlled study that we conducted, that the results suggested positive relief in the ten patients tested. However, the feasibility, case, and placebo-controlled studies were not of sufficient size to produce scientifically conclusive results. Furthermore, such tests were not adequate to support clearance of the device by the U.S. Food and Drug Administration, or FDA, for commercial distribution. Furthermore, the PoNS™ 2.2 device is a laboratory test device that is not designed for commercial use.

As described below, we are developing the PoNS™ 4.0 device to secure FDA clearance for commercial use in treating balance disorder in mild to moderate TBI subjects. We will be conducting clinical trials of our PoNS™ 4.0 device for the treatment of balance disorder in patients in the US with mild to moderate TBI and for the treatment of balance disorder associated with MS in patients in Canada. Both registration clinical trials are designed to be submitted for clearance, the TBI study in support of clearance of the PoNS™ 4.0 device by the FDA and the MS study in support of clearance by Health Canada, which is the counterpart to the FDA in Canada. Should the PoNS™ 4.0 device be cleared by the FDA and Health Canada, we believe the addressable markets for our PoNS™ 4.0 device to treat balance disorder associated with TBI and MS are potentially up to \$5.3 billion for TBI in the U.S. and potentially up to \$250 million for MS in Canada. According to the U.S. Center for Disease Control and Prevention, approximately 5.3 million individuals in the U.S. were living with permanent TBI symptoms in 1999, and the incidence of new TBI diagnoses, as measured by hospitalizations and emergency department visits, has increased between 2001 and 2010. Additionally, the Brain Injury Association of America estimates that approximately 40% of patients diagnosed with TBI experience balance disturbance. Our addressable market estimate for TBI in the U.S. is based on the product of the number of persons living with TBI (5.3 million) multiplied by the rate of balance disturbance in TBI patients (40%), and multiplied by the expected price per unit of our product. Our addressable market estimate for MS in Canada is calculated by multiplying the estimated number of persons with MS in Canada (the Multiple Sclerosis Society of Canada estimates there are approximately 100,000 persons with MS in Canada) by the expected price per unit of our product. In addition to the currently held method-of-use patent, we anticipate, based on our pending patent filings, additional patent protection for the PoNS™ device tied to uniquely designed therapy for specific therapeutic indications and functional innovations with respect to design and technology development.

### **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 design of the PoNS™ device, successful completion of the TBI and MS clinical studies, FDA and Health Canada clearance of the PoNS™ device for balance disorder associated with TBI and MS, respectively, manufacturing of a commercially-viable version of the PoNS™ device and demonstration of safety and effectiveness sufficient to generate commercial orders by customers for our product. In addition, given the importance of the U.S. Army to our early commercial plans, if the U.S. Army were to eventually decide not to purchase our product, we would need to replace those sales in the civilian market which will lower our early commercialization forecast. To date, we have not achieved any of these conditions, and the successful achievement of such conditions will require significant expenditures. Because we have not generated any revenues, we are significantly dependent 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 and Health Canada clearance, we do not currently have any contract or other arrangement to sell the PoNS™ device. Accordingly, we cannot assure you that we will ever be able to generate any revenue from the sales of products or services.

Additionally, our auditors have issued a going concern opinion. This means that there is substantial doubt that we can continue as an on-going business for the next twelve months unless we obtain additional capital to pay our expenditures. While we are currently seeking additional funding, we do not currently have sufficient resources to accomplish any of the above conditions necessary for us to generate revenue.

In reviewing this annual report on Form 10-K, you should carefully consider these risks and other risks described throughout the annual report on Form 10-K.

## **Our Principal Product**

### *History of the PoNS™ Device*

The original PoNS™ 1.0 experimental device was developed in 2007 in the TCNL. The experimental PoNS™ 2.2 device shown in the pictures below was released in 2010. We anticipate producing the clinical PoNS™ 4.0 device in the second quarter of 2015. The full commercial device will be ready for release in the first quarter of 2016.

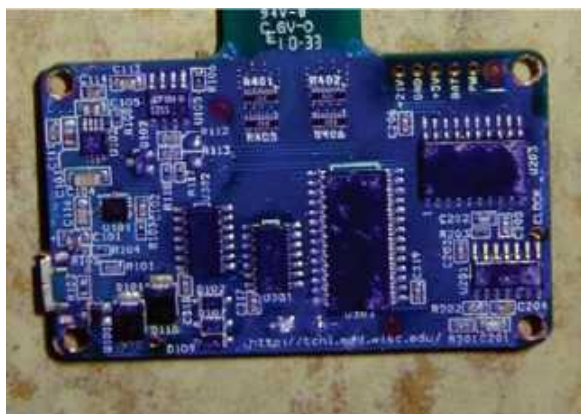
### *Physical Construction and User Interface of Version 2.2*

The PoNS™ version 2.2 device is an electrical pulse generator that delivers controlled electrical stimulation to the tongue. Pulses are generated and controlled by commercially available counter, timer, and wave-shaping electronic components. The components are mounted to a single printed circuit board (Figure 1 and Figure 2). The circuit board contains 143 gold-plated electrodes that contact the tongue. A rechargeable lithium- polymer battery with built-in charge safety circuitry provides power.

**Figure 1: Top of the PoNS™ Neuro-stimulator board**



**Figure 2: Bottom of the PoNS™ Neuro-stimulator board**





**Figure 3: Photographs of the PoNS™ Neuromodulation Stimulator Being Investigated in Conjunction with Physical Therapy for the Treatment of Balance and Gait Disorders.**



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, superior part of the tongue. The paddle-shaped tab of the device 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 four buttons: On, Off, Intensity “Up”, and Intensity “Down”.

While the voltage and pulse timing to each electrode are programmed into the device and cannot be altered, the stimulus intensity can be adjusted with a pair of buttons. At any instant in time, one of the electrodes in each of the nine sectors on the array is delivering stimulation while the remaining electrodes serve as the current return path to ground. The sensation produced by the array is similar to the feeling of drinking a carbonated beverage. The biphasic waveform is specifically designed to ensure zero net DC current to minimize the potential for tissue irritation.

When the PoNS™ 2.2 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. This procedure can be considered comparable to titrating a drug dosage according to a desired blood level so that the percept (and to a first approximation the neurophysiological impact) is held invariant.

#### *Proposed Improvements in Version 4.0*

Based on market research we have performed to date, we believe we have completed the technical and product design phases of the PoNS™ 4.0 device. While we expect to continue to enhance the PoNS™ 4.0 device design, we are now commencing efforts to complete the manufacturing development phase which will enable us to manufacture the device commercially. We anticipate performing the registration clinical trials for FDA and Health Canada clearance with the PoNS™ 4.0 device for use in treating balance disorder in mild to moderate TBI subjects and MS subjects. While we expect the PoNS™ 4.0 commercial device to deliver the same level of stimulation to the patient as the PoNS™ 2.2 laboratory device, we are designing the PoNS™ 4.0 device to be more ergonomic for better patient comfort, more hygienic (including a replaceable mouthpiece), more technologically advanced (including a data logging feature) and more feature laden than its predecessor. The proposed additional functionality of data logging and data communications for the PoNS™ version 4.0 device addresses certain stakeholder needs, such as providing useful information like time remaining during therapy and ready status of the device (e.g. charge level). We also expect to produce the PoNS™ 4.0 device in accordance with FDA’s Quality System Regulation, or QSR, including good manufacturing practices, or GMPs, as well as in accordance with Canadian regulatory requirements.

**Figure 4: Design of PoNS™ 4.0**



### **Our Design and Manufacturing Process**

#### *Ximedica*

Once we complete the design of and if we receive customer orders for the PoNS™ 4.0 device, we will subcontract the design and build of the PoNS™ device to Ximedica, LLC, or Ximedica (based in Providence, Rhode Island), a contract manufacturer we selected after an exhaustive procurement process. We expect to share with Ximedica our patented technology, trade secrets and know-how on a confidential, need to know basis. We expect that the PoNS™ 4.0 device will require some very light assembly and labeling that will be performed by Ximedica. Ximedica is certified to ISO 13485 and is registered as a medical device manufacturer and in good standing with the FDA.

Using monthly forecasts that we will provide to it, Ximedica will build to stock, warehouse and ship products to the customer as well as initially handle all customer service related tasks including order entry, order management and product warranty responsibility. We expect to retain responsibility for sales, marketing, research and development and all back office operations. At this stage, we anticipate the primary delivery points will be regional military centers and national physical therapy centers.

Under the Commercial Development-to-Supply Program between Ximedica and NHC, dated October 25, 2013, Ximedica's responsibilities will include:

- designing the commercial device following their proven design development process;
- developing the manufacturing process and completing the initial manufacturing of the device (their facility can produce PoNS™ units in quantities of tens of thousands per year); and

- developing the quality control process.

If larger industrial quantities will be required, then we plan to take over the manufacturing and quality control process.

### *U.S. Army*

We are designing the PoNS™ device with the cooperation of the U.S. Army pursuant to an agreement known as a cooperative research and development agreement, or CRADA. The U.S. Army was interested in signing the CRADA because of 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. Department of Defense statistics show that incidence of TBI in the U.S. Army has numbered approximately 30,000 per year from 2012 to 2014 in active duty personnel, and over 300,000 U.S. military personnel have been diagnosed with TBI since 2000. Of the 30,000 active duty personnel who suffer from TBI annually, we estimate that approximately 20-30% will develop chronic symptoms related to their TBI. 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 since this population is less subject to material, year-to-year fluctuation. The Army has expressed its desire to distribute our PoNS™ 4.0 device to service members who would benefit, should the device be cleared by the FDA. However, the U.S. Army is not under any obligation to purchase our product under the CRADA or any other agreement with us, and there is no assurance that the U.S. Army will ultimately purchase our product.

The parties to our CRADA with the U.S. Army are our subsidiary NHC, as cooperator, Advanced NeuroRehabilitation, LLC, or ANR, as the background patent holder, Yuri P. Danilov, Mitchell E. Tyler and Kurt A. Kaczmarek, as the inventors and background patent owners, the U.S. Army Medical Material Agency, or USAMMA, and the U.S. Army Medical Material Development Activity, or USAMMDA. Pursuant to the CRADA, as amended, the laboratories of the USAMMA and the USAMMDA, or collectively Army Laboratories, agree to cooperate with NHC on research for the ongoing design and development to determine if the PoNS™ device can be developed for commercial use in assisting physical therapy in the treatment of soldiers and others with military relevant neurological manifestations of TBI, including but not limited to Tinnitus, post-traumatic stress disorder, or PTSD, pain and any subsequent indications identified by the parties. 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 15, 2015 unless modified in writing by the parties, provided that the CRADA is subject to a four-year automatic extension as required for both FDA clearance in the event that a pre-market approval application with the FDA is required for a PoNS™ indication in respect of aid to therapy for chronic balance deficits resulting from mild to moderate TBI as well as for commercialization of the PoNS™ device.

We will initially seek FDA clearance only for treatment of patients with chronic balance deficit due to mild to moderate TBI and Health Canada clearance for balance disorder associated with MS. The U.S. Army has expressed an interest in supplying PoNS™ devices to the personnel who need it, subject to our ability to demonstrate its safety and effectiveness and our ability to obtain such FDA clearance. Based on this interest, we estimate that there is a sufficient potential market of active duty and retired soldiers who could potentially benefit from the PoNS™ device due to their chronic TBI symptoms. However, the U.S. Army has not made any guarantees and is not otherwise under any contractual obligations to purchase PoNS™ devices, even if we do demonstrate effectiveness and obtain FDA clearance.

If we are able to complete development of the PoNS™ device and obtain FDA clearance of the PoNS™ device to treat chronic balance deficit due to mild to moderate TBI and Health Canada clearance for balance disorder associated with MS, we plan to develop the PoNS™ device to treat other indications, or symptoms caused by neurological disorders. As set forth in the most recent January 12, 2015 amendment of our CRADA as described below, the U.S. Army has also expressed interest in our development of the PoNS™ device to treat other symptoms of TBI or any other indications caused by neurological disorders. We would be required to commit our own resources to sponsor the regulatory process for these additional indications. However, the Army Laboratories has agreed in the January 12, 2015 amendment to our CRADA to be responsible for supporting the execution of studies using the PoNS™ device as a treatment for mutually agreed-upon military relevant neurological disorders, which could include but not be limited to 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 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 Army Laboratories will not otherwise attempt to renegotiate its responsibilities under the CRADA. Some of the indications among active duty and retired personnel that are being considered under our CRADA are:

- Tinnitus;
- Post-Traumatic Stress Disorder;
- Sleep regulation; and
- Pain (headache) relief.

The parties agreed to the responsibilities set out below with respect to the development of the PoNS™ device.

Army Laboratories of the U.S. Armed Forces Responsibilities:

- Support the execution of studies using the PoNS™ device as a treatment for mutually agreed- upon military relevant neurological disorders, including but not limited to Tinnitus, post- traumatic stress disorder, or PTSD, pain and any subsequent indications identified by the parties.
- Conduct assessments of the manufacturing facility and assist/advise facility in meeting FDA manufacturing requirements.
- Aid in designing the clinical protocols to study the PoNS™ device as an adjunct to specialized physical therapy in patients with balance and gait disorders.
- Provide advice and expertise on all Army administrative protocols and approvals to execute the studies with military personnel, reservists, and/or veterans.

NHC Responsibilities:

- Complete the commercial design, including ergonomics (e.g. user controls, comfort), and design for improved manufacturability, reliability, and field support and regulatory testing to comply with the FDA regulations for such devices.
- Serve as the sole regulatory sponsor for all interactions with the FDA in order to gain approval and clearance from the FDA, including the initial 513(g) submission and the execution of any FDA-regulated studies.
- Prepare and submit the necessary regulatory filings for the FDA to secure regulatory clearance or approval.
- Ensure that the Army Laboratories receive copies of all formal and informal communications with the FDA related to the PoNS™ device.
- Supply the facilities and personnel to execute and/or oversee the execution of clinical studies of the device for FDA clearance/approval in support of an intended use of the PoNS™ device for use in assisting physical therapy in the treatment of soldiers and others with military relevant neurological disorders, including but not limited to Tinnitus, post-traumatic stress disorder, or PTSD, pain and any subsequent indications identified by the parties treatment of soldiers suffering from balance and gait disorders.
- Provide the supply of PoNS™ devices in support of mutually agreed upon studies governed by the CRADA.
- Supply all technical specifications, documentation and any other information required to address FDA requests to obtain FDA clearance/approval of the PoNS™ device.
- Finalize the commercial design of the PoNS™ device so that the devices would be commercially available to the Army should the results of the study be positive.
- Identify and engage a commercial manufacturer post-FDA clearance of the device to produce the device for purchase by the U.S. Army in the event it decides to order such devices for use by its personnel.

To date, no prior premarket notifications for clearance of the PoNS™ device have been submitted by NHC to the FDA, but the Army Laboratories, which previously was responsible as the regulatory sponsor until such role was assumed by NHC, submitted a request for information with the FDA with respect to the potential classification of the PoNS™ device through what is known as a 513(g) request for information. In response to a 513(g) request, the FDA provides information regarding the classification of the device or the requirements applicable to a device under the Federal Food, Drug, and Cosmetic Act, or the FD&C Act. Under the 513(g) request, the Army Laboratories sought guidance from the FDA regarding the classification of the PoNS™ device and the applicable requirements under the FD&C Act. As a result of this process, the FDA responded with guidance on pursuing de novo classification of the PoNS™ device as a Class II medical device.

We plan to utilize the de novo classification process to obtain Class II classification and 510(k) clearance from the FDA for the PoNS™ device. We have been deemed by the FDA through the pre-submission process a non-significant risk device and thus do not need an Investigation Device Exemption to complete our clinical trials. We are seeking to complete a safety and effectiveness clinical trial by the first quarter of 2016, and will thereafter submit a request for de novo classification and the premarketing notification (i.e., 510(k)) to the FDA.

On a parallel path to our request for de novo classification and premarket notification to the FDA, we expect to submit an application for the clearances of the PoNS™ device for both TBI and MS indications to Health Canada (the department of the government of Canada with responsibility for national public health). Our goal is that Canadian clearance for the PoNS™ device will be obtained on a similar timeline to the FDA clearance of the device.

On April 29, 2014, NHC, as cooperator, entered into Notice of Modification No. 1 of Cooperative Research and Development Agreement, or the Amended CRADA, with ANR, the inventors, and the Army Laboratories, whereby NHC will no longer provide expertise and training in the design of clinical study protocols or for U.S. Army and/or VA personnel in the physical therapy interventions required for clinical studies. In addition, pursuant to the Amended CRADA, ANR will share all data with USAMMA and NHC will provide all data supporting clinical claims for regulatory approval.

On January 12, 2015, NHC, as cooperator, entered into Notice of Modification No. 2 of the Amended CRADA, with ANR, the inventors, and the Army Laboratories. Under this Amended CRADA, the Army Laboratories agreed to transfer some of the CRADA responsibilities to NHC. We believe the Army Laboratories agreed to transfer certain responsibilities to us under the CRADA to enable us to accelerate development of the PoNS™ device for the eventual potential treatment of soldiers. One of the material changes reflected in the Amended CRADA is the shifting from the Army Laboratories to NHC of sole responsibility as the regulatory sponsor for all interactions with the FDA in order to gain approval and clearance from the FDA, including the initial 513(g) submission. As part of the amendments to the CRADA, NHC has agreed to be responsible to fund the FDA process as well as to provide the supply of all devices to support all studies governed by the CRADA. While under the amendments NHC gains control of the FDA regulatory process, the amendments materially increase the financial burden on NHC to meet these funding and supply obligations. The amendments also extend from two to four years both the time for regulatory approval in the event a pre-market approval application, or PMA, is required by the FDA as well as for commercialization of the PoNS™ device.

While NHC has sole responsibility as the regulatory sponsor under the CRADA, the Army Laboratories has published a Notice of Intent to enter into a sole-source contractual agreement to support the execution of the registration trial for treatment of balance disorder associated with mild to moderate TBI. The objective of this contract would be to defray the costs of the registration trial. The terms of the contract and the actual amount of the award are uncertain because we have not yet completed the negotiation for this contract, nor can we be assured that the Army will ever ultimately negotiate and enter into such a contract with us. The Army Laboratories also agreed in the January 12, 2015 amendment to our CRADA to be responsible for supporting the execution of studies using the PoNS™ device as a treatment for mutually agreed-upon military relevant neurological disorders, which could include but not be limited to 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 Army Laboratories will not otherwise attempt to renegotiate its responsibilities under the CRADA. 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.

## Our Market

NHC is in the neurostimulation market. According to a study by Grand View Research, the neurostimulation market was valued at \$3.4 billion in 2013 and is expected to grow at a compounded annual growth rate of 14.4% from 2014 to 2020. The leading sectors in the industry are Spinal Cord Stimulation, Deep Brain Stimulation, Sacral Nerve Stimulation and Vagal Nerve Stimulation. We believe that due to the lack of non-invasive devices, non-invasive stimulation addresses only approximately 3% of the overall neurostimulation market today.

## Market Competition

The neurostimulation market is competitive and growing. Our competitors in the industry are predominantly large, publically-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 as well.

We believe that our technology, the PoNS™ device, introduces an innovative target and method of stimulation because targeting the tongue for neurostimulation provides several advantages, which are discussed below. While we believe that the factors described below competitively distinguish our technologies and provide the PoNS™ device a competitive advantage for non-invasive neuromodulation therapy, we note that these factors are only supported by anecdotal evidence of efficacy. We therefore are making the assumption that the results of our upcoming clinical trial program will be positive and support these claims at that time.

- 1) 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.
- 2) 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.
- 3) 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.
- 4) 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.
- 5) 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 design efforts, obtain FDA clearance, and ultimately receive customer orders for the PoNS™ device, we plan to submit an application to the U.S. Department of Health and Human Services for an International Classification of Disease 10 reimbursement code so that the device is covered under Medicare and Medicaid. We plan to seek coverage and reimbursement of the PoNS™ device 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. 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™ device must fit within an identifiable coverage category and fully meet the requirements of such category.

Assuming we complete our design efforts, obtain FDA clearance, and ultimately receive customer orders for the PoNS™ device, we intend seeking 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. 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 approval 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.

## **Deployment**

We expect the PoNS™ 4.0 device to have a design feature that stops delivering therapy every 14 weeks. This is expected to force patients to return to their physician or physical therapy center, or 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 we expect the tongue array to be replaced by a new one to ensure no degradation of the electrodes occurs. 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 both the PoNS™ device and the “local” trained PTCs for their patients to receive the PoNS™ device and their training. We expect to launch a PoNS™ website and to develop a smart phone application to help physicians select the appropriate PTC convenient for the patient.

Upon discharge from the PTC, patients are expected to be monitored in their home therapy from a PTC phone center (set up by NHC through select PTCs) that plan to help the patients be compliant and ensure the therapy is performed appropriately. At the end of the 14 weeks of therapy, we expect patients to be directed back to their physician for assessment and then return to the PTC for replacement of the tongue array.

### *PoNS™ in the U.S. Army*

If it ultimately decides to purchase PoNS™ devices from us, we expect that the U.S. Army would deploy the device 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 have also approached the Canadian and United Kingdom Armed Forces to discuss their support of a similar program in Canada and discussions are ongoing. We also intend to pursue other military organizations in relevant countries based on need and size of potential deployment.

We expect to be able to leverage the deployment of the device in the U.S. Army in its marketing of the PoNS™ device to the civilian population.

### *PoNS™ in Civilian Population*

We believe that a key to deployment success will be to set up a national framework of PoNS™-trained Physical Therapists (PTs). We are actively developing a training certification program where PTs can become trained PoNS™ therapists. We expect there to be a strong financial incentive for the PT community to partner with us because PoNS™ training offers substantial opportunity for growth for the PTs. We anticipate that PTs will be able to use existing reimbursement codes for the physical therapy portion of the therapy. As discussed above, we plan to apply for reimbursement codes for the PoNS™ device.

We plan to concentrate our efforts in the United States, Canadian and UK marketplaces 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 either will launch at all. Following the launch of marketplaces in the United States, Canada and the UK, we intend to commercialize the PoNS™ device in the rest of Europe and Japan as second phase countries (2017) and Brazil, India and China as phase III countries (2018). In November 2014 we signed a development and distribution agreement with the Altair company in Russia to apply for registration and distribute the PoNS™ device in the territories of the former Soviet Union. However, there is no assurance that such commercialization will occur.

### **Licensed Intellectual Property**

The intellectual property relating to the PoNS™ device is the subject of U.S. Patent Applications 12/348,301, 14/340,144, 14/341,141 and Provisional Patent Applications 61/019,061 and 61/020,265, which we collectively refer to as the Patent Pending Rights. The Patent Pending Rights include the following patent applications, which cover a device that non-invasively delivers neurostimulation through the skin or intra-orally to the brain stem via the trigeminal nerve, the facial nerve or both:

<b>US Application No.</b>	<b>Filing Date</b>	<b>Status</b>	<b>Patent No.</b>	<b>Issue Date</b>
61/019,061 (Provisional)	1/4/2008	Expired	N/A	N/A
61/020,265 (Provisional)	1/10/2008	Expired	N/A	N/A
12/348,301	1/4/2009	Issued	8,849,407	9/30/2014
14/340,144	7/24/2014	Issued	8,909,345	12/9/2014
14/341,141	7/25/2014	Pending	N/A	N/A

The inventors received U.S. Patent No. 8,849,407 in relation to the patent application no. 12/348,301 on September 30, 2014. This patent covers 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. U.S. patent application 14/340,144, which became U.S. Patent No. 8,909,345 on December 9, 2014, and U.S. patent application 14/341,141 are continuations of application 12/348,301 (now U.S. Patent 8,849,407). U.S. Patent No. 8,909,345 covers 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. Patent application 14/341,141 covers 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.

A U.S. provisional patent application provides the means to establish an early effective filing date for a later filed non-provisional patent application. Therefore, though the two provisional applications have expired, they establish a priority date for U.S. Patent Nos. 8,849,407 and 8,909,345 and U.S. application 14/341,141 and any future filings that claim priority.



Now that the inventors have received the U.S. Patent Nos. 8,849,407 and 8,909,345, the use of the PoNS™ device for various treatment techniques is patented in the United States, and we have a license to practice these patented techniques from ANR.

ANR, which is one of our significant shareholders, holds an interest in the Patent Pending Rights pursuant to an exclusive license from the inventors. Patent applications 14/340,144 and 14/341,141 are included in the exclusive license as the exclusive license agreement covers (i) patent application 12/348,301 and provisional application 61/019,061, (ii) any patents issuing therefrom, and (iii) any patents claiming priority to patent application 12/348,301 or provisional application 61/019,061, which patent applications 14/340,144 and 14/341,141 claim priority through such provisional application as well as through provisional application 61/020,265.

Pursuant to an amended and restated sublicense agreement, or the Sublicense Agreement, ANR has granted NHC a worldwide, exclusive license to make, have made, use, lease and sell devices utilizing the Patent Pending Rights. 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 collection 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 sub-license 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”), 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 we are not willing or able to commercialize the PoNS™ technology within four years from the expiration of the CRADA, we are 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.

With respect to the Patent Pending Rights, the United States Patent and Trademark Office, or USPTO, issued U.S. Patent Nos. 8,849,407 and 8,909,345 and U.S. application 14/341,141 remains pending in the USPTO. In addition, we intend to file additional continuation applications in the USPTO claiming priority to U.S. application 14/341,141 to protect other aspects of the PoNS™ device and related non-invasive neurostimulation techniques.

### **Company Owned Intellectual Property**

We have obtained in September 2014 – US Patent No. 8,849,407, Skin Stimulation + physical therapy = Therapeutic outcome. In December 2014 – we were issued US Patent No. 8,909,345 Oral Cavity Stimulation + Physical exercise = Therapeutic output and in March 2015 – US Patent No. 9,020,612 Oral Cavity Stimulation + Cognitive exercise = Therapeutic outcome.

We filed 26 patent applications related to various technical and ornamental aspects of version 4.0 of the PoNS™ device. We filed ten non-provisional patent applications that describe various technical features in the version 4.0 device and 16 design patent applications describing various ornamental designs for the PoNS™ version 4.0 device. We are the sole assignee for these 26 new patent filings.

Currently, we use four trademarks in connection with the operation of the business: PoNS, NeuroHabilitation, NHC and Helius Medical Technologies. We own the rights to the PoNS mark by virtue of an assignment agreement having an effective date of October 27, 2014 and entered into with ANR and the inventors of the PoNS™ technology. We are the sole owner of the rights in the NeuroHabilitation and NHC trademarks, and Helius Medical Technologies, Inc. is the owner of the rights in the Helius Medical Technologies mark. On October 31, 2014, we filed trademark applications in the USPTO for these four trademarks.

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

Our intellectual property has been the subject of a lawsuit which has been dismissed. For a full description of this lawsuit, please see “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 clearance 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) premarket 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) premarket 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 in six months 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 and balance disorder associated with MS. Our overall goal for submission of the *de novo* application and FDA clearance of a 510(k) would be 18 months from December 2014. The application to the FDA will be made after the completion of the registration trial, which we anticipate will be completed at the end of 2015. It will take us approximately 12 weeks to prepare the premarket notification to the FDA. We thus anticipate that we will be applying for clearance in second quarter 2016. To the extent the FDA completed its review in 90 days, we anticipate clearance in the third quarter 2016.

Obtaining FDA clearance, *de novo* down-classification, or approval for medical devices can be expensive and uncertain, generally takes from several months to several years, and generally requires detailed and comprehensive scientific and clinical data. Notwithstanding the expense, these efforts may never result in FDA clearance. Even if we were to obtain regulatory clearance, 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 Clearance 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 candidates are safe and effective, sensitive and specific diagnostic tests, for their 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 candidates could prevent us from generating revenue from these product candidates and adversely affect our business operations and financial results.

Even if we obtain FDA clearance 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 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 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, 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 candidates and dissuade our customers from using our product candidates, 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**

### *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 constituted a reverse take-over of us by NHC.

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*

Prior to the acquisition of NHC, we had no active business. 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 Sublicense Agreement and Second Sublicense Agreement described above.

### *Listing of our Common Stock on the CSE and on a U.S. Stock Exchange*

Following our Reverse Merger, we obtained approval of the listing of our common stock on the Canadian Securities Exchange, or CSE. Our common stock currently trades on the CSE under the symbol “HSM”. Our common stock is currently quoted on the OTCQB under the symbol “HSDT.” We have applied to list our common stock on the Nasdaq Capital Market and the status of this application is pending. However, there is no guarantee that our listing application to the Nasdaq Capital Market will be approved or, even if we were approved, that we will satisfy continuing listing requirements.

### **Employees**

As of June 26, 2015, we have three employees.

## RISK FACTORS

***An investment in our common stock involves a number of very significant risks. You should carefully consider the following risks and uncertainties in addition to other information in this annual report on Form 10-K 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 Company**

***We have a very limited operating history.***

Helius Medical Technologies, Inc. is our holding company and it has no material assets other than cash and cash equivalents and its 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 is a development stage company that has had limited operations to date.

***We are heavily dependent upon the ability and expertise of our CEO 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 Mr. Phil Deschamps, our President and CEO. Currently Mr. Deschamps is joined by Misha Danilov, Project Manager, and Jonathan Sackier as our only full-time employees. We also have engaged 15 full-time equivalent persons as independent contractors, including our Chief Financial Officer. While employment agreements are customarily used as a primary method of retaining the services of key employees, these agreements cannot assure the continued services of such employees. Any loss of the services of such individuals could have a material adverse effect on our business, operating results or financial condition.

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

We have incurred substantial net losses since our inception. For our fiscal years ending March 31, 2015 and March 31, 2014, we incurred a net loss of \$8,894,555 and \$1,067,284, respectively, and used cash in operations of \$6,321,285 and \$348,698, respectively. We have an accumulated deficit of \$18,479,689 as of March 31, 2015. We have incurred net losses since our inception. Our losses have resulted principally 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 clearance 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 sell and market our current product and research and develop, and seek regulatory approvals for, other potential product candidates.

We will be subject to all of the business risks and uncertainties associated with any new business enterprise, including undercapitalization, 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 of our current product or product candidates that receive marketing clearance from the FDA or other regulatory body is insufficient, if we are unable to develop and commercialize any of our product candidates, or if our product development is delayed, we may never become profitable.



***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. Our cash and cash equivalents as of March 31, 2015 were \$418,893. 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 the design of the PoNS™ device, FDA clearance of the PoNS™ device for treating balance disorder in patients with mild to moderate TBI and balance disorder associated with MS, 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. 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 candidates or if, when, or to what extent we will generate revenues from the commercialization and sale of any of these product candidates for which we obtain regulatory approval. We may never succeed in achieving regulatory approval for our current and any 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.

***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.***

Our report from our independent registered public accounting firm for the year ended March 31, 2015 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 through the end of the third quarter of 2015. 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 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 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.

***Raising additional capital by issuing securities or through debt financings or licensing arrangements may cause dilution to existing stockholders, restrict our operations or require us to relinquish proprietary rights.***

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 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 specific actions such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or products or grant licenses on terms that are not favorable to us. 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.

***We currently only have one product candidate, which is still in development, and we have not obtained clearance from FDA to commercially distribute the device in the United States and clearance from Health Canada to commercially distribute the device in Canada, and we may never obtain such clearances.***

We currently are dependent on a single product which is our PoNS™ device for use in the neuromodulation market. We are still developing this product, and we cannot begin marketing and selling the device in the United States and Canada until we obtain clearances from the FDA and Health Canada, respectively. We have not yet submitted applications for regulatory clearance in either the United States or Canada. The process of obtaining regulatory clearance 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 clearance of a product candidate or rejection of a regulatory application altogether. The FDA has substantial discretion in the *de novo* review and clearance processes and may refuse to accept any application or may decide that our data are insufficient for clearance 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 regulatory clearance of a product candidate. Any marketing authorization from the FDA or regulatory clearance 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 clearance of the PoNS™ device for treatment of chronic balance deficit in patients with mild to moderate TBI in the United States and chronic balance deficit associated with MS in Canada, 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 clearance. The costs of such development efforts and FDA clearances 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 clearance.

***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 candidates.***

We currently have a limited number of employees and resources available to perform the research and development necessary to commercialize our PoNS™ device and future product candidates. We therefore rely at present and will need to continue to rely on third-party research institution collaborators for this capability.

Our subsidiary NHC is currently party to the CRADA with the inventors, background patent owners and the Army Laboratories. Pursuant to the CRADA, the Army Laboratories agree to cooperate with NHC on research for the ongoing design and development to determine if the PoNS™ device can be developed for commercial use in assisting physical therapy in the treatment of soldiers and others with military relevant neurological disorders, including but not limited to Tinnitus, post-traumatic stress disorder, or PTSD, pain and any subsequent indications identified by the parties. Under the terms of the CRADA, we are solely responsible to fund and oversee clinical studies for the PoNS™ device and seek FDA clearance and approval of the PoNS™ device. We are also solely responsible to complete the research and development efforts necessary to commercialize our PoNS™ device. However, the Army Laboratories has published a Notice of Intent to enter into a sole-source contractual agreement to support the execution of the registration trial for treatment of balance disorder associated with mild to moderate TBI. The objective of this contract is to defray the costs of the registration trial. The terms of the contract and the actual amount of the award are uncertain because we have not yet completed the negotiation for this contract, nor can we be assured that the Army will ever ultimately negotiate and enter into such a contract with us. The Army Laboratories also agreed in the January 12, 2015 amendment to our CRADA to be responsible to support the execution of clinical studies for the PoNS™ device as a treatment for mutually agreed upon military relevant neurological disorders, which could include but not be limited to 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 Army Laboratories will not otherwise attempt to renegotiate its responsibilities under the CRADA. 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 clearance 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.***

Under the CRADA if we fail to obtain FDA clearance 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™ device would have a material adverse effect on our business.

In addition, 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.

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

We believe our PoNS™ product has strong potential therapeutic benefits for the neuromodulation market. The neuromodulation market is relatively new and its long-term growth prospects are uncertain. Since we do not yet have FDA clearance for our product, there is limited to no market awareness of our product. In order to succeed, we must among other things increase market awareness of our PoNS™ product 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, should the neuromodulation market fail to expand, it could have a materially adverse effect on our business and financial position.

***Our PoNS™ technology is a new “untested” form of neurostimulation therapy and the medical community tends to be very conservative in not adopting new therapies very rapidly, which may have a material adverse effect on our business and financial position.***

The effectiveness of our PoNS™ technology to treat 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. Unproven and untested technologies are usually more slowly adopted by the medical community as the medical community tends to be very conservative and does not adopt new “untested” therapies very rapidly. 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;
- 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 of or improvement of competitive products.

If the medical community reacts in a similar fashion to adopting our PoNS™ device for neurostimulation therapy, we will not be able to generate significant revenues, if any.

***In order to be successful, we must expand our products beyond our single product by commercializing new 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™ device which is currently our only product. To succeed in our commercialization efforts, we must effectively continue product development and testing, obtain regulatory clearances and approvals, and enhance our sales and marketing capabilities. There is no assurance that we will succeed in bringing any of our current or 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, laboratory devices and products based on new technologies. These risks include: (i) delays in product development or manufacturing; (ii) unplanned expenditures for product development or manufacturing; (iii) failure of new products to have the desired effect or an acceptable accuracy profile; (iv) emergence of superior or equivalent products; (v) failure by any potential collaborative partners to successfully develop products; and (vi) 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.

***We can provide no assurance that the development by others of new or improved devices or products will not result in our present and future products from becoming obsolete.***

The areas in which we plan to commercialize, distribute, and/or sell products involves rapidly developing technology. There can be no assurance that we will be able to establish ourselves in such fields, or, if established, that we will be able to maintain our market position, if any. There can be no assurance that the development by others of new or improved products will not make our present and future products, if any, superfluous or obsolete.

***Our future success depends on our ability to obtain approval on the patent for the PoNS™ technology, failing which we may be unable to protect our proprietary information and any competitive advantage which may have a material adverse effect on our business and financial condition.***

Our future success will depend, in part, on our ability to obtain approval on the patent for the PoNS™ technology. There can be no assurance that the patent application made will result in the issuance of the patent or that the term of the patent will be extendable after it expires in due course, which will prevent us from being able to protect our proprietary information and may have a material adverse effect on our business and financial condition.

Much of our know-how and technology may not be patentable, though they may constitute trade secrets. There can be no assurance, however, that we will be able to meaningfully protect our trade secrets. To help protect our intellectual property rights and proprietary technology, we require employees, consultants, advisors and collaborators to enter into confidentiality agreements. There can be no assurance that these agreements will provide meaningful protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure.

Our intellectual property has been the subject of a lawsuit which has been dismissed. For a full description of this lawsuit, please see “Item 3. Legal Proceedings.”

***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.

***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 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.

***We depend on a single source for the manufacture of our product and the loss of this third-party manufacture could harm our business.***

We will be dependent on a single third-party to manufacture and supply our PoNS™ device. This manufacturer will also hold our inventory, warehouse and ship our products customers as well as handle all customer service related tasks including, order entry, order management and product warranty responsibility. Our reliance on a single third-party manufacturer to supply us with our PoNS™ device and 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 manufacturer 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 it could experience similar problems that result in the manufacture of insufficient quantities of our product candidates; and
- fail to follow and remain in compliance with the FDA-mandated 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.

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

***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 intend to develop may expose us to potential liability from personal injury claims by end-users of the product. We 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 third 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 are a small company with limited resources compared to some of our current and potential competitors and we may not be able to compete effectively and increase market share.***

There is potential that we will face intense competition from other companies, some of which can be expected to have longer operating histories and more financial resources and manufacturing and marketing experience than us. Increased competition by larger and better financed competitors could materially and adversely affect our business, financial condition and our results of operations.

Because of the early stage of the industry in which we intend to operate, we expect to face additional competition from new entrants. To be competitive, we will require a continued high level of investment in research and development, marketing, sales and client support. We may not have sufficient resources to maintain research and development, marketing, sales and client support efforts on a competitive basis which could materially and adversely affect our business, financial condition and our results of operations.

***We will incur increased costs and 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 will incur significant legal, accounting and other expenses that we have not incurred as a private company, including costs associated with public company reporting requirements. We will incur costs associated with the rules implemented by the SEC, any OTC market our common stock may become quoted on, and any national exchange that our common stock may become listed on. The expenses incurred by public companies generally for reporting and corporate governance purposes have been increasing. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly, although we are currently unable to estimate these costs with any degree of certainty. 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.

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***One of our officers serves only on a part-time consulting basis, and she and other persons who work for us on a part-time consulting basis may be subject to conflicts of interest.***

We have three employees, including Philippe Deschamps, our President, CEO and a director, and Jonathan Sackier, our Chief Medical Officer. All other persons who provide services to us do so on a part-time consulting basis. 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. For example, our Chief Financial Officer works for us on a part-time consulting basis and serves as the Assistant Manager, Corporate Finance of V Baron Global Financial Canada Ltd. Pursuant to an agreement with us, V Baron Global Financial Canada Ltd. offers consulting services to us for transaction structuring, corporate governance and compliance issues. 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.

Furthermore, to the extent that our agreement with V Baron Global Financial Canada Ltd. is terminated, we will lose the services of our Chief Financial Officer.

### **Risks Related to Government Regulation**

***Before we can market and sell our products, we will be required to obtain approval and clearance by the FDA and foreign regulatory authorities which 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 clearance 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, 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, 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 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.



**Obtaining FDA clearance 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 clearance, *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 clearance. Even if we were to obtain regulatory clearance, 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 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 candidates are safe and effective, sensitive and specific diagnostic tests, for their 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 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 candidates could prevent us from generating revenue from these product candidates 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
- 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 candidates and dissuade our customers from using our product candidates, if and when they are authorized for marketing.

*We expect to be required to conduct clinical trials to support regulatory approval of some of our product candidates. We have no experience in the clinical trials process, they may proceed more slowly than anticipated, and we cannot be certain that our product candidates will be shown to be safe and effective for human use.*

In order to commercialize our product candidates 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 or is not exempt from premarket review by the FDA. We could also be required to submit a PMA application for other 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 some of our 510(k) premarket notifications. We will receive approval or clearance 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 candidates are safe and effective and otherwise meet the appropriate standards required for approval or clearance 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 must 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.

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

- failure to obtain financing necessary to bear the cost of designing and conducting clinical trials;
- failure to obtain 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 candidates or other materials necessary to conduct our clinical trials;
- difficulties in enrolling 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 in whom our product candidates are implanted; or
- failure by any of our third-party contractors or investigators to comply with regulatory requirements 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 candidates, 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 candidates could be significantly reduced.

***If we are required to conduct clinical trials to obtain FDA clearance and approval, we will be substantially dependent on third parties to conduct clinical trials.***

In the event we were required to conduct clinical trials to obtain FDA clearance, we would 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 would ultimately be 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 would be 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. 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 approval 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 approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates 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 an International Classification of Disease 10 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 would 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.

***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.

## Risks Related to Our Common Stock

***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 shares are currently periodically quoted on the OTCQB. We have applied to list our common stock on the Nasdaq Capital Market and our application is still pending. However, there is no guarantee that our listing application to the Nasdaq Capital Market will be approved or, even if we were approved, that we will satisfy continuing listing requirements. As a result, a well-established market for our common stock may never develop in the United States.

Our common stock has been listed on the CSE since June 23, 2014. Our common stock is also restricted for immediate resale in Canada pursuant to Canadian securities laws. To date, trading on the CSE in our common stock has been limited and sporadic.

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.

***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 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 and ANR, hold approximately 50.1% of our outstanding shares of common stock and if they both consent in writing to take a particular corporate action, they could do so without a meeting that involves our other shareholders.

***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 Healthcare, LLC 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 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.

***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 for two consecutive years. 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 also limit a stockholder's ability to buy and sell our stock.***

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

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

Future sales or issuances of equity securities, including the issuance of 8,882,032 shares of our common stock underlying warrants currently exercisable, 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.

***We are authorized to issue an unlimited number of common stock which could result in substantial dilution to your investment in our shares.***

Our Articles of Incorporation authorize the issuance of an unlimited number of common shares, which shares 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. 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.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

**ITEM 2. PROPERTIES**

Our head office is located at Suite 400, 41 University Drive, Newtown, PA 18940. We currently lease three office rooms from Regus for approximately \$3,896 per month. The lease is for one year expiring on April 30, 2016 at which time we will determine whether we should have a dedicated office space. Currently, we do not have any other material physical properties as we seek to contract out all the non-core functions such as research and development, human resources and investor relations in order to maintain a low fixed cost business model. Our registered office and registered agent is located at CT Corporation System, 1712 Pioneer Ave., Ste. 120, Cheyenne, Wyoming 82001.

**ITEM 3. LEGAL PROCEEDINGS**

On January 5, 2015, Wicab filed a complaint against us, two of our directors, Yuri Danilov and Mitch Tyler, and ANR in the U.S. District Court for the Western District of Wisconsin. The complaint contained various state and common law claims arising from Danilov's and Tyler's prior employment with Wicab and our two issued patents for the PoNS™ device. The complaint alleged, among other things, that following their departure from Wicab, Danilov and Tyler knowingly filed patent applications for and used ideas and inventions developed at Wicab in violation of various non-competition and confidentiality agreements, and that our two issued patents are therefore rightfully the property of Wicab. The complaint sought an unspecified amount of monetary damages, an injunction preventing us from using the ideas and inventions in the two patents, an order transferring ownership of the patents from us to Wicab, and recovery of costs and attorneys' fees. The complaint was voluntarily dismissed without prejudice on January 14, 2015.

On January 27, 2015 we received a demand letter containing allegations that we had entered into a consulting arrangement with the complainants and breached certain of its terms, and used certain intellectual property in the form of business and marketing plans allegedly prepared by the complainants, and seeking damages. On May 7, 2015, Mr. Rainier Maas and Dr. Jochen Scheld filed a complaint in the U.S. District Court for the Eastern District of Pennsylvania seeking monetary damages. We intend to conduct a vigorous defense of this matter. At this point management is unable to determine the outcome of this matter.

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 May 1, 2015, 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

There is no established trading market for our common stock in the United States. Shares of our common stock have been listed on the CSE since June 23, 2014 under the symbol "HSM". The market for our common stock on the CSE is very recent, and therefore, limited, volatile and sporadic. The following table sets forth the high and low prices relating to our common stock for the periods indicated, as provided by the CSE. These quotations reflect inter-dealer prices without retail mark-up, mark-down, or commissions, and may not reflect actual transactions.

Quarter Ended	High	Low
June 30, 2014	CAD\$2.37	CAD\$1.00
September 30, 2014	CAD\$2.72	CAD\$2.27
December 31, 2014	CAD\$3.00	CAD\$2.25
March 31, 2015	CAD\$3.40	CAD\$2.24

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

#### Holder

As of June 24, 2015, we had approximately 188 shareholders of record.

#### Options

As of June 25, 2015, we have 4,920,000 stock options outstanding which are exercisable into 4,920,000 shares of our common stock.

#### Warrants

As of June 25, 2015, we have 8,882,032 common share purchase warrants outstanding which are exercisable into 8,882,032 shares of common stock.

#### Dividend Policy

We have not paid any cash dividends on our common shares 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.

## Securities Authorized For Issuance Under Compensation Plans

The following table sets forth the securities to be issued under the Stock Option Plan as at March 31, 2015:

	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	-	-	-
Equity compensation plans not approved by security holders <sup>(1)</sup>	4,920,000	\$ 0.8989 <sup>(2)</sup>	7,188,016
Total	4,920,000	\$ 0.8989 <sup>(2)</sup>	7,188,016

(1) Represents grants of stock options pursuant to the 2014 Plan. See “Item 11. Executive Compensation— June 2014 Stock Incentive Plan” for a description of the material features of the 2014 Plan.

The weighted-average exercise price was denominated in Canadian dollars and converted into U.S. dollars based on the Bank of Canada nominal noon exchange rate on March 31, 2015 of CAD\$1.00 = USD \$0.7885.

## RECENT SALES OF UNREGISTERED SECURITIES.

On April 15, 2014, we issued in aggregate 10,000,000 shares of our common stock to the shareholders of 0995162 BC Ltd. (174 individuals/entities from Canada and 1 individual from Germany) pursuant to the plan of arrangement between us, Boomerang Oil, Inc. and 0995162 BC Ltd., in exchange for all of the issued and outstanding shares of 0995162 BC Ltd. We relied upon the exemption provided under Section 2.11 of the Canadian Securities Administrators National Instrument 45-106 - *Prospectus and Registration Exemptions*. We did not issue any of our common stock to any U.S. persons.

On May 28, 2014 we filed our Articles of Continuance with the Wyoming Secretary of State, which was effective with the State of Wyoming on June 2, 2014, whereby we continued from the Province of British Columbia into the State of Wyoming pursuant to a plan of arrangement between us and our shareholders in accordance with section 288 of the BCBCA. This reincorporation resulted in the issuance of 10,000,000 shares of our common stock to our shareholders, in exchange for their existing common shares in the capital of our company that were issued and outstanding immediately prior to the effectiveness of the reincorporation transaction. The plan of arrangement between us and our shareholders required court approval under section 291 of the BCBCA. We advised the British Columbia Supreme Court, or the Court, prior to the hearing that we would be relying upon the registration exemption under Section 3(a)(10) of the Securities Act, and that in order for us to rely upon such Section 3(a)(10) exemption the Court must approve the fairness of the terms and conditions of the exchange of our shares from a British Columbia corporation to shares of us as a Wyoming corporation. The fairness hearing was open to all our shareholders to whom securities of us as a Wyoming corporation would be exchanged pursuant to the plan of arrangement and adequate notice was provided to all our shareholders. On May 27, 2014, the Court found that the terms and conditions of the plan of arrangement were fair and approved the plan of arrangement. None of our shareholders exercised their rights of dissent under the BCBCA in respect of the reincorporation transaction.

On May 30, 2014, we closed a private placement consisting of 15,240,000 subscription receipts at a price of CAD\$0.50 per subscription receipt for gross proceeds of \$7,016,002(CAD\$7,620,000). On June 13, 2014, each subscription receipt automatically converted, for no additional consideration, into one common share and one-half of one common share purchase warrant. We refer to each whole warrant as a Warrant. Each Warrant entitles the holder thereof to purchase one additional share of our common stock at a price of CAD\$1.00 until May 30, 2016. We relied on exemptions from registration under the Securities Act, provided by Rule 506 of Regulation D and/or Section 4(a)(2) for the one U.S. purchaser who was an “accredited investor” as defined under Rule 501(a) of Regulation D as well as Regulation S for the Canadian and offshore purchasers, based on representations and warranties provided by the purchasers of the subscription receipts in their respective subscription agreements entered into between us and each purchaser.

In connection with the May 30, 2014 private placement, we paid finder's fees of \$379,806 (CAD\$412,200) in cash and 824,400 finder's warrants, or a Finder's Warrant, in aggregate to five entities in British Columbia, Canada and one entity in Nevis, West Indies. The Finder's Warrants have the same attributes as the Warrants. We relied on the exemption from registration under the Securities Act provided by Regulation S for the issuance of the Finder's Warrants to each finder.

On June 13, 2014, we acquired a 100% interest in NHC, as discussed above, pursuant to an agreement and plan of merger whereby our wholly-owned subsidiary was merged with and into NHC and all of the common shares in the capital of NHC were cancelled in consideration for the issuance of an aggregate of 35,300,083 shares of our common stock to the NHC shareholders. We relied on the exemption from registration under the Securities Act provided by Section 4(a)(2) for the issuance of shares of our common stock to the four NHC shareholders with which we had a pre-existing relationship. Of the 35,300,083 shares issued in this private placement, 32,070,052 shares were held in escrow beginning on June 23, 2014.

On June 19, 2014, we granted 2,660,000 options to purchase our common stock to four of our directors (in individual amounts of 1,800,000; 400,000; 400,000 and 60,000) for services rendered as directors. We also granted 400,000 options to purchase our common stock to an advisor for consulting services rendered. We relied on Rule 701 under the Securities Act for these grants. Also on such date, we issued 460,000 options to purchase our common stock to four persons (in individual amounts of 60,000; 250,000; 50,000 and 100,000). The four persons did not pay cash for the options but rendered consulting services to us. We relied on Section 4(a)(2) of the Securities Act for the issuances of these options, as we had a substantive, pre-existing relationship with each of these four persons, and these persons had access to information about us.

On June 20, 2014, we issued 250,000 options to purchase our common stock to one entity. The entity did not pay cash for the options but rendered consulting services to us. We relied on Section 4(a)(2) of the Securities Act for the issuances of these options, as we had a substantive, pre-existing relationship with the entity, and the entity had access to information about us.

On June 30, 2014, we issued 2,564,705 common shares to one offshore individual pursuant to the conversion of a convertible note that was issued by our subsidiary, NHC, in the principal amount of \$1,000,100 (CAD\$1,090,000 when converted to CAD\$) at a price of CAD\$0.425 per share. Under the terms of the agreement and plan of merger with NHC, we agreed to assume responsibility for satisfying the payment obligations under such convertible note by issuing shares of our capital stock. We relied upon the exemption from registration as provided under Regulation S promulgated under the Securities Act as the securities were issued to the individual through an offshore transaction which was negotiated and consummated outside of the United States.

On July 14, 2014, we granted 100,000 options to purchase our common stock to an advisor for consulting services rendered. We relied on Rule 701 under the Securities Act for this grant.

On December 8, 2014, we granted 50,000 options to purchase our common stock to each of nine advisors for consulting services rendered. Also on such date, we granted 100,000 options to purchase our common stock to one of our directors and 400,000 options to purchase our common stock to one of our employees for services rendered as director and employee, respectively. We relied on Rule 701 under the Securities Act for these grants.

On March 16, 2015, we granted 100,000 options to purchase our common stock to one of our directors for services rendered as director. We relied on Rule 701 under the Securities Act for this grant.

On April 30, 2015, we closed a private placement to 12 accredited investors, which included one institution and 11 individuals, consisting of an aggregate of 849,273 units at a price of \$2.15 per unit for gross proceeds of approximately \$1,825,937. Each unit consisted of one share of our common stock and one-half of one common share purchase warrant. Each whole warrant entitles the holder to purchase one additional share of our common stock at a price of \$3.00 per share until April 30, 2018. We relied on the exemption from registration provided by Section 4(a)(2) of the Securities Act and Rule 506(b) thereunder for the private placement. In connection with the private placement, we issued 27,396 warrants to one institutional accredited investor that served as a finder for the private placement. The finder's warrant permits the holder to purchase one share of our common stock at a price of \$3.00 per share until April 30, 2018. We relied on the exemption from registration provided by Section 4(a)(2) of the Securities Act for the issuance of the finder's warrant.

**ITEM 6. SELECTED FINANCIAL DATA**

The operating and balance sheet data included in the following selected financial data table have been derived from our consolidated financial statements. The selected financial data presented below should be read in conjunction with our consolidated financial statements included elsewhere in this annual report on Form 10-K and with “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

	Years ended		
	2015	2014	2013
<b>Operating Data:</b>			
Revenues	-	-	-
Operating expenses:			
Direct operating	3,828,775	171,781	4,250,000
Selling, general and administrative	5,035,907	895,503	4,267,850
Depreciation and amortization	-	-	-
Operating loss	8,864,682	1,067,284	8,517,850
Other income (expense):			
Interest expense	176,488	-	-
Interest income	(20,074)	-	-
Change in fair value of derivative liability	739,375	-	-
Foreign exchange gain	(865,916)	-	-
Loss from operating before income taxes	29,873	1,067,284	8,517,850
Income tax expense	-	-	-
Net loss	8,894,555	1,067,284	8,517,850
<b>Balance Sheet Data</b>			
Total assets	1,216,347	315,968	217
Long-term liabilities	-	-	-

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

We are a medical technology company focused on neurological wellness. We seek to develop, license or acquire unique and non-invasive platform technologies that amplify the brain’s ability to heal itself.

Our mission is to develop, license and acquire non-invasive treatments designed to help patients affected by neurological symptoms caused by disease or trauma. Applying the principles of neuroplasticity, our patented PoNS™ device induces Cranial Nerve Non Invasive Neuromodulation that utilizes the brain’s innate ability to achieve neuroplastic change to aid persons with neurological, cognitive, sensory, and motor disorders when combined with the rehabilitation process.

The following discussion and analysis of our results of operations, financial condition and plan of operations should be read in conjunction with (i) our audited financial statements for the year ended March 31, 2015 and (ii) the audited financial statements of NHC for the year ended March 31, 2014 and for the period from January 22, 2013 (inception) to March 31, 2013. The discussion below contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including, but not limited to, those set forth under “Item 1. Business – Business Uncertainties and Going Concern Risk” and elsewhere in this annual report on Form 10-K.

### ***Fiscal Year Ended March 31, 2015 Compared to the Fiscal Year Ended March 31, 2014***

#### *Revenues*

During the fiscal years ended March 31, 2015 and 2014, we did not generate any revenues.

#### *Operating Expenses*

Operating expenses incurred during the fiscal year ended March 31, 2015 were \$8,864,682 as compared to \$1,067,284 during the period from inception to March 31, 2014. Significant changes and expenditures are outlined as follows:

- Advertising, marketing, and IR expenses were \$774,400 for the fiscal year ended March 31, 2015, and \$nil for the fiscal year ended March 31, 2014. The increase relates to advertising and promotion expenses and investor relation consulting fees. We have engaged both investor relations and public relations professionals in Canada and the US to help develop corporate material as well as arranging and participating in conferences and road shows to increase the public's awareness of our activities and the PoNS™ device.
- Audit and accounting fees were \$71,340 for the fiscal year ended March 31, 2015, and \$nil for the fiscal year ended March 31, 2014. The increase of \$71,340 was mainly due to the requirement to review and audit the Company's financial statements since it became a reporting issuer.
- Consulting fees were \$1,085,606 for the fiscal year ended March 31, 2015 and \$807,385 for the fiscal year ended March 31, 2014. The increase of \$278,221 was mainly due to the expense in 2015 associated with the granting of options to consultants for providing services in design and manufacturing and our strategic growth plan.
- Insurance expenses were \$75,425 for the fiscal year ended March 31, 2015, and \$nil for the fiscal year ended March 31, 2014. The increase of \$75,425 was mainly due to the need for general liability, directors' and officers', and product insurance as the Company continues its research and development plans.
- Legal fees were \$1,478,766 for the fiscal year ended March 31, 2015 as compared to \$33,966 for the fiscal year ended March 31, 2014. The increase of \$1,444,800 was primarily composed of fees incurred for general corporate matters and the reverse takeover transaction. In addition, our legal activity to ensure current and quality regulatory filings has increased significantly since becoming a public company in Canada. Furthermore, the engagement of various specialized legal counsels for the development of our intellectual properties and the commercialization of the PoNS™ device is carried out to secure our intellectual property. With the legal counsel's assistance, inventors have been issued two important patents so that we now have a license to practice patented techniques.
- Meals and travel expenses were \$272,338 for the fiscal year ended March 31, 2015 as compared to \$22,860 for the fiscal year ended March 31, 2014. The increase of \$249,478 was primarily due to travel to and from various investor and medical conferences as well as required travel for personnel to coordinate the clinical trials.
- Office expenses were \$166,282 for the fiscal year ended March 31, 2015 as compared to \$8,137 for the fiscal year ended March 31, 2014. The increase of \$158,145 was mainly due to general and administrative expenses but also includes computer and internet expenses, telephone expenses, and rent expenses. These expenses increased significantly as we ramped up our operations.

- Professional fees were \$14,136 for the fiscal year ended March 31, 2015 as compared to \$nil for the fiscal year ended March 31, 2014. The increase relates to corporate communications and industry research fees.
- Research and development expenses were \$3,828,775 for the fiscal year ended March 31, 2015 as compared to \$171,781 for the fiscal year ended March 31, 2014. The increase was primarily due to the continuous efforts on research and development activities of the PoNS™ device, especially activities relating to preparation of clinical trials which mostly includes Ximedica's commercial development-to-supply program and the NeuroFeedback's 12- month pilot clinical trial.
- Transfer agent and regulatory fees were \$104,214 for the fiscal year ended March 31, 2015, as compared to \$nil for the fiscal year ended March 31, 2014. The increase of \$104,214 stems from the Company's requirement as a public company to retain a transfer agent, as well as the associated filing fees.
- Wages and salaries expenses were \$993,400 for the fiscal year ended March 31, 2015 as compared to \$23,155 for the fiscal year ended March 31, 2014. The increase of \$970,245 was due to an increase in the CEO's salary, the hiring of an office assistant, and the hiring of the Company's Chief Medical Officer.

### *Non-Operating Items*

We recorded a loss of \$29,873 in respect of non-operating items during the year ended March 31, 2015 as compared to \$nil for the year ended March 31, 2014. Significant changes are outlined as follows:

- Interest expense for year ended March 31, 2015 was \$176,488 as compared to \$nil for the fiscal year ended March 31, 2014. The increase resulted from recording non-cash interest associated with the contingent beneficial conversion feature arising from the conversion of the convertible debenture.
- Interest income for the fiscal year ended March 31, 2015 was \$20,074 as compared to \$nil for the fiscal year ended March 31, 2014. The increase stems from the opening of a number of interest-bearing short- term investment accounts with our banking institutions.
- Change in fair value of derivative liability for the fiscal year ended March 31, 2015 was \$(739,375) as compared to \$nil for the fiscal year ended March 31, 2014. The change in fair value of derivative liability is based on the change of the remaining term of our options granted to non-employees providing services for NHC and the change in our stock price. The derivative liabilities do not represent cash liabilities.
- Foreign exchange gains for the fiscal year ended March 31, 2015 were \$865,916 as compared to \$nil for the fiscal year ended March 31, 2014. The gains stem from our exchange of a large sum of Canadian dollars into U.S. dollars interest-bearing short-term investments with our banking institutions as well as translating the balance of the Canadian dollar intercompany to the reporting currency.

### *Net Loss*

The net loss was \$8,894,555 for the fiscal year ended March 31, 2015 and \$1,067,284 for the fiscal year ended March 31, 2014. The increase in net loss of \$7,827,271 resulted primarily from an increase in most operating expenses, especially advertising, marketing and IR, consulting fees, insurance expenses, legal fees, research and development, and wages and salaries.

## ***Fiscal Year Ended March 31, 2014 Compared to the Fiscal Year Ended March 31, 2013***

### *Revenues*

During the fiscal year ended March 31, 2014 and the period from inception to March 31, 2013, we did not generate any revenues.

### *Operating Expenses*

Operating expenses incurred during the fiscal year ended March 31, 2014 were \$1,067,284 as compared to \$8,517,850 during the period from inception to March 31, 2013. Significant changes and expenditures are outlined as follows:

- Consulting fees were \$807,385 for the fiscal year ended March 31, 2014 and \$2,800 for the period from inception to March 31, 2013. The increase of \$804,585 was mainly due to the expense in 2014 associated with the granting of options to consultants for providing services in design and manufacturing and strategic growth plan, which were subsequently exercised.
- Interest expenses were \$1,344 for the fiscal year ended March 31, 2014 as compared to \$Nil for the period from inception to March 31, 2013.
- Legal fees were \$33,966 for the fiscal year ended March 31, 2014 as compared to \$14,192 for the period from inception to March 31, 2013. The increase of \$19,774 was mainly due to legal fees associated with patent applications and general corporate matters.
- Meals and entertainment expenses were \$833 for the fiscal year ended March 31, 2014 as compared to \$Nil for the period from inception to March 31, 2013.
- Office expenses were \$6,793 for the fiscal year ended March 31, 2014 as compared to \$482 for the period from inception to March 31, 2013. The increase of \$6,311 was mainly due to the increased number of activities of the operation and engagement of a part-time office assistant.
- Research and development expenses were \$171,781 for the fiscal year ended March 31, 2014 as compared to \$4,250,000 for the period from inception to March 31, 2014.
- Compensation expenses for shares issued for services was \$Nil for the fiscal year ended March 31, 2014 as compared to \$4,250,000 for the period from inception to March 31, 2013. The decrease of \$4,250,000 was a result of not issuing any shares as compensation for services rendered during the fiscal year ended March 31, 2014.
- Travel expenses were \$22,027 for the fiscal year ended March 31, 2014 as compared to \$376 for the period from inception to March 31, 2013. The increase of \$21,651 was mainly due to the required traveling of the CEO as we were actively seeking for external financing and interviewing external parties in preparation of the research and development activities.
- Wages and salaries expenses were \$23,155 for the fiscal year ended March 31, 2014 as compared to \$Nil for the period from inception to March 31, 2013. The increase of \$23,155 was due to the new employment contract with the CEO.

## Net Loss

The net loss was \$1,067,284 for the fiscal year ended March 31, 2014 and \$8,517,850 for the period from inception to March 31, 2013. The decrease in net loss of \$7,450,566 resulted primarily from a decrease in research and development expenses and compensation expenses for shares issued for services, which was offset somewhat by an increase in consulting fees, legal fees, travel expenses and wages and salaries.

## 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 sets out our cash and working capital as of March 31, 2015 and March 31, 2014:

	<b>March 31, 2015</b>	<b>March 31, 2014</b>
Cash and cash equivalents	\$ 418,893	\$ 15,968
Working capital (deficit)	\$ 18,543	\$ (267,977)

As of March 31, 2015, our current assets were \$1,216,347 (March 31, 2014 - \$315,968), which increased mostly due to the closing of a private placement on June 13, 2014. Current liabilities were \$1,197,804 (March 31, 2014 - \$583,945), which increased due to an increase in our operations since the closing of a private placement and our acquisition of NHC. Working capital was \$18,543 (March 31, 2014 - (\$267,977)). Our current assets as of March 31, 2015 consisted of cash and cash equivalents of \$418,893 (March 31, 2014 - \$15,968), which increased mostly due to the closing of the private placement, short-term investment of \$378,000, which increased as a result of acquiring a term deposit with our banking institution, receivables of \$8,833 (March 31, 2014 - \$nil), which increased due to the opening of numerous interest-bearing short-term investments with our banking institutions, and prepaid expenses of \$410,621 (March 31, 2014 - \$300,000), which mostly include a prepayment to Ximedita and insurance expenses. Our current liabilities as of March 31, 2015 consisted of accounts payable and accrued liabilities of \$1,197,804 (March 31, 2014 - \$215,921), which increased due to our increased operations, and a convertible debenture amount of \$nil (March 31, 2014 - \$368,024). During the year ended March 31, 2015, we received an additional \$632,076 in respect of convertible debenture. Upon completion of a qualifying transaction, the convertible debenture was settled on conversion of the debt in exchange for 2,564,705 common shares.

As a result of our increased activity, the accumulated deficit increased from \$9,585,134 as at March 31, 2014 to \$18,479,689 as at March 31, 2015.

We currently have limited working capital and liquid assets. Our cash and cash equivalents as of March 31, 2015 were \$418,893. 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 design of the PoNS™ device, FDA clearance of the PoNS™ device for treating balance disorder associated with mild to moderate TBI and MS, 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.

We will have to continue to rely on equity and debt financing. There can be no assurance that financing, whether debt or equity, will always be available to us in the amount required at any particular time or for any particular period or, if available, that it can be obtained on terms satisfactory to us. Without additional financing, we do not believe our resources will be sufficient to meet our operating and capital needs through the third quarter of 2015.



## Statement of Cash Flows

### ***Fiscal year ended March 31, 2015 compared to Fiscal year ended March 31, 2014***

During the year ended March 31, 2015, our net cash increased by \$402,925 (March 31, 2014 - \$15,751), which included net cash used in operating activities of \$6,321,285 (March 31, 2014 - \$348,698) stemming from our increase in operations, and net cash provided by financing activities of \$7,482,728 (March 31, 2014 - \$364,449) stemming mainly from the closing of the private placement, proceeds from the bridge loan, and funds received for the issuance of a convertible debenture.

#### *Cash Used in Operating Activities*

Operating activities in the year ended March 31, 2015 used cash of \$6,321,285 (March 31, 2014 - \$348,698). This was made up of a net loss of \$8,894,555 (March 31, 2014 - \$1,067,284) less adjustments for non-cash items such as accretion of beneficial conversion feature of \$176,488 (March 31, 2014 - \$1,344), change in fair value of derivative liability of \$739,375 (March 31, 2014 - \$nil), stock based compensation of \$1,397,114 (March 31, 2014 - \$807,157), a foreign exchange re-measurement of \$598,929 (March 31, 2014 - \$nil), receivables of (\$8,945) (March 31, 2014 - \$nil), accounts payable of \$979,040 (March 31, 2014 - \$210,085) and prepaid expenses of (\$110,873) (March 31, 2014 - \$300,000). Receivables increased due to the opening of numerous interest-bearing short-term investments. Payables and prepaid expenses increased due to our increase in operations.

#### *Cash Used in Investing Activities*

During the year ended March 31, 2015, cash used in investing activities totaled \$378,000 (March 31, 2014 - \$nil) as a result of the purchase of a short-term investment with our banking institution.

#### *Cash Provided by Financing Activities*

During the year ended March 31, 2015, financing activities provided cash of \$7,482,728 (March 31, 2014 - \$364,449). Financing activities during the year ended March 31, 2015, consisted of: issuance of share capital of \$7,017,009 (March 31, 2014 - \$nil) and share issuance costs of (\$379,806) (March 31, 2014 - \$nil) stemming from the private placement, cash acquired on the recapitalization of \$23,904 (March 31, 2014 - \$nil), proceeds from shares to be issued of \$39,545 (March 31, 2014 - \$nil), proceeds from a bridge loan of \$150,000 (March 31, 2014 - \$nil), short-term loan of \$nil (March 31, 2014 - (\$2,231)), and proceeds from the debenture of \$632,076 (March 31, 2014 - \$368,024).

### ***Fiscal year ended March 31, 2014 compared to Fiscal year ended March 31, 2013***

During the year ended March 31, 2014, our net cash increased by \$15,751 (March 31, 2013 - \$217), which included net cash used in operating activities of \$348,698 (March 31, 2013 - \$12,014) stemming from our increase in operations, and net cash provided by financing activities of \$364,449 (March 31, 2013 - \$12,231) stemming mainly from the funds received for the issuance of a convertible debenture.

#### *Cash Used in Operating Activities*

Operating activities in the year ended March 31, 2014 used cash of \$348,698 (March 31, 2013 - \$12,014). This was made up of a net loss of \$1,067,284 (March 31, 2013 - \$8,517,850) less adjustments for non-cash items such as stock based compensation of \$807,157 (March 31, 2013 - \$8,500,000), accounts payable of \$210,085 (March 31, 2013 - \$5,836) and prepaid expenses of (\$300,000) (March 31, 2014 - \$nil). Payables increased due to an increase in operations. Prepaid expenses increased due to an upfront payment to Ximedica.

### *Cash Provided by Financing Activities*

During the year ended March 31, 2014, financing activities provided cash of \$364,449 (March 31, 2013 - \$12,231). Financing activities during the year ended March 31, 2014, consisted of: issuance of share capital of \$nil (March 31, 2013 - \$10,000), repayment of a short-term loan of \$2,231 (March 31, 2013 – proceeds from a short-term loan of \$2,231), and proceeds from the debenture of \$366,680 (March 31, 2014 - \$nil).

### **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 March 31, 2015, we did not have any contractual obligations required to be disclosed by Item 303(a)(5) of Regulation S-K during the year ended March 31, 2015.

### **Subsequent Events**

On April 30, 2015 the Company closed a non-brokered private placement (the "Financing") raising gross proceeds of CAD \$2,208,110 (approximately USD \$1,825,937) by the issuance of 849,273 units (each a "Unit") at a price of CAD \$2.60 per Unit (USD \$2.15 per Unit). Each Unit consists of one (1) common share and one half of one (1/2) common share purchase warrant (each a "Warrant"). Each whole Warrant entitles the holder thereof to purchase one additional common share of the Company at a price of approximately CAD \$3.62 per share (USD \$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 CAD 101,494 (USD \$84,074) in connection with this Financing, as well as 27,396 finder's warrants (the "Finder's Warrants"). Each Finder's Warrant entitles the holder thereof to purchase one additional common share of the Company at a price of CAD \$3.62 per share (USD \$3.00 per share) for a period of thirty-six (36) months from the closing date of the Financing.

### **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 compensation for services, valuation of options and valuation of income taxes.

### **Stock-Based Compensation**

We account for all of our stock-based payments and awards under the fair value based method. We recognize our stock-based compensation using the accelerated attribution 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 share purchase 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 share purchase options are expensed over their vesting period with a corresponding increase to additional capital surplus. Upon exercise of share purchase 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. Share purchase 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 our share purchase options. Option pricing models require the input of highly subjective assumptions, including the expected price volatility. Changes in these assumptions can materially affect the fair value estimate.

### **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. 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 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 reassessed 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 settlement of the derivative instrument is expected within 12 months of the balance sheet date.

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

### **Recently Issued Accounting Pronouncements**

In August 2014, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") No. 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, which for the Company is April 1, 2017. Early adoption is permitted. The Company does not intend to early adopt this standard. The adoption of this standard will not have a material impact on the Company's financial position or results of operations.

In June 2014, the FASB issued ASU No. 2014-10, "Development Stage Entities" ("ASU 2014-10") which removes the definition of a development stage entity from the Master Glossary of the Accounting Standards Codification, thereby removing the financial reporting distinction between development stage entities and other reporting entities from U.S. GAAP. In addition, the update eliminates the requirements for development stage entities to (1) present inception-to-date information in the statements of income, cash flows, and shareholder equity, (2) label the financial statements as those of a development stage entity, (3) disclose a description of the development stage activities in which the entity is engaged, and (4) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage. ASU No. 2014-10 is effective for fiscal years and interim periods beginning after December 15, 2014, with early adoption permissible. The Company early adopted ASU 2014-10 allowing the financial statements to be cast without the inception to date information and without references to the development stage.

The amendments also clarify that the guidance in Topic 275, *Risks and Uncertainties*, is applicable to entities that have not commenced planned principal operations. The central feature of the guidance disclosure requirements is that required disclosures are limited to matters significant to a particular entity. The disclosures focus primarily on risks and uncertainties that could significantly affect the amounts reported in the financial statements in the near term or the near-term functioning of the reporting entity.

In June 2014, the FASB issued ASU No. 2014-12, *Compensation - Stock Compensation (Topic 718): Accounting for Share-Based Payments When the Terms of an Award Provide that a Performance Target Could be Achieved after the Requisite Service Period*. This update requires that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. As such, the performance target should not be reflected in estimating the grant date fair value of the award. This update further clarifies that compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the periods for which the requisite service has already been rendered. This update is effective for annual reporting periods (including interim reporting periods within those periods) beginning after December 15, 2015, which for the Company is April 1, 2016. Early adoption is permitted. Entities may apply the amendments in this update either: (a) prospectively to all awards granted or modified after the effective date; or (b) retrospectively to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements and to all new or modified awards thereafter. The adoption of this standard will not have a material impact on the Company's financial position or results of operations.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*. This update outlines a new, single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. This new revenue recognition model provides a five-step analysis in determining when and how revenue is recognized. The new model will require revenue recognition to depict the transfer of promised goods or services to customers in an amount that reflects the consideration a company expects to receive in exchange for those goods or services. This new guidance is effective for annual reporting periods (including interim reporting periods within those periods) beginning after December 15, 2016, which for the Company is April 1, 2017; early adoption is not permitted. Entities have the option of using either a full retrospective or a modified approach to adopting the guidance. The Company does not anticipate that the adoption of this update will have a material impact on its financial position or results of operations.

## **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

### **Financial Instruments and Other Risks**

We are exposed to credit risks and market risks related to changes to interest rates and foreign currency exchange rates, each of which could affect the value of our current assets and liabilities. We invest our cash equivalents in fixed rate, highly liquid and highly rated financial instruments such as guaranteed investment contracts, or GICs. At March 31, 2015, our cash and cash equivalents were primarily held as GICs, the majority of which was denominated in U.S. dollars. We do not believe that the results of operations or cash flows would be affected to any significant degree by a sudden change in market interest rates relative to our investment portfolio, due to the relative short-term nature of the investments. We have not entered into any forward currency contracts or other financial derivatives to hedge foreign exchange risk. We are subject to foreign exchange rate fluctuations that could have a material effect on our total net assets or net loss. We are exposed to interest rate cash flow risk on our cash and cash equivalents as these instruments bear interest on current market rates.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

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

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

On February 19, 2015, the Board of Directors approved the dismissal of Davidson & Company LLP, or Davidson, as our independent registered public accounting firm, effective February 19, 2015.

Davidson's report on our annual financial statements for the fiscal year ended March 31, 2014 and the period from January 22, 2013 to March 31, 2013 did not contain an adverse opinion or a disclaimer of opinion, nor was it qualified or modified as to uncertainty, audit scope, or accounting principles.

During the fiscal year ended March 31, 2014 and for the period from January 22, 2013 (date of inception) to March 31, 2013 as well as the subsequent interim period through February 19, 2015, there have been no disagreements (as defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions) between us and Davidson on any matter of accounting principles or practices, financial statement disclosures, or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of Davidson, would have caused it to make reference to the subject of such disagreements in connection with any report prepared by Davidson. Further, there have been no reportable events (as described in Item 304(a)(1)(v) of Regulation S-K).

On February 19, 2015, the Board of Directors approved the engagement of BDO Canada LLP, or BDO Canada, as our independent registered public accounting firm to perform independent audit services. Neither we, nor anyone on our behalf, has consulted BDO Canada regarding the application of accounting principles related to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on our financial statements or as to any disagreement or reportable event as described in Item 304(a)(1)(iv) and Item 304(a)(1)(v), respectively, of Regulation S-K.

**ITEM 9A. CONTROLS AND PROCEDURES**

(a) *Disclosure Controls and Procedures.*

In connection with this annual report on Form 10-K, under the direction of our Chief Executive Officer and our Chief Financial Officer, our management has evaluated our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act, and has concluded that our disclosure controls and procedures were ineffective as of March 31, 2015. As of the date of this filing, we are still in the process of remediating the material weakness that caused our disclosure controls and procedures to not be effective.

Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information we are required to disclose in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure. In connection with the preparation of the consolidated financial statements for the year ended March 31, 2015, our management determined that our accounting staff does not have sufficient technical accounting knowledge relating to accounting for income taxes and complex U.S. GAAP matters, which our management determined has caused our disclosure controls and procedures to be ineffective.

We intend to take appropriate and reasonable steps to make the necessary improvements to our accounting staff to remediate this material weakness in our disclosure controls and procedures as resources to do so become available. There are inherent limitations to the effectiveness of any system of disclosure controls and procedures, including the possibility of human error and the circumvention or overriding of the controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objective.

*(b) Management's Report on Internal Control Over Financial Reporting*

This annual report does not include a report of management's assessment regarding internal control over financial reporting due to a transition period established by the rules of the Securities and Exchange Commission for newly public companies.

**ITEM 9B. OTHER INFORMATION**

None.

## PART III

### ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Our directors and executive officers and their respective ages as of the date of June 26, 2015 are as follows:

<b>Name</b>	<b>Age</b>	<b>Position Held</b>
Philippe Deschamps	53	CEO, President and Director
Amanda Tseng	32	CFO and Corporate Secretary
Jonathan Sackier	57	Chief Medical Officer
Savio Chiu	32	Director
Yuri Danilov	58	Director
Mitch Tyler	62	Director
Edward M. Straw	76	Director
Joyce LaViscount	53	Director

The following describes the business experience of each of our directors and executive officers, including other directorships held in reporting companies:

***Philippe Deschamps, Chief Executive Officer, President and a Director***

Mr. Deschamps has served as our CEO, President and director since June 13, 2014. Mr. Deschamps offers extensive experience in pharmaceutical and healthcare commercialization. The depth of his expertise stems from his 27 years in the health sciences industry, half spent at Bristol Myers Squibb (NYSE: BMY), and half on the service side as CEO of GSW Worldwide, a healthcare advertising agency. Mr. Deschamps started at GSW Worldwide in February 1998 as a Vice President and Account Director and became President and CEO of GSW Worldwide from January 2002 to September 2011. Mr. Deschamps was responsible for the GSW Worldwide operations which includes offices in the 15 major markets around the world. He primarily consulted on global marketing, commercialization and new business model development for pharmaceutical, device and diagnostics companies. From 1986 to 1998, Mr. Deschamps served as director of neuroscience marketing at Bristol Myers Squibb in Princeton, N.J., where he participated on several pre-launch global marketing teams in the neuroscience and pain therapeutic areas.

In February 2012, Mr. Deschamps joined MediMedia Health, a marketing services company as CEO until October 2013 when he finished his assignment. At MediMedia Health, he was responsible for the strategic development of the organization, nurturing their clients and developing new non-personal products and services for the healthcare industry. In October 2013, he became CEO of NHC.

Mr. Deschamps has a BSc. from the University of Ottawa in Canada which he obtained in 1985.

***Amanda Tseng, Chief Financial Officer, Corporate Secretary***

Ms. Tseng has served as our CFO and Corporate Secretary since June 13, 2014 and as a director from June 13, 2014 to November 17, 2014. Ms. Tseng is a Chartered Accountant and holds a Bachelor of Commerce degree from the University of British Columbia which she obtained in 2007. From January 2012 to present, she serves as the Manager, Corporate Finance of V Baron Global Financial Canada Ltd. From December 2008 to December 2011, Ms. Tseng served as the Manager of MNP LLP (Chang Lee LLP). V Baron Global Financial Canada Ltd. is the Canadian arm of V Baron Group which is a merchant bank headquartered in Hong Kong. The corporate finance of V Baron Global Financial Canada offers consulting services on transaction structuring, corporate governance and compliance issues. Ms. Tseng's primary responsibilities are managing the investment banking projects and assisting in executing all facets of the investment bank projects. For managing an investment banking project, Ms. Tseng reviews the quarterly and yearly financial statements and management discussion and analysis and interacts with professionals such as lawyers, auditors and transfer agents to facilitate smooth operations. MNP LLP is a chartered accountant firm where its principal services include tax, accounting and a wide range of business advisory services. Ms. Tseng started as a staff accountant and was promoted to a manager at MNP LLP from March 2007 to December 2011 where her primary responsibilities were managing audit engagements specifically in relation to public company audits. The audit engagements ranged in various industries including mining, education, film, gaming, technology and wholesale. These audit engagements covered compliance in Canadian GAAP, U.S. GAAP and IFRS. In addition, Ms. Tseng was a staff accountant of Steingarten & Company LLP from March 2007 to December 2008.

Ms. Tseng is serving as our CFO and Corporate Secretary pursuant to an agreement we have with V Baron Global Financial Canada Ltd. Accordingly, Ms. Tseng is not an employee and devotes approximately 50% of her time to our business. If our agreement with V Baron Global Financial Canada Ltd. were to terminate, we would likely lose the services of Ms. Tseng.

***Jonathan Sackier, Chief Medical Officer***

With more than 30 years in the healthcare industry, Mr. Sackier brings to his role as Chief Medical Officer extensive experience in new technologies and treatment methodologies. He is widely recognized as one of the leaders of the laparoscopic surgery revolution.

A trained surgeon, Mr. Sackier has helped build several companies including medical technology, research and product-design and medical contract sales organizations. He has also collaborated with pharmaceutical and medical device technology partners including Bristol Myers, Pfizer, Karl Storz, Applied Medical, Stryker, Siemens, Bayer and Novartis.

Mr. Sackier recently served as Chairman of Adenosine Therapeutics, which became part of Clinical Data and then Forest Laboratories. Prior, he worked to develop and market the AESOP robot with Computer Motion and that company went through a successful IPO. He also founded Genethics, which patented and licensed amniotic stem cell technology

As a Professor at George Washington University in Washington, DC, Mr. Sackier founded and funded the Washington Institute of Surgical Endoscopy, a center for education, research, innovation and technology transfer. He is now a pro bono Visiting Professor of Surgery at the Nuffield Department of Surgical Sciences at Oxford University.

Mr. Sackier sits on the board of directors of Kypha, Clinvue, and Hemoshear. He is Chairman of the Board of The Load Zero Foundation and a Trustee of First Star and previously chaired The Larry King Cardiac Foundation Board of Governors. He has also served as a board member of The American College of Surgeons Foundation, The Surgical Fellowship Foundation and Rex Bionics, winner of London's 2014 Aim Award for outstanding achievement for most successful growth market.

A keen pilot, Mr. Sackier advises the Aircraft Owners & Pilots Association (AOPA) on medical issues germane to pilots and authors the "Fly Well" column in AOPA Pilot magazine.

***Savio Chiu, Director***

Mr. Chiu has served as one of our directors since June 13, 2014. From April 2011 to present, Mr. Chiu serves as the Chief Financial Officer and Corporate Secretary of Confederation Minerals Ltd. (TSXV: CFM). From December 2010 to present, Mr. Chiu serves as a director of Finore Mining Inc. (CSE: FIN). From June 2009 to present, Mr. Chiu has been the Senior Manager, Corporate Finance of V Baron Global Financial Canada Ltd. From October 2010 to August 2013, Mr. Chiu served as the Chief Financial Officer of Golden Fame Resources Corp. (TSXV: PFE). From July 2010 to June 2011, he served as the Chief Financial Officer of Cassius Ventures Ltd. (TSXV: CZ).

Mr. Chiu is a Chartered Accountant and holds a Bachelor of Commerce degree in Accounting from the University of British Columbia which he obtained in 2005.



***Yuri Danilov, Director***

Mr. Danilov has served as one of our directors since June 13, 2014. Mr. Danilov, a co-inventor of the PoNS™ device, is currently the Research Director of the Tactile Communication and NeuroRehabilitation Laboratory, UW-Madison (2008 to present), co-owner and Neuroscience Director of ANR (2009 to present), and former Research Director of Wicab (2002 to 2007). He is also currently a Senior Scientist of Biomedical Engineering Department of University of Wisconsin-Madison (2008 to present).

Mr. Danilov received his Ph.D. in Neuroscience from Pavlov Institute of Physiology, Russian Academy of Science in 1984.

***Mitch Tyler, Director***

Mr. Tyler has served as one of our directors since June 13, 2014. Mr. Tyler is a co-inventor of the PoNS™ device and co-owner of ANR (2009 to present). Mr. Tyler is the Clinical Director of the Tactile Communication and NeuroRehabilitation Laboratory, UW-Wisconsin (2008 to present), a Senior Lecturer in Biomedical Engineering, and Clinical Director of ANR. He received his M.S. of Bioengineering from University of California in 1985 and is currently working on his Ph.D. in Biomedical Engineering at the University of Wisconsin. In addition, Mr. Tyler was the Principal Investigator for Wicab from 1998 to 2006.

***Edward M. Straw, Director***

Admiral Straw has served as one of our directors since November 18, 2014. Admiral Straw is the founder and managing partner of Ospey Venture Partners, a firm that finds investment capital and assists with business development for start-up entrepreneurs. He is the retired President, Global Operations of The Estee Lauder Companies, and currently sits on the boards of the following companies: Performance Equity Management, Odyssey Logistics, Capital Teas and Document Capture Technologies. He is also the Chairman of Odyssey Logistics. Prior to joining the Estee Lauder Companies, he was Senior Vice President, Global Manufacturing and Supply Chain Manager at the Compaq Corporation in Houston and President of Ryder Logistics in Miami. Prior to joining the private sector, Admiral Straw had a distinguished career in the U.S. Navy, retiring as a three-star admiral in 1996.

***Joyce LaViscount, Director***

Ms. LaViscount has served as one of our directors since March 2, 2015. Ms. LaViscount currently serves as the Chief Financial Officer of MediMedia Pharmaceutical Solutions, the pharmaceutical division of MediMedia USA. Prior to joining MediMedia, Ms. LaViscount was Executive Director/Group Controller North America for Aptalis Pharmaceuticals and spent more than five years at Endo Pharmaceuticals in a variety of roles including Chief Accounting Officer, VP-Investor Relations and Corporate Communications, and VP Finance Operations, as well as operational roles in Sales Operations and Training and Corporate Strategy Development. Ms. LaViscount's pharmaceutical industry experience also includes more than 15 years in finance at Bristol-Myers Squibb and Pharmacia. Ms. LaViscount began her career with Ernst & Young and is a New Jersey Certified Public Accountant.

**Term of Office**

Our directors are appointed for a one-year term to hold office until the next annual general meeting of our stockholders or until they resign or are removed from the board in accordance with our bylaws. Our officers are appointed by our Board of Directors and hold office until they resign or are removed from office by the Board of Directors.

We have formed an audit committee that is comprised of Savio Chiu, Mitchell Tyler, and Yuri Danilov. Mr. Chiu is an "audit committee financial expert", as that term is defined in Item 407(d)(5)(ii) of Regulation S-K.

## Family Relationships

There are no family relationships among our directors and officers.

## Code of Ethics

As a newly public company, we have not yet adopted a code of ethics as defined in Item 406(b) of Regulation S-K. When we adopt a code of ethics that applies to our principal executive officer, principal financial officer and principal accounting officer or controller, we intend to post the text of such code of ethics on our Internet website.

## ITEM 11. EXECUTIVE COMPENSATION

During the fiscal year ended March 31, 2015, our named executive officers consisted of Marco Babini and Philippe Deschamps, each of whom served as our principal executive officer during a portion of the fiscal year, and Jonathan Sackier, our Chief Medical Officer. Mr. Babini served as our principal executive officer until June 13, 2014, at which time Mr. Deschamps became our principal executive officer.

**Summary Compensation Table**

<u>Name and principal position</u>	<u>Year</u>	<u>Salary (\$)</u>	<u>Option awards (\$)</u>	<u>All other compensation (\$)</u>	<u>Total (\$)</u>
Marco Babini <i>Chief Executive Officer</i>	2015	6,607 <sup>(1)</sup>	-	-	6,607
Philippe Deschamps <i>Chief Executive Officer</i>	2015	360,417	382,329 <sup>(2)</sup>	5,000	747,746
Jonathan Sackier <i>Chief Medical Officer</i>	2015	100,000	543,941 <sup>(3)</sup>	-	643,941

(1) The salary was denominated in Canadian dollars and converted into U.S. dollars using the average Bank of Canada nominal noon exchange rate between April 1, 2014 and March 31, 2015 of CAD\$1.00 = USD\$0.8809.

(2) The grant date fair value was denominated in Canadian dollars and converted into U.S. Dollars using the Bank of Canada nominal noon exchange rate on June 19, 2014 (the grant date) of CAD\$1.00 = USD\$0.9235.

(3) The grant date fair value was denominated in Canadian dollars and converted into U.S. dollars using the Bank of Canada nominal noon exchange rate on December 8, 2014 (the grant date) of CAD\$1.00 = USD\$0.8717.

## Narrative Disclosure to Summary Compensation Table

### *Employment Agreement with Philippe Deschamps*

On June 13, 2014, we entered into an employment agreement with Philippe Deschamps to serve as our President and CEO. This employment agreement was amended on September 1, 2014. Pursuant to the employment agreement, Mr. Deschamps will receive a base salary at an annualized rate of \$250,000 until investments reach a level of \$5 million, or the Financing Threshold, and after such Financing Threshold is met, his base salary will increase to \$400,000 until the end of the employment term, which is at-will. In addition to Mr. Deschamps' base salary, he shall have the opportunity to receive a target annual bonus of 30% of the base salary, conditional upon, and subject to upward or downward adjustment based upon, achievements and individual goals to be established in good faith by the Board of Directors and Mr. Deschamps, which goals have not yet been established. If Mr. Deschamps is terminated without cause or if Mr. Deschamps resigns for good reason, we shall pay Mr. Deschamps an aggregate amount equal to the sum of his base salary and the earned portion of the annual bonus paid for the year preceding the year of his termination of which such amount is to be paid in equal monthly installments during the twelve month period following such termination of employment.

On December 1, 2014, we entered into an employment agreement with Jonathan Sackier to serve as our Chief Medical Officer. Pursuant to the employment agreement, Mr. Sackier will receive a base salary at an annualized rate of \$300,000 for his employment term, which is at-will. In addition to Mr. Sackier's base salary, he shall have the opportunity to receive a target annual bonus of 25% of the base salary, conditional upon, and subject to upward or downward adjustment based on upon, achievements and individual goals to be established in good faith by our CEO and Mr. Sackier, which goals have not yet been established. If Mr. Sackier is terminated without cause or if Mr. Sackier resigns for good reason, we will pay Mr. Sackier an aggregate amount equal to the sum of his base salary and the earned portion of the annual bonus paid for the year of his termination of which such amount is to be paid in equal monthly installments during the twelve month period following such termination of employment.

*Option Grants during Fiscal Year 2015*

During the fiscal year ended March 31, 2015, we granted 1,800,000 options and 400,000 options to Philippe Deschamps and Jonathan Sackier, respectively. The grants were made pursuant to the 2014 Stock Incentive Plan, or the 2014 Plan, which is further described below. One-third of Mr. Deschamps's options vested upon grant, and one-third will vest on each of the first and second anniversaries of the grant date. Mr. Deschamps's options have an exercise price of CAD\$0.60 and expire on June 18, 2019. One-quarter of Mr. Sackier's options vested upon grant, and one-quarter will vest every six months from the grant date. Mr. Sackier's options have an exercise price of CAD\$2.96 and expire on December 8, 2019.

**Management Contract with V Baron Global Financial Canada Ltd.**

Effective July 1, 2014, V Baron Global Financial Canada Ltd. has been engaged as an advisor to provide corporate advisory and CFO services for a period of 12 months ending on July 1, 2015. The corporate advisory services will include advising on corporate governance, assisting in compliance with the standards and policies of stock exchanges and regulators, advising on continuous disclosure requirements, assisting in compilation of financial statements, liaising with legal counsel, auditors and transfer agent, and assisting/advising on corporate finance related matters. The CFO services will be provided by Amanda Tseng, who is an employee of V Baron Global Financial Canada Ltd. During the duration of the agreement, each party may terminate the agreement by providing the other party with 60 days written notice. Once the 12 month period has passed, a renewal contract is required to be entered into between the parties in order to continue the relationship. V Baron Global Financial Canada Ltd. will receive CAD\$12,500 per month for the services provided. During the year ended March 31, 2015, the Company incurred charges totaling \$99,146 (CAD\$112,500) in respect of this agreement.

**June 2014 Stock Incentive Plan**

On June 18, 2014, our Board of Directors authorized and approved the adoption of the 2014 Plan, effective June 18, 2014, under which an aggregate of 12,108,016 shares of our common stock may be issued. The purpose of the 2014 Plan is to enhance our long-term stockholder value by offering opportunities to our directors, officers, employees and eligible consultants to acquire and maintain stock ownership in order to give these persons the opportunity to participate in our growth and success, and to encourage them to remain in our service. Pursuant to the terms of the 2014 Plan, we are authorized to grant stock options, as well as awards of stock appreciation rights, restricted stock, unrestricted shares, restricted stock units and deferred stock units.

The foregoing summary of the 2014 Plan is not complete and is qualified in its entirety by reference to the 2014 Plan.

### Outstanding Equity Awards at Fiscal Year-End

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date
Marco Babini	-	-	-	-
Philippe Deschamps	600,000	1,200,000 <sup>(1)</sup>	\$ 0.55 <sup>(2)</sup>	06/18/2019
Jonathan Sackier	100,000	300,000 <sup>(3)</sup>	\$ 2.58 <sup>(4)</sup>	12/08/2019

(1) 600,000 options will vest on each of June 19, 2015 and June 19, 2016.

(2) The option exercise price of CAD\$0.60 was converted from Canadian dollars to U.S. dollars based on the Bank of Canada nominal noon exchange rate on June 19, 2014 (the grant date) of CAD\$1.00 = USD\$0.9235.

(3) 100,000 options will vest on each of June 8, 2015, December 8, 2015 and June 8, 2016.

(4) The option exercise price of CAD\$2.96 was converted from Canadian dollars to U.S. dollars based on the Bank of Canada nominal noon exchange rate on December 8, 2014 (the grant date) of CAD\$1.00 = USD\$0.8717.

### Director Compensation

Name	Option Awards (\$)	All Other Compensation (\$)	Total Compensation (\$)
Savio Chiu	22,146 <sup>(1)</sup>	-	22,146
Yuri Danilov	147,639 <sup>(2)</sup>	8,250 <sup>(6)</sup>	155,889
Mitch Tyler	147,639 <sup>(3)</sup>	19,950 <sup>(6)</sup>	167,589
Edward Straw	246,051 <sup>(4)</sup>	-	246,051
Joyce LaViscount	224,585 <sup>(5)</sup>	-	224,585

(1) Mr. Chiu had 60,000 options outstanding as of March 31, 2015, of which 40,000 were not vested. The grant date fair value was denominated in Canadian dollars and converted into U.S. dollars using the Bank of Canada nominal noon exchange rate on June 19, 2014 (the grant date) of CAD\$1.00 = USD\$0.9235.

(2) Mr. Danilov had 400,000 options outstanding as of March 31, 2015, of which 266,666.67 were not vested. The grant date fair value was denominated in Canadian dollars and converted into U.S. dollars using the Bank of Canada nominal noon exchange rate on June 19, 2014 (the grant date) of CAD\$1.00 = USD\$0.9235.

(3) Mr. Tyler had 400,000 options outstanding as of March 31, 2015, of which 266,666.67 were not vested. The grant date fair value was denominated in Canadian dollars and converted into U.S. dollars using the Bank of Canada nominal noon exchange rate on June 19, 2014 (the grant date) of CAD\$1.00 = USD\$0.9235.

(4) Mr. Straw had 100,000 options outstanding as of March 31, 2015, of which 66,666.67 were not vested. The grant date fair value was denominated in Canadian dollars and converted into U.S. dollars using the Bank of Canada nominal noon exchange rate on December 8, 2014 (the grant date) of CAD\$1.00 = USD\$0.8717.

(5) Ms. LaViscount had 100,000 options outstanding as of March 31, 2015, of which 66,666.67 were not vested. The grant date fair value was denominated in Canadian dollars and converted into U.S. dollars using the Bank of Canada nominal noon exchange rate on March 16, 2015 (the grant date) of CAD\$1.00 = USD\$0.7834.

(6) These amounts were paid pursuant to a consulting agreement between each of Messrs. Danilov and Tyler and us. See "Item 13. Certain Relationships and Related Transactions, and Director Independence—Related Party Transactions" for a description of each agreement.

## Narrative Disclosure to Director Compensation Table

During the fiscal year ended March 31, 2015, our directors did not receive any fees for their service. Instead, we granted each director stock options. We granted 60,000; 400,000; 400,000; 100,000 and 100,000 options to Messrs. Chiu, Danilov, Tyler and Straw and Ms. LaViscount, respectively. Messrs. Chiu, Danilov and Tyler's options expire on June 18, 2019 and have an exercise price of CAD\$0.60. Mr. Straw's options expire on December 8, 2019 and have an exercise price of CAD\$2.92. Ms. LaViscount's options expire on March 15, 2020 have an exercise price of CAD\$3.20.

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

The following table sets forth certain information concerning the number of shares of our common stock owned beneficially as of June 26, 2015 by: (i) each person (including any group) known to us to beneficially own more than 5% of our shares of common stock; (ii) each of our directors; (iii) each of our named executive officers; and (iv) our executive officers and directors as a group. To our knowledge, each holder listed possesses sole voting and investment power with respect to the shares shown.

<u>Title of class</u>	<u>Name and address of beneficial owner</u>	<u>Amount and nature of beneficial owner</u>	<u>Percentage of class<sup>(1)</sup></u>
<i>Officers and Directors</i>			
Common Stock	Marco Babini (former CEO) <sup>(2)</sup>	671,600	1.0%
Common Stock	Philippe Deschamps	1,204,700 <sup>(3)</sup>	1.8%
Common Stock	Jonathan Sackier	200,000 <sup>(4)</sup>	(*)
Common Stock	Savio Chiu	40,000 <sup>(5)</sup>	(*)
Common Stock	Yuri Danilov	266,667 <sup>(6)</sup>	(*)
Common Stock	Mitch Tyler	266,667 <sup>(7)</sup>	(*)
Common Stock	Edward Straw	33,334 <sup>(8)</sup>	(*)
Common Stock	Joyce LaViscount	33,334 <sup>(9)</sup>	(*)
Common Stock	All executive officers and directors as a group (8 persons)	2,084,702 <sup>(10)</sup>	3.2%
<i>Persons owning more than 5% of voting securities</i>			
Common Stock	MPJ Healthcare, LLC 208 Palmer Aly Newtown, PA 18940	16,035,026 <sup>(11)</sup>	25.1%
Common Stock	Advanced NeuroRehabilitation, LLC 510 Charmany Dr., Suite 175F Madison, WI 53719	16,035,026 <sup>(12)</sup>	25.1%

(\*) indicates less than 1%.

<sup>(1)</sup> Based on 63,918,461 shares of our common stock issued and outstanding as of May 1, 2015.

<sup>(2)</sup> Mr. Babini resigned as our CEO, President and a director on June 13, 2014.

<sup>(3)</sup> This figure includes 1,200,000 stock options which are immediately exercisable or which will become exercisable within 60 days.

<sup>(4)</sup> This figure includes 200,000 stock options which are immediately exercisable or which will become exercisable within 60 days.

<sup>(5)</sup> This figure includes 40,000 stock options which are immediately exercisable or which will become exercisable within 60 days.

<sup>(6)</sup> This figure includes 266,667 stock options which are immediately exercisable or which will become exercisable within 60 days.

<sup>(7)</sup> This figure includes 266,667 stock options which are immediately exercisable or which will become exercisable within 60 days.

<sup>(8)</sup> This figure includes 33,334 stock options which are immediately exercisable or which will become exercisable within 60 days.

<sup>(9)</sup> This figure include 33,334 stock options which are immediately exercisable or which will become exercisable within 60 days.

(10) This figure includes 2,080,002 stock options, which are immediately exercisable or which will become exercisable within 60 days.

(11) Investment and voting decisions for the shares held by MPJ Healthcare, LLC are made by a board of three members, each holding one vote. The three board members are Philippe Deschamps, Jonathan Sackier and Montel Williams. This amount includes 12,026,270 shares held in escrow. The holder has only voting power and no investment power with respect to the escrowed shares.

(12) Investment and voting decisions for shares held by Advanced NeuroRehabilitation, LLC are made by Kurt Kaczmarek, as the managing member. This amount includes 12,026,270 shares held in escrow. The holder has only voting power and no investment power with respect to the escrowed shares.

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

Except as described below, there are no transactions since the beginning of our last fiscal year, or any currently proposed transactions, in which we were or are to be a participant where the amount involved exceeds \$120,000 and in which any “related person” had or will have a direct or indirect material interest. “Related person” includes:

- (a) any of our directors or executive officers;
- (b) any person proposed as a nominee for election as a director;
- (c) any person who beneficially owns more than 5% of our common stock; or
- (d) any child, stepchild, parent, stepparent, spouse, sibling, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, sister-in-law or person (other than a tenant or employee) sharing the same household of any person enumerated in paragraph (a), (b) or (c).

#### **Related Party Transactions**

##### *Agreement and Plan of Merger with NHC*

On June 6, 2014, we entered into an Agreement and Plan of Merger among us, HMT Mergersub, Inc., our wholly-owned subsidiary, and NHC. Pursuant to the Agreement and Plan of Merger we issued 35,300,083 shares of our common stock to the shareholders of NHC. Two of the shareholders of NHC that received 16,035,026 shares each were MPJ Healthcare, LLC and ANR. Messrs. Philippe Deschamps, our President, CEO and director, and Jonathan Sackier, our Chief Medical Officer, are shareholders of MPJ Healthcare, LLC, and Messrs. Yuri Danilov and Mitch Tyler, two of our directors, are shareholders of ANR.

##### *Sublicense Agreement with Advanced Rehabilitation, LLC*

Pursuant to the Second Sublicense Agreement, ANR has granted NHC a worldwide, exclusive license to make, have made, use, lease and sell devices utilizing the Patent Pending Rights. In addition, ANR has agreed that ownership of any improvements, enhancements or derivative works of the Patent Pending Rights which 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 collection 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. Messrs. Yuri Danilov and Mitch Tyler, two of our directors, are shareholders of ANR.

##### *Consulting Agreement with Yuri Danilov*

On July 1, 2014, Mr. Danilov entered into a consulting agreement, or the Danilov Consulting Agreement, with NHC to provide consulting services in relation to the development of the PoNS™ technology. The Danilov Consulting Agreement is valid for a period of 12 months and Mr. Danilov will charge an hourly fee of \$150 per hour or \$1,000 per day if 8 or more hours are worked. Pursuant to the Danilov Consulting Agreement, Mr. Danilov will be an independent contractor and subject to the confidentiality provisions contained in the Danilov Consulting Agreement. The Company incurred charges from Mr. Danilov totaling \$8,250 for the year ended March 31, 2015 in respect of this agreement

On December 10, 2014, Mr. Tyler entered into a consulting agreement, or the Tyler Consulting Agreement, with NHC to provide consulting services in relation to the development of the PoNS™ technology. The Tyler Consulting Agreement is valid for a period of 12 months and Mr. Tyler will charge an hourly fee of \$150 per hour or \$1,000 per day if 8 or more hours are worked. Pursuant to the Tyler Consulting Agreement, Mr. Tyler will be an independent contractor and subject to the confidentiality provisions contained in the Tyler Consulting Agreement. The Company incurred charges from Mr. Tyler totaling \$19,950 for the year ended March 31, 2015 in respect of this agreement.

### Review, Approval and Ratification of Related Party Transactions

Our Board of Directors has responsibility for establishing and maintaining guidelines relating to any related party transactions between us and any of our officers or directors. Any conflict of interest between a related party and us must be referred to the non-interested directors, if any, for approval. We intend to adopt written guidelines for the board of directors which will set forth the requirements for review and approval of any related party transactions.

### Director Independence

We believe that Savio Chiu, Joyce LaViscount and Edward Straw qualify as independent directors under the listing standards of the Nasdaq Capital Market. However, our Board of Directors has not made a formal determination on this matter.

### ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following are aggregate fees billed to us by BDO Canada LLP during the fiscal years ended March 31, 2015 and March 31, 2014:

	Fiscal Year Ended March 31, 2015	Fiscal Year Ended March 31, 2014
Audit Fees	\$ 86,715	Nil
Audit-Related Fees	Nil	Nil
Tax Fees	\$ 5,090	Nil
All Other Fees	—	—
Total Fees	<u>\$ 91,805</u>	<u>Nil</u>

### Audit Fees

Audit fees consist of fees billed for professional services rendered for the audit of our consolidated financial statements and review of the interim consolidated financial statements included in quarterly reports and services that are normally provided by BDO Canada LLP in connection with statutory and regulatory filings, our registration statements and securities offerings.

### Audit Related Fees

Audit-related fees are fees billed for assurance and related services that are reasonably related to the performance of the audit or review of our consolidated financial statements and are not reported under "Audit Fees."

## Tax Fees

Tax fees consist of fees billed for professional services for tax compliance, tax advice and tax planning. These services include assistance regarding federal, state and tax compliance, customs and duties, mergers and acquisitions and tax planning.

## All Other Fees

All other fees consist of fees for products and services other than the services reported above.

A majority of our independent directors, or the independent director to whom such authority was delegated by the independent directors, must pre-approve all services provided by the independent registered public accounting firm.

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## PART IV

### ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

The following documents are filed as part of this annual report:

1. Financial Statements—See the Index to Consolidated Financial Statements on Page F-1.
2. Financial Statement Schedules—None. We have omitted financial statement schedules because they are not required or are not applicable, or the required information is shown in the consolidated financial statements or notes to the consolidated financial statements.
3. Exhibits.

<u>Exhibit No.</u>	<u>Description of Exhibit</u>
2.1	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 Securities and Exchange Commission on July 14, 2014)
3.1	Articles of Continuation (incorporated by reference to Exhibit 3.1 to the Form S-1 filed with the Securities and Exchange Commission 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 Securities and Exchange Commission 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 on May 4, 2015)
3.4	Bylaws (incorporated by reference to Exhibit 3.3 to the Form S-1 filed with the Securities and Exchange Commission on July 14, 2014)
3.5	First Amendment to the Bylaws (incorporated by reference to Exhibit 3.4 to the Amendment to Form S-1 filed with the Securities and Exchange Commission on September 23, 2014)
3.6	Second Amendment to the Bylaws (incorporated by reference to Exhibit 3.3 to amendment no. 1 to the Form 10 filed on May 4, 2015)
10.1	2014 Stock Incentive Plan (incorporated by reference to Exhibit 4.1 to the Form S-1 filed with the Securities and Exchange Commission on July 14, 2014)
10.2	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 Securities and Exchange Commission on July 14, 2014)
10.3	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 Securities and Exchange Commission on September 23, 2014)
10.4	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 Securities and Exchange Commission on April 15, 2015)
10.5	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 Securities and Exchange Commission on September 23, 2014)
10.6	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 Securities and Exchange Commission on February 6, 2015)
10.7	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 Securities and Exchange Commission on July 14, 2014)
10.8	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 Securities and Exchange Commission on September 23, 2014)
10.9	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 Securities and Exchange Commission on July 14, 2014)



10.10	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 Securities and Exchange Commission on July 14, 2014)
10.11	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 Securities and Exchange Commission on July 14, 2014)
10.12	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 Securities and Exchange Commission on July 14, 2014)
10.13	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 Securities and Exchange Commission on February 6, 2015)
10.14	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 Securities and Exchange Commission on July 14, 2014)
10.15	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 Securities and Exchange Commission on July 14, 2014)
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 Securities and Exchange Commission on April 15, 2015)
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.
<a href="#">23.1</a>	<a href="#">Consent of Davidson &amp; Company LLP (filed herewith)</a>
<a href="#">23.2</a>	<a href="#">Consent of BDO Canada LLP (filed herewith)</a>
<a href="#">31.1</a>	<a href="#">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 (filed herewith)</a>
<a href="#">31.2</a>	<a href="#">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 (filed herewith)</a>
<a href="#">32.1</a>	<a href="#">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 (filed herewith)</a>

## INDEX TO FINANCIAL STATEMENTS

<a href="#">BDO CANADA LLP REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM</a>	<a href="#">F-2</a>
<a href="#">DAVIDSON &amp; CO. REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM</a>	<a href="#">F-3</a>
<a href="#">CONSOLIDATED BALANCE SHEETS</a>	<a href="#">F-5</a>
<a href="#">CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS</a>	<a href="#">F-6</a>
<a href="#">CONSOLIDATED STATEMENTS OF CAPITAL DEFICIT</a>	<a href="#">F-7</a>
<a href="#">CONSOLIDATED STATEMENTS OF CASH FLOWS</a>	<a href="#">F-8</a>
<a href="#">NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS</a>	<a href="#">F-9</a>

## 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, 2015 and the related consolidated statements comprehensive loss, capital (deficit), and cash flows for the year then ended. 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 March 31, 2015, 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 accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As described in Note 2 to the consolidated financial statements, the Company incurred a net loss of \$8,894,555 for the year ended March 31, 2015, had an accumulated deficit of \$18,479,689 at March 31, 2015 and the Company expects to incur further losses in the development of its business. These conditions raise 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 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

*/s/ BDO CANADA LLP*

Chartered Accountants

Vancouver, Canada  
June 21, 2015

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Shareholders and Directors of  
Helius Medical Technologies, Inc.  
(formerly NeuroHabilitation Corporation)

We have audited the accompanying financial statements of Helius Medical Technologies, Inc. (formerly NeuroHabilitation Corporation) (the "Company"), which comprise the balance sheet of Helius Medical Technologies, Inc. as of March 31, 2014 and the related statements of loss and comprehensive loss, stockholders' equity (deficiency), and cash flows for the year ended March 31, 2014, and the period from inception on January 22, 2013 to March 31, 2013. 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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes 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 provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Helius Medical Technologies, Inc. as of March 31, 2014, and the results of its operations and its cash flows for the year ended March 31, 2014, and the period from inception on January 22, 2013 to March 31, 2013 in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that Helius Medical Technologies, Inc. will continue as a going concern. As discussed in Note 2 to the financial statements, Helius Medical Technologies, Inc. has suffered recurring losses from operations and has a net capital deficiency. These matters, along with the other matters set forth in Note 2, indicate the existence of material uncertainties that raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**"DAVIDSON & COMPANY LLP"**

Vancouver, Canada

Chartered Accountants

January 30, 2015



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Telephone (604) 687-0947 Fax (604) 687-6172

**HELIUS MEDICAL TECHNOLOGIES, INC.**  
**CONSOLIDATED FINANCIAL STATEMENTS**  
**March 31, 2015 and 2014**  
(Expressed in United States Dollars)

**Helius Medical Technologies, Inc.**  
**Consolidated Balance Sheets**  
March 31, 2015 and 2014  
(Expressed in United States Dollars)

	2015	2014
	\$	\$
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	418,893	15,968
Short-term investment	378,000	-
Receivables	8,833	-
Prepaid expenses (Note 8)	410,621	300,000
<b>Total current assets</b>	<b>1,216,347</b>	<b>315,968</b>
<b>TOTAL ASSETS</b>	<b>1,216,347</b>	<b>315,968</b>
<b>LIABILITIES</b>		
Current liabilities		
Accounts payable and accrued liabilities	1,197,804	215,921
Convertible debenture (Note 4)	-	368,024
<b>Total current liabilities</b>	<b>1,197,804</b>	<b>583,945</b>
Derivative liability (Note 2)	1,581,444	-
<b>TOTAL LIABILITIES</b>	<b>2,779,248</b>	<b>583,945</b>
<b>CAPITAL (DEFICIT)</b>		
Common stock (Unlimited Class A common shares authorized); (63,104,788 shares outstanding at March 31, 2015 and 32,070,052 at March 31, 2014) (Note 5)		
	16,358,093	8,510,000
Additional paid-in capital (Note 5)	1,490,790	807,157
Shares to be issued	39,545	-
Accumulated other comprehensive income	(971,640)	-
Accumulated deficit	(18,479,689)	(9,585,134)
<b>TOTAL SHAREHOLDERS' EQUITY (CAPITAL DEFICIT)</b>	<b>(1,562,901)</b>	<b>(267,977)</b>
<b>TOTAL LIABILITIES &amp; CAPITAL (DEFICIT)</b>	<b>1,216,347</b>	<b>315,968</b>

Nature and continuance of operations (Note 1)  
Commitment and contingencies (Note 8)  
Subsequent events (Note 11)

These financial statements are authorized for issue by the Board of Directors:

"Philippe Deschamps "

Director

"Savio Chiu "

Director

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

**Helius Medical Technologies Inc.****Consolidated Statements of Comprehensive Loss**

for the years ended March 31, 2015 and 2014 and for the period from January 22, 2013 (date of inception) to March 31, 2013  
(Expressed in United States Dollars)

	2015	2014	2013
	\$	\$	\$
<b>Operating Expenses</b>			
Advertising, marketing, & IR	774,400	-	
Audit & accounting	71,340	-	
Consulting fees	1,085,606	807,385	4,252,800
Insurance	75,425	-	
Legal fees	1,478,766	33,966	14,192
Meals & travel	272,338	22,860	376
Office & general	166,282	8,137	482
Professional fees	14,136	-	-
Research & development	3,828,775	171,781	4,250,000
Transfer agent & regulatory	104,214	-	
Wages and salaries	993,400	23,155	
<b>Loss from operations</b>	<b>(8,864,682)</b>	<b>(1,067,284)</b>	<b>(8,517,850)</b>
<b>Other items</b>			
Interest expense	(176,488)	-	-
Interest income	20,074	-	-
Change in fair value of derivative liability	(739,375)	-	-
Foreign exchange gain (loss)	865,916	-	-
	(29,873)	-	-
<b>Net loss for the period</b>	<b>(8,894,555)</b>	<b>(1,067,284)</b>	<b>(8,517,850)</b>
<b>Other comprehensive income (loss)</b>			
Translation adjustments	(971,640)	-	-
<b>Comprehensive loss for the period</b>	<b>(9,866,195)</b>	<b>(1,067,284)</b>	<b>(8,517,850)</b>
<b>Basic and diluted loss per common stock</b>	<b>(0.16)</b>	<b>(0.03)</b>	<b>(0.27)</b>
<b>Weighted average number of common stock outstanding – basic &amp; diluted</b>	<b>57,048,406</b>	<b>32,070,052</b>	<b>32,070,052</b>

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

**Helius Medical Technologies Inc.****Consolidated Statements of Capital (Deficit)**for the years ended March 31, 2015 and 2014 and for the period from January 22, 2013 (date of inception) to March 31, 2013  
(Expressed in United States Dollars)

	Common Stock	Amount \$	Additional Paid-In Capital \$	Shares to be Issued \$	Accumulated Deficit \$	Accumulated other comprehensive income (loss) \$	Capital (Deficit) \$
<b>Balance at January 22, 2013 (date of inception)</b>	-	-	-	-	-	-	-
Shares issued for cash, intellectual property and services (Note 6)	32,070,052	8,510,000	-	-	-	-	8,510,000
Net loss for the period					(8,517,850)		(8,517,850)
<b>Balance – March 31, 2013</b>	<b>32,070,052</b>	<b>8,510,000</b>	<b>-</b>	<b>-</b>	<b>(8,517,850)</b>	<b>-</b>	<b>(7,850)</b>
Stock-based compensation on 654,481 options granted	-	-	173,873	-	-	-	173,873
Stock-based compensation on 2,300,000 options granted	-	-	560,082	-	-	-	560,082
Stock-based compensation on 275,550 options granted	-	-	73,202	-	-	-	73,202
Net loss for the year				-	(1,067,284)	-	(1,067,284)
<b>Balance – March 31, 2014</b>	<b>32,070,052</b>	<b>8,510,000</b>	<b>807,157</b>	<b>-</b>	<b>(9,585,134)</b>	<b>-</b>	<b>(267,977)</b>
Stock-based compensation on 2,300,000 options granted			50,303	-	-	-	50,303
Shares issued to consultant for option exercise (Note 6)	2,300,000	717	-	-	-	-	717
Shares issued to consultant for option exercise (Note 6)	930,031	290	-	-	-	-	290
Fair value of options allocated to share capital on exercise of options	-	857,460	(857,460)	-	-	-	-
Recapitalization of Helius Medical Technologies, Inc. (Note 3)	10,000,000	-	162,890	-	-	-	162,890



Issuance of common stock for private placement (Note 5)	15,240,000	6,437,041	578,961	-	-	-	7,016,002
Share issuance cost (Note 5)	-	(447,515)	67,709	-	-	-	(379,806)
Beneficial conversion feature (Note 4)	-	-	176,488	-	-	-	176,488
Stock-based compensation on 3,370,000 options granted (Note 6)	-	-	283,962	-	-	-	283,962
Conversion of debenture (Note 4)	2,564,705	1,000,100	-	-	-	-	1,000,100
Stock-based compensation on 100,000 options granted (Note 6)	-	-	74,190	-	-	-	74,190
Stock-based compensation on 100,000 options granted (Note 6)	-	-	43,229	-	-	-	43,229
Stock-based compensation on 400,000 options granted (Note 6)	-	-	135,564	-	-	-	135,564
Stock-based compensation on 100,000 options granted (Note 6)	-	-	41,987	-	-	-	41,987
Fair value of vested non-employee options reallocated to derivative liability	-	-	(74,190)	-	-	-	(74,190)
Private placement proceeds	-	-	-	39,545	-	-	39,545
Net loss for the year	-	-	-	-	(8,894,555)	-	(8,894,555)
Translation adjustments	-	-	-	-	-	(971,640)	(971,640)
<b>Balance – March 31, 2015</b>	<b>63,104,788</b>	<b>16,358,093</b>	<b>1,490,790</b>	<b>39,545</b>	<b>(18,479,689)</b>	<b>(971,640)</b>	<b>(1,562,901)</b>

**Helius Medical Technologies, Inc.****Consolidated Statements of Cash Flows**

for the years ended March 31, 2015 and 2014 and for the period from January 22, 2013 (date of inception) to March 31, 2013  
(Expressed in United States Dollars)

	2015 \$	2014 \$	2013 \$
<b>Cash flows from operating activities</b>			
Net loss for the period	(8,894,555)	(1,067,284)	(8,517,850)
Adjustments for:			
Change in fair value of derivative liability	739,375	-	-
Accretion of beneficial conversion feature	176,488	1,344	-
Stock-based compensation	1,397,114	807,157	8,500,000
Changes in non-cash working capital items:			
Receivables	(8,945)	-	-
Accounts payable	979,040	210,085	5,836
Prepaid expenses	(110,873)	(300,000)	-
Foreign exchange re-measurement	(598,929)	-	-
<b>Net cash used in operating activities</b>	<b>(6,321,285)</b>	<b>(348,698)</b>	<b>(12,014)</b>
<b>Cash flows from Investing Activities</b>			
Purchase of short-term investment	(378,000)	-	-
<b>Net cash used in Investing Activities</b>	<b>(378,000)</b>	<b>-</b>	<b>-</b>
<b>Cash flows from financing activities</b>			
Cash acquired on recapitalization	23,904	-	-
Proceeds from issuance of shares	7,017,009	-	10,000
Share issuance costs	(379,806)	-	-
Proceeds from shares to be issued	39,545	-	-
Proceeds from bridge loan	150,000	-	-
Short term loan	-	(2,231)	2,231
Proceeds from issuance of convertible debt	632,076	366,680	-
<b>Net cash provided by financing activities</b>	<b>7,482,728</b>	<b>364,449</b>	<b>12,231</b>
<b>Effect of Foreign Exchange Rate Changes on Cash</b>	<b>(380,518)</b>	<b>-</b>	<b>-</b>
<b>Net change in cash and cash equivalents</b>	<b>402,925</b>	<b>15,751</b>	<b>217</b>
<b>Cash and cash equivalents, beginning of the period</b>	<b>15,968</b>	<b>217</b>	<b>-</b>
<b>Cash and cash equivalents, end of the period</b>	<b>418,893</b>	<b>15,968</b>	<b>217</b>
<b>Supplemental information of cash flows</b>			
Interest paid in cash	11,144	-	-
Income taxes paid in cash	-	-	-
	<b>11,144</b>	<b>-</b>	<b>-</b>

Supplemental Cash Flow Information – Note 10

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

**1. NATURE AND CONTINUANCE OF OPERATIONS**

Helius Medical Technologies, Inc. (“Helius” or the “Company”) is in the development stage and 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.

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’s head office is located at 41 University Drive, Suite 400, Newtown, PA, USA 18940.

The Company is listed on the Canadian Securities Exchange (the “CSE”) and began trading on June 23, 2014, under the ticker symbol “HSM”. 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, Helius 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 Helius. 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.

The Company had a wholly-owned subsidiary, 0995162 B.C. Ltd, which was dissolved on October 23, 2014. 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.

**2. SIGNIFICANT ACCOUNTING POLICIES**

**Basis of Presentation and Liquidity**

The Company’s consolidated financial statements have been presented in accordance with U.S. generally accepted accounting principles (“U.S. GAAP”) and the rules and regulations of the Securities and Exchange Commission (“SEC”) that are published at the time of preparation and that are effective or available on March 31, 2015. The Company has incurred a net loss of \$8,894,555 for the year ended March 31, 2015 and, as of March 31, 2015, the Company has an accumulated deficit of \$18,479,689 (March 31, 2014 - \$9,585,134; March 31, 2013 - \$8,517,850). Until the Company generates a level of revenue to support its cost structure, the Company expects to continue to incur substantial operating losses and net cash outflows. While the Company had cash and cash equivalents of \$418,893 as of March 31, 2015 (March 31, 2014 - \$15,968), management does not believe these resources will be sufficient to meet the Company’s operating and capital needs for the ensuing fiscal year.

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 an intellectual property asset. This material uncertainty gives rise to substantial doubt about the Company’s ability to continue as a going concern.

**Use of Estimates**

The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and reported amounts of expenses during the reporting period. Significant estimates include valuation of share-based payment transactions, compensation expense related to shares issued for services, valuation of options and warrants and deferred income tax asset valuation allowances. Actual outcomes could differ from these estimates. Financial statements include estimates which, by their nature, are uncertain. The impacts of such estimates are pervasive throughout the financial statements, and may require accounting adjustments based on future occurrences. Revisions to accounting estimates are recognized in the period in which the estimate is revised and the revision affects both the current and future periods.

## **Principles of Consolidation**

The consolidated financial statements include the historic accounts of Neuro and are consolidated with Helius and its subsidiaries beginning June 13, 2014. All intercompany balances and transactions have been eliminated in consolidation.

## **Cash and Cash Equivalents**

Cash and cash equivalents comprise cash at banks and on hand, and short-term highly liquid investments that have an insignificant interest rate risk and an original maturity of 3 months or less.

## **Short-term investment**

The short-term investments are readily redeemable term deposits held at the Company's financial institution. As at March 31, 2015, the short-term investment consists of a one year guaranteed investment certificate ("GIC") in the amount of \$378,000 yielding 0.25% per annum. Due to the Company's intention to have the short-term investment available for liquidity purposes, it has been classified as available-for-sale and recorded at its fair value. Any unrealized gains or losses are excluded from earnings and are recorded in other comprehensive income.

## **Concentrations of Credit Risk**

Financial instruments that potentially subject the Company to credit risk consist principally of cash and its short-term investments. The Company is not currently exposed to any significant concentrations of credit risk from these financial instruments. The Company seeks to maintain the safety of its investments and diversify its risk, while maintaining sufficient liquidity of its investments to meet its cash flow requirements while receiving a competitive after-tax rate of return.

## **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 using the accelerated attribution method.

Stock-based payments to non-employees are measured at the fair value of the consideration received, 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 accounts for the granting of share purchase 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 share purchase options are expensed over their vesting period with a corresponding increase to additional capital surplus. Upon exercise of share purchase 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. Share purchase 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.

The Company uses the Black-Scholes option pricing model to calculate the fair value of share purchase options. Option pricing models require the input of highly subjective assumptions, including the expected price volatility. Changes in these assumptions can materially affect the fair value estimate.

## **Foreign Exchange**

The functional currency of the Company and Helius Canada is the Canadian Dollar and the functional currency of Neuro is the U.S. Dollar. The Company's reporting currency is the U.S. dollar.

The assets and liabilities of the Company and Helius Canada are translated into U.S. dollars using year-end exchange rates; income and expenses are translated using the average exchange rates for the reporting period. Unrealized foreign currency translation adjustments are deferred in accumulated other comprehensive loss, a separate component of shareholders' equity.

The foreign exchange adjustment in the books of Neuro relating to inter-company advances from Helius that are denominated in Canadian dollars is recorded in the Statements of Loss. At March 31, 2015, Neuro recorded a foreign exchange gain of \$573,917 in respect of this adjustment which is reflected in the consolidated statement of loss for the year ended March 31, 2015.

### Net Loss per Common Share

Basic net earnings (loss) per share is computed by dividing net earnings (loss) available to common stockholders by the weighted average number of outstanding common stock for the period, without consideration for common stock equivalents. Diluted net income (loss) per common share includes both the weighted-average number of common shares outstanding for the period plus the potentially dilutive securities from stock options and warrants outstanding determined using the treasury-stock method and the if-converted method, as applicable. As at March 31, 2015, there were 4,920,000 options (March 31, 2014 – 3,230,031; March 31, 2013- nil) outstanding and 8,444,400 warrants (March 31, 2014 – nil; March 31, 2013 - nil) outstanding which have not been included in the weighted average common stock outstanding as these were anti-dilutive.

### Fair Value of Financial Assets and Liabilities

The Company’s financial instruments consist primarily of cash and cash equivalents, short-term investment and 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 quoted prices included within Level 1 that are either directly or indirectly observable; and

Level 3 – Unobservable inputs that are supported by little or no market activity, therefore requiring an entity to develop its own assumptions about the assumptions that market participants would use in pricing.

Cash and cash equivalents and short-term investment are measured using Level 1 inputs.

The Company had certain Level 3 liabilities required to be recorded at fair value on a recurring basis in accordance with US GAAP as at March 31, 2015. As at March 31, 2015, the Company’s Level 3 liabilities consisted of the grant of share purchase options to non-employees. The resulting Level 3 liabilities have no active market and are required to be measured at their fair value each reporting period based on information that is unobservable.

A summary of the Company’s Level 3 liabilities for the fiscal years ended March 31, 2015 and 2014 are as follows:

	March 31, 2015	March 31, 2014
	\$	\$
Non-employee options (Note 6(a))		
Beginning fair value	-	-
Issuance	767,879	-
Reallocation of vested non-employee options	74,190	-
Change in fair value	739,375	-
Ending fair value of Level 3 liability	1,581,444	-

Certain assets and liabilities are measured at fair value on a nonrecurring basis; that is, the instruments are not measured at fair value on an ongoing basis but are subject to fair value adjustments only in certain circumstances (for example, when there is evidence of impairment). There were no assets or liabilities measured at fair value on a nonrecurring basis during the periods ended March 31, 2015 and 2014.

## 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 FASB ASC 740 "Income Taxes" regarding accounting for uncertainty in income taxes. The Company initially recognizes tax provisions 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. When applicable, the Company classifies penalties and interest associated with uncertain tax positions as a component of income tax expense in its consolidated Statement of Income (Loss) and Comprehensive Income (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 and materials and supplies. R&D costs are charged to operations when they are incurred.

## 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. 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 statement of 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 reassessed 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 settlement of the derivative instrument is expected within 12 months of the balance sheet date.

The Company uses the Black-Scholes option valuation model to value derivative liabilities. This model uses Level 3 inputs in the fair value hierarchy established by ASC 820 Fair Value Measurement.

## Recent Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") No. 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, which for the Company is April 1, 2017. Early adoption is permitted. The Company does not intend to early adopt this standard. The adoption of this standard will not have a material impact on the Company's financial position or results of operations.

In June 2014, the FASB issued ASU No. 2014-10, "Development Stage Entities" ("ASU 2014-10") which removes the definition of a development stage entity from the Master Glossary of the Accounting Standards Codification, thereby removing the financial reporting distinction between development stage entities and other reporting entities from U.S. GAAP. In addition, the update eliminates the requirements for development stage entities to (1) present inception-to-date information in the statements of income, cash flows, and shareholder equity, (2) label the financial statements as those of a development stage entity, (3) disclose a description of the development stage activities in which the entity is engaged, and (4) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage. ASU No. 2014-10 is effective for fiscal years and interim periods beginning after December 15, 2014, with early adoption permissible. The Company early adopted ASU 2014-10 allowing the financial statements to be cast without the inception to date information and without references to the development stage.

The amendments also clarify that the guidance in Topic 275, *Risks and Uncertainties*, is applicable to entities that have not commenced planned principal operations. The central feature of the guidance disclosure requirements is that required disclosures are limited to matters significant to a particular entity. The disclosures focus primarily on risks and uncertainties that could significantly affect the amounts reported in the financial statements in the near term or the near-term functioning of the reporting entity.

In June 2014, the FASB issued ASU No. 2014-12, *Compensation - Stock Compensation (Topic 718): Accounting for Share-Based Payments When the Terms of an Award Provide that a Performance Target Could be Achieved after the Requisite Service Period*. This update requires that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. As such, the performance target should not be reflected in estimating the grant date fair value of the award. This update further clarifies that compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the periods for which the requisite service has already been rendered. This update is effective for annual reporting periods (including interim reporting periods within those periods) beginning after December 15, 2015, which for the Company is April 1, 2016. Early adoption is permitted. Entities may apply the amendments in this update either: (a) prospectively to all awards granted or modified after the effective date; or (b) retrospectively to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements and to all new or modified awards thereafter. The adoption of this standard will not have a material impact on the Company's financial position or results of operations.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*. This update outlines a new, single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. This new revenue recognition model provides a five-step analysis in determining when and how revenue is recognized. The new model will require revenue recognition to depict the transfer of promised goods or services to customers in an amount that reflects the consideration a company expects to receive in exchange for those goods or services. This new guidance is effective for annual reporting periods (including interim reporting periods within those periods) beginning after December 15, 2016, which for the Company is April 1, 2017; early adoption is not permitted. Entities have the option of using either a full retrospective or a modified approach to adopting the guidance. The Company does not anticipate that the adoption of this update will have a material impact on its financial position or results of operations.

### 3. RECAPITALIZATION

On June 13, 2014 the Company completed a recapitalization transaction where the Company acquired 100% of the issued and outstanding shares of Neuro. In exchange, the Company issued a total of 35,300,083 shares to the shareholders of Neuro which merged with a wholly-owned subsidiary of the Company, HMT Mergersub, for the purpose of the three-corner amalgamation. As a result, the former Neuro shareholders owned the majority of the outstanding shares of the Company upon completion of the transaction. Prior to the recapitalization transaction, the Company did not meet the definition of a business. Thus, the transaction is considered to be a capital transaction of Neuro accompanied by a recapitalization.

The ongoing Company has adopted the name Helius Medical Technologies, Inc. These financial statements present the results of Neuro with the exception of common stock which has been retroactively restated to reflect the Recapitalization (see Note 6). In connection with the Recapitalization, the Company advanced Neuro an unsecured loan in the amount of \$150,000 (the "Bridge Loan"). The Bridge Loan was for a term of one year commencing on May 30, 2014, and was payable in a lump sum at the end of the term. The Bridge Loan bears interest at a rate of 8% per annum.

The net assets of Helius acquired were as follows,

Cash and cash equivalents	\$	23,904
Receivables		1,644
Bridge loan receivable		150,000
Prepaid expenses		5,970
Accounts payable and accrued liabilities		(18,628)
	<u>\$</u>	<u>162,890</u>

The recapitalization transaction reflects a credit to additional paid-in capital of \$162,890, the carrying value of the net assets of Helius at the time of the reverse merger.

In connection to the completion of the transaction, the Company completed a private placement of 15,240,000 units at CAD \$0.50 per unit for a total of \$7,016,002 (CAD \$7,620,000) (Note 5). Each unit consisted of one common share of the Company and one-half of a share purchase warrant. Each whole share purchase warrant is exercisable at CAD \$1.00 for a period of twenty-four months. In respect of this private placement, the Company paid aggregate finders' fees of \$379,806 (CAD \$412,200) and issued 824,400 finders' warrants. Each finder's warrant is exercisable at CAD \$1.00 per share for a period of two years.

#### 4. CONVERTIBLE DEBENTURE

On February 19, 2014, the Company entered into a securities purchase agreement where the Company agreed to sell and issue a note with annual simple interest at 8% (the "Debenture"). A total of \$1,000,100 in principal had been received.

Upon completion of a qualified financing in which the Company was to raise at least \$2,000,000, the debenture would automatically convert into equity securities of the Company at a price per share equal to 85% of the price per share of the qualified financing. If a qualified financing did not occur on or before the maturity date, at the option of the Company's board of directors, the outstanding balance of the debenture would be converted into the Company's equity securities at a conversion price per common stock determined using a valuation of \$8.5 million and the number of shares outstanding at that date.

On June 13, 2014, the Debenture matured on the closing of the Company's qualified financing. Upon completion of the qualified financing, the Debenture automatically converted into equity securities of the Company at a price per share equal to 85% of the price per share of the qualified financing.

The conversion option of the Debenture was accounted for as a contingent beneficial conversion feature valued at \$176,488 which was recorded as interest expense in the Statement of Comprehensive Loss on settlement of the contingency.

Upon conversion of the Debenture, the Company issued a total of 2,564,705 common shares. In addition, the Company paid the Debenture holders \$11,131 with respect to the accrued and unpaid interest outstanding.

#### 5. COMMON STOCK

Authorized:

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. 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.

Class B common shares and Class A preferred shares were deleted from the list of classes of shares the Company is authorized to issue by way of amendment to the Company's articles effective June 12, 2014.

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.

##### *Prior to the Recapitalization*

The number of securities below reflects the Recapitalization and the exchange ratio retrospectively.

On January 22, 2013, the Company issued a total of 16,035,026 shares to Advanced NeuroRehabilitation LLC ("ANR") for cash proceeds of \$5,000 and an exclusive license right to ANR's patent pending technology and knowhow valued at \$4.25 million per an independent valuation report. The valuation expert was engaged to assess the valuation of the costs incurred to date as well as the ongoing costs which would be required to bring the product to commercialization, discounted to the date of purchase. The Company recorded the \$4.25 million exclusive license right as research and development expense per the Company's accounting policy.



On January 22, 2013, the Company also issued a total of 16,035,026 shares to MPJ Healthcare LLC (“MPJ”) for cash proceeds of \$5,000. In addition, the Company recorded \$4.25 million of stock based compensation expense.

On May 1, 2014, 2,300,000 options were exercised for 2,300,000 common shares for total proceeds of \$717.

On May 11, 2014, 930,031 options were exercised for 930,031 common shares for total proceeds of \$290.

In conjunction with the private placement completed on May 30, 2014 and recapitalization transaction completed on June 13, 2014 (Note 3), the Company entered into an escrow agreement with each of ANR, MPJ and the Company’s transfer agent whereby the 32,070,052 common shares issued to ANR and MPJ were placed in escrow in accordance with Canadian securities regulations. These shares were scheduled to be released from escrow over a period of 3 years from the date of the escrow agreement with 10% of the shares placed in escrow released on the completion date of the reverse merger and with 15% of the remaining outstanding balance of shares released every 6 months thereafter. The release of the escrow is not subject to any performance conditions and therefore not considered to be compensatory in nature. In addition, on their release, the value recorded in respect of these shares will not change and they are included in the calculation of earnings per share.

#### *After the Recapitalization*

Upon completion of the Recapitalization, the Company issued a total of 35,300,083 shares to the shareholders of Neuro. (Note 3)

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 (CAD \$7.62 million) on May 30, 2014 (Note 3). 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 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.

## **6. SHARE BASED PAYMENTS**

### **(a) Stock options**

The number of securities below reflects the Recapitalization and the exchange ratio retrospectively.

The Company has a stock option plan whereby the Company is authorized to grant up to 12,108,016 options. Vesting and the term of an option is determined at the discretion of the Board of Directors of the Company.

On April 1, 2013, the Company granted a consultant company 930,031 options for 10 years upon completion of certain services in accordance with a consulting agreement to lead the design and manufacturing program of the Company’s technology. On December 4, 2013, 654,481 options vested. On May 11, 2014, all these options had vested and were exercised for 930,031 common shares.

On October 30, 2013, the Company granted 2,300,000 options exercisable for 10 years to a consultant company for strategic business advisory services which are to vest upon completion of two milestones. On February 11, 2014, 1,150,000 options were vested upon completion of the first of the two milestones. On April 28, 2014, the remaining 1,150,000 options were vested upon completion of the second milestone. On May 1, 2014, all 2,300,000 options were exercised for 2,300,000 shares.

On June 19, 2014, the Company granted 3,520,000 options to directors, officers, and consultants exercisable at CAD \$0.60 for 5 years. One third of these options vested immediately upon granting. The remaining two thirds of the options will vest on June 19, 2015, and June 19, 2016 respectively.

On June 20, 2014, the Company granted 250,000 options to an investor relations consultant exercisable at CAD \$0.60 for 5 years. 12.5% of these options vested immediately upon granting. The remaining 87.5% will vest at a rate of 12.5% every three months beginning September 20, 2014.

On July 14, 2014, the Company granted 100,000 options to a consultant exercisable at CAD \$2.52 for 3 years. 25% of these options vested immediately upon granting. The remaining options will vest at a rate of 25% on September 30, 2014, December 31, 2014, and March 31, 2015, respectively.

On December 8, 2014, the Company granted 450,000 options to members of its scientific advisory board exercisable at CAD \$2.92 for 5 years. All of these options vested immediately upon granting.

On December 8, 2014, the Company granted 100,000 options to a new director exercisable at CAD \$2.92 for 5 years. One third of these options vested immediately upon granting. The remaining two thirds of the options will vest on December 8, 2015, and December 8, 2016 respectively.

On December 8, 2014, the Company granted 400,000 options to its new Chief Medical Officer exercisable at CAD \$2.96 for 5 years. 25% of these options vested immediately upon granting. The remaining options will vest at a rate of 25% on June 8, 2015, December 8, 2015, and June 8, 2016, respectively.

On March 16, 2015, the Company granted 100,000 options to a new director exercisable at CAD \$3.20 for 5 years. One third of these options vested immediately upon granting. The remaining two thirds of the options will vest on March 16, 2016, and March 16, 2017 respectively.

The continuity of stock options for the period ended March 31, 2015 and 2014 is as follows:

	Number	Weighted Average Exercise Price (CAD)	Aggregate Intrinsic Value (CAD)
Balance, March 31, 2013	-	-	-
Granted	3,230,031	\$ 0.0003	\$ -
Balance, March 31, 2014	3,230,031	\$ 0.0003	\$ -
Granted	4,920,000	\$ 1.14	\$ -
Exercised	(3,230,031)	\$ 0.0003	\$ -
Balance outstanding at March 31, 2015	4,920,000	\$ 1.14	\$ 10,120,000
Balance exercisable at March 31, 2015	2,015,001	\$ 1.41	\$ 7,757,667

The options outstanding and exercisable at March 31, 2015 are as follows:

Number of options	Expiry date	Options outstanding remaining contractual life (years)	Exercise Price (CAD)	Grant date fair value (CAD)	Number of options exercisable
3,520,000	June 18, 2019	4.22	\$ 0.60	\$ 0.23	1,173,333
250,000	June 20, 2019	4.22	\$ 0.60	\$ 0.23	125,000
100,000	July 14, 2017	2.29	\$ 2.52	\$ 1.06	100,000
450,000	December 8, 2019	4.69	\$ 2.92	\$ 1.65	450,000
100,000	December 8, 2019	4.69	\$ 2.92	\$ 1.49	33,334
400,000	December 8, 2019	4.69	\$ 2.96	\$ 1.56	100,000
100,000	March 16, 2020	4.96	\$ 3.20	\$ 1.61	33,334
4,920,000					2,015,001

The weighted average grant date fair value of stock options granted during the year ended March 31, 2015 of CAD\$0.54 was estimated using the Black-Scholes option pricing model with the following weighted average assumptions: stock price – CAD\$1.06; exercise price – CAD\$1.14; expected risk-free interest rate – 1.08%; expected life – 4.1 years; expected volatility – 67.85% and expected dividend rate – 0%. 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.

#### 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 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 accounted for as equity awards until the terms associated with their vesting requirements have been met.

The non-employee stock options are accounted for at their respective fair values and are summarized as follows for the years ended March 31, 2015 and 2014:

	2015	2014
	\$	\$
Fair value of non-employee options, beginning of the period	-	-
Fair value of non-employee options, at issuance	767,879	-
Reallocation of vested non-employee options	74,190	-
Change in fair value of non-employee stock options during the period	739,375	-
Fair value of non-employee options, end of the period	1,581,444	-

The non-employee options 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 Loss at the end of each reporting period. The fair value of the 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.

Stock-based compensation related to the grant of each of employee and non-employee options is summarized as follows for the years ended March 31, 2015 and 2014 and for the period from January 22, 2013 (date of inception) to March 31, 2013:

Date of grant	Number	2015	2014	2013
		\$	\$	\$
<i>Employee options</i>				
April 1, 2013	930,031	-	247,075	-
October 30, 2013	2,300,000	50,303	560,082	-
June 19, 2014	3,370,000	283,962	-	-
July 14, 2014	75,000	74,190	-	-
December 8, 2014	100,000	43,229	-	-
December 8, 2014	400,000	135,564	-	-
March 16, 2015	100,000	41,987	-	-
	7,275,031	629,235	807,157	-
<i>Options exercised</i>	(3,230,031)	-	-	-
	4,045,000			
<i>Non-employee options</i>				
June 19, 2014	400,000	97,094	-	-
July 14, 2014	25,000	24,730	-	-
December 8, 2014	450,000	646,055	-	-
	875,000	767,879	-	-
	4,920,000	1,397,114	807,157	-

Share-based payments are classified in the Company's Statement of Loss as follows for the years ended March 31, 2015 and 2014 and for the period from January 22, 2013 (date of inception) to March 31, 2013:

	2015	2014	2013
	\$	\$	\$
Consulting fees	894,817	807,157	4,250,000
Research and development	50,303	-	4,250,000
Wages and salaries	451,994	-	-
	1,397,114	807,157	8,500,000

At March 31, 2015, the aggregate unamortized stock based compensation cost remaining to be recognized totals \$1,021,495 with \$838,268 expected to be recognized in the year ended March 31, 2016 and \$183,227 expected to be recognized in the fiscal year ended March 31, 2017.

The Company used the Black Scholes option pricing model to estimate the fair value of the options as the fair value of the services provided could not be reliably calculated. The following assumptions were used:

		March 31, 2015	March 31, 2014
Stock Price	CAD\$	0.50 – 3.18	0.27
Exercise Price	CAD\$	0.60 – 3.20	0.0003
Risk-free interest rate (%)		0.53 – 1.42	1.20 – 1.65
Dividend yield (%)		0.00	0.00
Expected volatility (%)		67.85	97.73 – 116.82
Expected option life (years)		3.00 – 5.00	4.33 – 5.00

The Black Scholes option pricing model was developed for use in estimating the fair value of share options that have no vesting provisions and are fully transferable. Also, option-pricing models require the use of estimates and assumptions including the expected volatility. The Company uses expected volatility rates which are based upon the average volatility rates of other companies in the same industry, due to the Company's limited history. The Company based the current stock price on the value per shares issued to date. Changes in the underlying assumptions can materially affect the fair value estimates.

(b) **Share Purchase Warrants**

The Company closed its Private Placement at CAD \$0.50 per unit of 15,240,000 units raising CAD \$7.62 million 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 share.

The proceeds of the private placement were allocated between the common shares and the warrants on a relative fair value basis with an amount of \$578,961 allocated to the warrants. In addition, the Company issued 824,400 finder's warrants exercisable at CAD \$1.00 for 2 years. The fair value of the finders' warrants was determined to be \$67,709.

The fair values attributable to the warrants were determined by using the Black Scholes model based on the following assumptions:

Stock price	CAD\$0.50
Exercise price	CAD\$1.00
Risk-free interest rate (%)	1.09
Dividend yield (%)	-
Expected volatility (%)	67.85
Expected option life (years)	1.17

The continuity of warrants for the period ended March 31, 2015 and 2014 is as follows:

	Number of warrants	Warrants Outstanding Weighted Average Exercise Price
Balance, March 31, 2013 and 2014	-	\$ -
Granted	8,444,400	\$ CAD 1.00
Balance, March 31, 2015	8,444,400	\$ CAD 1.00

The warrants outstanding and exercisable at March 31, 2015 are as follows:

Number of warrants outstanding	Exercise Price (CAD)	Grant date	
		Fair value (CAD)	Expiry Date
7,620,000	\$ 1.00	\$ 0.0899	May 30, 2016
824,400	\$ 1.00	\$ 0.0899	May 30, 2016

## 7. INCOME TAXES

The components of net loss for the years ended March 31, 2015 and 2014 and for the period from January 22, 2013 (date of inception) to March 31, 2013 are as follows:

	2015 \$	2014 \$	2013 \$
U.S.	8,358,226	1,067,284	8,517,850
Non-U.S.	536,329	-	-
	8,894,555	1,067,284	8,517,750

A reconciliation of the income tax provision computed at statutory rates to the reported income tax provision for the years ended March 31, 2015 and 2014 is as follows:

	2015 \$	2014 \$	2013 \$
Statutory tax rate	34.00%	25.00%	25%
Loss before income taxes	(8,894,555)	(1,067,284)	(8,517,850)
Expected income tax recovery	(3,024,000)	(270,000)	(2,151,000)
Increase (decrease) in income tax recovery resulting from:			
Derivative liability	251,000	-	-
Share based payments	475,000	275,000	2,890,000
Other permanent difference	12,000	-	-
Share issue costs	(140,000)	-	-
Effect of change in statutory rate	(41,000)	(93,000)	(745,000)
Effect of foreign exchange	89,000	-	-
Foreign income taxed at foreign rate	14,000	-	-
Increase in valuation allowance	2,364,000	88,000	6,000
Income tax expense	-	-	-

The significant components of the Company's deferred income tax assets and liabilities after applying enacted corporate tax rates at March 31, 2015 and 2014 are as follows:

	2015 \$	2014 \$	2013 \$
Deferred income tax assets (liabilities)			
Operating losses carried forward	2,074,000	94,000	6,000
Intangible costs	285,000	-	-
Share issuance costs	99,000	-	-
Valuation allowance	(2,458,000)	(94,000)	(6,000)
Net deferred income tax asset	-	-	-

At March 31, 2015, the Company has accumulated non-capital losses totaling \$1,463,000 in Canada and net operating losses of \$5,853,000 in the USA, which are available to carry forward and offset future years' taxable income. The losses expire in various amounts from 2016 to 2034.

### *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. The Company is subject to tax examinations by tax authorities for all taxation years commencing after 2014.

At March 31, 2015, 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) The Company entered into a license agreement with ANR for an exclusive right on ANR's patent pending technology, claims and knowhow. In addition to the issuance of 16,035,026 shares (Note 5), 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.
- (b) On March 7, 2014, the Company entered into a commercial development-to-supply program with Ximedica where Ximedica will design, develop and produce PoNS product solution suitable for clinical trial and commercial sale. Under the program, the Company is responsible for ensuring the device is in compliance with relevant laws and regulations. The agreed budget for phase 1B of development is \$499,000; phase 2 is \$1,065,000; Phase 3 and 4 is \$1,389,000 and 2<sup>nd</sup> software development cycle is \$586,000, of which \$3,099,998 was expensed as research and development since inception to March 31, 2015. The estimated duration of the project is 10 months. Invoices are to be issued monthly for work in progress. The Company can cancel the project at anytime with a written notice at least 30 days prior to the intended date of cancellation. As of March 31, 2015, the Company recorded a prepaid expense of \$300,000 to Ximedica which will be applied at the end of the project. During the year ended March 31, 2015, the Company incurred charges of \$2,928,289 (March 31, 2014 - \$171,781) pursuant to this agreement.
- (c) On January 5, 2015, Wicab filed a complaint against us, two of our directors, Yuri Danilov and Mitch Tyler, and ANR in the U.S. District Court for the Western District of Wisconsin. The complaint contained various state and common law claims arising from Danilov's and Tyler's prior employment with Wicab and our two issued patents for the PoNS™ device. The complaint alleged, among other things, that following their departure from Wicab, Danilov and Tyler knowingly filed patent applications for and used ideas and inventions developed at Wicab in violation of various non-competition and confidentiality agreements, and that our two issued patents are therefore rightfully the property of Wicab. The complaint sought an unspecified amount of monetary damages, an injunction preventing us from using the ideas and inventions in the two patents, an order transferring ownership of the patents from us to Wicab, and recovery of costs and attorneys' fees. The complaint was voluntarily dismissed without prejudice on January 14, 2015.
- (d) On January 27, 2015 we received a demand letter containing allegations that we had entered into a consulting arrangement with the complainants and breached certain of its terms, and used certain intellectual property in the form of business and marketing plans allegedly prepared by the complainants, and seeking damages. On May 7, 2015, Mr. Rainier Maas and Dr. Jochen Scheld filed a complaint in the U.S. District Court for the Eastern District of Pennsylvania seeking monetary damages, and at this point management is unable to determine the outcome of this matter.

## **9. RELATED PARTY TRANSACTIONS**

For the year ended March 31, 2015, the Company was a party to the following related party transactions:

During the period ended March 31, 2015, the Company paid \$6,610 (March 31, 2014 - \$nil; March 31, 2013 - \$nil) in consulting fees to a former director of the Company.

During the period ended March 31, 2015, the Company paid \$47,100 (March 31, 2014 - \$nil; March 31, 2013 - \$nil) in consulting fees to directors of the Company.

During the period ended March 31, 2015, the Company paid \$99,146 (March 31, 2014 - \$nil; March 31, 2013 - \$nil) to a company acting as the Company's corporate advisor and Chief Financial Officer.

## 10. SUPPLEMENTAL CASH FLOW INFORMATION

Investing and financing activities that affect recognized assets or liabilities but that do not result in cash receipts or cash payments are excluded from the consolidated statements of cash flows. During the year ended March 31, 2015, the following transactions were excluded from the consolidated statement of cash flows:

- (a) The Company issued 2,564,705 common shares valued at \$1,000,100 based on the carrying value of the convertible debenture upon its conversion. (Note 4)
- (b) The Company recorded a beneficial conversion feature of \$176,488 in respect of a qualifying transaction recorded in connection with the convertible debenture ( Note 4)
- (c) The Company recorded a credit to additional paid-in capital of \$162,890 representing the carrying values of the net assets acquired in a reverse merger recapitalization transaction. (Note 3).

## 11. SUBSEQUENT EVENTS

The Company has evaluated subsequent events through the date of the issuance of the financial statements.

On April 30, 2015 the Company closed a non-brokered private placement (the “Financing”) raising gross proceeds of CAD \$2,208,110 (approximately USD \$1,825,937) by the issuance of 849,273 units (each a “Unit”) at a price of CAD \$2.60 per Unit (USD \$2.15 per Unit). Each Unit consists of one (1) common share and one half of one (1/2) common share purchase warrant (each a “Warrant”). Each whole Warrant entitles the holder thereof to purchase one additional common share of the Company at a price of approximately CAD \$3.62 per share (USD \$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 CAD 101,494 (USD \$84,074) in connection with this Financing, as well as 27,396 finder’s warrants (the “Finder’s Warrants”). Each Finder’s Warrant entitles the holder thereof to purchase one additional common share of the Company at a price of CAD \$3.62 per share (USD \$3.00 per share) for a period of thirty-six (36) months from the closing date of the Financing.

On April 29, 2015, 14,400 finder’s warrants were exercised for gross proceeds of CAD \$14,400.

## 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 June 29, 2015

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: June 29, 2015

Philippe Deschamps  
*President, Chief Executive Officer and a Director*

By /s/ Amanda Tseng Date: June 29, 2015

Amanda Tseng  
*Chief Financial Officer (Principal Accounting Officer), and Corporate Secretary*

By /s/ Savio Chiu Date: June 29, 2015

Savio Chiu  
*Director*

By /s/ Yuri P. Danilov Date: June 29, 2015

Yuri P. Danilov  
*Director*

By /s/ Mitchell E. Tyler Date: June 29, 2015

Mitchell E. Tyler  
*Director*

By /s/ Edward M. Straw Date: June 29, 2015

Edward M. Straw  
*Director*

By /s/ Joyce LaViscount Date: June 29, 2015

Joyce LaViscount  
*Director*

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**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 333-204155) pertaining to the Helius Medical Technologies Inc. (formerly NeuroHabilitation Corporation) June 2014 Stock Incentive Plan of our report dated January 30, 2015 relating to the financial statements of Helius Medical Technologies Inc. (formerly NeuroHabilitation Corporation), included in this Annual Report (Form 10-K) of the Company for the year ended March 31, 2015.

Vancouver, Canada

**“DAVIDSON & COMPANY LLP”**  
Chartered Accountants

June 26, 2015



1200 - 609 Granville Street, P.O. Box 10372, Pacific Centre, Vancouver, B.C., Canada V7Y 1G6  
Telephone (604) 687-0947 Fax (604) 687-6172



CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 333-204155) pertaining to the Helius Medical Technologies, Inc. June 2014 Stock Incentive Plan of our report dated June 21, 2015, relating to the financial statements of Helius Medical Technologies, Inc. (formerly NeuroHabilitation Corporation) (the “Company”) included in this Annual Report (Form 10-K) of the Company for the year ended March 31, 2015.

*/s/ BDO CANADA LLP*

Vancouver, Canada  
June 21, 2015

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

I, Philippe Deschamps, certify that:

1. I have reviewed this annual report on Form 10-K of Helius Medical Technologies, Inc.;
  2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
  3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
  4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation;
    - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
  5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
-

- (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
- (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: June 29, 2015

/s/ Philippe Deschamps

Philippe Deschamps  
*President, Chief Executive Officer, and a  
Director*

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

I, Amanda Tseng, certify that:

1. I have reviewed this annual report on Form 10-K of Helius Medical Technologies, Inc.;
  2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
  3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
  4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation;
    - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
  5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
-



- (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
- (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: June 29, 2015

/s/ Amanda Tseng

Amanda Tseng

*Chief Financial Officer*

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

In connection with the annual report on Form 10-K of Helius Medical Technologies, Inc. (the "Company") for the year ended March 31, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Philippe Deschamps, as Chief Executive Officer of the Company, and Amanda Tseng, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: June 29, 2015

/s/ Philippe Deschamps

Philippe Deschamps  
*President, Chief Executive Officer, and a  
Director*

/s/ Amanda Tseng

Amanda Tseng  
*Chief Financial Officer*

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

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