

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 9, 2020



HELIUS MEDICAL TECHNOLOGIES, INC.

(Exact name of Registrant as Specified in Its Charter)

DELAWARE
(State or Other Jurisdiction
of Incorporation)

001-38445

36-4787690
(IRS Employer
Identification No.)

642 Newtown Yardley Road, Suite 100
Newtown, PA
(Address of Principal Executive Offices)

(Commission File Number)

18940
(Zip Code)

Registrant's Telephone Number, Including Area Code: (215) 944-6100

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock	HSDT	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01 Regulation FD Disclosure.

On September 9, 2020, Heliuss Medical Technologies, Inc. (the "Company") posted an updated corporate presentation to its website at <http://heliussmedical.com/index.php/investor-relations/overview>, which the Company may use from time to time in communications or conferences. A copy of the corporate presentation is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information set forth in this Item 7.01 and in the investor presentation attached hereto as Exhibit 99.1, is deemed to be "furnished" and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section. The information set forth in this Item 7.01, including Exhibit 99.1, shall not be deemed incorporated by reference into any filing under the Exchange Act or the Securities Act of 1933, as amended, except to the extent that the Company specifically incorporates it by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit Number</u>	<u>Exhibit Description</u>
99.1	Corporate Presentation, dated September 9, 2020.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

HELIUS MEDICAL TECHNOLOGIES, INC.

Date: September 9, 2020

By: _____ /s/ Joyce LaViscount
Joyce LaViscount
Chief Financial Officer, Chief Operating Officer and Secretary



The Last Frontier in Healthcare
Empowering the Natural Healing Process of the Brain

September 2020

Legal Disclaimers

This presentation contains forward-looking statements, including statements about: uncertainties regarding the FDA regulatory approval process, 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 and strategic 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 impact of the COVID-19 pandemic, uncertainties associated with clinical trial enrollments and the results of clinical trials, uncertainties associated with the clinical development process and regulatory submission and approval process, and other risks described in the "Risk Factors" section of Company's Annual Report on Form 10-K for the year ended December 31, 2019 and the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, as well as those set forth from time to time in the Company's other filings with the securities and exchange commission and the Canadian securities regulators available at <http://www.sec.gov> or www.sedar.com. 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.

Certain data in this presentation was obtained from various external sources. Neither the Company nor its affiliates, advisers or representatives have verified such data with independent sources. Accordingly, neither the Company nor any of its affiliates, advisers or representatives make any representations as to the accuracy or completeness of that data or commits to update such data after the date of this presentation. Such data involves risks and uncertainties and is subject to change based on various factors.

The Company's first product, known as the Portable Neuromodulation Stimulator ("PoNS™"), is an authorized class II, non-implantable medical device authorized for sale in Canada. PoNS is intended as a short term treatment (14 weeks) of gait deficit due to mild and moderate symptoms from MS and balance deficit due to mild-to-moderate traumatic brain injury ("mTBI") and is to be used in conjunction with physical therapy ("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 FDA for use in gait dysfunction due to MS and 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.



Investment Highlights



Platform Technology

- First-in-Class, non-implantable neurotechnology with the opportunity to evolve with advancements in AI, compliance and data collection technologies
- Broad potential in treating symptoms of neurological disease, trauma, and potentially wellness and human performance
- High barrier to entry due to development timelines



Large Lifetime Addressable Markets

- MS in Canada and US: ~1.2M
- TBI in Canada and US: ~6.9M
- Other Neurological Disease/ Trauma
 - CP
 - Stroke
 - Parkinson's
- Cognitive and Human Performance
- Wellness
- Enhancement to the technology to further drive market adoption



PoNS Treatment™

- “Portable Neuromodulation Stimulator” with a controller & mouthpiece connected by a cord
- Electrodes on the mouthpiece send mild signals to the surface of the tongue exciting the neural network that flows to the brain
- Mild stimulation combined with physical therapy may enhance neuroplasticity

Undervalued asset poised for growth: science-backed neurotechnology with ready-to-scale operation



Investment Highlights cont'd

Regulatory Progress

- FDA Breakthrough Device Designation; FDA submission for de novo classification and clearance related to MS pending
- Authorization for gait deficits due to mild and moderate symptoms of MS in Canada in March 2020
- Authorization for balance deficit due to TBI in Canada in Oct 2018
- TGA pending
- ISO / MDSAP Certification

Clinical Evidence

- Publications and real-world evidence showing improvements in gait or balance in MS
- Multiple publications showing statistically significant improvements in balance/gait in TBI
- Real world evidence appears to complement findings in RCTs
- Add'l studies in stroke, CP, to be developed
- Engagement of renowned KOLs and SAB

Commercial

- Commercial infrastructure established
- Sales & Marketing success in Canada
- Research, Regulatory and Quality systems established
- Scale manufacturing and supply chain
- Reimbursement strategies in development for US
- China partners

Robust IP Portfolio

- Exclusively licensed from inventors
- 29 US and 41 Foreign patents issued and owned by Helius
- Patents expire between 2026 and 2040
- 3 Chinese Design Patents
- Independent Verification of Patents and Freedom to operate

Helius Leadership Team:

Experienced Leadership With Healthcare and Commercialization Expertise

Dane Andreeff

Interim CEO and
Member, Board of
Directors

- 20+ years at Maple Leaf Partners as the General Partner and Portfolio manager, a value-based hedge fund which grew to over \$2b in assets under management.
- Board member and trusted advisor to Helius Medical Technologies, Inc for over 3 years and HDL Therapeutics, Inc for over 15 years
- Owns approximately 3.4% of the company through Maple Leaf Partners and affiliates



Joyce LaViscount

Chief Financial Officer
and Chief Operating
Officer

- 30+ 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

VP, 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



Helius Leadership Team:

Deep Expertise in Key Functional Areas

Harry Kovelman, VP, Medical Affairs

- 25+ years medical affairs leader in rehabilitation, orthopedics and CNS
- Proven experience in clinical operations, KOL and market development for innovative solutions
- Former Medical Director, Besins Critical Care, Convatec, Ferring, and Dynaspint
- Experience in practice management as former Executive Director of Orthopaedics at St. Joseph's Medical



Larry Picciano VP, Quality & Regulatory Affairs

- 20+ years global medical device quality and regulatory experience
- Extensive experience with electro-mechanical medical devices
- Former Quality, Regulatory and Clinical Head at Philips
- Former senior roles in Quality, Regulatory and Clinical Affairs at FujiFilm, Animas/J&J, CircuLite, Technidyne, St. Jude
- MBA, M.Eng.Sc, Penn State



Ellyn Ito, VP, Human Resources

- 20+ years Human Resources in scale-ups, in tech, media & life-sciences in global public and private companies
- Former President & Managing Director, Sigma Integrated Resources
- Former CAO, Granahan McCourt Capital
- Former, SVP, Human Resources, RCN Corp.,
- Board Member, Redeemer Hospital Systems
- SPHR, HRCI 2005



Lola Abhulimen Sr. Director, Clinical Operations

- 15+ years in Clinical Operations
- Former Senior Trial Project Manager, Novocure
- Former, Clinical Operations Consultant at Quintiles, CRO and Consulting Services
- Former Clinical Trial Project Manager at United Global Health
- MBA, Penn State



Dr. Kim Skinner, DPT, PT Director, Physical Therapy

- 20+ years in clinical and research-oriented neurorehab physical therapy
- Neuromodulation research collaborator and Clinical Trial Manager at Univ Wisconsin
- Former Director, PT and Clinical Study Manager at Wicab
- MS, Physical Therapy, University of Wisconsin



Allison Northup, CPA Director, Accounting & Finance

- 13+ years in public accounting and SEC reporting with domestic and int'l experience
- Former Director, SEC and Accounting Policy, Brightview Holdings
- Former Senior Audit Manager, Ernst & Young AB
- Former Sr. Accountant & SEC reporting, Exelon
- MS, Accountancy, Wake Forest



Helius Board of Directors

Blane Walter

Chairman of the Board,
Member, Audit Committee,
Nominating and
Governance Committee

- Partner, Talisman Capital Partners
- Vice Chair of InVentive Health
- Chair of the Governor of Ohio's Executive Workforce Board
- Former CEO of InVentive Health
- Former Founder of InChord Communications

Jeff Mathiesen, CPA

Chairman, Audit Committee
Member, Compensation
Committee

- Vice Chair, Lead Independent Director, and Audit Committee Chair of Sun Biopharma (Nasdaq: SNBP)
- Director and Audit Committee Chair of NeuroOne Medical Technologies Corporation (OTCQB: NMTC)
- Former Board Member and Audit Committee Chair of eNeura, Inc.
- Former CFO at Teewinot Life Sciences
- Former CFO at Gemphire Therapeutics and Sunshine Heart

Ed Straw

Member, Compensation
Committee, Nominating
Committee

- Founder and Managing Partner of Osprey Venture Partners
- Chairman of Odyssey Logistics
- Member of the Board of Directors of Performance Equity Management, Capital Teas and Document Capture Technologies, Inc.
- Former President, Global Operations, Estee Lauder
- Former SVP, Global Manufacturing and Supply Chain Management at Compaq Computer Corporation
- Distinguished 3-star Admiral, US Navy

Mitch Tyler

Board Member

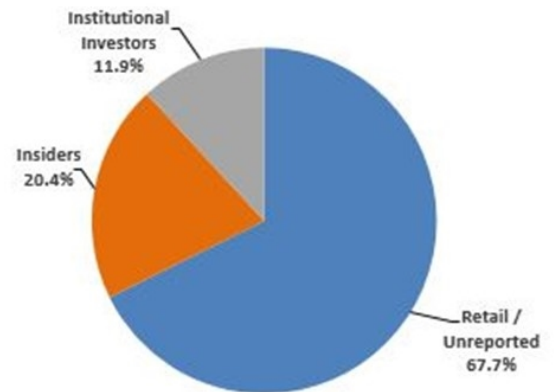
- Founder and Co-Inventor of PoNS™ technology
- Co-founder of Wicab, Inc and former VP, Research and Development
- Lead Inventor of the BrainPort Balance Device
- Former University of Wisconsin Biomedical Engineering faculty member
- MS, Biomedical Engineering and Registered Professional Engineer



Company Overview (as of June 30, 2020)

- Listed on the Nasdaq Capital Market since April 2018 (HSDT) - Market cap of \$20M
- Class A Common Stock shares issued and outstanding: 45.1M
- \$5.3M Cash and no long-term debt as of June 30, 2020
- China Medical Systems - 5.5% (ownership and development of PoNS asset in China)
- Coverage by Steven Lichtman, Oppenheimer

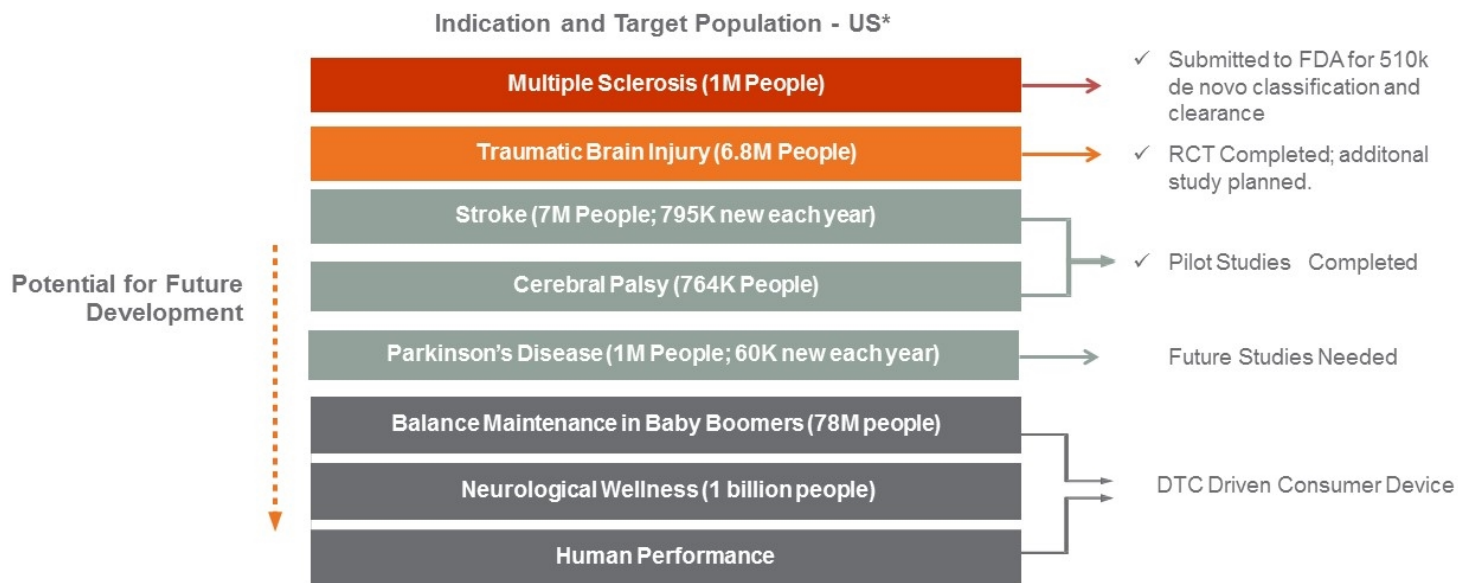
Shareholder Base Overview*



*Shareholder data sourced from IR Insight as of 6/30/20; based on 45.1M common shares outstanding as of 6/30/20

Large Lifetime Addressable Market

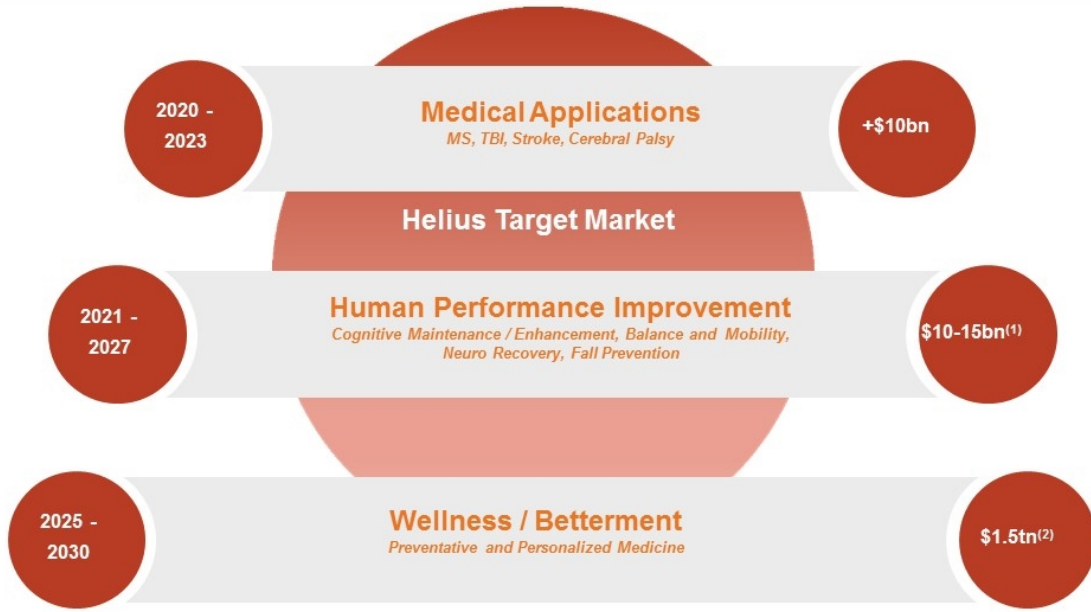
Additional Clinical Progress and Potential Opportunities



* See reference slides for sources

Large Lifetime Addressable Market

Strategic Vision PoNS Lifecycle Management



PoNS Treatment™

The PoNS™ Device



Treatment Hypothesis

- Researchers believe that targeted physical therapy performed during neurostimulation may promote neural network changes including rebuilding and reorganization (neuroplasticity) thereby restoring communication with the body and improving functionality such as balance
- Used in conjunction with physical therapy

Smart Device

- The PoNS™ is a smart device that tracks frequency, duration and intensity of use

Data Intelligence Capabilities

- Data is uploaded to the cloud for analysis, the results of which provide compliance profiles for clinician review and payer reimbursement opportunities

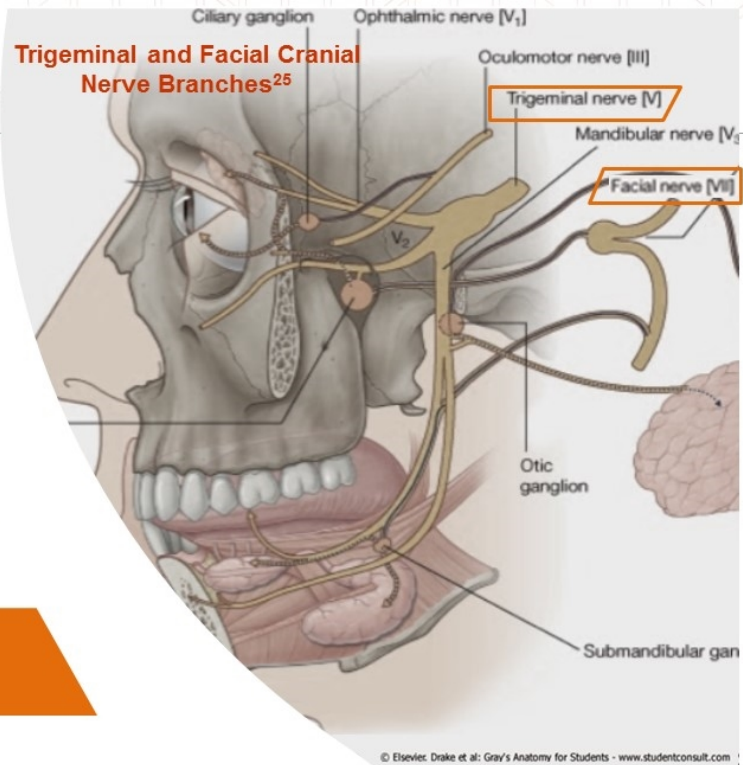
PoNS Treatment™

Mechanism of Action

Neuromodulation is the modification of nerve activity through delivery of a targeted stimulus

Translingual Neurostimulation provides neuromodulation of the cranial nerves via the tongue

~14MM pulses per 20-minute session
Feels like champagne or carbonated water bubbles



© Elsevier, Drake et al: Gray's Anatomy for Students - www.studentconsult.com



www.heliusmedical.com | Nasdaq:HSDT | TSX:HSM

Daniilov Y et al. Cranial Nerve Noninvasive Neuromodulation: New Approach to Neurorehabilitation, in Kobeissy FH (ed): Brain Neurotrauma: Molecular, Neuropsychological, and Rehabilitation Aspects. Frontiers in Neuroengineering. Boca Raton (FL), 2015. International Neuromodulation Society, January 24, 2013. Neuromodulation, or neuromodulatory effect. Available at <https://www.neuromodulation.com/neuromodulation-defined>. Accessed December 7, 2018.

Regulatory Progress

FDA Submission under the Breakthrough Device Designation

- Published studies earned PoNS™ Breakthrough Device Designation for the treatment of gait deficits due to symptoms of Multiple Sclerosis
- On August 4th, 2020, the Company filed its application to FDA for de novo classification and clearance of the PoNS™ Device for the treatment of gait deficit due to symptoms of Multiple Sclerosis
 - FDA guides to a 150-day review period for 60% of de novo applications
 - Our submission featured data from two published placebo controlled clinical trials and real-world evidence (RWE) from our treatment of people with MS in Canada
 - Data demonstrates acceptable risk benefit ratio
 - We look forward to working interactively with FDA in the context of the Breakthrough Device Designation

Regulatory Progress

Evolution of Our Regulatory Strategy in Canada

- We received label expansion for MS by Health Canada on March 26, 2020
 - MS market characteristics
 - 93,500 MS patients in Canada
 - Strong advocacy for MS (MS Society)
 - Urgency to treat
 - Similar treatment protocol as mmTBI
- TBI Authorization in October 2018
 - Mild to Moderate TBI market characteristics
 - ~350,000 patients in Canada
 - Build collaborative network with Payors
 - Developing key KOLs in TBI treatment



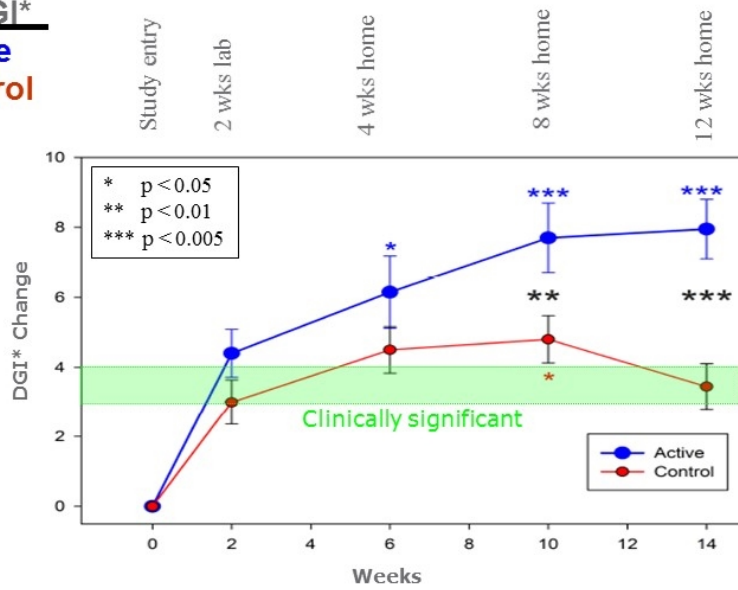
Clinical Evidence

Multiple Sclerosis Study – Mild and Moderate MS (EDSS score 3.5-6)

Mean DGI*

10 Active

10 Control



Two groups (10 each):

1. "Active" PoNS + exercises
2. Placebo PoNS + exercises

100%

Improvement in
Dynamic Gait Index
scores for the Active
Group

- All 10 subjects in the active treatment group experienced at least a 4 point improvement from baseline to Week 14 in DGI. Mean average of 7.95.
- Only 3 of 10 (30%) subjects in the placebo control group experienced an improvement in DGI of at least 4 points from baseline to week 14. Mean average of 3.45.

Clinical Evidence

Real-World Evidence in MS Patients Treated with PoNS™ in Canada

- 42 patients with MS were treated with PoNS in Canada between March 2019 and September 2019 in a validated electronic database capture system and Participant Disposition, Demographics, and Clinical Characteristics reflect improvements similar to other studies reported in literature evaluating physical therapy outcomes.

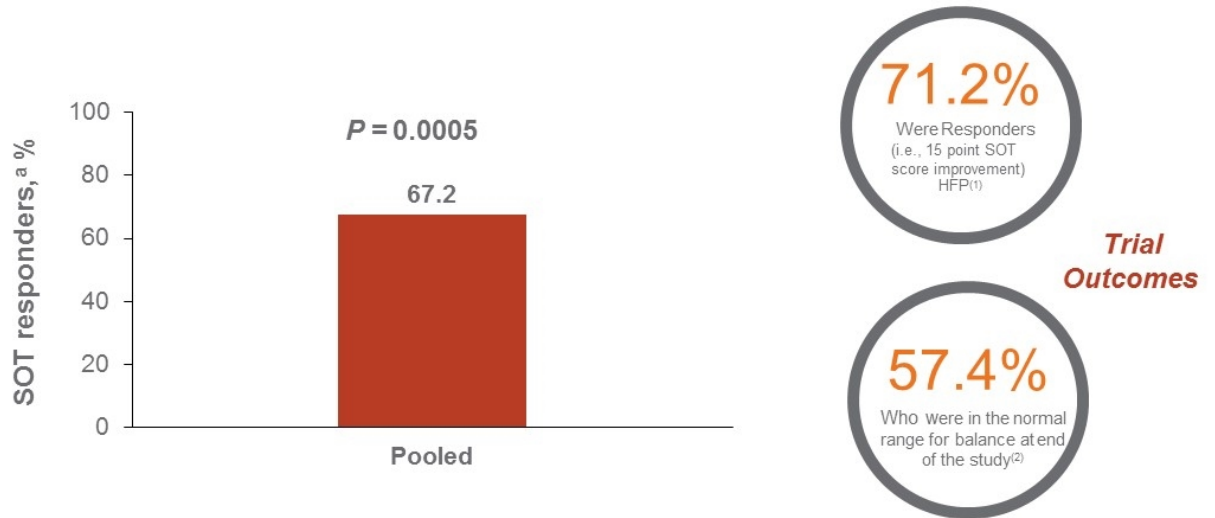


**An average improvement in FGA surpasses the MDC for older adults, stroke patients and those with Parkinson's disease*

Clinical Evidence

TBI-001: SOT Responders at 5 Weeks in Pooled and HFP Population

- While the trial included both high and low frequency groups, there was no statistical difference between patients between groups so the data was pooled.

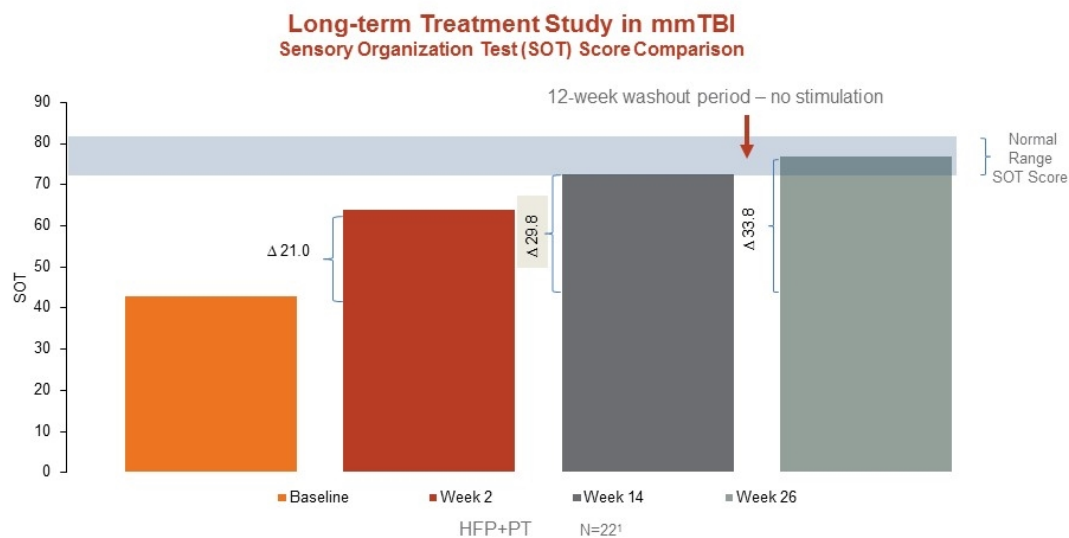


Clinical Support for PoNS Treatment™:

Long-term Treatment Study in mild-to-moderate TBI

In patients with mmTBI, balance improvements shown 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



Commercialization

Canadian Market Opportunity

Helius' target markets in Canada are providing meaningful real-world clinical experience

Mild-to-Moderate Traumatic Brain Injury ("mTBI")

- 350,000 patients in Canada
- 19 Clinic Locations
- Target of 25 at end of 2020
- Engagement w/ Toronto Rehabilitation

Multiple Sclerosis ("MS")

- 93,500 patients in Canada
- High urgency to treat
- High Patient Awareness
- Specialty clinic system
- Engagement with MS Society of Canada



www.heliusmedical.com | Nasdaq:HSDT | TSX:HSM

Brain Injury Canada. Acquired Brain Injury (ABI) – The Basics. Available at <https://www.braininjurycanada.ca/acquired-brain-injury/>. Accessed February 26, 2020.
Brain Injury Association of Durham Region. About Brain Injury. Available at <https://biad.ca/about-brain-injury/>. Accessed February 28, 2020.
Li, M., Zhao Z., Yu G., Zhang, J. Epidemiology of traumatic brain injury over the world: a systematic review. *Austin Neurology & Neurosciences*. 2016;1(2):1007
Kieffelegaard I et al. *Disabil Rehabil*. 2012;34(9):788-794.
<https://www.cihi.ca/en/canadian-multiple-sclerosis-monitoring-system-metadata>

Commercialization Canadian Strategic Focus

- Establish robust network of Canadian Clinics to deploy PoNS
 - 19 established clinic locations to date
 - Additional 6 clinics to target 25 by year-end
 - New neuro-centric clinics in Ontario, Western Canada & Quebec
- Label expansion for MS approved in March 2020
- Gain KOL support through clinical experience programs (CEP) in Canada's most respected Neuro Treatment Centers
 - Partnership with Toronto Rehab for TBI
 - Partnership with MS Society of Canada for MS
- Drive reimbursement by using health economic data to establish financial ROI for treatment



Engaging, training and authorizing Canadian clinics to provide PoNS Treatment™



International Strategy

AUSTRALIA: Awaiting decision from Therapeutic Goods Administration (TGA)

- Submission review in process – we supplemented our submission and responded to all follow-up questions to date

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 (LRQA) withdrawal from the business created uncertainty in clearance process
 - New notified body in place – GMED; Company will resubmit once EU process clarity returns



CHINA:

- October 2015, Strategic Agreement with A&B, LTD (later transferred to China Medical Systems or "CMS") for development and commercialization of PoNS in China plus 4 territories;
- Transferred ownership of Asian patents, patent applications and granted exclusive license to market, promote distribute and sell the technology
- Assumed all development, patent (both application and defense), future manufacturing, clinical trial, and regulatory clearance costs for the Territories

Extensive IP Portfolio

Exclusively licensed from inventors (4% royalty):

- 9 US Medical Method Patents Issued
- Patents expire between 2029 and 2031

A Significant Barrier to Competitor Entry

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





THANK YOU



References

Slide 9: Disease State Prevalence

- MS <https://www.nationalmssociety.org/What-is-MS/MS-FAQ-s>
- Cerebral Palsy: <http://www.cerebralpalsy.org/about-cerebral-palsy/prevalence-and-incidence>
- Stroke – 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
- Grandview Research Brain Health Supplements Market Size, Industry Report, 2019-2025
- Global Wellness Economy Monitor – October 2018
- Parkinson's Disease <https://www.parkinson.org/Understanding-Parkinsons/Statistics#:~:text=Approximately%2060%2C000%20Americans%20are%20diagnosed,are%20diagnosed%20before%20age%2050.>

