



**Helius**  
MEDICAL TECHNOLOGIES

A Revolution in Mind  
July 2017



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  - the potential results of the Company’s ongoing and planned clinical trials;
  - the Company’s estimate of the size of the potential markets for its products;
  - the estimated clinical, regulatory and commercial milestones and the timelines for achieving such milestones;
  - the Company’s ability to enroll and successfully complete, clinical trials;
  - the expected timelines for patent filings and issuance;
  - the Company’s future manufacturing strategy;
  - the therapeutic benefits, effectiveness and safety of the Company’s product candidates;
  - whether the Company will receive, and the timing and costs of obtaining, regulatory clearances in the U.S., Canada, EU and Australia;
  - regulatory developments and the regulatory environments in which the Company operates; and
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  - 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”), CE Mark, TGA (Australia) 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 the Strategic Agreement with A&B;
  - the risk that the Strategic Agreement with A&B 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; and
  - development by others of new or improved devices or products that may result in the Company’s present and future products from becoming obsolete.
- This presentation speaks as of its date and we, our advisors, and our and their affiliates and representatives undertake no obligation to update, revise or correct the information contained herein, except as required by law.
- This presentation contains industry and market data that we obtained from independent industry publications. We have not independently confirmed this data and, although we believe it is generally reliable, it involves a number of assumptions and limitations, it is inherently imprecise, and you are cautioned not to place undue reliance on it.

# Helius Medical Technologies Management



**Philippe Deschamps**  
**President and CEO**  
**Chairman and Director**

- Over 30 years in the health sciences industry
- Former CEO at MediMedia Health Marketing Services (Division of inVentiv Health)
- Former President and CEO at GSW Worldwide
- Former Director of Neuroscience Marketing at Bristol-Myers Squibb



**Joyce LaViscount**  
**CFO and COO**

- 29 years in the health sciences industry
- Accomplished pharmaceutical/healthcare public company CAO
- Former Executive Director/group controller at Aptalis Pharmaceuticals
- Former Chief Operating Officer and CFO MM Pharmaceutical Solutions



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

- 31 years in the health sciences industry
- Trained surgeon and pioneer of new medical technologies
- Has helped build several companies including medical technology, research and product-design and medical contract sales organizations

*Experienced management team with expertise in health sciences and commercialization*

# Equity Overview: Helius Medical Technologies

Tickers: HSM:TSX, HSDT:OTCQB	
Market Cap 7/17: US\$146.7 M	Shares Outstanding as of 7/17: 95.25 M
Price: HSM.T - CAD\$1.98   HDST - US\$1.54	Shares Incl. Warrants & Options as of 7/17: 115.4 M
52 Week High: CAD\$2.59   52 Week Low: CAD\$1.11	Mgmt Ownership as of 7/17: 32.5 M (39.9 M Incl. Options)
Average Daily Volume: 92,370	3/31/17 Cash & Equivalents: US\$7.7 M, \$0 Debt Gross Proceeds from 6/17 Offering: \$5.3 M



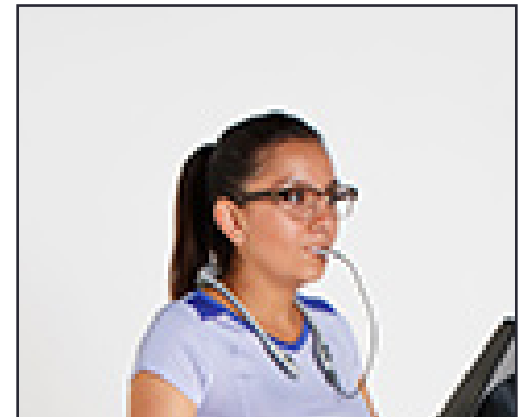
\*as of 7/6/17

# 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 physiotherapy may help treat patients with chronic neurological symptoms caused by disease or trauma
- Used investigationally with over 250 patients at the University of Wisconsin-Madison. Tests in pilot studies (MS, TBI and CP) and case series in 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 2H 2017

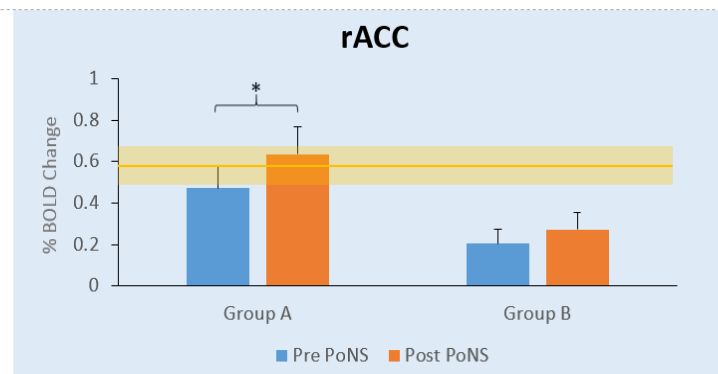
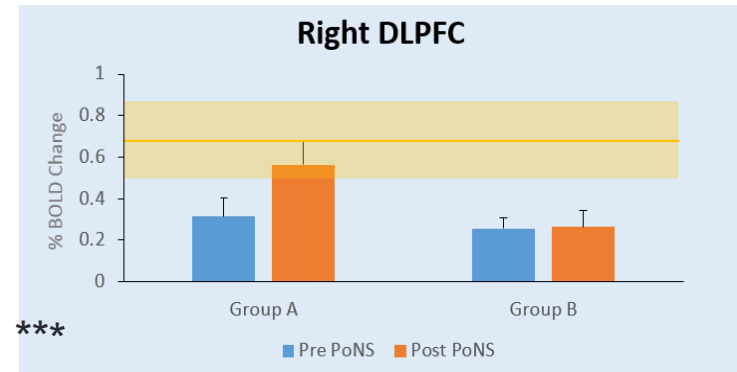
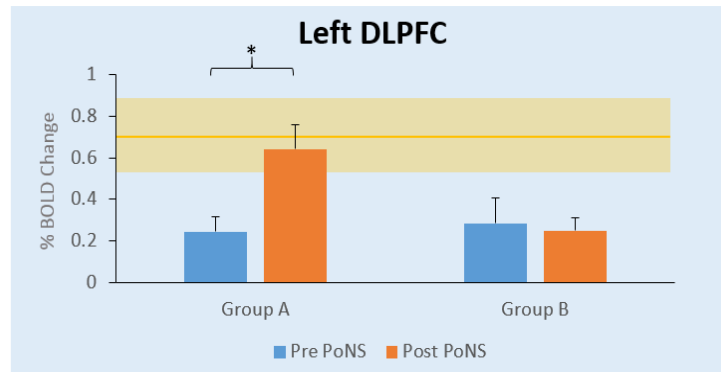


# Results from Multiple Sclerosis Pilot\* Study

## fMRI Changes Vs Healthy Controls

14 subject study: All received physiotherapy with 7 receiving PoNS™ device stimulation and 7 in the sham group.

### \*\*VOIs BOLD signal vs. Healthy Controls



\* See appendix

\*\*dorsolateral prefrontal cortex (DLPFC)  
 \*\*\*rostral anterior cingulate cortex (rACC)

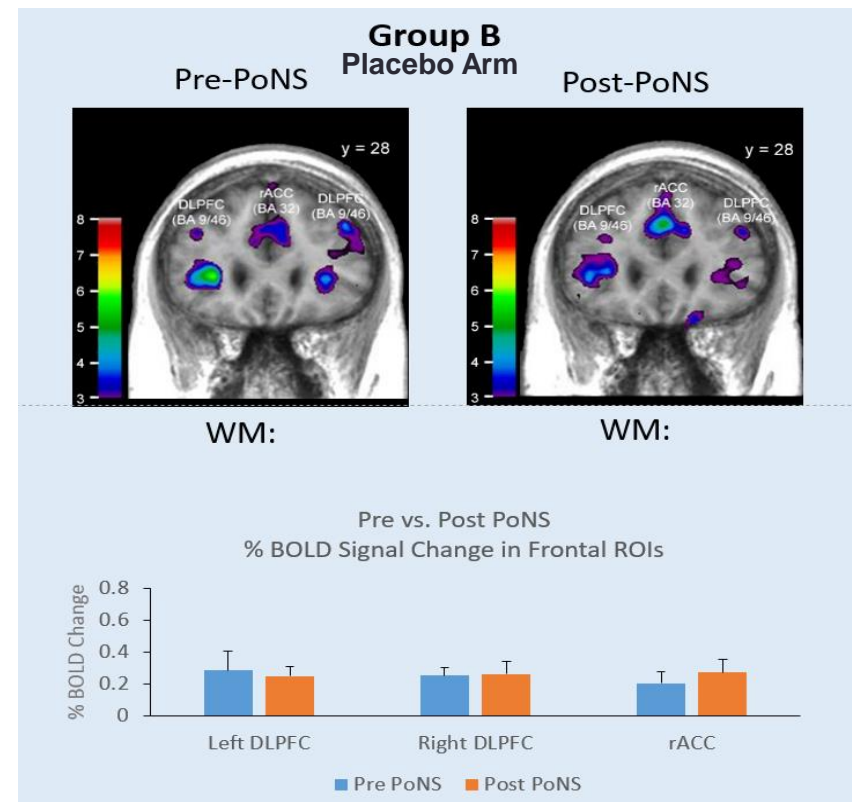
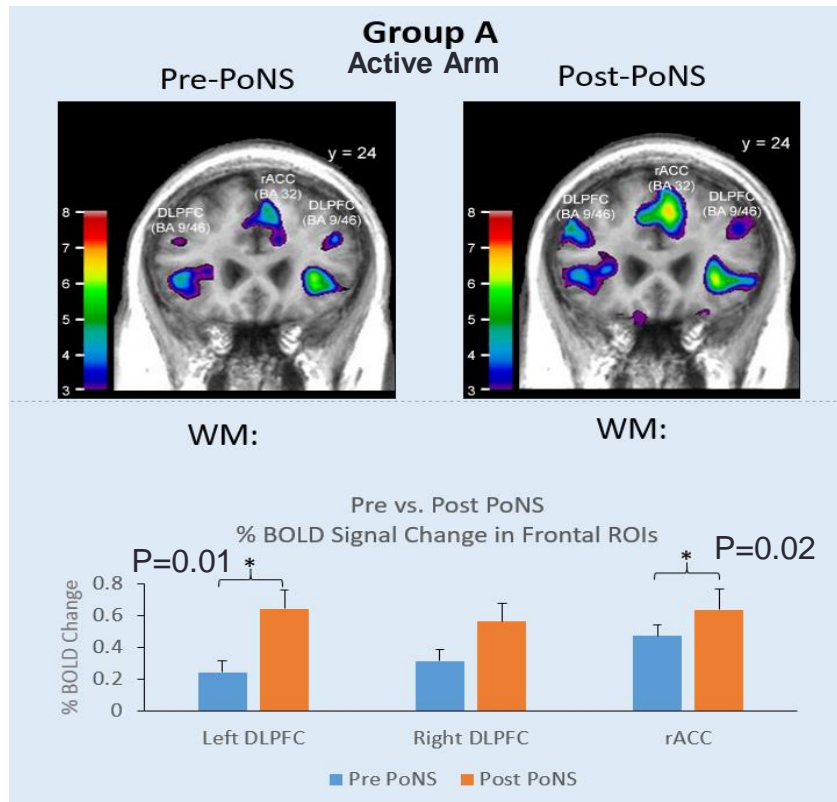
Mean and 95% quantile of healthy control's BOLD signal change

# Results from Multiple Sclerosis Pilot Study

## Working Memory fMRI\*

**Group A:** Post PoNS™ device training fMRI shows significant increase in BOLD signal in the left DLPFC\*\* ( $t=3.55$ ,  $p=0.01$ ), rACC\*\*\* ( $t=3.057$ ,  $p=0.02$ ) and a trend for significance in the right DLPFC ( $t=2.3$ ,  $p=0.06$ ).

**Group B:** Baseline as well as post-PoNS™ fMRI shows sub-threshold peaks in bilateral DLPFC and rACC. Paired-t tests comparing pre and post PoNS™ scans did not reveal any significant changes.



\* See appendix

\*\*dorsolateral prefrontal cortex (DLPFC)

\*\*\*rostral anterior cingulate cortex (rACC)

# PoNS™ Ongoing Pivotal Trial in TBI

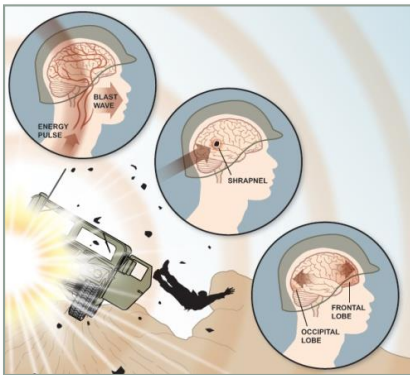
<b>Clinical Study Title</b>	A double-blind, randomized, sham-controlled study of the safety and effectiveness of the PoNS™ device for cranial nerve noninvasive neuromodulation (“CN-NINM”) training in subjects with a chronic balance deficit due to mTBI.
<b>Indication</b>	Chronic balance deficit due to non-severe TBI
<b>Start Date</b>	August 2015
<b>Expected Completion</b>	Q3:17
<b>Description</b>	<p>Helius as sponsor launched a Pivotal Registrational clinical trial in conjunction with US Army Medical Research and Material Command at:</p> <ul style="list-style-type: none"> <li>• Montreal NeuroFeedback Centre (Montreal, QB)</li> <li>• Oregon Health and Science University (Portland, OR)</li> <li>• Orlando Regional Medical Center (Orlando, FL)</li> <li>• HealthTech Connex (Surrey, BC)</li> <li>• VCU (Richmond, VA)</li> <li>• MedStar National Rehabilitation Center (Washington, D.C.)</li> <li>• University of Wisconsin (Madison, WI)</li> </ul>
<b>Patient Enrollment</b>	<ul style="list-style-type: none"> <li>• 120 patient double-blind, active control study</li> <li>• Primary endpoint is improvement in chronic balance deficit at 5 weeks</li> </ul>
<b>Long Term Treatment Study (Fully Enrolled) to end on May 26, 2017</b>	<ul style="list-style-type: none"> <li>• Tactile Communication Neurorehabilitation Laboratory at University of Wisconsin-Madison</li> <li>• Sponsored by US Army</li> <li>• 44 patients (active/sham; 14-weeks active treatment, 12-week washout)</li> </ul>



# Traumatic Brain Injury Market

- **Large Population:** 2.1 million people with balance disorder related to non severe TBI<sup>1</sup>
- **Unmet Need:** Current treatment paradigm offers few viable therapeutic options

## Military



### Common Types of TBI due to Military Activity:

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

- 30,000/year active duty soldiers with TBI<sup>2</sup>
- 200,000 retired soldiers diagnosed with TBI<sup>3</sup>
- 20-30% of new cases result in chronic symptoms<sup>4</sup>

## Athletic / Civilian



### Causes of Civilian TBI:

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

- 1.7M new cases of TBI reported in U.S. each year<sup>5</sup>
- 20-30% of new cases result in chronic symptoms<sup>4</sup>
- 3.2 - 5.3M living with TBI related disability<sup>6</sup>

<sup>1,2,3,4,5,6</sup> see appendix

# Clearly Defined Regulatory Pathway

**FDA deemed the study of the PoNS™ for mild-moderate TBI a ‘non-significant risk (NSR) device study’ under the IDE regulations**

- Assessed the study as not posing a significant risk to human subjects
- FDA guidance points to 120-day regulatory review upon submission for de novo clearance for Class II

**FDA indicated that a de novo request for classification into Class II for the mild-moderate TBI indication would be an appropriate path to seek marketing authorization**

- Balance disorder related to non-severe TBI
- FDA reviewed and provided feedback on the registrational trial protocol
- Primary endpoint is improvement in balance at week 5 as measured by Sensory Observation Test (SOT)

**Concurrent to FDA filing, seeking EU CE Mark, Health Canada MDL and TGA approval**

**ISO 13485 received in December 2016 from LRQA an independent organization to review companies quality systems**

# Building a Moat: Extensive IP Portfolio

## Exclusively licensed from inventors (4% royalty):

- 7 US Medical Method Patents Issued
  - ❖ Skin Stimulation + Physical Therapy = Therapeutic Outcome
  - ❖ Skin Stimulation + Cognitive Therapy = Therapeutic Outcome
  - ❖ Oral Cavity Stimulation + Physical Therapy = Therapeutic Outcome
  - ❖ Oral Cavity Stimulation + Cognitive Therapy = Therapeutic Outcome
  - ❖ Oral Cavity Stimulation with Pulse Generator + Exercise = Therapeutic Outcome
  - ❖ Oral Cavity Stimulation + Cognitive Therapy = Treatment of Tinnitus and other Neurological Disorders
  - ❖ Oral Cavity Stimulation + Exercise = Enhanced Human Performance
- 1 US Patent Application Pending
  - ❖ Oral or Skin Stimulation + Physical or Cognitive Exercise = Enhanced Human Performance
- 1 US Application Forthcoming – to be filed Q2 2017: Treatment of Addiction

## Patents owned by Helius (no royalty):

- 24 US Patents Issued
- 1 US Patent Application Allowed
- 3 US Patent Applications Pending
- 1 US Patent Application Forthcoming – to be filed Q2 2017: Mouth-Breathing and Retainer Features
- 11 Non-US Design Patents Issued: Europe (1); Canada (7); Russia (3)
- 3 International Patent Applications Pending
  - ❖ 1 Eurasian National Phase Patent Application Pending – filed in 2017: Methods of Providing Physical and Cognitive Therapy

## Helius patents transferred to CMS (China Medical System Holdings):

- 3 Chinese Design Patents



# Helius

MEDICAL TECHNOLOGIES

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