Helius

MEDICAL TECHNOLOGIES

A Revolution in Mind

January 2017

Forward Looking Statements

- This presentation contains forward-looking statements and forward-looking information as such terms are defined under applicable Canadian securities legislation. All statements other than statements of historical fact contained in this presentation constitute forward-looking statements and forward-looking information, including, without limitation, statements containing the words “believe”, “may”, “plan”, “should”, “predict”, “potential”, “will”, “estimate”, “continue”, “anticipate”, “intend”, “expect”, “seek”, “mission”, “goal” and similar words, variations, expressions or the negative thereof. Forward-looking statements are necessarily based on estimates and assumptions made by management of the Helius Medical Technologies, Inc. (“Helius”, “we” or the “Company”) in light of experience and perception of historical trends, current conditions and expected future developments, as well as the factors management of the Company believes are appropriate. Forward-looking statements and information in this presentation include but are not limited to statements relating to:
  - the benefits and risks of the Company’s products as compared to others;
  - the Company’s estimate of the size of the potential markets for its products;
  - the timing and amount of reimbursement for the Company’s products;
  - the Company’s ability to advance its product candidates into, and successfully complete, clinical trials;
  - the therapeutic benefits, effectiveness and safety of the Company’s product candidates;
  - the Company’s selection and licensing of products;
  - the success and pricing of other competing therapies that are currently or may become available;
  - the Company’s ability to attract and retain qualified personnel;
  - the Company needing to do a technology transfer to a scale manufacturer once the product is launched;
  - sources of revenues and anticipated revenues, including contributions from distributors and collaborators, product sales, license agreements and other collaborative efforts for the development and commercialization of products;
  - whether the Company will receive, and the timing and costs of obtaining, regulatory clearances in the U.S. and Canada;
  - regulatory developments and the regulatory environments in which the Company operates; and
  - anticipated trends and challenges in the Company’s business and the markets in which it operates.
- Such statements reflect management of the Company’s current views with respect to future events and are subject to risks and uncertainties and are necessarily based upon a number of estimates and assumptions that, while considered reasonable by the Company, are inherently subject to significant business, economic, competitive, political and social uncertainties and contingencies. The factors and assumptions used by management of the Company to develop such forward-looking statements include, but are not limited to, obtaining positive results of clinical trials, obtaining regulatory clearances, general business and economic conditions, the availability of financing on reasonable terms, the Company’s ability to attract and retain skilled staff, market competition, the assumption that our current good relationships with our manufacturer and other third parties will be maintained, the products and technology offered by the Company’s competitors and the Company’s ability to protect patents and proprietary rights. In addition to the foregoing, many factors could cause our actual results, performance or achievements to be materially different from any future results, performance, or achievements that may be expressed or implied by such forward-looking statements, including, among others:
  - risks related to the Company’s limited operating history;
  - the Company being dependent on the ability and expertise of its Chief Executive Officer, Chief Medical Officer and a very limited number of employees;
  - the Company having incurred losses since its inception and its anticipation that it will continue to incur substantial net losses for the foreseeable future and may never achieve or sustain profitability;
  - risks relating to the Company requiring additional financing to carry out its plan of operations;
  - the Company’s independent registered public accounting firm having included an explanatory paragraph relating to the Company’s ability to continue as a going concern in its report on the Company’s audited financial statements for the year ended March 31, 2015, as amended on January 11, 2016;
  - the Company’s failure to maintain effective internal controls over financial reporting
  - risks related to the Company raising additional capital by issuing securities or through debt financing or licensing arrangements that may cause dilution to existing shareholders, restrict its operations or require the Company to relinquish proprietary rights;
  - risks concerning the Company only having one product candidate, which is still in development, and the Company not having obtained clearance from the United States Food and Drug Administration (the “**FDA**”) or Health Canada with respect thereto;
  - the Company’s dependence on outside scientists and third-party research institutions for its research and development in order to be able to commercialize its product candidates;
  - the risk that if the Company fails to obtain FDA clearance for commercialization of or otherwise fails to ensure that the PoNS™ device is available for purchase by the U.S. Government by December 31, 2017, the Company will be subject to significant risk of loss of data and proprietary rights and a US$2,000,000 contract penalty payable to A&B pursuant to Section 7(f) of the Strategic Agreement (as such terms are defined herein);
  - the risk that the Strategic Agreement may be terminated;
  - risks related to the limited market awareness of the Company and its product;
  - risks related to the neuromodulation market being new and growing but undefined;
  - the Company’s PoNS™ technology being a new “untested” form of neurostimulation therapy and the medical community tending to be very conservative in adopting new therapies;
  - risks related to the Company needing to expand its products beyond its single product by commercializing new product candidates, and the Company not being able to do so in a timely fashion and at expected costs, or at all;
  - the Company cannot provide assurances that the development by others of new or improved devices or products will not result in the Company’s present and future products from becoming obsolete;

Equity Overview:

- **Helius Medical Technologies:**

  HSM and HSM.WT (TSE), HSDT (OTCBB) Average daily volume ~90k

Capital Structure *	
Market Cap	**US$120.8 mln (HSM:TSX, HSDT:OTCBB)** ($1CAD=$0.7523USD)
Current Shares Outstanding:	**84.53 M Shares**
Weighted average exercise price	**US$1.09: C$1.35**
Fully Diluted Shares:	**104.8 M Shares (incl. outstanding options and warrants)**
Management Ownership	**33.00 M Shares (included in Full Diluted Count)**
Cash and equivalents:	**Approx. US$6.0M (September 30, 2016)**
Debt:	**-**

***as of 01/04/17**

Funding to Date

TCNL Lab funding:

- $7.1M ($3.0M NIH grants, $4.1 in cash donations from treated subjects) – 2008-2013

Cash from Private Placement/Prospectus Offerings/Warrants:

- $7.2M initial investment reverse merger to a public purpose built shell – Q2 2014
- $1.1M convertible debentures to stock – Q2 2014
- $2.8M non-brokered private placement – Q2 2015
- $7.0M A&B Company (China) strategic investment – Q4 2015
- $8.0M US private placement/prospectus offering in Canada – Q2 2016
- $1.4M warrant exercise – Q2 2016

$27.5M total funding through September 2016

Non-Dilutive Commitment: US Army

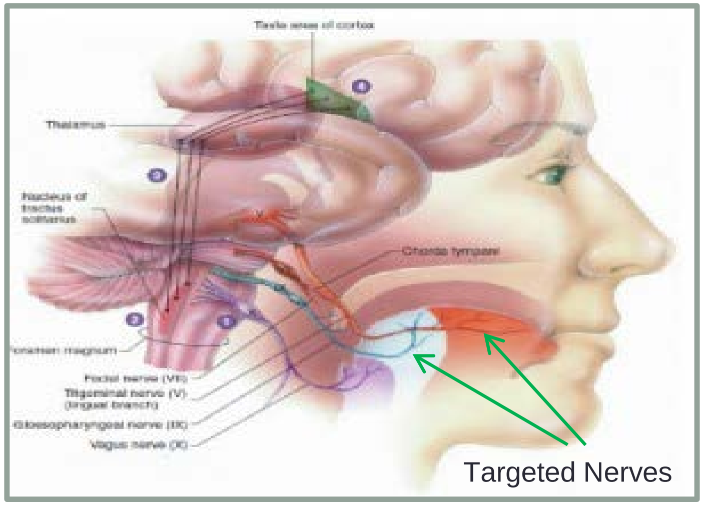
- $12.0M-plus non-dilutive investment by US Army to date (April 2015)
- $2M expense reimbursement from sole source contract

Helius Medical Technologies

"Developing a platform technology for the treatment of symptoms of neurologic disease or trauma."

Portable Neuromodulation Stimulator ("PoNS™")

- Delivers specially-patterned nerve impulses to the lower brainstem through disposable appliance placed on the tongue.
- Combined with specialized therapy may help treat patients with chronic neurological symptoms caused by disease or trauma.
- Clinical experience with over 250 patients at the University of Wisconsin-Madison. Tested in pilot studies in MS, TBI and CP, and case series in a number of other neurologic diseases have generated encouraging results.
- Pivotal study for the treatment of symptoms of TBI (120 subjects, multiple sites) currently enrolling.
- FDA submission expected Q3/Q4, 2017.



Cornerstone Neuromodulation IP Portfolio

- **Licensed from inventors[1]:**
  - 3 US Medical Method Patents Issued
    - Skin Stimulation + physical therapy = Therapeutic outcome
    - Oral Cavity Stimulation + physical therapy = Therapeutic outcome
    - Oral Cavity Stimulation + cognitive therapy = Therapeutic outcome
  - 5 US Patent Applications Pending or Forthcoming
    - 3 Pending US Applications – filed in 2015: Treatment of Tinnitus and others; Skin + Cognitive Exercise; Stimulation with Pulse Generator
    - 1 Pending US Application (Prioritized Examination Track) – filed July 2016: Human Performance
    - 1 Forthcoming US Application – filed August 2016: Human Performance
- **Patents owned by Helius[2] (Please see appendix for further details):**
  - 22 US Patents Issued
  - 6 US Patent Applications Pending
  - 1 European Design Patent Issued
  - 7 Canadian Design Patents Issued
  - 3 Russian Design Patent Applications allowed by Russian Patent Office – to be issued in 2016
  - 3 International Patent Applications Pending
- **Helius patents transferred to CMS (China Medical System Holdings):**
  - 3 Chinese Design Patents

[1]Exclusive license – 4% royalty granted to inventors
[2]100% owned by Helius, no royalties owed

Third-Party Review of Early Stage Data

Optum Analysis of the Use Of PoNS™ Therapy Led To Better Outcomes In Patients With Resistant Neurological Conditions

OPTUM™

Study	Test	Subjects	Statistically Significant ($p<0.05$)?
MS Pilot	Dynamic Gait Index (DGI)	13	Yes
MS - RCT		10	Yes
NIMN Balance Disorders		23	Yes
TOTAL		**46**	**Yes**
MS Pilot	Multiple Sclerosis Impact Scale (MSIS-29)	12	Yes
MS - RCT		10	Yes
TOTAL		**22**	**Yes**
NIMN	Sensory Organization Test (SOT)	10	Yes
Stroke		5	Yes
TOTAL		**15**	**Yes**
NIMN	Activities-Specific Balance Confidence Scale	15	Yes
TOTAL		**15**	**Yes**

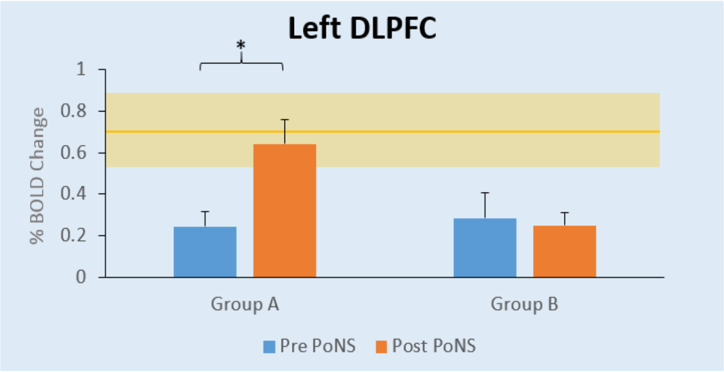
- The **Dynamic Gait Index (DGI)** is a clinical tool to assess gait.
- The **Multiple Sclerosis Impact Scale (MSIS-29)** is a 29-item self-report rating scale for measuring the physical and psychological impact of multiple sclerosis (MS).
- The **Sensory Organization Test (SOT)** is a composite score calculated and normalized for age and gender. A composite change of 5 points or greater is considered statistically significant.

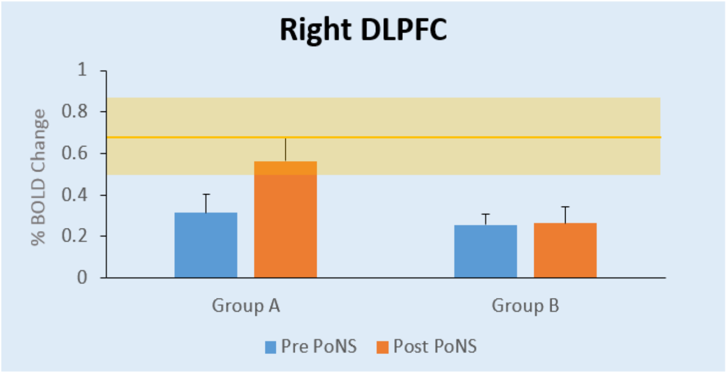
Results from MS Pilot Study

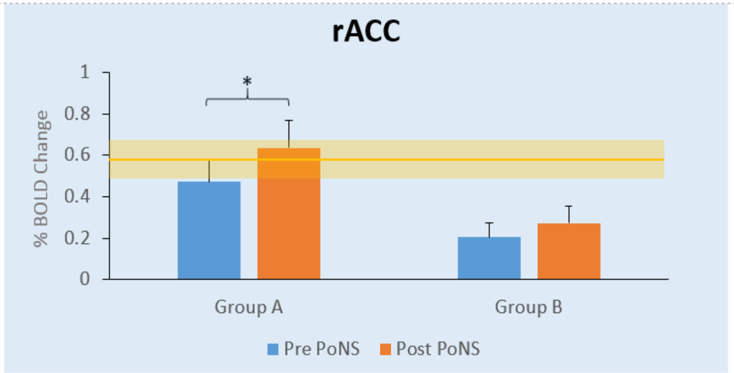
- **Multiple Sclerosis (“MS”) pilot study evaluating the PoNS™ device**
  - 14 subjects (7-control (no stimulation) and 7 active) received neural stimulation and concomitant physiotherapy
  - Independent trial at the Montreal Neurological Institute and Hospital and Concordia University’s PERFORM Center
  - Study objectives:
    - Explore the putative beneficial effects of PoNS™ device stimulation
    - Provide data to be used for the design of future registrational studies
  - Pioneered use of functional MRI (“fMRI”) to differentiate between study groups by measuring the physical effect of neuromodulation induced by the PoNS™ device

fMRI Changes Vs Healthy Controls

Voxels of Interest (VOIs) BOLD signal vs. Healthy Controls





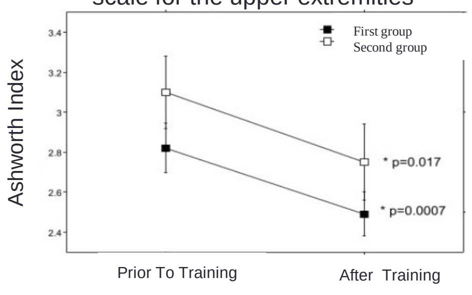


Mean and 95% quantile of healthy control's BOLD signal change

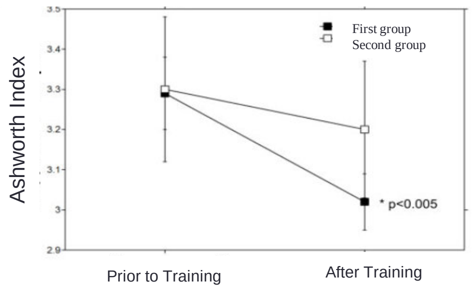
Cerebral Palsy Study

- 65-subject (45-active, 20 control) study included children (ages 3-13) with Gross Motor Function Classification Scores (GMFCS) ranging from II-IV*
- All subjects received 10-days of standard physiotherapy and movement control therapy with the active group receiving 20-25 minutes of concomitant electro-lingual neurostimulation with PoNS™
- Primary outcomes were scored by Ashworth Scale (spasticity), Berg Scale (Balance) and GMFCS
- Statistically significant differences in spasticity ($p<0.005$) and lower limb gross motor function ($p<0.00001$) were reported in favor of the active group
- Secondary measures included preferred walking speed, step length, lower extremity strength and quality of life measures.
- Positive changes in quality of life, cognitive function, and social status were also observed.
- The researchers concluded physiotherapy with the PoNS™ device can improve motor control in patients with CP

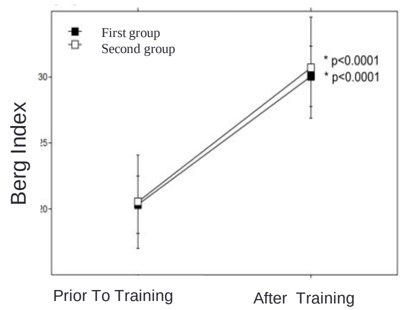
Assessment of spasticity base on the Ashworth scale for the upper extremities



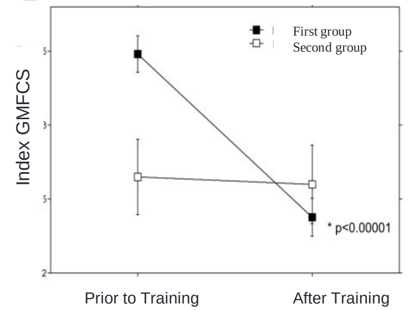
Assessment of spasticity base on the Ashworth scale for the lower extremities



Assessment of Balance on the Berg Scale

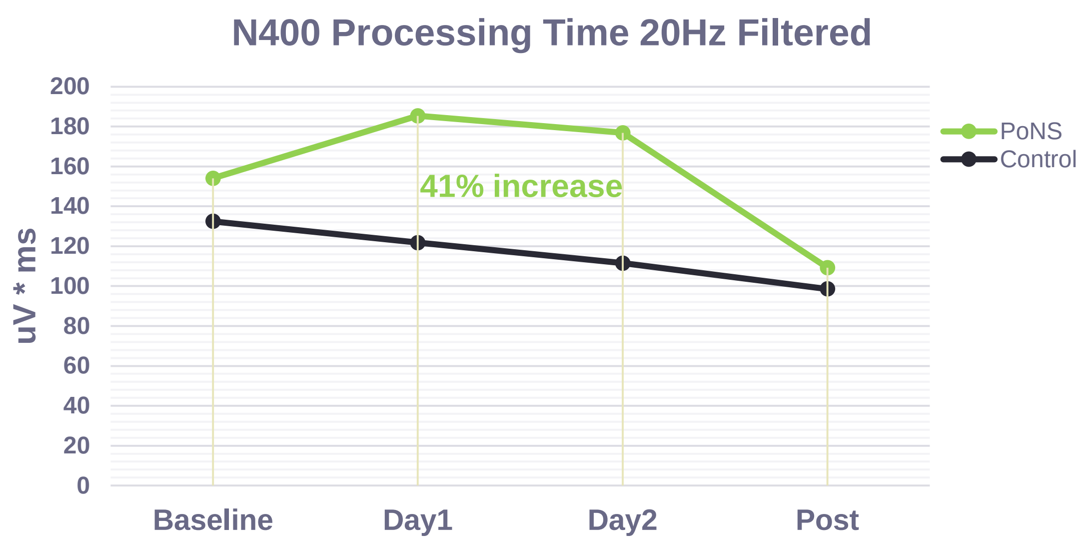


Assessment of general motor skills based on the GNCFS scale



Cognitive Study Expanded to Confirm Encouraging Data

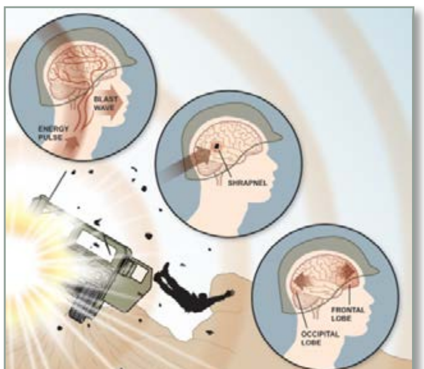
- 24 volunteers put into two groups of 12
  - One group had PoNS + Cognitive Enhancement Protocol, the other just the Cognitive Enhancement Protocol
  - Brain Vital Signs were tested in all 24 subjects
- Favorable preliminary results were found:
  - The group with the PoNS therapy had a stronger cognitive response to the Cognitive Enhancement Protocol
  - The cognitive marker, a response known as the N400, had specific improvements in speech processing and semantic comprehension.



Traumatic Brain Injury ("TBI")

- **$60B Annual Direct and Indirect Cost to US[1]**
- **$5B Estimated Market Size for PoNS™ Therapy[2]**

Military



Common Types of TBI due to Military Activity:

- Explosive blast injury
- Overpressure
- Penetrating injury
- Diffuse axonal injury

- 30,000/year active duty soldiers withTBI[3]
- 200,000 retired soldiers diagnosed with TBI[4]
- 20-30% of new cases result in chronic symptoms[5]

Athletic / Civilian

Causes of Civilian TBI:

- Blunt trauma
- Motor vehicle accident
- Sports related injury
- Assaults

- 1.75M new cases of TBI reported in U.S. each year[6]
- 20-30% of new cases result in chronic symptoms[5]
- 5.3M living with TBI related disability[7]

[1,2,3,4,5,6,7] *Please see appendix (slide 26)*

Regulatory Pathway

- **FDA deemed the PoNS^{TM} device a 'non-significant risk device' for the TBI indication**
  - Does not pose a significant risk to human subjects
  - FDA guidance points to 90-day regulatory review upon submission for de-novo clearance for Class II
- **Seeking a de-novo to Class II clearance from the FDA in TBI**
  - Balance disorder related to non severe TBI
  - FDA reviewed and cleared the registrational trial protocol
  - Primary endpoint is improvement in balance at week 5 at measured by Sensory Observation test (SOT)
- **Concurrent to FDA filing, seeking EU CE Mark, Health Canada MDL and TGA approval**
- **ISO 13485 received in November 2016**

Anticipated PoNS™ Clinical Milestones

Helius MEDICAL TECHNOLOGIES	Pre-clinical	Pilot Study	Begin FDA Reg. Trial	Complete FDA Reg. Trial	Submit FDA Filing	Obtain Clearance/ Approval
PoNS™ 4.0 Device | Cranial Nerve Non-Invasive Neuromodulation + Exercise						
CLINICAL STAGE PROGRAMS						
Traumatic Brain Injury			*Q3:15*	*Q2:17*	*Q3/Q4:17*	*Q1:18*
Cognition			*Q4:16*	*Q1:17*	*N/A*	*N/A*

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