Legal Disclaimers

This presentation contains forward-looking statements, including statements about: uncertainties regarding the FDA regulatory approval process, including whether the results of our clinical trials will be sufficient to support an FDA, CE Mark or TGA approval of the PoNS™ device for marketing or whether the agencies may require that the Company conduct future clinical trials; future economic, competitive, reimbursement and regulatory conditions; new product introductions; ability to commercialize its PoNS Treatment™; demographic trends; the intellectual property landscape; financial market conditions; continued availability of capital and financing, including its ability to continue as a going concern; and future business decisions made by the Company and its competitors. These statements involve substantial known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. Factors that may cause actual results to differ materially from any future results expressed or implied by any forward looking statements include the risks described in the “Risk Factors” section of Company’s Annual Report on Form 10-K for the period ended December 31, 2018 and the Company’s Quarterly Report on Form 10-Q for the period ended September 30, 2019, as well as those set forth from time to time in the Company’s other SEC filings, available at http://www.sec.gov. The forward-looking statements in this presentation represent our views as of the date of this presentation. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this presentation.

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The Company’s first product, known as the Portable Neuromodulation Stimulator (“PoNS™”), is an active, therapeutic, class II medical device authorized for sale in Canada intended as a short term treatment (14 weeks) of chronic balance deficit due to mild-to-moderate traumatic brain injury (“mmTBI”) and is to be used in conjunction with therapeutic activities (“PoNS Treatment™”). It is an investigational medical device in the United States, the European Union (“EU”), and Australia (“AUS”), and it is currently under review for clearance by the AUS Therapeutic Goods Administration. PoNS Treatment™ is not currently commercially available in the United States, the European Union or Australia.

The Company has withdrawn its application from the EU marketing process due to uncertainty in Europe due to the switch from the Medical Device Directive (MDD) to the Medical Device Regulation (MDR) and the withdrawal of Lloyd’s Register Quality Assurance, the Company’s notified body, from the notified body business. The Company will reconsider submitting to the EU when conditions stabilize.
Helius Leadership Team:
Experienced Leadership With Healthcare and Commercialization Expertise

Philippe Deschamps
President, Chief Executive Officer & Chairman
- 30+ years in the health sciences industry
- Former CEO at MediMedia Health
- Former President and CEO at GSW Worldwide (Division of inVentiv Health)
- Former Director of Neuroscience Marketing at Bristol-Myers Squibb

Joyce LaViscount
Chief Financial Officer and Chief Operating Officer
- 29+ years in the health sciences industry
- Accomplished pharmaceutical/healthcare public company CAO
- Former COO and CFO at MM Pharmaceutical Solutions
- Former Executive Director/Group Controller at Aptalis Pharmaceuticals

Dr. Jonathan Sackier
Chief Medical Officer
- 30+ 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

Mark Leno
General Manager, Canadian Operations
- 17+ years in the medical devices industry
- Sales and Marketing Director, Boston Scientific Canada
- National Sales Manager, Canada Johnson & Johnson
- Former Media Relations and Marketing executive for Blue Jays & NHL
Investment Highlights

Platform Technology
• First in class, non-invasive neurotechnology with broad potential in treating symptoms of neurological disease and trauma

Large Initial Market
• Over 350K people with chronic balance deficit caused by mild-to-moderate traumatic brain injury (mmTBI) in Canada

PoNS Treatment™
• “First mover advantage” with demonstrated safety and efficacy in a market with few viable treatment options

Clinical Pipeline
• Pilot studies completed in Stroke, Multiple Sclerosis, and Cerebral Palsy

Regulatory Progress
• Cleared in Canada. TGA submission under review. Efforts to resubmit to FDA in process.

Robust IP
• Method Patent portfolio coverage extends to 2028; utility and design patents to 2035

www.heliusmedical.com | Nasdaq:HSDT | TSX:HSM
Large and Growing Addressable Market

Chronic balance deficit is a long-term disability associated with neuro trauma and disease\(^2\)

Gait speed, cadence, stride length and time spent on double-limb support are frequently affected in individuals with balance deficit

People worldwide experience new TBI cases annually\(^1\)

People living with chronic balance deficit following an mmTBI in the US\(^3\) and Canada\(^5\)

New cases annually of chronic balance deficit caused by mmTBI in the US\(^4\) and Canada\(^6\)

>1.5M

>350K

50-60M

After the initial medical event, TBI can present significant long-term disabilities and challenges to the individual, family, and society

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Tongue Based Neuromodulation

The PoNS™ investigational medical device gently stimulates the trigeminal nerve through the tongue. It is designed to activate neuroplasticity in the brain and unlock its ability to restore lost function which we call neuromodulation.

A mild-to-moderate TBI damages a part of the brain, reducing the ability of the brain’s neural impulses to communicate clearly with the body.

To restore balance and function, the brain needs to be “rewired” to work around the damaged area and reestablish neural impulses to the body. This “rewiring” is called neuroplasticity.

The nerves in the tongue are directly connected to the brainstem, which is the body’s control center. It is dense with nerve endings in a warm, dark environment making it ideal for stimulation.
The PoNS™ device is also a smart technology that tracks frequency, duration and intensity of use.

Data captured is uploaded to the cloud to be analyzed to drive treatment decisions and provide details on compliance for payer reimbursement opportunities.
Clinical Support for PoNS Treatment™:  
**RCT Enrollment Criteria for Mild-to-Moderate TBI with Chronic Balance Deficit**¹,²

- Safety and efficacy of PoNS Treatment™ demonstrated in two double-blind randomized controlled trials (RCTs):
  - PoNS™ Registrational Trial in TBI (“TBI-001”)
  - Long-Term Treatment Study in mmTBI

- Enrollment criteria included patients with persisting balance deficit, despite treatment with physical therapy (PT), the current standard of care

<table>
<thead>
<tr>
<th>Inclusion Criteria for Both Trials</th>
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<tbody>
<tr>
<td><strong>Aged 18-65 years at screening</strong></td>
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<tr>
<td><strong>Balance disorder as a result of mmTBI</strong></td>
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<tr>
<td><strong>≥ 1-year since mmTBI</strong></td>
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<tr>
<td><strong>Plateaued in recovery with current PT rehabilitation regimen</strong></td>
</tr>
<tr>
<td><strong>Sensory Organization Test (SOT) score &gt; 16 points below normal</strong></td>
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</tbody>
</table>

PT = physical therapy; SOT = Sensory Organization Test; TBI = traumatic brain injury.

Because there was no statistically significant difference in the percentage of SOT responders between the HFP and LFP arms in the intention-to-treat population, the arms were pooled for additional assessments.

\[ P = 0.0005 \]

**Trial Outcomes**

- **71.2%** Were Responders (i.e., 15 point SOT score improvement) in the HFP arm.
- **57.4%** who were in the normal range for balance at end of the study.

HFP = high-frequency pulse; LFP = low-frequency pulse; SOT = Sensory Organization Test.

\(^a\)Responders were defined as participants who had an improvement of ≥ 15 points in SOT score from baseline.

Clinical Support for PoNS Treatment™:
Long-term Treatment Study in mmTBI Demonstrates Significant, Sustained Improvement

In patients with mmTBI, balance was significantly better at 2 Weeks, 14 Weeks and 26 Weeks

- On average, patients with mmTBI improved from an impaired SOT score to normal SOT score in 14 weeks of treatment with HFP version of PoNS™ device.

- On average, normal SOT score was maintained throughout the 12-week washout period for all patients.

1 Patients treated with high frequency pulse (HFP) device. Low frequency pulse (LFP) data not shown since it was not statistically different from HFP. Archives of Rehabilitation Research and Clinical Translation (2019), doi: https://doi.org/10.1016/j.arrct.2019.100026.
Commercializing PoNS Treatment™ in Canada

Initial Commercial Progress

- Regulatory, quality management and post-market surveillance systems for PoNS Treatment™ in place
- Two founding neuroplasticity clinics established in Montreal and Surrey
  - Began shipping devices to Montreal and Surrey clinics in Q1 2019
- Added three additional neuroplasticity clinics (Toronto, Calgary, Ottawa) in Canada in June 2019
  - Began shipping devices to these clinics in Q2/Q3, 2019
  - Will continue to try to add clinics in Q4, 2019 and beyond

Engaging, training and authorizing Canadian clinics to provide PoNS Treatment™
• **Real-world results of initial TBI patients consistent with Helius’ two RCTs in mmTBI:**
  - Patients demonstrated the same pattern of positive change over their course of treatment
  - Majority of patients showed improvement in comfortable gait speed, a measure of their ability to walk, with a meaningful clinical difference at the end of treatment
  - Not all patients treated with PoNS™ have responded to treatment

• **Securing reimbursement by insurers for our treatment is a key goal of the company.**
  - Obtained two fully reimbursed patient treatments from different private insurers at different clinics
  - Working with our reimbursement specialist to use these two successes to target multiple insurers to formalize the reimbursement process
  - Gathering anonymized outcomes and compliance data on the patients treated in the Canadian clinics to make our reimbursement presentations more meaningful to private and public insurers
Evolution of Our Regulatory Strategy in Canada

• Engaged with Health Canada to pursue a potential label expansion for the treatment of balance and gait disorder caused by Multiple Sclerosis
  • Based on the positive results in our two peer reviewed studies in MS of PoNS Treatment™ in participants with MS demonstrating improvements in balance and gait and, in one study, significant improvements in blood oxygen level-dependent functional MRI scans\(^1,\!^2\)
• MS market characteristics
  • 93,500 patients in Canada\(^3\)
  • High urgency to treat
  • Less price sensitive
  • Very similar treatment protocol as mmTBI

\(^1\) Tyler et al. Journal of NeuroEngineering and Rehabilitation 2014, 11:79
\(^3\) https://www150.statcan.gc.ca/n1/pub/82-003-x/2018001/article/54902-eng.htm
FDA declined request for de novo classification in April 2019

In reaching its conclusion, the Agency noted:
- it did not have sufficient information to discern the relative independent contributions of the PoNS™ device and physical therapy on the improvements from baseline in the effectiveness endpoints observed in the Company’s clinical studies
- there were no device-related serious adverse events in either of the Company’s two supporting clinical trials
- participants in both arms of the two supporting clinical trials demonstrated improvements from baseline in all pre-specified clinical endpoints
- Because the intended control group (low frequency arm) also improved, along with the high frequency group, FDA requested additional control group data
- The FDA also noted that the Company could generate additional data to address its concerns and resubmit its application
US Regulatory Strategy

**Strategy:** Resubmit application for regulatory clearance of PoNS™ device

**Progress since April 2019:**

A. **Added external resources with specialized clinical and regulatory expertise**
   - New resources include:
     - Former Director of FDA's Division of Biostatistics Center for Devices and Radiological Health
     - Regulatory counsel with extensive experience in de novo applications to the Neuromodulation division at FDA

B. **Developed strategy and initial action plan to guide resubmission process**

C. **Informal discussion with FDA in June focused on the issues raised in its April response to our submission**
   - Discussion focused on the issues raised in FDA's response to our submission

D. **Designed new clinical protocol to generate data evaluating the efficacy of physical therapy alone**
   - Study design: Augment TBI-001 with PT alone arm
     - Inclusion/exclusion criteria and 5-week physical therapy treatment to be identical to TBI-001 trial

E. **Completed FDA Presub Meeting**
   - FDA accepted single-arm study generating PT alone data as an alternative to a randomized study and recommended crossing over patients from PT alone to PT + PoNS
   - Patients will receive PT alone treatment for 5 weeks followed by 5 weeks of PT+PoNS
   - Following the pre-submission meeting, initiated formal study startup activities including site selection, protocol, contracts, budget, site engagement and planned initiation visits to support first patient enrollment expected in January, 2020
   - Expect to submit study results to FDA in Q3, 2020
Canada: Authorization received on 10/17/18
The PoNS™ device is intended for use as a short-term treatment (14 weeks) of chronic balance deficit due to mild-to-moderate traumatic brain injury (TBI) and is to be used in conjunction with physical therapy.

Australia: Awaiting decision from regulators
• Australia: Therapeutic Goods Administration (TGA) review began 9/19
  • Received and responded to administrative follow-up questions from TGA
  • Awaiting TGA decision

EU: Company withdrew its CE Mark Application
• Decision made due to EU’s move to Medical Device Regulation (MDR) from Medical Device Directive (MDD), and the Company’s Notified Body withdrawal from the business created uncertainty in clearance process
  • Company will resubmit once a new notified body selected and process clarity returns to EU
PoNS Treatment™
Additional Clinical Progress and Potential Opportunities

Indication and Target Population - US*

- Multiple Sclerosis (1M People)
- Cerebral Palsy (764K People)
- Stroke (7M People; 795K new each year)
- PTSD (25M People)
- Facial Nerve Palsy (75K People)
- Depression (15.7M People)
- Parkinson’s Disease (1M People; 60K new each year)

*See reference slides for sources

Potential for Future Development

- Pilot Studies Completed

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Extensive IP Portfolio

Exclusively licensed from inventors (4% royalty):
• 9 US Medical Method Patents Issued
• Patents expire between 2029 and 2031

Patents owned by Helius (no royalty):
• 29 US Patents Issued
• 41 Foreign Patents Issued
• Patents expire between 2026 and 2040

Helius Patents Transferred to China Medical System Holdings (CMS):
• 3 Chinese Design Patents

Independent Verification of Patents and Freedom to Operate Opinion – September 2017
Financial Overview

• Third Quarter Revenue: $0.2M
  • Q3’19 revenue almost exclusively comprised of sales of our PoNS™ devices to the new PoNS authorized clinics that became operational in Q3.
  • In Q1 we had 23 treatment starts, in Q2 we had 38 treatment starts, and in Q3 we had 32 treatment starts.
  • We believe the modest decline in Q3, is due to fewer patients scheduling their 14-week treatment program in the month of August due to summer vacations.

• Third Quarter Operating Expenses: Operating loss for the third quarter of 2019 was $5.7 million, compared to operating loss of $4.9 million for the prior year period.

• $9M cash and no outstanding debt as of September 30, 2019

*Note: Changed functional currency from $CAD to $USD, effective April 1, 2018. Financial statements prior to and including the period ending March 31, 2018 have not been restated for the change in functional currency.
2019 Guidance:

For 2019, we now expect total revenue in a range of $1.5 million to $1.6 million U.S. dollars, compared to our prior revenue guidance range of $1.6 million to $2.0 million U.S. dollars.

Range contemplates lower revenue contributions from one of the founding PoNS™ clinics in Surrey, British Columbia.

- Our prior guidance range of $1.6 million to $2.0 million dollars had assumed contributions from sales to the Surrey clinic, during the second half of 2019, of approximately $500,000.
- The expected revenue from the Surrey clinic in the second half of 2019 was included in the total consideration for our new agreement with HTC, and thus will not be recognized in our revenue in 2019.

- Partially offsetting the impact from lower than expected Surrey revenue in the second half of 2019, is the incremental contribution from the three new clinics that became fully operational during the third quarter.

- Additionally, for modeling purposes, for the full year 2019:
  - Our revenue guidance assumes an exchange rate of $1.00 Canadian dollar to $0.75 US dollars.
  - We continue to expect our revenue will be generated primarily from contributions by the neuroplasticity clinics that are fully operational and treating patients in Canada.
References

Slide 4: Investment Highlights


Calculations 1.5M x 90% (have a traumatic brain injury) x 85% (mmTBI) 31% (suffer Chronic balance disorder) (1.5M x .90 x .85 x .31)= 356K

Slide 5: Large and Growing Addressable Market


Helius Medical Technologies Data on File. Global Data.


Ma VY, Chan L, Carruthers KJ. Incidence, prevalence, costs, and impact on disability of common conditions requiring rehabilitation in the United States: stroke, spinal cord injury, traumatic brain injury
References

Slide 8: Clinical Support for PoNS Treatment™

Slide 17: Disease State Prevalence
- Multiple Sclerosis - [http://www.nationalmssociety.org/About-the-Society/MS-Prevalence](http://www.nationalmssociety.org/About-the-Society/MS-Prevalence)
- Stroke – [http://www.strokeassociation.org/STROKEORG/LifeAfterStroke/Life-After-Stroke_UCM_308546_SubHomePage.jsp](http://www.strokeassociation.org/STROKEORG/LifeAfterStroke/Life-After-Stroke_UCM_308546_SubHomePage.jsp)
  - [https://www.cdc.gov/dhdsp/data_statistics/fact_sheets/fs_stroke.htm](https://www.cdc.gov/dhdsp/data_statistics/fact_sheets/fs_stroke.htm)
- Bells Palsy: [https://www.news-medical.net/health/Bells-Palsy-Epidemiology.aspx](https://www.news-medical.net/health/Bells-Palsy-Epidemiology.aspx) - US rate of 23 cases per 100,000 persons – (326 Million US Population /100,000 * 23 = 75,000)
  - [http://www.cdc.gov/nchs/fastats/depression.htm](http://www.cdc.gov/nchs/fastats/depression.htm)
Multiple Sclerosis Pilot Study

Two groups (10 each):
1. “Active” PoNS + exercises
2. “Control” PoNS + exercises

“Control” PoNS = no electrical stimulus

 Tyler et al. Journal of NeuroEngineering and Rehabilitation 2014, 11:79
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 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

VOIs BOLD signal vs. Healthy Controls

Left DLPFC

Right DLPFC

rACC

Mean and 95% quantile of healthy control’s BOLD signal change
**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.
Cross over of Control Patients to Active Treatment

Analysis of the total composite score:
- Both groups show a trend for improvement over time but it is more consistent for the Active Group.
- T tests comparing the week 14 score to the pre score reveals that the improvement for the Active Group is significant ($p < .001$)
- the Sham group difference did not reach statistical significance ($p < .06$).
- For the Rollover Group, a steady increase in mean SOT scores from initial baseline to final testing (Baseline: 49.80; Sham: 61.60; Sham-rollover: 68.0).
- Repeated ANOVA showed a significant effect of stimulation on SOT ($F(1,4) = 16.529$, $p = 0.015$), pairwise comparison indicated that SOT scores improved significantly from baseline to post CN-NINM training ($p = 0.046$).