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

January 23, 2023
Date of Report (Date of earliest event reported)

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** **(Address of Principal Executive Offices)**		**18940** **(Zip Code)**

Registrant's Telephone Number, Including Area Code: (215) 944-6100
Not Applicable
(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
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 2.02 Results of Operations and Financial Condition.

On January 23, 2023, Helius Medical Technologies, Inc. (the "Company") issued a press release which includes certain preliminary unaudited consolidated financial results as of and for the quarter ended December 31, 2022. A copy of this press release is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K ("Current Report") and is incorporated herein by reference.

In accordance with General Instruction B.2. of Form 8-K, the information in this Item 2.02, and Exhibit 99.1 hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any of the Company's filings under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, whether made before or after the date hereof, regardless of any incorporation language in such a filing, except as expressly set forth by specific reference in such a filing.

Item 7.01 Regulation FD Disclosure.

On January 23, 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 99.2 to this Current Report.

The information in this Current Report, including Exhibit 99.2 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 99.2 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 99.2 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	Press Release, dated January 23, 2023.
99.2	Corporate Presentation, dated January 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: January 23, 2023

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

Exhibit 99.1

Helius Medical Technologies, Inc. Announces Preliminary Results for the Fourth Quarter and Full Year 2022

-- Q4 2022 revenue projected to range from $275,000 to $285,000 --
-- Full year 2022 revenue projected to range from $780,000 to $790,000 --
-- Unaudited year end cash balance of $14.5 million --

NEWTOWN, Pa., January 23, 2023 (GLOBE NEWSWIRE) -- Helius Medical Technologies, Inc. (Nasdaq:HSDT) ("Helius" or the "Company"), a neurotech company focused on neurological wellness, today announced preliminary, unaudited results for the quarter and full year ended December 31, 2022, and provided a corporate update.

Business Highlights and Preliminary, Unaudited 2022 Financial Results

- Revenue for the fourth quarter of 2022 is anticipated to be in the range of $275,000 and $285,000, a sequential increase of approximately 40% over the third quarter of 2022, reflecting the U.S. commercial launch of PoNS® for multiple sclerosis (MS) during the second quarter and increased quarterly sales of PoNS in Canada
- Revenue for full year 2022 is anticipated to be in the range of $780,000 and $790,000, an increase of approximately 50% over full year 2021
- Expected 2022 year-end cash, cash equivalents and restricted cash balance of $14.5 million, compared to $16.7 million as of September 30, 2022 reflecting the Company's ongoing efforts to closely manage cash burn
- Introduced UpScript Telehealth e-commerce site, making it easier for Americans with MS to access online health evaluations, fulfill PoNS Therapy prescriptions, and obtain PoNS through home delivery, with initial shipments occurring in January 2023
- Launched online module for physical therapists seeking to treat gait deficit in adults with MS, standardizing the process and reducing training time to bring faster relief to patients

"We are very pleased with our preliminary fourth quarter revenue performance, which was driven in large part by the U.S. commercial launch of PoNS Therapy earlier in the year. PoNS is a breakthrough technology for people suffering from gait and balance impairment, and we are dedicated to ensuring access to qualifying patients. In July 2022, we introduced our online training curriculum, enabling physical therapists to access PoNS training online, in three hours, or less, at the therapist's own pace. More recently, we launched an e-commerce site to facilitate patients' access to PoNS therapy," said Dane Andreeff, President and Chief Executive Officer of Helius. "With these important milestones behind us and the proper groundwork set, we believe Helius is in a strong position to greatly expand access to PoNS Therapy across North America in 2023 and beyond."

The Company intends to provide a detailed operational and financial update during its fourth quarter and full-year 2022 earnings call in March 2023. Closing procedures for the fiscal quarter and year ended December 31, 2022, are not yet complete. The preliminary unaudited financial information presented in

this press release reflects the Company's current estimates based on information available as of the date of this press release and is subject to change as a result of the completion of the Company's financial and operating closing procedures, customary audit procedures, and other developments that may occur before the completion of these procedures. Accordingly, you should not place undue reliance on this preliminary financial information, which may differ materially from actual results. See "Cautionary Disclaimer Statement" below for a discussion of certain factors that could result in differences between the estimated unaudited financial information reported in this press release and actual results.

About Helius Medical Technologies, Inc.

Helius Medical Technologies is a leading neurotech company in the medical device field focused on neurologic deficits using non-implantable platform technologies that amplify the brain's ability to compensate and promotes neuroplasticity, aiming to improve the lives of people dealing with neurologic diseases. The Company's first commercial product is the Portable Neuromodulation Stimulator (PoNS). For more information, visit www.heliusmedical.com.

About the PoNS Device and PoNS Therapy

The Portable Neuromodulation Stimulator (PoNS) is an innovative non-surgical medical device, inclusive of a controller and mouthpiece, which delivers electrical stimulation to the surface of the tongue to improve balance and gait. The PoNS device 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 is to be used as an adjunct to a supervised therapeutic exercise program in patients 22 years of age and over by prescription only.

PoNS is also authorized for sale in Canada for two indications: (i) for use 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 physical therapy; and (ii) for use as a short term treatment (14 weeks) of gait deficit due to mild and moderate symptoms from MS and is to be used in conjunction with physical therapy. PoNS is also authorized for sale in Australia for short term use by healthcare professionals as an adjunct to a therapeutic exercise program to improve balance and gait. For more information visit www.ponstherapy.com.

Cautionary Disclaimer Statement

Certain statements in this news release are not based on historical facts and constitute forward-looking statements or forward-looking information within the meaning of the U.S. Private Securities Litigation Reform Act of 1995 and Canadian securities laws. All statements other than statements of historical fact included in this news release are forward-looking statements that involve risks and uncertainties. Forward-looking statements are often identified by terms such as "believe," "expect," "continue," "will," "goal," "aim" and similar expressions. Such forward-looking statements include, among others, statements regarding the Company's expected business and financial results for the quarter and full year ended December 31, 2022 and the Company's performance in 2023 .

There can be no assurance that such statements will prove to be accurate and actual results and future events could differ materially from those expressed or implied by such statements. Important factors that could cause actual results to differ materially from the Company's expectations include uncertainties associated with the Company's capital requirements to achieve its business objectives, the impact of the COVID-19 pandemic, the Company's ability to train physical therapists in the supervision of the use of the PoNS

Treatment, the 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 is 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 with Key Opinion Leaders, neurology experts and neurorehabilitation centers, market awareness of the PoNS device, future clinical trials and the clinical development process, manufacturing and supply chain risks, the product development process and FDA regulatory submission review and approval process, other development activities, ongoing government regulation, and other risks detailed from time to time in the "Risk Factors" section of the Company's Annual Report on Form 10-K for the year ended December 31, 2021, and its other filings with the United States Securities and Exchange Commission and the Canadian securities regulators, which can be obtained from either at www.sec.gov or www.sedar.com.

The reader is cautioned not to place undue reliance on any forward-looking statement. The forward-looking statements contained in this news release are made as of the date of this news release and the Company assumes no obligation to update any forward-looking statement or to update the reasons why actual results could differ from such statements except to the extent required by law.

Investor Relations Contact

Lisa M. Wilson, In-Site Communications, Inc.
T: 212-452-2793
E: lwilson@insitecony.com

Helius
MEDICAL TECHNOLOGIES

Empowering Neuroplasticity

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

January 2023

NASDAQ:HSDT

Legal Disclaimers

This presentation contains forward-looking statements, including statements regarding the Company's future strategic and operational execution, the next phase of the Company's market development activities, clinical and regulatory development plans for the PoNS® device, the pursuit of commercial and government reimbursement programs, and the success of the Company's continued commercialization 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 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.

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, the impact of the COVID-19 pandemic, the 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 is covered by Medicare and Medicaid, the Company's ability to obtain FDA clearance for stroke, the Company's ability to build internal commercial infrastructure, market awareness of the PoNS device, future clinical trials and the clinical development process, manufacturing and supply chain risks, potential changes to the MCIT program, the product development process and FDA regulatory submission review and approval process, other development activities, 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 December 31, 2021 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, 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 is to 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 class II, non-implantable, medical device intended as a short term treatment (14 weeks) of gait deficit due to mild and moderate symptoms from MS, and chronic balance deficit due to mild-to-moderate traumatic brain injury (mmTBI) and is to be used in conjunction with physical therapy. The PoNS device is authorized for 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 gait.

The Portable Neuromodulation Stimulator "PoNS" Device

The first and only patented therapy combining trigeminal nerve neurostimulation via the tongue with physical therapy to improve functional outcomes in **balance** and **gait**

Authorized for the treatment of gait deficit due to multiple sclerosis ("MS")

FDA Breakthrough Designation granted for the treatment of gait deficit due to MS

FDA Breakthrough Designation granted for the temporary treatment of dynamic gait and balance deficits following a stroke

Authorized for the treatment of gait deficit due to MS and chronic balance deficit due to mild and moderate traumatic brain injury ("mmTBI")

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

A Path to Commercialization: FDA Breakthrough Designation

May 2020

- ***Breakthrough Designation granted*** *for the treatment of gait deficit due to symptoms of MS*

March 2021

- ***Received FDA marketing authorization***
- *Only medical device cleared in the U.S. for this indication*

August 2021

- ***Breakthrough Designation granted*** *for the treatment of dynamic gait and balance deficits following a stroke*

Next Milestones

- *Pivotal trial*
- *Potential FDA marketing authorization*

Large Potential Addressable Markets

U.S. Clinical Progress and Future Opportunities

Gait and balance deficits are commonly experienced by individuals with a variety of neurologic disorders. These deficits can be particularly frustrating because they often profoundly impact a person's quality of life.

✓ FDA Breakthrough Designation	**1M** Americans Affected by **MS** **70%** report having **difficulty walking**	→ ✓ Authorized for gait deficit due to symptoms of MS
✓ FDA Breakthrough Designation	**13M** Americans affected by **stroke** **Impaired walking** affects about **60%** of survivors	→ ✓ Pilot Study Conducted Additional Study in Development
	An estimated **2.8M** Americans sustain a **TBI** every year **80%** report **balance** impairments with days of injury	→ ✓ Studies Completed; Additional Study Planned

Potential for Future Development

- Cerebral Palsy (764K)
- Parkinson's Disease (1M, 90K new each year)

Ongoing Evaluation

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

The Long-Lasting Impact of Balance Deficit

Balance and gait deficit have a significant negative impact on functional status, capacity to return to work, and quality of life[1,2]

Dizziness/ coordination

Difficulty walking

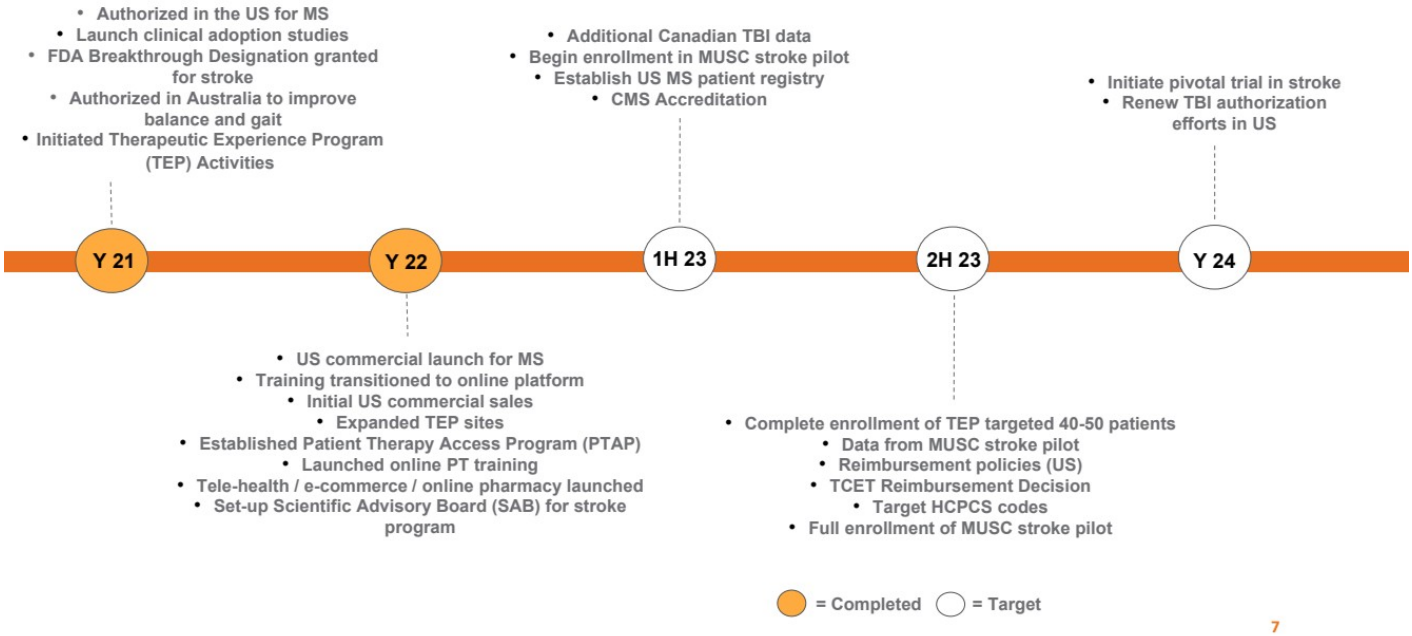
Trouble climbing stairs

Difficulty completing everyday tasks[11]

High risk of falling[12]

1. Peterson M, Greenwald BD. Balance problems after traumatic brain injury. Available at http://uwmsktc.washington.edu/sites/uwmsktc/files/files/TBI_balance.pdf. Accessed September 17, 2018.
2. Centers for Disease Control and Prevention. Report to Congress on Traumatic Brain Injury in the United States: Epidemiology and Rehabilitation. National Center for Injury Prevention and Control; Division of Unintentional Injury Prevention. Atlanta, GA. 2015. Available at http://www.cdc.gov/traumaticbraininjury/pdf/tbi_report_to_congress_epi_and_rehab-a.pdf. Accessed March 11, 2019.

Recent Milestones and Anticipated Value Creation Events



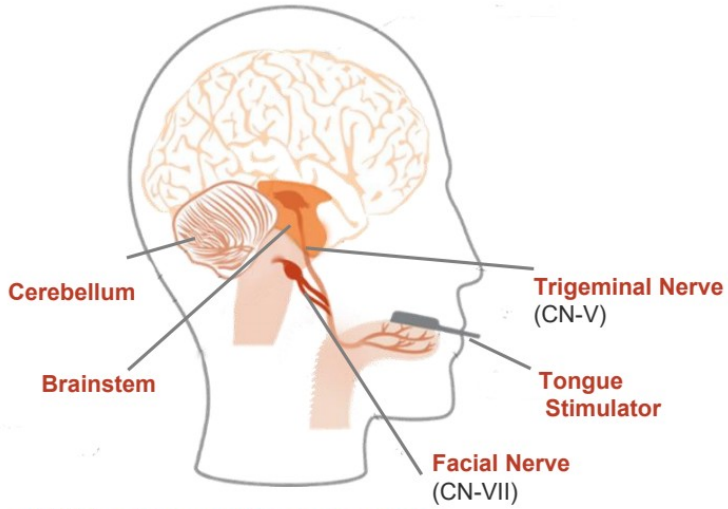
PoNS Therapy™

PoNS Device

Empowering the brain and improvement during PoNS Therapy™

- Mouthpiece electrodes stimulate the tongue surface, sending signals to the brain
- The stimulation produced by PoNS is believed to help strengthen the neural connections associated with balance and walking when combined with physical rehabilitation

Inducing Neuromodulation to Create Long Term Neuroplastic Changes[1,2]



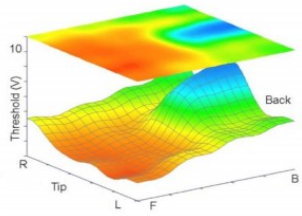
~25MM pulses per 20-minute session
Feels like champagne or carbonated water bubbles

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

1. Ptito A, Skinner K. The evolution of translingual neurostimulation – from science fiction to fact. Presented at The 9th Annual Traumatic Brain Injury Conference; May 16-17, 2019; Arlington, Virginia, USA.
2. Danilov Y, Kaczmarek K, Skinner K, Tyler M. Cranial nerve noninvasive neuromodulation: new approach to neurorehabilitation. In: Kobeissey FH, ed. Brain Neurotrauma: Molecular, Neuropsychological, and Rehabilitation Aspects. Boca-Raton, FL: CRC Press. 2015; 605-28

PoNS Stimulation[1,2]

The <u>first and only</u> patented therapy combining trigeminal nerve neurostimulation via the tongue with physical therapy to improve balance and gait deficit

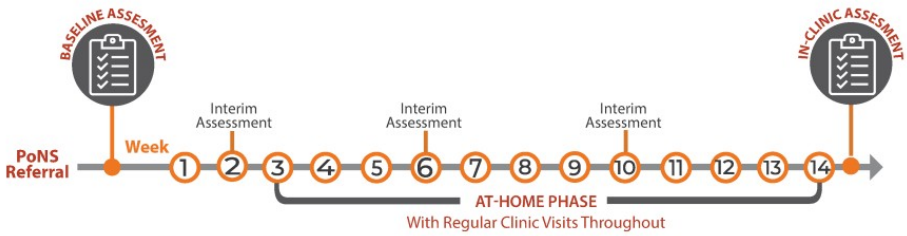


- Stimulation intensity of the electrode array on the mouthpiece **matches the sensitivity map of the tongue**
- Electrode array designed to make the **sensation felt uniformly** in the front and the back, with less input at the front, increasing toward the back

- PoNS: Adjustable pulse width = **0-60 µs**
- Sensory level stimulation (nerve fibers): 20-100 µs
- Motor level stimulation (muscle activation): 100-600 µs

1. Ptito A, Skinner K. The evolution of translingual neurostimulation – from science fiction to fact. Presented at The 9th Annual Traumatic Brain Injury Conference; May 16-17, 2019; Arlington, Virginia, USA.
2. Kaczmarek KA. The Portable Neuromodulation Stimulator (PoNS) for neurorehabilitation. Sci Iran D Comput Sci Eng Electr Eng. 2017;24(6):3171- 3180.

14 Weeks of PoNS Therapy



Phase 1:
The patient works with a PoNS Trainer 1 to 2 times per day for 5 days for 2 weeks and completes 1 session per day at home independently. One day per week is a rest day.

Phase 2:
The patient sees the PoNS Trainer once per week and performs their PoNS Therapy training sessions at home.

SAMPLE DAILY TRAINING SCHEDULE

Schedule may vary depending on PT and patient completing PoNS Therapy

Morning Session

Warm-Up exercises	10 minutes
Balance training with PoNS	20 minutes
Gait training with PoNS	20 minutes
Breathing awareness training with PoNS for first two weeks	20 minutes
Break	**3-4 hours**

Afternoon Session

Balance training with PoNS	20 minutes
Movement control exercises	20 minutes
Gait training with PoNS	20 minutes

Evening Session

Breathing awareness training with PoNS	20 minutes

Current Strategies for Managing Neurological Disorders

Prescription Drugs

Therapy

Surgery

Medical Devices

Commercialization and Reimbursement

Potential Addressable U.S. Opportunity in Multiple Sclerosis

Americans estimated to be affected by MS[1]

Report having difficulties walking[2]

1. Wallin, Mitchell T et al. "The prevalence of MS in the United States: A population-based estimate using health claims data." Neurology vol. 92,10 (2019): e1029-e1040. doi:10.1212/WNL.0000000000007035
2. Williams, Angela E et al. "Symptoms and Association with Health Outcomes in Relapsing-Remitting Multiple Sclerosis: Results of a US Patient Survey." Multiple sclerosis international vol. 2014 (2014): 203183. doi:10.1155/2014/203183

Understanding the “MS” Market Opportunity in US

MS is a well-characterized chronic disease with a fast-growing diagnosed population[1]

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[1]

MS patients are vocal and connected on social media

MS patients actively seek out new and promising treatments

1. Larocca, Nicholas G. “Impact of walking impairment in multiple sclerosis: perspectives of patients and care partners.” The patient vol. 4,3 (2011): 189-201. doi:10.2165/11591150-000000000-00000

US Commercialization Launch Initiatives

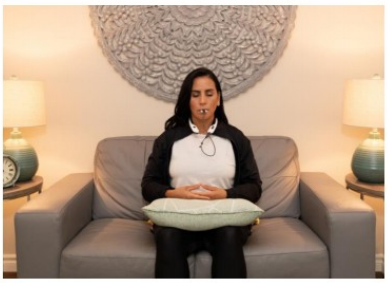
- Patient Therapy Access Program (PTAP)
  - Provides MS patients with gait deficit access to PoNS at a significantly reduced price
- Therapeutic Experience Program (TEP)
  - Helius sponsored open-label, interventional, observational, outcome study
  - Evaluating PoNS on-label therapy in target population (Multiple Sclerosis) aiming to investigate patients' adherence to PoNS Therapy regimen
  - Enrolling ~ 40-50 subjects with gait deficit due to mild-moderate MS at Centers of Excellence across the US (10-12 sites)
  - Started enrollment in Q3' 22 and will continue through 2H 23
  - 5 Centers of Excellence announced (NYU Langone Health, Shepherd Center, OHSU, MGH Institute and NCNE)

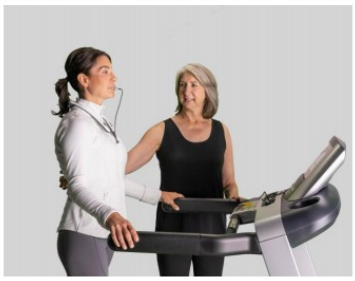
U.S. Commercial Activities

- Actively identifying and onboarding neuro rehab clinics currently treating MS patients to provide therapy
  - Training evolved to online platform to facilitate ease and convenience
  - PoNS provides a significant value add for PT clinics giving them an impactful tool for treating gait deficit in MS patients leveraging the power of neuroplasticity to drive meaningful functional outcomes
  - Digital presence to engage with and enroll PTs in training
    - Leveraging claims data to target ads for PTs, monthly APTA newsletter, and social campaigns
- Implement key marketing strategies to generate awareness
  - Advocacy engagement
  - Social and digital presence
  - Conference attendance (ACTRIMS, APTA, CMSC, ACRM)
  - Enhancing educational resources on disease state, PoNS and PoNS Therapy for both patients and HCPs
    - Patient testimonials, animated PoNS video, enhanced website for both patients and HCPs

Online Training for PoNS

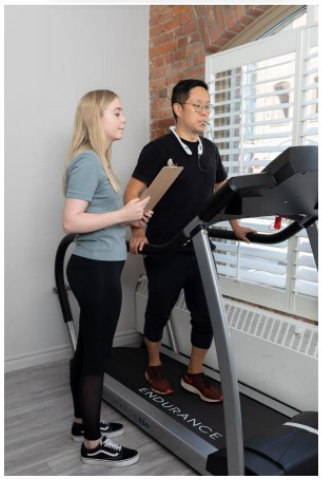
- Standardized training with reduced training time
- Online platform allows for more efficient and broader training to expand commercial access to PoNS Therapy in all 50 states and Canada
  - Online modules allow training to be completed in 3 hrs or less, at Physical Therapist's own pace
- Training content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





Tele-health / E-commerce / Online Pharmacy Initiative

- Partnered with UpScript Health
- Streamline access to PoNS Therapy to align with current trends of self-care, home health care, get-it-now
- Immediate distribution across all 50 states
- Direct to consumer e-commerce platform
- Network of fully licensed and compliant providers to provide tele-health services
  - E-prescribing capabilities
  - Telemedicine access option added directly to ponstherapy.com
  - Reduces appointment times post Covid
- Direct delivery to patient's door
- Launched Dec 2022 – first units delivered Jan 2023



PoNS Established US List Pricing

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

Cash	$14,500

Patient Therapy Access Program (PTAP)	$3,895

- Cash pay option available
  - Discounted modestly below anticipated reimbursement rate
- Direct to consumer financing option through a 3rd party
- National MS Society - potential financial assistance

Reimbursement

- Pursuing commercial and government reimbursement programs with initial cash pay option
  - Proposed Transitional Coverage of Emerging Technologies (TCET) for Medicare coverage
- Registry program to generate evidence for coverage
  - Designed to gather important health economic information (over 18-month period) to establish the value of the PoNS Device on key therapeutic outcomes
    - Disease-associated injury risks (i.e, falls)
    - Resuming professional and daily activities
    - Disease progression and patient management outcomes
    - In-patient/out-patient hospital and/or office visits
    - Side effects

Potential Addressable Canadian Opportunity

Canadians estimated to be affected by MS[1]

Canadians Living with Chronic Balance Disorder after mmTBI[2-5]

1. Amankwah, Nana et al. "Multiple sclerosis in Canada 2011 to 2031: results of a microsimulation modelling study of epidemiological and economic impacts." "La sclérose en plaques au Canada, 2011-2031 : résultats d'une étude de modélisation par microsimulation des répercussions épidémiologiques et économiques." Health promotion and chronic disease prevention in Canada : research, policy and practice vol. 37,2 (2017): 37-48. doi:10.24095/hpcdp.37.2.02
2. Brain Injury Canada. Acquired Brain Injury (ABI) – The Basics. Available at https://www.braininjurycanada.ca/acquired-brain-injury/. Accessed February 26, 2020.
3. Brain Injury Association of Durham Region. About Brain Injury. Available at https://biad.ca/about-brain-injury/. Accessed February 28, 2020.
4. 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
5. Kleffelgaard I et al. Disabil Rehabil. 2012;34(9):788-794.

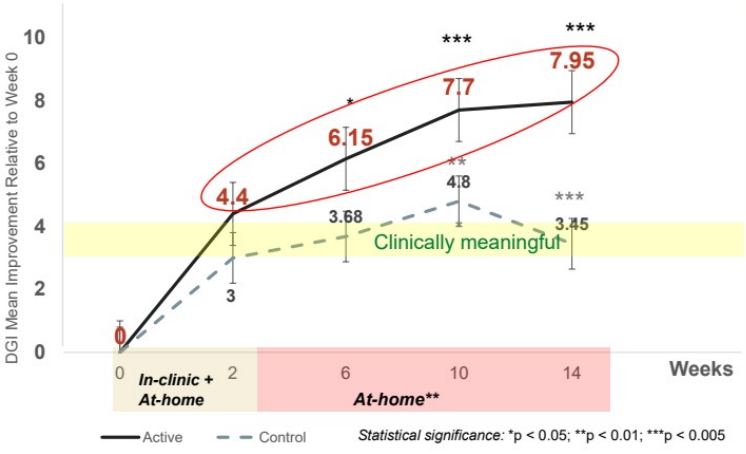
Canada Commercialization

- Engaging with Neuro Rehab clinics across the country
- 45 clinics across 8 provinces
- Expanding clinics for provincial and national insurance coverage
- Public and private insurance pilots for Long term-disability-cases (Across Canada)
- Awareness in the medical field about the therapy and its outcomes

Clinical Evidence: Multiple Sclerosis

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

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 group experienced at least a 4-point improvement from baseline to Week 14 in DGI.

Mean avg of **3.45**

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.

100%

Improvement in Dynamic Gait Index scores for the Active Group

*Error on publication regarding EDSS Score[9]
**One visit per week was in-clinic

1. Tyler, Mitchell E et al. "Non-invasive neuromodulation to improve gait in chronic multiple sclerosis: a randomized double blind controlled pilot trial." Journal of neuroengineering and rehabilitation vol. 11 79. 1 May. 2014, doi:10.1186/1743-0003-11-79

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

PoNS Therapy™ for Symptoms Due to Stroke

FDA Breakthrough Designation for Treatment of Symptoms Due to Stroke

- Announced receipt of FDA Breakthrough Designation on August 17, 2021
- Indication of use as a temporary treatment of dynamic gait and balance deficits due to symptoms from stroke
- PoNS Therapy to be used as an adjunct to a supervised therapeutic exercise program in patients 22 years of age and over

Potential Addressable U.S. Opportunity in Stroke

Americans estimated to be living with complications of stroke[1]

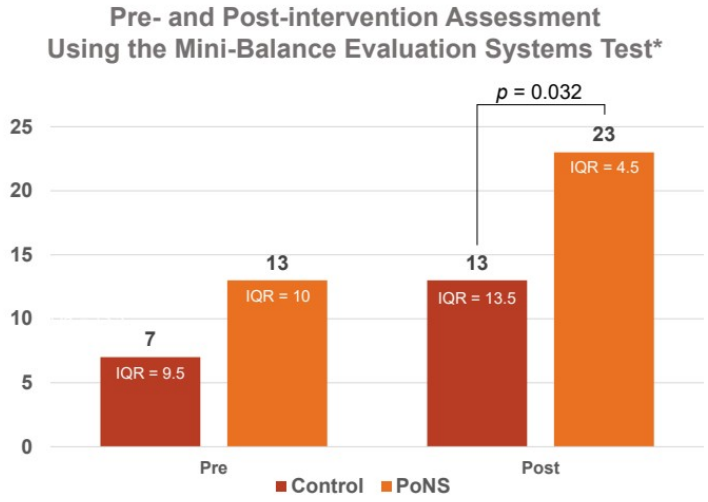
Of those individuals have a gait impairment[2]

1. Dobkin BH, Dorsch A. New evidence for therapies in stroke rehabilitation. Curr Atheroscler Rep. 2013;15(6):331.doi:10.1007/s11883-013-0331-y.
2. Carmen M. Cirstea. Gait Rehabilitation After Stroke, Should we re-evaluate our practice? Stroke 2020;51(10):2892-94.

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



*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.

1. Galea MP et al. *Brain Stimul.* 2017;10(6):1133-35.

Capitalization & Ownership

Capitalization, Ownership & Cash Position

Nasdaq	
Symbol	HSDT
Market Cap*	$10.4M
Price Per Share*	$0.367
Shares Outstanding*	28.2M
50 Day Avg Volume	1.0M
Cash at 12/31/22	$14.5M
* Based upon shares outstanding at Nov 11, 2022 and closing price on Jan 20, 2023	

Capitalization (in thousands)	As Reported 9/30/22
Common Stock	28,203
Warrants (WAEP $1.00)	36,594
Options (WAEP $17.76)	1,174
RSUs	14
Total Fully Diluted	65,985

Ownership at September 30, 2022	As Reported # Common Shares (in thousands)	As Reported % of Common Outstanding
Intracoastal Capital LLC	1,000	3.5%
Executive Officers and Directors**	980	3.5%
Maple Leaf Funds	715	2.5%
Columbus Capital Management L.L.C.	278	1.0%
** Computed using latest reported beneficial ownership, adjusted for subsequent reported purchases		

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

Extensive IP Portfolio

Exclusively licensed from inventors (4% royalty):

- 11 US Medical Method Patents Issued
- Patents expire between 2029 and 2041

Patents owned by Helius (no royalty):

- 36 US Patents Issued
- 53 Foreign Patents Issued
- Patents expire between 2026 and 2041

Helius Patents Transferred to China Medical System Holdings (CMS):

- 3 Chinese Design Patents

Independent Verification of Patents and Freedom to Operate Opinion:

- September 2017

First-in-Class Neurotech

- Unique and innovative therapy authorized to improve impaired function by stimulating cranial nerves via the tongue, supported by an extensive IP portfolio
- Authorized and commercially available in the US for gait deficit due to MS with initial sales in Q2
- Authorized and commercially available in over 45 clinics in Canada for gait deficit due to MS and balance deficit due to mmTBI with continued expansion across the country
- Authorized in Australia as an adjunct to a therapeutic exercise program to improve balance and gait
- FDA Breakthrough Designation granted for the treatment of balance and gait deficits due to symptoms of stroke

Thank you

NASDAQ:HSDT

Appendix

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 3 years, Myocardial Solutions for 4 years and HDL Therapeutics, Inc. for over 15 years
- ~2.5% 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

MS Scientific Advisory Board

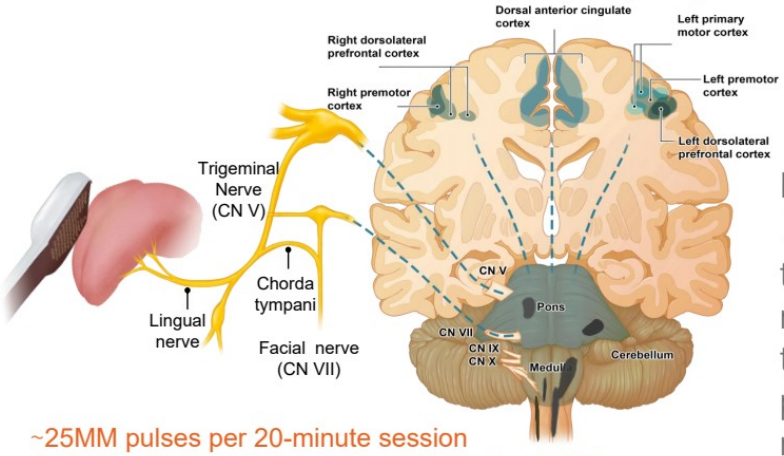
- Dr. Deborah Backus, PT, PhD, FACRM, Director, MS Research, Shepherd Center, immediate past president and current Board Member, ACRM
- Dr. Francois Bethoux, MD, Director of Rehabilitation Services at the Cleveland Clinic Mellen Center
- Dr. Michelle Cameron, MD, PT, MCR, Neurologist, Associate Professor, Multiple Sclerosis Center, Oregon Health & Science University
- Dr. Evan T. Cohen, PT, MA, PhD, NCS., Associate Professor, Rehabilitation and Movement Sciences, Rutgers University School of Health Professions
- Dr. Nora Fritz, PT, PhD, Assistant Professor, Department of Health Care Sciences and Department of Neurology, Wayne 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 Management 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

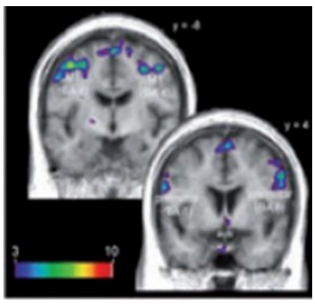
PoNS Therapy™ Mechanism of Action

Neuromodulation:
modification of the nervous system by targeted stimuli



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

Blood oxygen level-dependent (BOLD) signal



PoNS device designed to induce *Translingual Neurostimulation*:
trigeminal and facial nerve-mediated neuromodulation via the tongue induces increased blood perfusion in specific brain areas resulting in neuroplasticity.

Clinical Evidence[1]

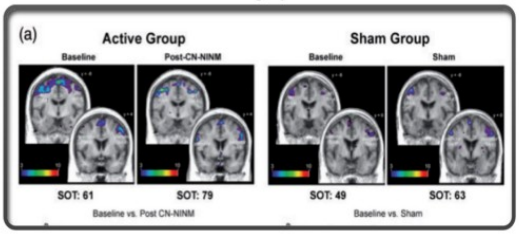
Multiple Sclerosis Study – Mild and Moderate MS (EDSS score 3.0-6*)

Change over time for Sensory Organization Test (SOT) composite

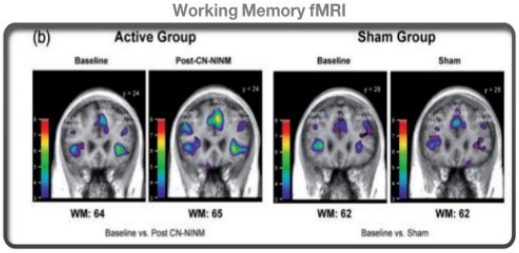
Statistical analysis of SOT week 14 scores vs pre-training reveals that improvement in the active group is significant (p<0.001) whereas sham group difference did not reach statistical significance (p<0.06)

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

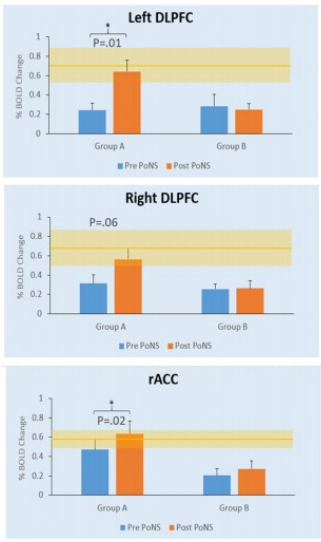
Gait Imagery fMRI



Working Memory fMRI



VOIs BOLD signal vs. Healthy Controls



*Error on publication regarding EDSS Score[10]

1. Leonard, Gabriel et al. "Noninvasive tongue stimulation combined with intensive cognitive and physical rehabilitation induces neuroplastic changes in patients with multiple sclerosis: A multimodal neuroimaging study." Multiple sclerosis journal - experimental, translational and clinical vol. 3,1 2055217317690561. 1 Feb. 2017, doi:10.1177/2055217317690561

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 12.31.2019
Presented at Consortium for Multiple Sclerosis Centers Annual Conference, June 2022

42

Patients with MS treated with PoNS in Canada

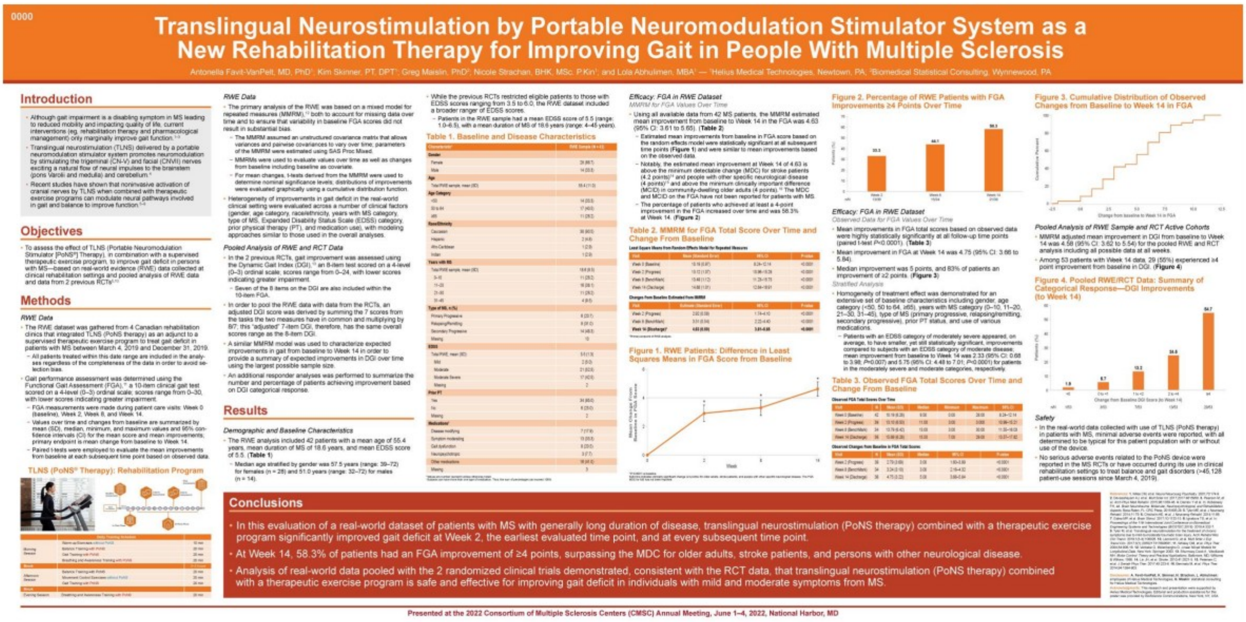
58.3%

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 publication

1. Helius Medical, Inc Portable Neuromodulation Stimulator (PoNS) Real World Evidence Study, August 2, 2020

Real-World Evidence Poster Presentation



Visit ponstherapy.com to view the poster online