

## **GENERAL**

The following information, prepared as of May 14, 2015, should be read in conjunction with the condensed interim consolidated financial statements for the six months ended September 30, 2014 of Helius Medical Technologies, Inc. (the “**Company**” or “**Helius**”) and audited financial statements as of March 31, 2014 of Neurohabilitation Corp. (“**Neuro**”) and the related notes contained therein which have been prepared in accordance with International Financial Reporting Standards (“**IFRS**”). All amounts are expressed in United States dollars (USD) unless otherwise noted.

The preparation of Management's Discussion and Analysis (“**MD&A**”) may require 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. IFRS provides the framework from which to make these estimates, assumptions and disclosures. Management chooses accounting policies within IFRS that management believes are appropriate to accurately and fairly report the Company's 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.

References in this MD&A to “**we**”, “**our**”, “**us**” or similar terms refer to Helius Medical Technologies, Inc.

Additional information relevant to the Company's activities can be found on SEDAR at [www.SEDAR.com](http://www.SEDAR.com) and the Company's website at [heliusmedical.com](http://heliusmedical.com).

## **CAUTIONARY NOTE REGARDING FORWARDING LOOKING STATEMENTS**

This MD&A contains or incorporates forward-looking statements and information relation to the Company that are based on the beliefs of management and assumptions made by and information currently available to management. Certain statements contained in the foregoing MD&A constitutes 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. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date the statements were made, and readers are advised to consider such forward-looking statements in light of the risks set forth below.

## **DESCRIPTION OF BUSINESS AND OVERALL PERFORMANCE**

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

In connection with the Recapitalization, we completed a non-brokered private placement financing of CDN\$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 CDN\$1.00 per share for a period of two years. In connection with the concurrent private placement financing, we paid aggregate finders' fees of \$412,200 and issued 824,000 finder's warrants. Each finder warrant is exercisable at CDN\$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 OTCQB*

Following our Recapitalization, 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”. On February 10, 2015, we also obtained approval to list our common stock on the OTCQB under the symbol “HSDT”.

### *Incorporation of Subsidiary*

On December 17, 2014, we incorporated a Canadian subsidiary wholly-owned by NHC.

## **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<sup>TM</sup>, 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<sup>TM</sup> 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.

## **Our Principal Product**

### *History of the PoNS<sup>TM</sup> Device*

The original PoNS<sup>TM</sup> 1.0 experimental device was developed in 2007 in the TCNL. We anticipate producing the commercial PoNS<sup>TM</sup> 4.0 device in the second quarter of 2015.

Based on market research we have performed to date, we believe we have completed the technical and product design phases of the PoNS<sup>TM</sup> 4.0 device. While we expect to continue to enhance the PoNS<sup>TM</sup> 4.0 device design, we are now commencing efforts to complete the manufacturing development phase which will enable us to manufacture the device commercially. While we expect the PoNS<sup>TM</sup> 4.0 commercial device to deliver the same level of stimulation to the patient as the PoNS<sup>TM</sup> 2.2 laboratory device, we are designing the PoNS<sup>TM</sup> 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<sup>TM</sup> 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<sup>TM</sup> 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.

## **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.

## **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 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 & 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.

### *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 balance disorder associated with mild to

moderate TBI and 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 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 approval of the PoNS™ device to treat balance disorder associated with mild to moderate TBI and 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 new indications. The Army Laboratories has committed to be responsible to fund the execution of clinical studies for the PoNS™ device as a treatment for mutually agreed upon military relevant neurological disorders, including but not limited to Tinnitus, PTSD, and pain and any subsequent indications identified by the parties. 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 requests 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. In order to obtain such classification, we need to demonstrate that the PoNS™ device is low to moderate risk, and that general and special controls would provide reasonable assurance of the safe and effective use of the PoNS™ device. Device classification depends on the intended use of the device and also upon indications for use and under Class II, and the applicability of general controls (e.g., premarket notification) and special controls (e.g., specific performance testing). We are seeking to complete a safety and effectiveness clinical trial by November 2015, 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. However, 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. The Army Laboratories has published a Notice of Intent to enter into a

sole-source contractual agreement to support the execution of the registrational clinical trial for treatment of balance disorder associated with mild to moderate TBI. The objective of this contract is to defray the costs of the registrational 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.

### **Licensed Intellectual Property**

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.

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

### **Company Owned Intellectual Property**

We filed 26 patent applications related to various technical and ornamental aspects of version 4.0 of the PoNS<sup>TM</sup> 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<sup>TM</sup> 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<sup>TM</sup> 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.

## **RESULTS OF OPERATIONS**

### *Revenues*

During the three-month and six month periods ended September 30, 2014, the Company did not generate any revenues (three-month and six-month periods ended September 30, 2013 - \$nil).

### *Operating Expenses*

**Management's Discussion and Analysis**  
**For the six months ended September 30, 2014**  
**AMENDED & RESTATED**



Operating expenses incurred during the three-month period ended September 30, 2014, were \$2,767,604 (three-month period ended September 30, 2013 - \$67,280) and \$8,955,404 for the six-month period ended September 30, 2014 (six-month period ended September 30, 2013 - \$131,263). Significant changes and expenditures are outlined as follows:

A listing expense during the three-month period ended September 30, 2014 of \$nil (three-month period ended September 30, 2013 - \$nil) and \$4,440,611 for the six-month period ended September 30, 2014 (six-month period ended September 30, 2013 - \$nil) was recorded. Please see Note 3 – Recapitalization in the Company's condensed interim consolidated financial statements for the six months ended September 30, 2014.

Research and development expenses for the three-month period ended September 30, 2014 were \$1,062,927 (three-month period ended September 30, 2013 – \$nil) and \$1,665,883 for the six month period ended September 30, 2014 (six-month period ended September 30, 2013 - \$nil). The increase was primarily due to research and development of the Company's PoNS<sup>TM</sup> device, mostly including Ximedica's commercial development-to-supply program and the NeuroFeedback's 12-month pilot clinical trial.

Stock-based compensation for the three-month period ended September 30, 2014 was \$607,786 (three-month period ended September 30, 2013 – \$58,804) and \$1,121,802 for the six-month period ended September 30, 2014 (six-month period ended September 30, 2013 - \$115,915). The increase was mainly caused by the issuance of stock options to the Company's directors, officers, and consultants. The significant increase in stock-based compensation stems from the Company's issuance of stock options in June and July 2014 and subsequent revaluation at each vesting period.

Advertising, marketing, and IR expenses for the three-month period ended September 30, 2014 were \$357,956 (three-month period ended September 30, 2013 – \$nil) and \$404,182 for the six-month period ended September 30, 2014 (six-month period ended September 30, 2013 - \$nil). The increase relates to advertising and promotion expenses and investor relation consulting fees. The Company has engaged investor relations and public relations professionals in Canada and the US in order to increase the public's awareness of its activities and the Device.

Accreted interest expenses for the three-month period ended September 30, 2014 were \$226 (three-month period ended September 30, 2013 - \$nil) and \$183,058 for the six-month period ended September 30, 2014 (six-month period ended September 30, 2013 - \$nil). The increase was related to interest and amortization of a beneficial conversion feature on the Debenture.

Legal fees for the three-month period ended September 30, 2014 were \$344,491 (three-month period ended September 30, 2013 - \$625) and \$564,425 for the six-month period ended September 30, 2014 (six-month period ended September 30, 2013 - \$4,175). The increase was primarily composed of fees incurred for general corporate matters and the reverse takeover transaction. In addition, the legal activity for the Company has increased significantly since inception due to the acquisition of Neuro and the engagement of various specialized legal counsels for the development of our intellectual properties and the commercialization of the PoNS<sup>TM</sup> device.

Wages and salaries for the three-month period ended September 30, 2014 were \$100,014 (three-month period ended September 30, 2013 - \$nil) and \$176,705 for the six-month period ended September 30, 2014 (six-month period ended September 30, 2013 - \$nil). The increase relates to employee payroll. The employment contract with the CEO was effective on March 15, 2014, and the Company hired a full-time employee on June 1, 2014.

General office and administrative expenses for the three-month period ended September 30, 2014 were \$82,744 (three-month period ended September 30, 2013 – \$2,810) and \$104,170 for the six-month period ended September 30, 2014 (six-month period ended September 30, 2013 - \$4,270). The increase mainly relates to general and administrative expenses but also includes computer & internet expenses, telephone expenses, and rent expenses. These expenses increased significantly as the Company ramps up its operations.



Meals and travel expenses for the three-month period ended September 30, 2014 were \$77,611 (three-month period ended September 30, 2013 - \$5,041) and \$107,052 for the six-month period ended September 30, 2014 were \$107,052 (six-month period ended September 30, 2013 - \$6,603). The increase relates to general corporate meal and travel expenses. Travel to and from various investor and medical conferences caused the significant increase.

Transfer agent & regulatory fees for the three-month period ended September 30, 2014 were \$43,713 (three-month period ended September 30, 2013 - \$nil) and \$58,973 for the six-month period ended September 30, 2014 (six-month period ended September 30, 2013 - \$nil). The increase is mainly composed of transfer agent fees, the CSE's monthly listing fees, and other regulatory fees. These fees increased since the Company listed on the CSE.

Consulting fees for the three-month period ended September 30, 2014 were \$36,013 (three-month period ended September 30, 2013 - \$nil) and \$43,164 for the six-month period ended September 30, 2014 (six-month period ended September 2013 - \$300). The increase is primarily due to financial consulting expenses.

Audit and accounting fees for the three-month period ended September 30, 2014 were \$30,836 (three-month period ended September 30, 2013 - \$nil) and \$41,481 for the six-month period ended September 30, 2014 (six-month period ended September 30, 2013 - \$nil). The increase relates to the previous year's financial statement audit.

Insurance expenses for the three-month period ended September 30, 2014 were \$22,287 (three-month period ended September 30, 2013 - \$nil) and \$29,773 for the six-month period ended September 30, 2014 (six-month period ended September 30, 2013 - \$nil). The increase relates to clinical trial insurance and directors' and officers' liability insurance coverage.

Professional fees for the three-month period ended September 30, 2014 were \$1,000 (three-month period ended September 30, 2013 - \$nil) and \$14,125 for the six-month period ended September 30, 2014 (six-month period ended September 30, 2013 - \$nil). The increase relates to corporate communications and industry research fees.

#### *Non-Operating Items*

Non-operating items incurred during the three-month period ended September 30, 2014 were \$398,145 (three-month period ended September 30, 2013 - \$nil) and \$395,437 during the six-month period ended September 30, 2014 (six-month period ended September 30, 2013 - \$nil). Significant changes are outlined as follows:

Interest income for the three-month period ended September 30, 2014 were \$14,381 (three-month period ended September 30, 2013 - \$nil) and \$17,191 for the six-month period ended September 30, 2014 (six-month period ended September 30, 2013 - \$nil). The increase stems from the opening of a number of interest-bearing short-term investment accounts with the Company's banking institutions.

Foreign exchange losses for the three-month period ended September 30, 2014 were \$412,526 (three-month period ended September 30, 2013 - \$nil) and \$412,628 for the six-month period ended September 30, 2014 (three-month period ended September 30, 2013 - \$nil). The increase stems from the Company's exchange of a large sum of \$CAD into \$USD interest-bearing short-term investments with its banking institutions.

During the three-month period ended September 30, 2014, the Company recognized foreign exchange gains on the translation of subsidiaries of \$206,786 (September 30, 2013 - \$nil) and foreign exchange gains of \$312,485 on the translation of subsidiaries for the six-month period ended September 30, 2014 (six-month period ended September 30, 2013 - \$nil) in other comprehensive income. The increase stems from the fact that the Company now holds most of its funds in \$USD which reduces the foreign exchange risks upon converting Canadian dollars to the USD.

During the period from Neuro's incorporation on January 22, 2013 to September 30, 2014, there were no operating revenues as the Company was still in the development stage.

Due to the Company being in its early stage of development, management foresees further increases in the Company's expenses during the coming year resulting from its development activities. These expenses are

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contingent upon the Company's ability to fund these projects through private placements and other forms of financing. In the event that the Company does not receive the required funding, management will review all on-going expenditures and take appropriate actions to remedy the funding shortage.

**SUMMARY OF QUARTERLY RESULTS**

The following table presents unaudited selected financial information for each of the last six quarters:

	Q2 September 30, 2014 \$	Q1 June 30, 2014 \$	Q4 March 31, 2014 \$	Q3 December 31, 2013 \$	Q2 September 30, 2013 \$	Q1 June 30, 2013 \$	Q4 March 31, 2013 \$
Net sales	-	-	-	-	-	-	-
Net loss	(3,165,749)	(1,744,479)	(602,368)	(333,653)	(67,280)	(63,983)	(8,517,850)
Basic and diluted loss per share	(0.05)	(0.04)	(0.02)	(0.01)	(0.00)	(0.00)	(0.27)
Total assets	5,391,499	7,446,374	315,968	111	163	217	217

**Net Loss**

The net loss for the three-month period ended September 30, 2014 was \$3,164,749 (September 30, 2013 - \$67,280). The increase in net loss of \$3,097,469 resulted primarily from an increase in operating activities as the Company had the resources to continue its research and development and investor relation activities. The increase is mainly due to the increase in advertising and marketing expenses, legal expenses, research and development expenses, stock-based compensation and wages and salaries.

**Working Capital**

The Company has experienced recurring losses since inception and, as of September 30, 2014, the Company has working capital of \$4,222,723 (March 31, 2014 - \$(267,977)) and an accumulated deficit of \$18,935,975 (March 31, 2014 - \$9,585,134). 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 \$5,000,026 as of September 30, 2014 (March 31, 2014 - \$15,968), management does not believe these resources will be sufficient to meet the Company's operating and capital needs through 2015.

**LIQUIDITY AND CAPITAL RESOURCES**

The Company's financial statements have been prepared assuming that it 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 the Company's cash and working capital as of September 30, 2014 and March 31, 2014:

	As of September 30, 2014	As of March 31, 2014
Cash and cash equivalents	\$5,000,026	\$15,968
Working capital (deficit)	\$4,222,723	(\$267,977)

As at September 30, 2014, the Company's current assets were \$5,391,499 (March 31, 2014 - \$315,968), which increased mostly due to the closing of the Private Placement on June 13, 2014. Current liabilities were \$1,168,776 (March 31, 2014 - \$583,945), which increased due to an increase in the Company's operations since the closing of the Private Placement and its acquisition of Neuro. Working capital was \$4,222,723 (March 31, 2014 - \$(267,977)). The Company's current assets as at September 30, 2014 consisted of cash and cash equivalents of \$5,000,026 (March 31, 2014 - \$15,968) which increased mostly due to the closing of the Private Placement, receivables of

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\$1,589 (March 31, 2014 - \$nil) which increased due to the opening of numerous interest-bearing short-term investments with the Company's banking institutions, and prepaid expenses of \$389,884 (March 31, 2014 - \$300,000) which mostly include a prepayment to Ximedica. The Company's current liabilities as at September 30, 2014 consisted of accounts payable and accrued liabilities of \$1,168,776 (March 31, 2014 - \$215,921) which increased due to the Company's increased operations, and a convertible debenture amount of \$nil (March 31, 2014 - \$368,024) which was paid off in full on by issuing 2,564,705 common stock (see *Description Of Business And Overall Performance* section above).

As a result of the Company's increased activity, the accumulated deficit increased from \$9,585,134 as at March 31, 2014 to \$18,935,975 as at September 30, 2014.

The Company has not yet put the PoNS<sup>TM</sup> device into commercial production, and, therefore, has no operating revenues. Accordingly, the Company is dependent on equity and debt financing as its sole source of operating working capital. The Company's capital resources are largely determined by the strength of the markets and its ability to compete for investor support of its projects.

The Company 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.

***Contractual obligations***

A summary of the Company's contractual obligations at September 30, 2014 is outlined in the table below:

Contractual Obligations	Payments Due by Period				
	Total	Less than 1 Year	1 – 3 Years	4 – 5 Years	After 5 Years
Long-term debt	N/A	N/A	N/A	N/A	N/A
Capital lease obligations	N/A	N/A	N/A	N/A	N/A
Operating leases	\$42,856	\$42,856	N/A	N/A	N/A
Purchase Obligations	N/A	N/A	N/A	N/A	N/A
Other long term obligations	N/A	N/A	N/A	N/A	N/A
<b>Total contractual obligations</b>	<b>\$42,856</b>	<b>\$42,856</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>

**Statement of Cashflows**

During the six-month period ended September 30, 2014, the Company's net cash increased by \$4,659,236 (September 30, 2013 – decreased by \$54), which included net cash used in operating activities of \$2,763,913 (September 30, 2013 - \$17,038) stemming from the Company's increase in operations, net cash provided by investing activities of \$173,903 (September 30, 2013 - \$nil) stemming from the acquisition of Neuro, and net cash provided by financing activities of \$7,249,246 (September 30, 2013 - \$16,984) stemming from the closing of the Private Placement.

***Cash Used in Operating Activities***

Operating activities in the six-month period ended September 30, 2014 used cash of \$2,763,913 (September 30, 2013 - \$17,038). This was made up of a net loss of \$9,350,841 (September 30, 2013 - \$131,263) less adjustments for non-cash items such as: accreted interest of \$171,927 (September 30, 2013 – \$nil), stock based compensation of \$1,121,802 (September 30, 2013 - \$115,915), a listing expense stemming from the recapitalization of 4,440,611 (September 30, 2013 - \$nil), receivables of (\$693) (September 30, 2013 - \$nil), accounts payable of \$937,740 (September 30, 2013 – (\$1,690)) and prepaid expenses of (\$84,459) (September 30, 2013 – \$nil).

Receivables increased due to the opening of numerous interest-bearing short-term investments. Payables and prepaid expenses increased due to the Company's increase in operations.

*Cash Provided by Investing Activities*

During the six-month period ended September 30, 2014, investing activities provided cash of \$173,903 (September 30, 2013 - \$nil). Investing activities during the six-month period ended September 30, 2014, consisted of: cash acquired on reverse take-over of \$23,903 (September 30, 2013 - \$nil), and proceeds from bridge financing of \$150,000 (September 30, 2013 - \$nil).

*Cash Provided by Financing Activities*

During the six-month period ended September 30, 2014, financing activities provided cash of \$7,249,246 (September 30, 2013 - \$16,984). Financing activities during the six-month period ended September 30, 2014, consisted of: issuance of share capital (net of share issuance costs) of \$6,616,051 (September 30, 2013 - \$nil) stemming from the Private Placement, loans from shareholders of \$nil (September 30, 2013 - \$16,984), and proceeds from the Debenture of \$633,195 (September 30, 2013 - \$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 the results of operations or financial condition of the Company.

**TRANSACTIONS WITH RELATED PARTIES**

For the period ended September 30, 2014, the Company was a party to the following related party transactions not disclosed elsewhere:

During the period ended September 30, 2014, the Company paid \$150,000 (September 30, 2013 - \$nil) as wages to the CEO of the Company.

During the period ended September 30, 2014, the Company paid \$6,875 (September 30, 2013 - \$nil) in consulting fees to a former director of the Company.

During the period ended September 30, 2014, the Company paid \$6,050 (September 30, 2013 - \$nil) in consulting fees to a director of the Company.

During the period ended September 30, 2014, the Company paid \$34,418 (September 30, 2013 - \$nil) to a company acting as the Company's corporate advisor and Chief Financial Officer.

During the period ended September 30, 2014, the Company recorded \$473,297 (September 30, 2013 - \$nil) in stock based compensation for officers and directors of the Company.

See also Notes 3, 5 and 7 of the condensed interim consolidated financial statements for the six months ended September 30, 2014.

**PROPOSED TRANSACTIONS**

The Company does not currently have any proposed transactions approved by the Board of Directors. All current transactions are fully disclosed in the condensed interim consolidated financial statements for the period ended September 30, 2014.

**CRITICAL ACCOUNTING ESTIMATES**

All significant accounting policies and critical accounting estimates are fully disclosed in Note 2 of the condensed interim consolidated financial statements for the period ended September 30, 2014.

## NEW STANDARDS, INTERPRETATIONS AND AMENDMENTS

- IFRS 9 Financial Instruments

IFRS 9 Financial Instruments is part of the IASB's wider project to replace IAS 39 Financial Instruments: Recognition and Measurement. IFRS 9 retains but simplifies the mixed measurement model and establishes two primary measurement categories for financial assets: amortized cost and fair value. The basis of classification depends on the entity's business model and the contractual cash flow characteristics of the financial asset. The standard is effective for annual periods beginning on or after February 1, 2015. The Company is in the process of evaluating the impact of the new standard on the accounting for the Company's investments classified as available-for-sale and fair value through profit and loss.

### FINANCIAL INSTRUMENTS AND OTHER INSTRUMENTS

All financial assets and financial liabilities are initially recorded at fair value and designated upon inception into one of the following categories: held-to-maturity, available-for-sale, loans and receivables or held for trading.

Financial assets classified as held for trading are measured at fair value with unrealized gains and losses recognized through profit and loss. Available-for-sale instruments are measured at fair value with unrealized gains and losses recognized in other comprehensive income. Held-to-maturity instruments, loans and receivables and financial liabilities not at fair value through profit and loss are measured at amortized cost using the effective interest rate method.

The Company has implemented the following classifications for its financial instruments:

- Cash and cash equivalents has been classified as held for trading;
- Receivables have been classified as loans and receivables; and
- Accounts payable and accrued liabilities and convertible debenture have been classified as other financial liabilities.

Assets and liabilities measured at fair value on a recurring basis were presented on the Company's balance sheet as at September 30, 2014, as follows:

	Fair Value Measurements Using			Balance, September 30, 2014 \$	Balance, March 31, 2014 \$
	Quoted prices in active markets for identical instruments (Level 1) \$	Significant other observable inputs (Level 2) \$	Significant unobservable inputs (Level 3) \$		
Cash and cash equivalents	5,000,026	-	-	5,000,026	15,968

The Company's financial instruments are exposed to a number of financial and market risks, including credit, liquidity, interest rate and currency risks. The Company may, or may not, establish from time to time active policies to manage these risks. The Company does not currently have in place any active hedging or derivative trading policies to manage these risks since the Company's management does not believe that the current size, scale and pattern of its operations would warrant such hedging activities.

### Concentrations of Credit Risk



The financial instrument which potentially subjects the Company to concentration of credit risk is cash and cash equivalents. The Company maintains cash and cash equivalents in bank accounts that, at times, may exceed federally insured limits. As at September 30, the Company has exceeded the federally insured limit. The Company has not experienced any losses in such amounts and believes it is not exposed to any significant risks on its cash and cash equivalents in bank accounts.

#### Foreign Exchange Risk

The Company incur some operating expenses and had an equity financing in Canadian dollars which are subject to foreign currency fluctuations. The fluctuation of the Canadian dollar in relation to the US dollar will have an impact upon the profitability of the Company and may also affect the value of the Company's assets and the amount of shareholders' equity. The Company has not entered into any agreements or purchased any instruments to hedge possible currency risks. A 10% change in currency will have an impact of \$306,062 on net assets and \$174,832 on net loss.

### OTHER MD&A DISCLOSURE REQUIREMENTS

#### *Disclosure of outstanding share data*

The Company's issued and outstanding share capital as at the date of this report is as follows:

- (1) Authorized: Unlimited Class A common stock without par value.
- (2) As at the date of this MD&A, the Company has 63,968,461 common stock, 4,920,000 options, 8,882,032 warrants issued and outstanding.

#### *Additional disclosure for issuers without significant revenue*

The Company has expensed the following material cost components:

	Six-month Period Ended September 30, 2014	Six-month Period Ended September 30, 2013
	\$	\$
Listing expense	4,440,611	-
Research & development	1,665,883	-
Stock-based compensation	1,121,802	115,915
Legal fees	564,425	4,175
Advertising, marketing & IR	404,182	-
Accreted interest expense	183,058	-
Wages & salaries	176,705	-
Meals & travel	107,052	6,603
Office & general	104,170	4,270

A listing expense during the three-month period ended September 30, 2014 of \$nil (three-month period ended September 30, 2013 - \$nil) and \$4,440,611 for the six-month period ended September 30, 2014 (six-month period

ended September 30, 2013 - \$nil) was recorded. Please see Note 3 – Recapitalization in the Company's condensed interim consolidated financial statements for the six months ended September 30, 2014.

Research and development expense of \$1,665,883 (September 30, 2013 - \$nil) primarily include the development of the Company's PoNS<sup>TM</sup> device, mostly including Ximedica's commercial development-to-supply program and the NeuroFeedback's 12-month pilot clinical trial.

Stock-based compensation expenses of \$1,121,802 (September 30, 2013 - \$115,915) relate to the issuance of stock options to the Company's directors, officers, and consultants. The significant increase in stock-based compensation stems from the Company's issuance of stock options in June and July 2014 and subsequent revaluation at each vesting period.

Legal fees of \$564,425 (September 30, 2013 - \$4,175) increased primarily due to fees incurred for general corporate matters and the reverse takeover transaction. In addition, the legal activity for the Company has increased significantly since inception due to the acquisition of Neuro and the engagement of various specialized legal counsels for the development of our intellectual properties and the commercialization of the PoNS<sup>TM</sup> device.

Advertising, marketing, and IR expenses of \$404,182 (September 30, 2014 – \$nil) increased due to advertising and promotion expenses and investor relation consulting fees. The Company has engaged investor relations and public relations professionals in Canada and the US in order to increase the public's awareness of its activities and the Device.

Accreted interest expense of \$183,058 (September 30, 2014 - \$nil) relates to interest and amortization of a beneficial conversion feature on the Debenture.

Wages and salaries of \$176,705 (September 30, 2013 - \$nil) relate to employee payroll. The employment contract with the CEO was effective on March 15, 2014, and the Company hired a full-time employee on June 1, 2014.

Meals and travel expenses of \$107,052 (September 30, 2013 - \$6,603) relate to general corporate meal and travel expenses. Travel to and from various investor and medical conferences caused the significant increase.

General office and administrative expenses of \$104,170 (September 30, 2013 – \$4,270) relate to general and administrative expenses but also includes computer & internet expenses, telephone expenses, and rent expenses. These expenses increased significantly as the Company ramps up its operations.

#### **FUTURE ACCOUNTING STANDARDS AND INTERPRETATIONS**

The Company reviewed recently issued accounting pronouncements and concluded that they are either not applicable or not expected to have a significant impact on the Company's financial statements.

#### **RISKS AND UNCERTAINTIES**

##### **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 year ended March 31, 2014 and the nine months ended December 31, 2014, we incurred a net loss of \$1,067,284 and \$12,913,218, respectively, and used cash in operations of \$348,698 and \$4,293,452, respectively. We have an accumulated deficit of \$9,585,134 as of March 31, 2014 and \$22,498,352 as of December 31, 2014. 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 PoNST<sup>TM</sup> 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 under-capitalization, cash shortages, limitations with respect to personnel, financial and other resources, lack of revenue and the risk that we will not achieve our growth objective. If sales revenue from any 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 December 31, 2014 were \$2,906,399. 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 PoNST<sup>TM</sup> device, FDA clearance of the PoNST<sup>TM</sup> 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 PoNST<sup>TM</sup> 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, 2014 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, without the expected proceeds from this offering, our existing capital resources will be insufficient to fund our operations through the end of the first quarter of 2016. 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 that is still in technical development and we have not obtained marketing authorization from the FDA or regulatory clearance for this product in any jurisdiction and may never obtain such marketing authorization from FDA or regulatory clearance.***

We currently are dependent on a single product which is our PoNS<sup>TM</sup> device for use in the neuromodulation market. We are still in technical development of this product and it is not yet ready for marketing and sale. However, we cannot begin marketing and selling our device until we obtain marketing authorization from the FDA or regulatory clearance of the PoNS<sup>TM</sup> device for treating balance disorder in patients with mild to moderate TBI and balance disorder associated with MS. We have not submitted our PoNS<sup>TM</sup> device yet for regulatory review and approval by the FDA. 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, or receipt of marketing authorization from the FDA for, 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<sup>TM</sup> device and obtain FDA approval of the PoNS<sup>TM</sup> device for treating balance disorder in patients with mild to moderate TBI and balance disorder associated with MS, we plan to develop the PoNS<sup>TM</sup> 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 clearance 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<sup>TM</sup> 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<sup>TM</sup> 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<sup>TM</sup> device and seek FDA clearance and approval of the PoNS<sup>TM</sup> device. We are also solely responsible to complete the research and development efforts necessary to commercialize our PoNS<sup>TM</sup> 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 registrational trial for treatment of balance disorder associated with mild to moderate TBI. The objective of this contract is to defray the costs of the registrational 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<sup>TM</sup> 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<sup>TM</sup> device.

***If we fail to obtain FDA clearance for commercialization of or otherwise fail to ensure that the PoNS<sup>TM</sup> 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<sup>TM</sup> device or otherwise fail to ensure that the PoNS<sup>TM</sup> 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<sup>TM</sup> 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 payors for our product;
- Medicare, Medicaid or other third-party payors 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.

***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 in the process of registering under Section 12(g) of the Securities Exchange Act of 1934, or the Exchange Act, so that we may apply our shares for quotation on a well-established OTC market or for listing on a stock exchange in the United States. Once our registration statement becomes effective, we will become subject to certain reporting requirements under the Exchange Act as 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.

***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 Baron Global Financial Canada Ltd. Pursuant to an agreement with us, 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 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 on-going 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 payors at the federal and state levels, including Medicare and Medicaid, private health insurers and other third-party payors 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 payors 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 payors 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 payors 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 payors also denying coverage for our products. Third-party payors 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 payor, or was used for an unapproved use. Unfavorable coverage or reimbursement decisions by government programs or private payors 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 payors 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 payors frequently follow government payment policies and are likewise interested in controlling increases in the cost of medical care. In addition, some payors 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 payor 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 payors 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 payors 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 payors, that reimbursement will be available or, if available, that the third-party payors' 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 common stock has been listed on the CSE since June 23, 2014, and on the OTCQB since Feb 10, 2015. 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 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 share than our two major shareholder 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 15c-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 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.

#### **ADDITIONAL INFORMATION**

Additional information about the Company is available for viewing on SEDAR at [www.sedar.com](http://www.sedar.com).