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): December 04, 2023

HELIUS MEDICAL TECHNOLOGIES, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-38445**	**36-4787690**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
642 Newtown Yardley Road, Suite 100 Newtown, PA		**18940**
(Address of principal executive offices)		**(Zip Code)**

Registrant's telephone number, including area code: (215) 944-6100

N/A

(Former name or former address, if changed since last report)

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:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Class A Common Stock, $0.001 par value	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 December 4, 2023, the Company posted an updated corporate presentation to its website at https://ir.heliusmedical.com/, 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.

The information in this Current Report, including Exhibit 99.1 hereto, is furnished pursuant to Item 7.01 and shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as expressly set forth by specific reference in such a filing. The Company's submission of this Current Report shall not be deemed an admission as to the materiality of any information required to be disclosed solely to satisfy the requirements of Regulation FD.

This Current Report and Exhibit 99.1 hereto contain forward-looking statements within the meaning of the federal securities laws. These forward-looking statements are based on current expectations and are not guarantees of future performance. Further, the forward-looking statements are subject to the limitations listed in Exhibit 99.1 and in the other reports of the Company filed with the Securities and Exchange Commission, including that actual events or results may differ materially from those in the forward-looking statements.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Corporate Presentation, dated December 2023.
104	Cover Page Interactive Data File (embedded within Inline XBRL document).

SIGNATURE

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 hereunto duly authorized.

HELIUS MEDICAL TECHNOLOGIES, INC.

Dated: December 4, 2023

By: /s/ Jeffrey S. Mathiesen
Jeffrey S. Mathiesen
Chief Financial Officer, Treasurer and Secretary

Helius
MEDICAL TECHNOLOGIES

Empowering Neuroplasticity

PoNS Therapy™ for Balance and Gait Deficits in Patients with Neurological Disorders

December 2023

NASDAQ:HSDT

Legal Disclaimers

This presentation contains forward-looking statements, including statements regarding the Company's future strategic and operational execution, the success of the Company's PoNS de and related treatment, the next phase of the Company's market development activities, clinical and regulatory development plans for the PoNS® device, future decisions and approvals f applicable regulatory entities in the U.S. and Canada, the pursuit of commercial and government reimbursement programs, and the success of the Company's continued commercializati efforts in the United States and Canada. These statements involve substantial known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activ 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 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 plans, intentions and expectations disclosed in the forward-looking statements we make.

Risk Factors:
Factors that may cause actual results to differ materially from any future results expressed or implied by any forward looking statements uncertainties regarding the Company's capital requirements to achieve its business objectives, disruptions in the banking system and financial markets, lingering impacts, the impact of the COVID-19 pandemic, the effect of macroeconomic conditions and the Company's ability to access capital markets, the Company's ability to train physical therapists in the supervision of the use of the PoNS Treatment, th Company's ability to secure contracts with rehabilitation clinics, the Company's ability to obtain national Medicare coverage and to obtain a reimbursement code so that the PoNS device covered by Medicare and Medicaid, the Company's ability to build internal commercial infrastructure, secure state distribution licenses, build a commercial team and build relationships w Key Opinion Leaders, neurology experts and neurorehabilitation centers, market awareness of the PoNS device, availability of funds, manufacturing, labor shortage and supply chain risk disruptions in the manufacturing process of the PoNS device due to the transition to a new manufacturer, ability to maintain and enforce its intellectual property rights, clinical trials and th clinical development process, the product development process, the regulatory submission review and approval process, operating costs and use of cash, and the Company's ability to achieve significant revenues, ongoing government regulation, and other risks described in the "Risk Factors" section of Company's Annual Report on Form 10-K for the year ended Dece 31, 2022, its Quarterly Report on Form 10-Q for the quarter ended September 30, 2023 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 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, PoNS, is indicated for use in the United States as a short term treatment of gait deficit due to mild-to-moderate symptoms from multiple sclerosis ("MS") and be used as an adjunct to a supervised therapeutic exercise program in patients 22 years of age and over by prescription only. The PoNS device is authorized for sale in Canada as a cla non-implantable, medical device intended as a short term treatment (14 weeks) of gait deficit due to mild and moderate symptoms from MS, chronic balance deficit due to mild-to-modera traumatic brain injury ("mmTBI"), and gait deficit due to mild and moderate symptoms from stroke and is to be used in conjunction with physical therapy. The PoNS device is authorized f sale in Australia as a non-implantable neurostimulator intended for short term use by healthcare professionals as an adjunct to a therapeutic exercise program to improve balance and ga

Executive Team

Experienced Leadership With Healthcare and Commercialization Expertise

Dane Andreeff
President & CEO

- 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
- Board member and advisor to Helius for over 6 years, Myocardial Solutions for 4 years and HDL Therapeutics, Inc. for over 15 years
- ~10.5% ownership of the company

Jeff Mathiesen, CPA
Chief Financial Officer

- Vice Chair, Lead Independent Director, and Audit Committee Chair of Panbela Therapeutics, Inc. (Nasdaq: PBLA)
- Director and Audit Committee Chair of NeuroOne Medical Technologies Corporation Nasdaq: NMTC)
- Former Board Member and Audit Committee Chair of eNeura, Inc.
- Former CFO at Gemphire Therapeutics and Sunshine Heart

Antonella Favit-Van Pelt, MD, PhD
Chief Medical Officer

- Board-certified neurologist with 20+ years in the health sciences industry
- Led U.S. Medical Strategy for the Neurology program of H. Lundbeck A/S
- Founded and led as President and CEO, Synaerion Therapeutics and its affiliate Thera Neuropharma, Inc.
- Served as Senior Director and Global Medical Lead at Shire Pharmaceuticals, Director of Medical Strategy at Bristol-Myers Squibb, and as Global Clinical Development Lead at GE Healthcare

Non-Executive Directors

Experienced Leadership With Healthcare and Commercialization Expertise

Blane Walter
Chairman of the Board

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

Sherrie Perkins
Director

- 20 years neuromodulation medical device experience in neurology, psychiatry, and sleep medicine
- Former Marketing and Business Development Executive, Cyberonics, Inc. (Nasdaq: CYBX) and LivaNova PLC (Nasdaq: LIVN)
- Former member Board of Directors, eNeura, Inc.
- Former member Board of Directors, ImThera Medical, Inc.

Ed Straw
Director

- Founder, 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

Paul Buckman
Director

- Thirty-nine years of medical device experience in general management, sales, marketing, finance, international and operations
- President, North America – LivaNova PLC
- Former President of the Cardiovascular Divisions of both Boston Scientific and St. Jude Medical
- Director on the Boards of NeuroOne (Chairman), Miromatrix (Chairman), Ablative Solutions, ActivOrtho, Inc. (Co-Founder), and Shoulder Innovations

About Helius

A neurotech company focused on delivering a novel therapeutic neuromodulation approach for balance and gait deficits

The Portable Neuromodulation Stimulator "PoNS" Device

The first and only orally applied therapy combining trigeminal nerve neurostimulation via the tongue wi physical therapy to improve functional outcomes

Supported by an **extensive IP portfolio** (47 U.S. patents issued; 53 foreign patents issued) expiring between 2026 and 2041

Authorized and commercially available to treat gait deficit due to multiple sclerosis ("MS") following FDA Breakthrough Designation

FDA Breakthrough Designation granted for the treatment of balance and gait deficits due to stroke

Authorized and commercially available in over 72 clinics for balance or gait deficit due to MS, stroke, or mild and moderate traumatic brain injury ("mmTBI") with continued expansion across the country

Authorized as an adjunct to a therapeutic exercise program to improve balance and gait

The Long-Lasting Impact of Balance Deficit[1,2]

- Balance and gait deficits are commonly experienced by individuals with neurologic disorders
- These deficits can be particularly frustrating because they often profoundly impact a person's quality of life
- Balance and gait deficits have a significant negative impact on functional status, capacity to return to work, and quality of life

Dizziness/ coordination

Difficulty walking

Trouble climbing stairs

Difficulty completing everyday tasks

High risk of falling

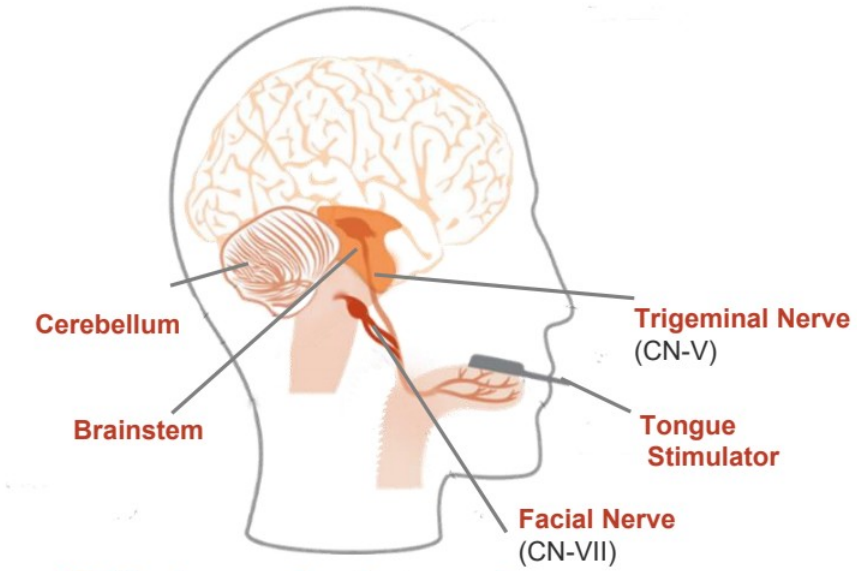
PoNS Therapy™

PoNS Device

Empowering the brain and improvement during PoNS Therapy™

- Mouthpiece electrodes stimulate t tongue surface, sending signals to the brain
- The stimulation produced by PoN believed to help strengthen the neural connections associated wit balance and walking when combi with physical rehabilitation exercis

Inducing Neuromodulation to Create Long Term Neuroplastic Change

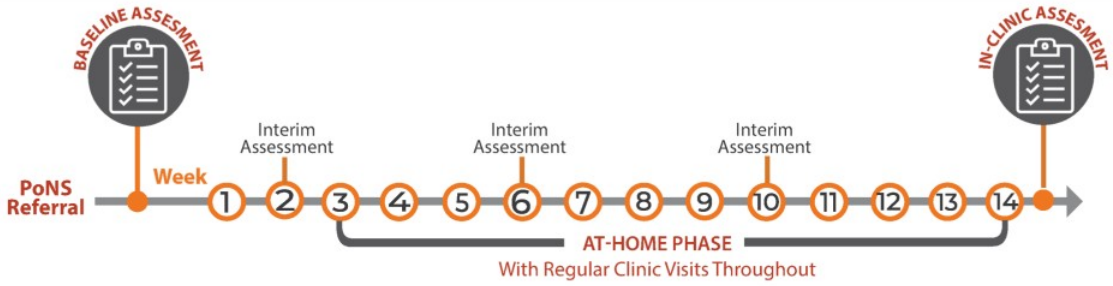


~25MM pulses per 20-minute session
Feels like champagne or carbonated water bubbles

- When PoNS is on, translingual neurostimulatic ("TLNS") is initiated.
- TLNS delivers electrical impulses that stimulat the lingual branch of the trigeminal nerve and chorda tympani branch of the facial nerve.
- This stimulation triggers a flow of neural impul to the brain structures: pons varolii and medul (in the brainstem), and cerebellum.
- While using PoNS and engaging in movement and coordination tasks, PoNS Therapy promo neuromodulation, activating the brains pathwa to help improve gait, balance, movement, and coordination.

PoNS Therapy

14-Week PoNS Therapy
Safe and Effective



91% of PoNS sessions are completed at home

~70+%

69% of stroke patients had a **significant improvement** in gait and **28%** were no longer at risk of fallin

74% of patients with traumatic brain injury showed **significant improvement** in balance[2]

Commercialization and Reimbursement

Large Potential Addressable Markets

U.S. Market

Affected by MS
70% report difficulty walking[2]

Authorized for gait deficit due to symptoms of MS

Affected by stroke
Impaired walking affects about
80% of survivors[4]

Pilot Study Conducted
Additional Study Ongoing (MUSC)

Sustain a TBI annually
80% report balance impairment[6]

Studies Completed
Additional Study Planned

Potential for Future Development
- **Cerebral Palsy (764K)[7]**
- **Parkinson's Disease (1M, 90K new each year)[8]**

Ongoing Evaluation
- **Balance Maintenance in Baby Boomers (78M)**
- **Neurological Wellness (1B)**
- **Human Performance**

Understanding the MS Market Opportunity in U.S.

1 MILLION[1]

Americans affected by MS
70% report difficulty walking[2]

MS is a well-characterized chronic disease with a fast-growing diagnosed population[3]

MS patients are cared for by neurologists, a relatively discrete group

(approx. 16,000 in USA)

Gait dysfunction is a common and distressing symptom experienced by MS patients[3]

MS patients are vocal and connected on social media

MS patients actively seek out new and promising treatments

U.S. Commercialization Launch Initiatives

Driving Awareness

Education & Outreach

- Engage with general and MS neurologists about the benefits of PoNS and how to prescribe
- Identify and onboard neuro rehab clinics currently treating MS patients; emphasize that PoNS provides a significant value add for PT clinics giving them an impactful tool to leverage the power of neuroplasticity and drive meaningful functional outcomes
- Digital presence to engage with and enroll PTs in training

Targeted Marketing

- Advocacy engagement
- Social and digital presence
- Conference attendance (APTA, AAN, CMSC, ANPT)
- Educational resources on disease state, PoNS and PoNS Therapy for patients and HCPs
- Ambassador program, patient and PT testimonials, animated PoNS video, enhanced website for both patients and HCPs

Multiple Sclerosis Foundation

msaa Improving Lives Today!™ Multiple Sclerosis Association of America

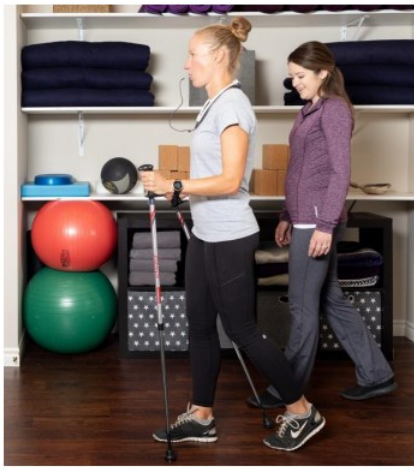
National Multiple Sclerosis Society

U.S. Commercialization Launch Initiatives

Building Experience

Therapeutic Experience Program ("PoNSTEP")

- Helius sponsored open-label, interventional, observational, outcome study evaluating PoNS on-label therapy in target population (MS) aiming to investigate adherence to PoNS Therapy regimen
- Enrolling ~ 40-50 subjects with gait deficit due to mild-moderate MS at Centers of Excellence
- Started enrollment in Q3' 22 and will continue through 2H 23
- 6 Centers of Excellence announced (NYU Langone Health, Shepherd Center, OHSU, MGH Institute, NCNE, Montefiore Medical Center)



U.S. Commercialization Launch Initiatives

Expanding Access / Increasing Ease of Use

Telehealth/E-Commerce/Online Pharmacy

- Partnered with UpScript Health on direct-to-consumer platform to streamline access to PoNS Therapy, aligning with current trends of self-care, home health care, get-it-now
- Network of fully licensed and compliant providers with e-prescribing capabilities
- Immediate distribution across all 50 states
- Reduced appointment times; direct delivery to patient's door
- Launched Dec 2022 – first units delivered Jan 2023

UpScript

Online Training for Rehabilitation Specialists

- Standardized training with reduced training time
- Online platform allows for more efficient and broader training to expand commercial access to PoNS Therapy in all 50 states and Canada
- Online modules allow training to be completed in 3 hrs or less, at therapist's own pace
- Training content remains accessible and readily available for future reference

Reimbursement

Established US List Price	
Controller	$17,800
Mouthpiece	$7,900
Complete PoNS System	$25,700

Cash	$14,500

- All sales currently are cash pay
  - Discounted modestly below anticipated reimbursement rate
  - Direct to consumer financing option through a 3rd party
  - National MS Society - potential financial assistance

- Pursuing commercial and government reimbursement programs w initial cash pay option
- Dual path for reimbursement
- DME
  - Proposed Transitional Coverage of Emerging Technologies ("TCET") for Medicare coverage
  - Applied for HCPCs codes
- NDC/UPC/HRI
  - Codes established for both PoNS System and PoNS Mouthpie
  - Medi-Span database price is equal to list price
- Registry program to generate evidence for coverage
  - Designed to gather important health economic information (ov 18-month period) to establish the value of PoNS on key therapeutic outcomes

Potential Addressable U.S. Opportunity in Stroke

Compelling Clinical Evidence[3]

*~Approximately 1-3% of stroke patients who routine physical therapy are no longer at risk falling[4]

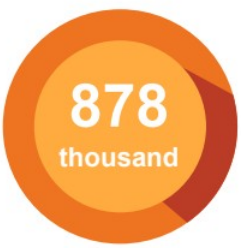
US Path for Stroke Authorization

- Granted second FDA Breakthrough Designation with the proposed indication for dynamic gait and balance deficits due to symptoms from stroke
- Engaged with the FDA on Data Development Plan for stroke
- Plan includes expansion of Medical University of South Carolina (“MUSC”) study with the objective to leverage as a registrational study
- Targeting regulatory submission for stroke indication in early 2025
- If authorized, PoNS is expected be eligible for coverage under the proposed Transitional Coverage of Emerging Technologies (“TCET”) pathway

Potential Addressable Canadian Opportunity

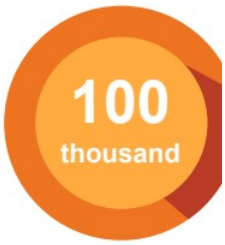
Canadian Reimbursement Efforts

- PBC study to evaluate return-to-work data for long-term disability patients (TBI)
- Quebec Ministry of Health Letter of Intent for 30 patient reimbursement study (stroke)
- University of Montreal to conduct 10 patient study (stroke)
- Private insurance pilots for Long term-disability-cases (across Canada)
- Public provincial payer - real-world evidence pilot for motor vehicles accident (TBI)
- Educating and conducting trials with hospital stroke rehabilitation centers (across Canada)
- Expanding clinics for provincial and national insurance coverage



Affected by **stroke**[1]

Living with chronic balance disorder after **mmTBI**[2-5]



Affected by **MS**[6]

Pacific Blue Cross Study[1]

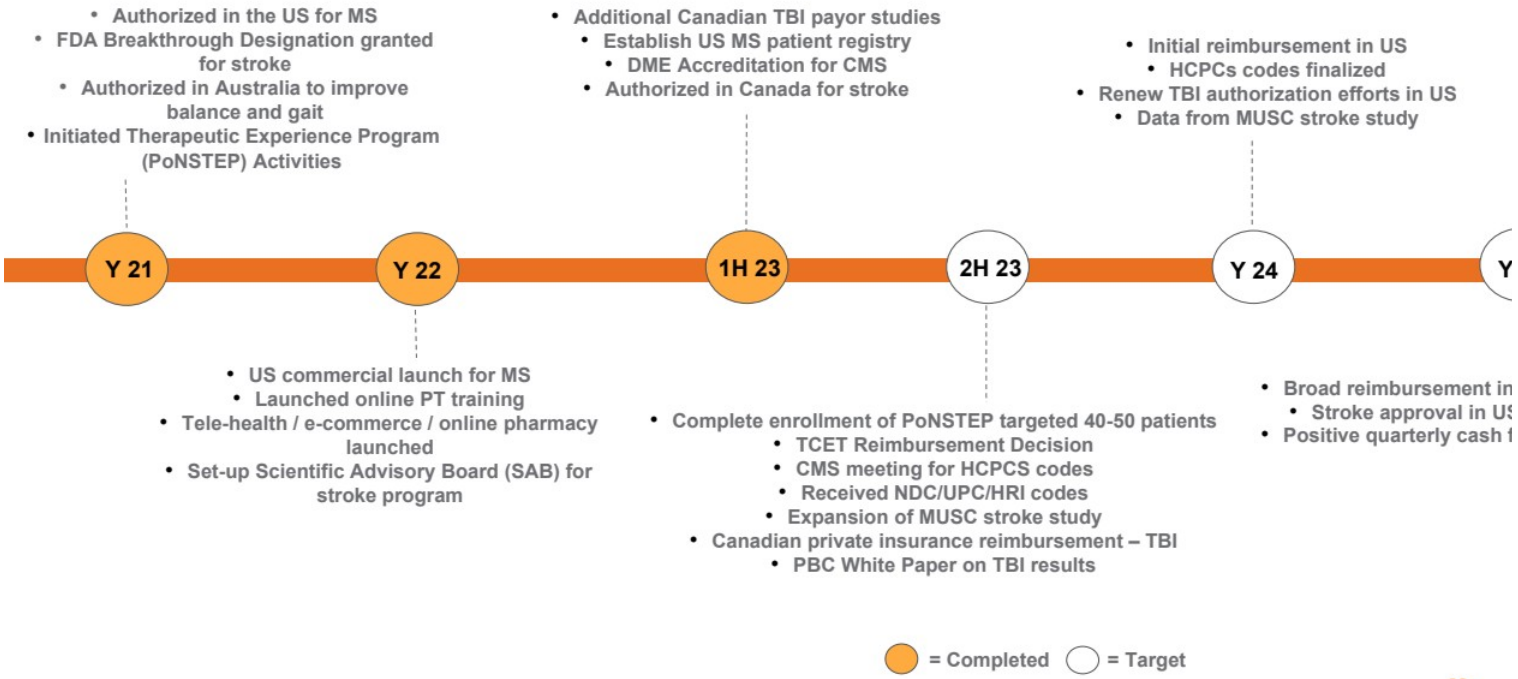
Return to Work Outcomes

Collaborative project between Pacific Blue Cross ("PBC") and HealthTech Connex to evaluate the real-world impact of PoNS Therapy on return-to-work outcomes in 9 individuals on long-term disability due to Traumatic Brain Injury

- 100% Balance/Gait Improvement (SOT)
- 89% Balance/Gait No Longer Barrier to Work
- 50% Headache Frequency/Severity Reduction
- 56% Returned to Work
- 80% Have returned to their prior occupation **full-time** for more than 6 months (4 of the 5 that returned to work)

PBC estimated that the five individuals who returned to work saved the provider approximately $1.6 million in long-term disability claims

Recent Milestones and Anticipated Value Creation Events



Financial Update, Capitalization & Ownership

Financial Update

($ in thousands)

Summary Operations and Cash Flows	Q3 2023	Q3 2022	YTD (9/30/23)	YTD (9/30/22)
Total Revenue	$143	$196	$510	$505
Operating Loss	$(3,153)	$(4,853)	$(10,182)	$(12,847)
Net Loss	$(3,663)	$(1,030)	$(7,805)	$(9,186)
Cash Used in Operations	$(2,452)	$(3,821)	$(8,382)	$(12,167)

($ in thousands)

Summary Balance Sheet	9/30/2023	12/31/2022
Cash, Cash Equivalents, and Proceeds Receivable from Warrant Exercises	$7,031	$14,549
Derivative Liability	$4,239	$6,917
Long-term Debt	$ --	$ --
Total Stockholders' Equity	$3,021	$8,151

Capitalization & Cash Position

Nasdaq	
Symbol	HSDT
Market Cap*	$4.5M
Price Per Share*	$6.36
Shares Outstanding*	708K
50 Day Avg Volume	395K
Cash (including proceeds receivable from warrant exercises) at 9/30/23	$7.0M

* Based upon shares outstanding at November 3, 2023 and closing price on November 27, 2023

Capitalization (in thousands)	As Reporte 9/30/23
Common Stock	68
Warrants**	63
Options	24
RSUs	
Total Fully Diluted	1,57

**Includes 627K warrants @ $6.9135 strike price

HSDT Analyst Coverage		
LADENBURG THALMANN & CO. INC.	MAXIM GROUP, LLC	ROTH CAPITAL PARTNERS, LLC
Jeffrey S. Cohen	Anthony Vendetti	Jonathan Aschoff, PhD

Testimonials

"I have been living with MS for 35 years and have just completed my 14 week of PoNS Therapy. I am impressed with the results. The difference is apparent on before- and after- videos of me on the treadmill, and I feel steadier and more self-assured in my overall ability to move. I feel my improved gait since PoNS has led me to attempt things such as parking further from an entrance to a store or across the street from my destination instead of circling the block to find a closer spot. As a result of my improved walking, I was able to participate in a more active excursion on my vacation, such as walking and scrambling through an underground cave in the Yucatan. My starting speed on the treadmill went from 1.3 to 2.6 during the protocol. PoNS Therapy was a serious commitment of time and energy but the improvements in my gait, at least for me, have changed my life."

– Kerrie Walters,
PoNS Patient Ambassador

"As a physical therapist, I have worked with many patients with neurological deficits. When I heard about PoNS, I had doubts that tongue-based electrical stimulation could effectively retrain the brain to improve walking ability. But as I worked with Anna, the improvement was undeniable. I'm excited about using PoNS with more patients".

– Dr. Naseem Chatiwala, PT, DPT, MS, NCS
PoNS Trainer

References

Slide 4
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2. Helius Medical Technologies. Data on File. 2019 Post Hoc Analysis - Long Term Treatment Trial - Responder Rate - Pharma Data Associates.

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Slide 10
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Thank you

NASDAQ:HSDT

Appendix

MS Scientific Advisory Board

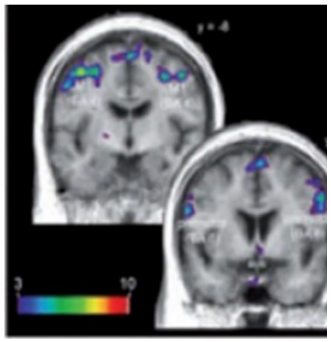
- Dr. Deborah Backus, PT, PhD, FACRM, Director, MS Research, Shepherd Center, immediate past president and currer Board Member, ACRM
- Dr. Francois Bethoux, MD, Director of Rehabilitation Services at the Cleveland Clinic Mellen Center
- Dr. Michelle Cameron, MD, PT, MCR, Neurologist, Associate Professor, Multiple Sclerosis Center, Oregon Health & Science University
- Dr. Evan T. Cohen, PT, MA, PhD, NCS., Associate Professor, Rehabilitation and Movement Sciences, Rutgers Universi School of Health Professions
- Dr. Nora Fritz, PT, PhD, Assistant Professor, Department of Health Care Sciences and Department of Neurology, Wayn State University School of Medicine.
- Brian Hutchinson, PT, MSCS, Executive Director, Dignity Health, Multiple Sclerosis Achievement Center
- Dr. Stephen Kanter, PT, DPT, ATC, Director of Rehabilitation Services at the International Multiple Sclerosis Manageme Practice (IMSMP)
- Dr. Prudence Plummer, PT, PhD, Professor, Department of Physical Therapy in the School of Health and Rehabilitation Sciences at MGH Institute of Health Professions
- Dr. Mandy Rohrig, PT, DPT, MSCS, Can Do Multiple Sclerosis

Stroke Scientific Advisory Board

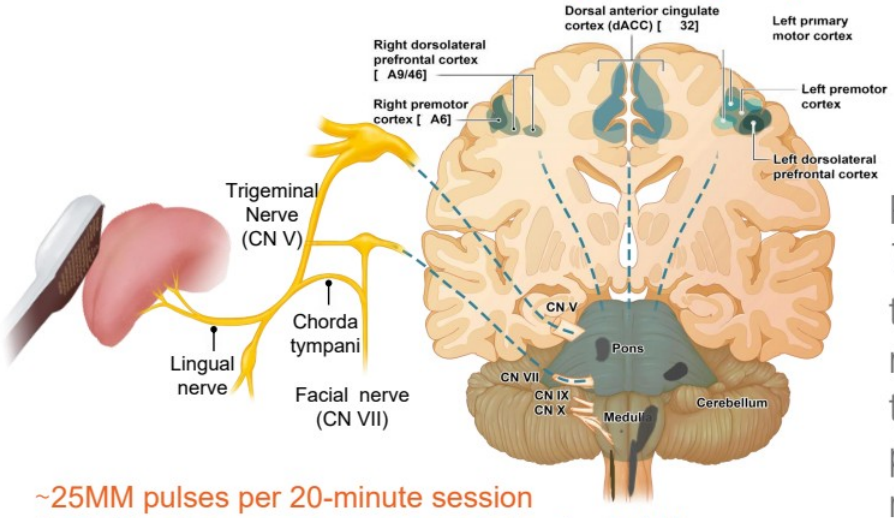
- Carl J. Hauser, MD, Beth Israel Deaconess Medical Center, Acute Care, Trauma & Critical Care, Lecturer, Surgery, Harvard Medical School
- Steven C. Cramer, MD, MMSc, FAAN, FAHA, Susan and David Wilstein Endowed Chair in Rehabilitation Medicine Professor, Department of Neurology, Medical Director of Research, California Rehabilitation Institute
- Teresa Kimberley, PT, PhD, FAPTA, Director, Brain Recovery Lab, Director of the PhD in Rehabilitation Science Program, MGH Institute
- Mark Bowden, PT, PhD, Professor and Division Director of Physical Therapy, MUSC
- Steve Kautz, PhD, Professor, Chair, Department of Health Sciences and Research, MUSC
- Charles Liu, MD, PhD, Professor of Clinical Neurological Surgery, Director, USC Neurorestoration Center

PoNS Therapy™
Mechanism of Action

Blood oxygen level-dependent (BOLD)



Neuromodulation:
modification of the nervous system by targeted stimuli

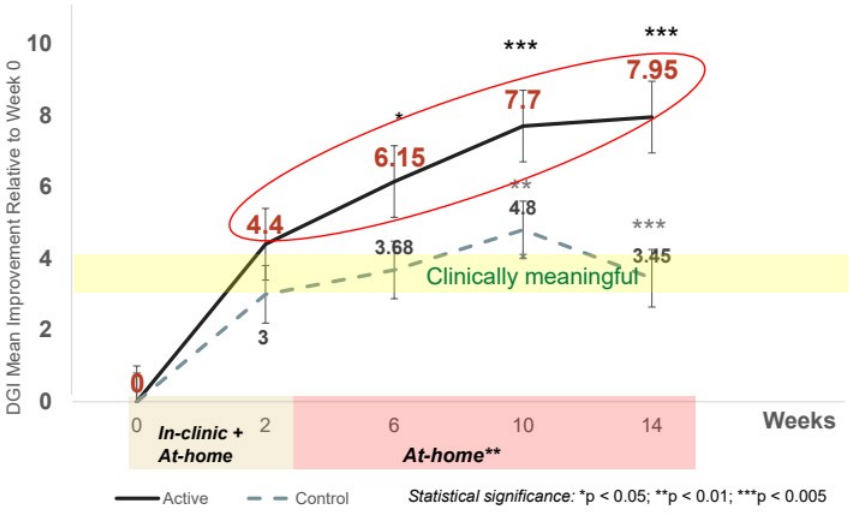


~25MM pulses per 20-minute session
Feels like champagne or carbonated water bubbles

PoNS device designed to induc*Translingual Neurostimulation*:
trigeminal and facial nerve mediated neuromodulation via th tongue induces increased bloo perfusion in specific brain area resulting in neuroplasticity.

Clinical Evidence[1]

Multiple Sclerosis Study – Gait Deficit in Mild and Moderate MS (EDSS score 3.0-6*)



Change In DGI Score Versus Time Within The Study Period

*Error on publication regarding EDSS Score
**One visit per week was in-clinic

Two groups (10 each):

1. **Active Group: PoNS + PT**
2. Control Group: *Placebo PoNS + PT*

Mean avg of **7.95**

All 10 subjects in the active treatment experienced at least a 4-point improv from baseline to Week 14 in DGI.

Mean avg of **3.45**

Only 3 of 10 (30%) subjects in the pla control group experienced an improve in DGI of at least 4 points from baseli week 14.

100%

Improvement in Dynamic Gait Index scores for the Active Grou

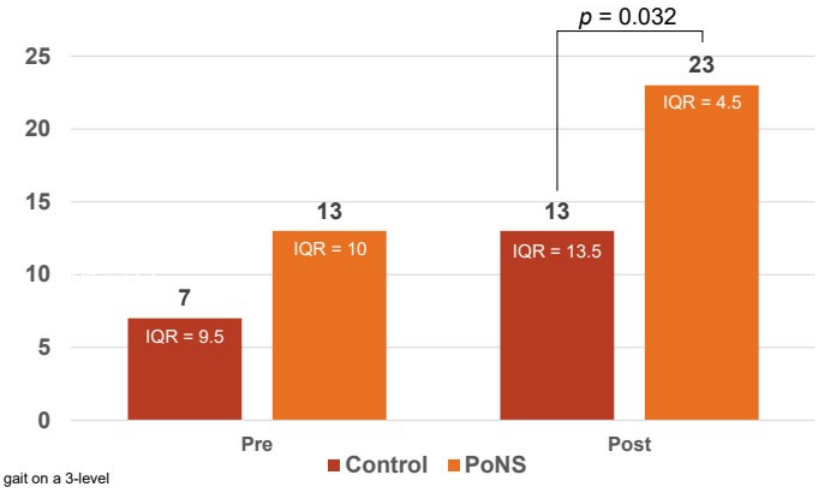
DGI = Dynamic Gait Index, a measure of the ability to

Clinical Evidence[1]

Stroke – Results from a Pilot Randomized Controlled Trial

- Post-intervention assessment demonstrated significant and clinically meaningful improvement with PoNS Therapy vs. high-intensity physiotherapy alone
- A cutoff score of 17.5 on the Mini-BEST has been shown to discriminate between fallers and non-fallers with chronic stroke (>6 months)IQR = 10

Pre- and Post-intervention Assessment Using the Mini-Balance Evaluation Systems Test*



*Mini-BEST is a 14-item test that assesses measures dynamic balance, functional mobility, and gait on a 3-level ordinal scale (0–2).
IQR, interquartile range.

Clinical Evidence[1]

Multiple Sclerosis Study – Mild and Moderate MS (EDSS score 3.0-6*)

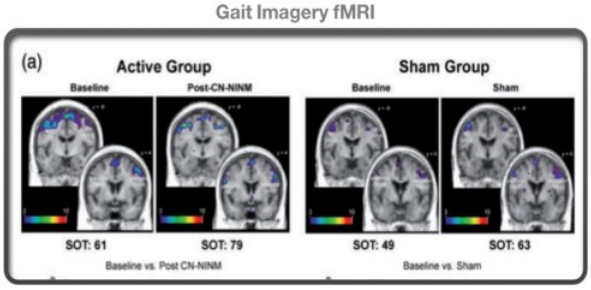
Change over time for Sensory Organization Test (SOT) composite

Statistical analysis of SOT week 14 scores vs pre-training reveals that improvement in the active group is significant (p<0.001) whereas sham group difference did not reach statistical significance (p<0.06)

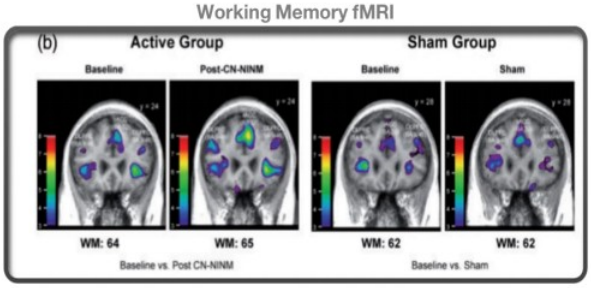
Gait imagery revealed task-related activations in bilateral premotor and motor regions, and a higher BOLD signal in the left motor cortex

*Error on publication regarding EDSS Score

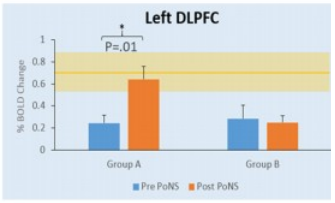
Gait Imagery fMRI

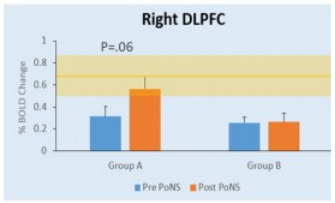


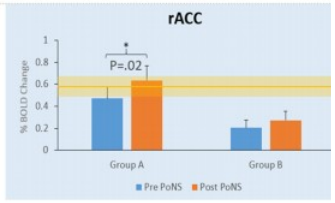
Working Memory fMRI



VOIs BOLD signal vs. Healthy Cor







PoNS™ Device[1]

Authorized in Canada for gait deficit due to symptoms of MS since March 2020

Promising results from initial real-world evidence gathered through December 31, 20
Presented at Consortium for Multiple Sclerosis Centers Annual Conference, June 20

42

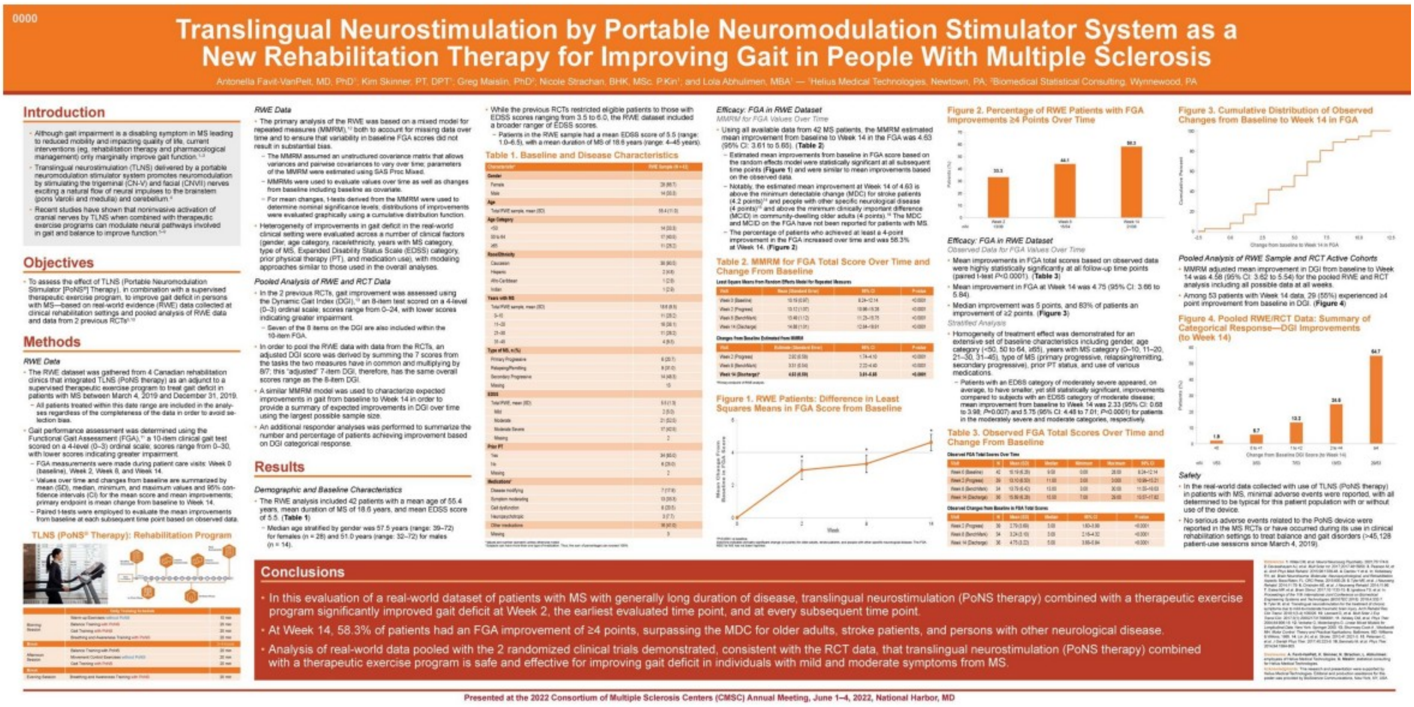
Patients with MS treated with PoNS in Canada

58.3%

Patients had achieved at least a 4-point improvement in their functional gait assessment (FGA)

Currently evaluating additional data gathered on MS patients for commercial and medical insights and publicatio

Real-World Evidence Poster Presentation



Visit ponstherapy.com to view the poster online

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