Helius
MEDICAL TECHNOLOGIES

# Empowering Neuroplasticity

## PoNS Therapy® for Balance and Gait Deficits and Reduction in the Risk of Falls in Patients with Neurological Disorders

March 2024

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 device 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 from 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 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, availability of funds and the ability to find additional sources of funding, disruptions in the banking system and financial markets, the effect of macroeconomic conditions, manufacturing, labor shortage and supply chain risks including risks related to manufacturing delays, 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, ability to maintain and enforce its intellectual property rights, clinical trials and the 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 December 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 to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this presentation.

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The Company's first product, 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, chronic balance deficit due to mild-to-moderate 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 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.

# 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
- Over 10% 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 with 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 and Gait 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**

# The Impact of a Fall

- Between 70% and 80% of individuals with a neurological disorder report having issues with their balance or gait[1-3]
- Mobility challenges put individuals with neurological disorders at an increased risk of falls[4]
- 46% of individuals with a neurological disorder report one or more falls per year[4]
- Healthcare insurers in search of cost savings should focus on fall prevention


**Average cost of a fall[5]**


**Cost to the healthcare system each year[5]**

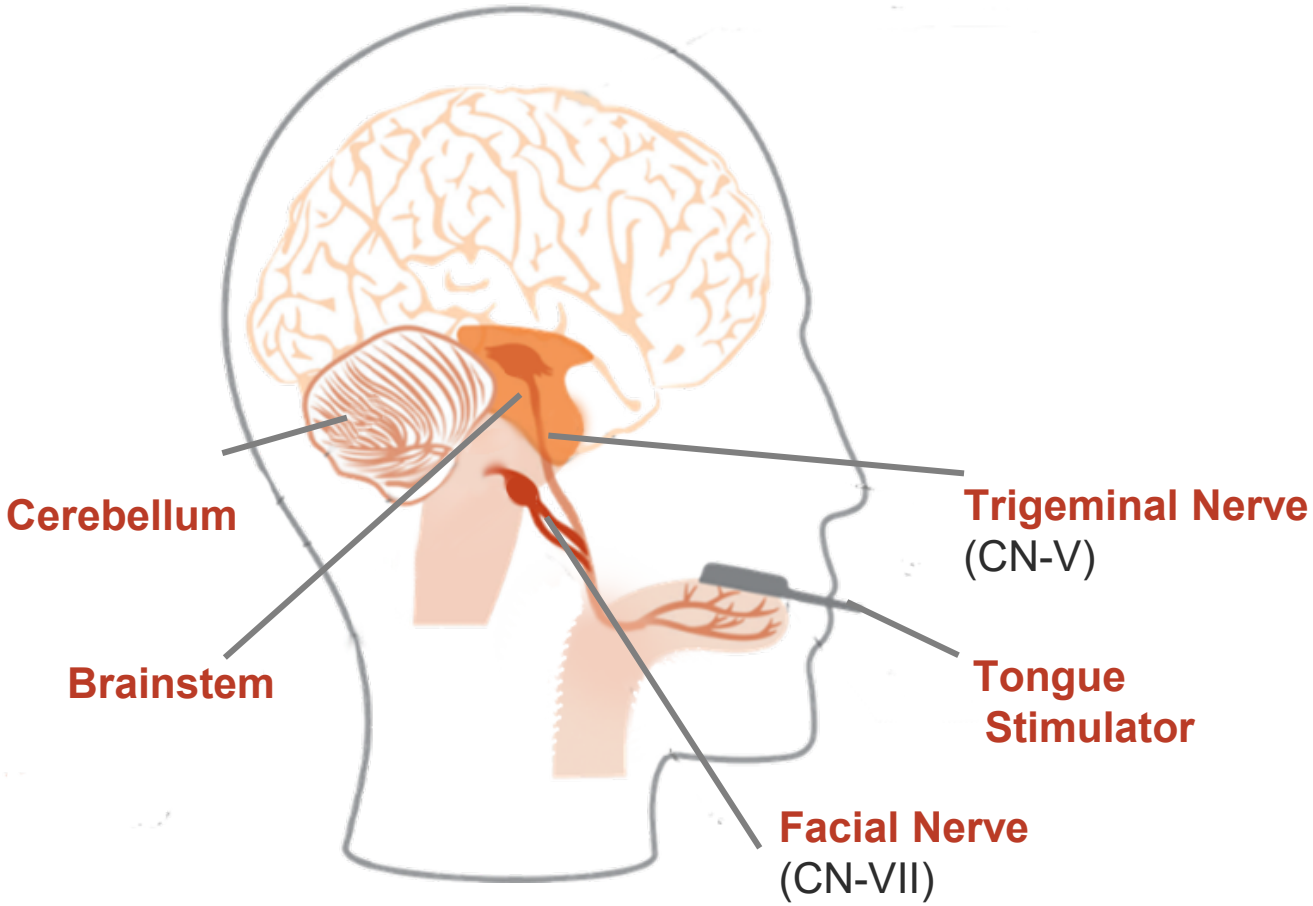
# PoNS Therapy™

# 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 exercise

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

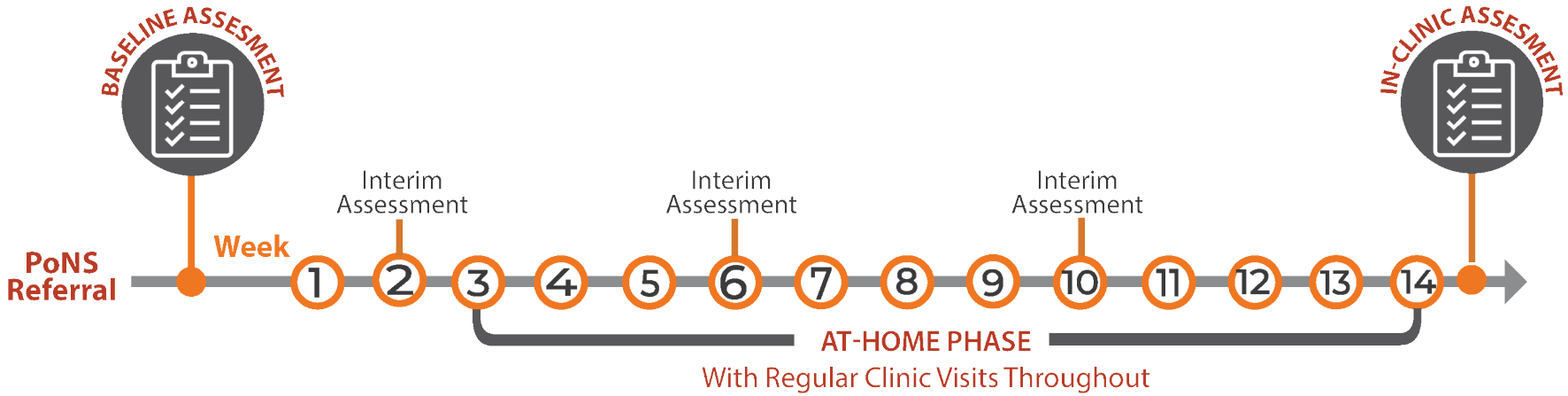



~25MM pulses per 20-minute session
Feels like champagne or carbonated water bubbles

- When PoNS 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 PoNS and engaging in movement and coordination tasks, PoNS Therapy promotes neuromodulation, activating the brains pathways 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**

~80+%

**69%** of stroke patients had a **significant improvement** in gait and **28%** were no longer at risk of falling**[1]

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

**100%** of multiple sclerosis patients in the active group experienced a **clinically meaningful improvement** in gait**[3]

*Study results from clinical trial
**Study results from real-world database analysis

# Commercialization and Reimbursement

# Large Potential Addressable Markets

## U.S. Market


**Affected by MS**

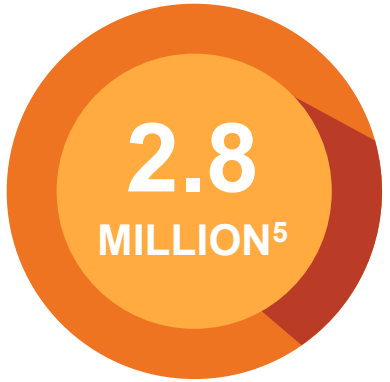
**70%** report difficulty walking[2]

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.


**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

# 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 ~ 50 subjects with gait deficit due to mild-moderate MS at Centers of Excellence
- Started enrollment in Q3' 22 and will continue through Q1' 24
- 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 with initial cash pay option
- Dual path for reimbursement
- DME
  - Secured HCPCs codes for both Controller and Mouthpiece
  - Meeting with CMS Q2' 24 with objective of obtaining reimbursement effective Oct 1, 2024
  - Proposed Transitional Coverage of Emerging Technologies ("TCET") for Medicare coverage
- NDC/UPC/HRI
  - Codes established for both PoNS System and PoNS Mouthpiece
  - Medi-Span database price is equal to list price
- Initiate discussions with distribution 3PLs for the VA to establish distribution and reimbursement pathways
- Registry program to generate evidence for coverage
  - Designed to gather important health economic information (over 18-month period) to establish the value of PoNS on key therapeutic outcomes

# Potential Addressable U.S. Opportunity in Stroke


**Americans estimated to be living with complications from stroke**

**80%** have a gait impairment[2]

## Compelling Clinical Evidence[3]

**31**

Stroke patients treated with PoNS in Canada

**69.2%**

Improved more than 5 points on functional gait assessment measure

**28%**

Were no longer at risk of falling*

*~Approximately 1-3% of stroke patients who do routine physical therapy are no longer at risk of 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
- Aligned with the FDA on Data Development Plan for stroke that streamlines cost and timeline
- Plan includes randomized control study as well as open-label study led by Medical University of South Carolina (“MUSC”) and Brooks Rehabilitation
- Reducing the risk of falls - Secondary endpoint
- Targeting regulatory submission for stroke indication in early 2025
- Secured HCPCS codes from CMS Medicare for both Controller and Mouthpiece
  - 90% covered by Medicare
- If authorized, PoNS is expected to 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 a **TBI**[2] Affected by **MS**[3]

# Pacific Blue Cross Study[1]

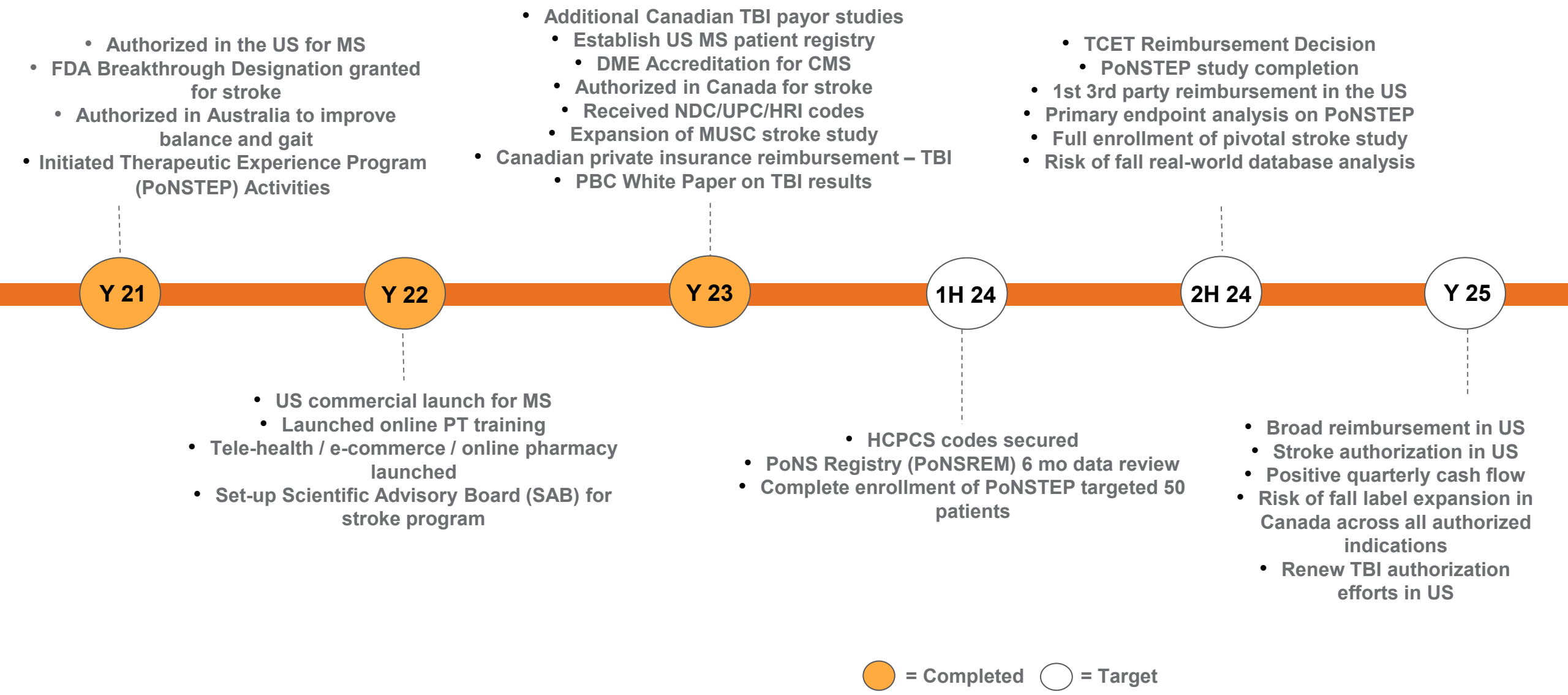
## Return to Work Outcomes

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 occupations **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 |
| *$1.5M additional net proceeds from ATM share sales received through 2/9/2024 | | |

# Capitalization & Cash Position

| Nasdaq | |
|---|---|
| Symbol | HSDT |
| Market Cap* | $5.3M |
| Price Per Share* | $6.00 |
| Shares Outstanding* | 887K |
| 50 Day Avg Volume | 382K |
| Cash (including proceeds receivable from warrant exercises) at 9/30/23** | $7.0M |
| * Based upon shares outstanding at February 9, 2024 and closing price on March 7, 2024 | |
| *$1.5M additional net proceeds from ATM share sales received through 2/9/2024 | |

| Capitalization (in thousands) | Pro forma as of 2/9/2024 |
|---|---|
| Common Stock | 887 |
| Warrants** | 639 |
| Options | 246 |
| RSUs | 4 |
| Total Fully Diluted | 1,776 |
| **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**

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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 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.
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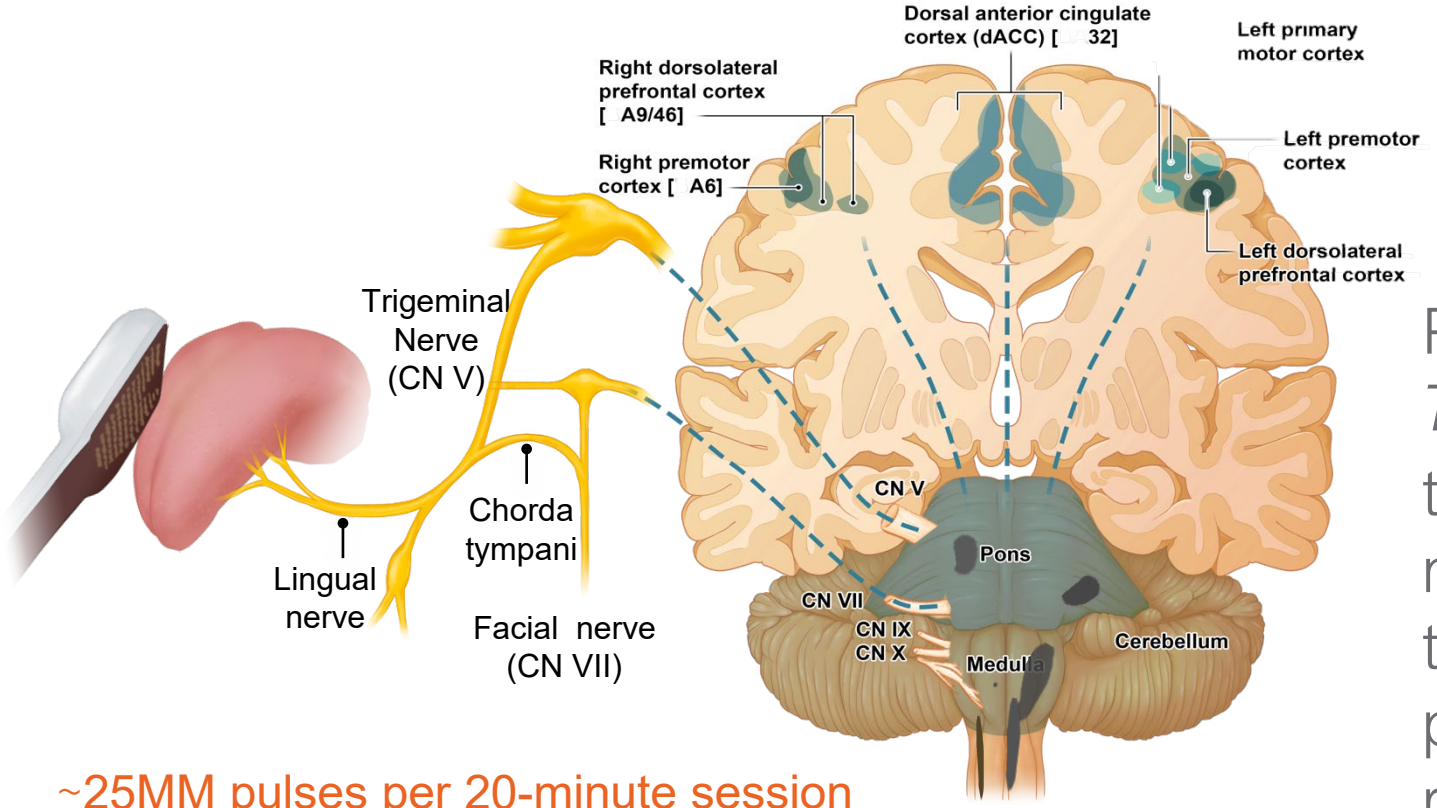
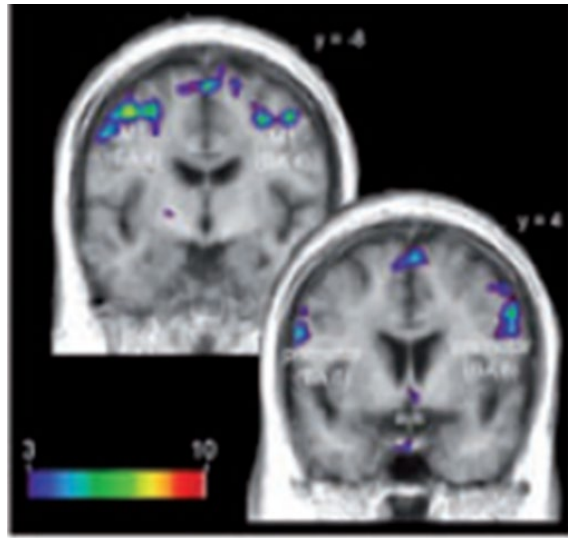
# PoNS Therapy™ Mechanism of Action

*Neuromodulation:*
modification of the nervous system by targeted stimuli




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

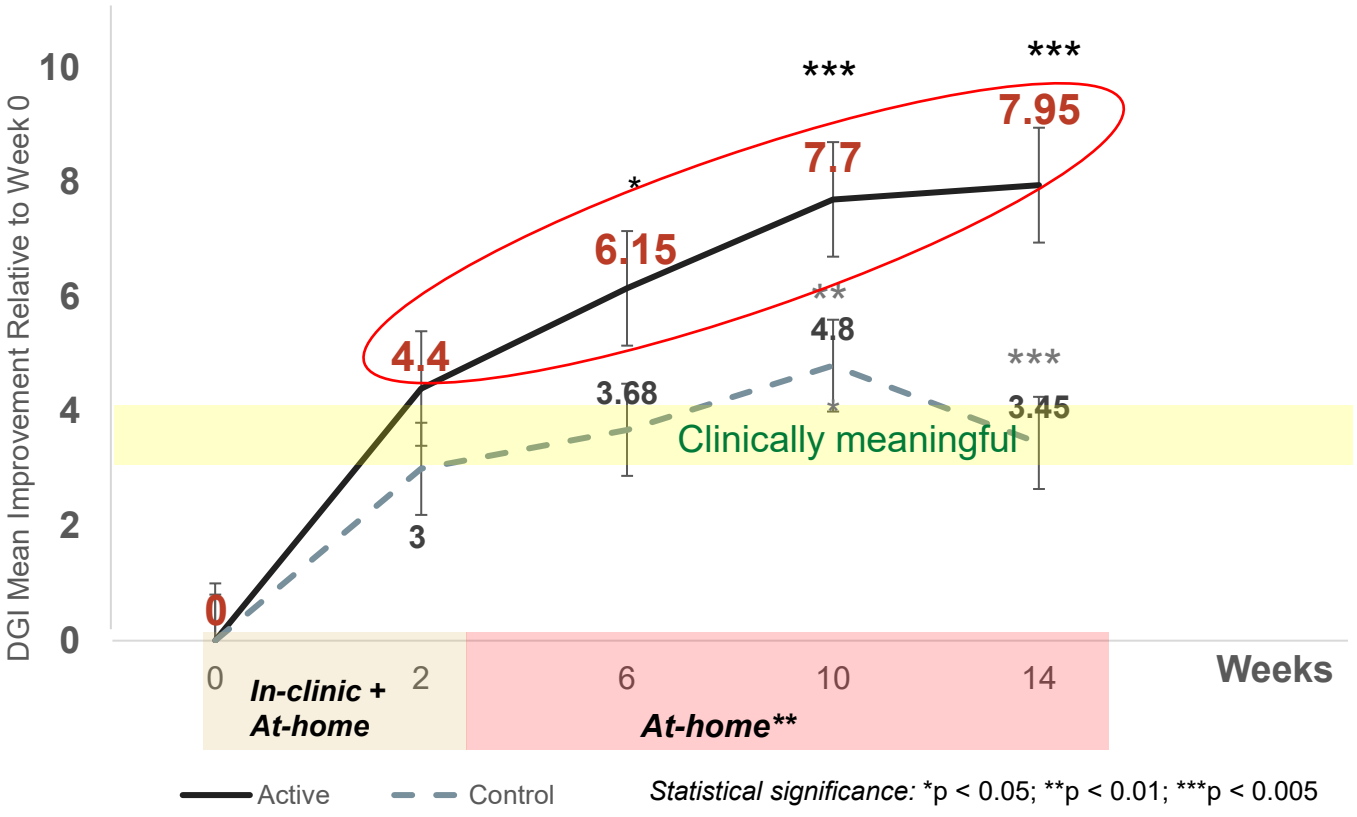
Blood oxygen level-dependent (BOLD) signal



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 – 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*

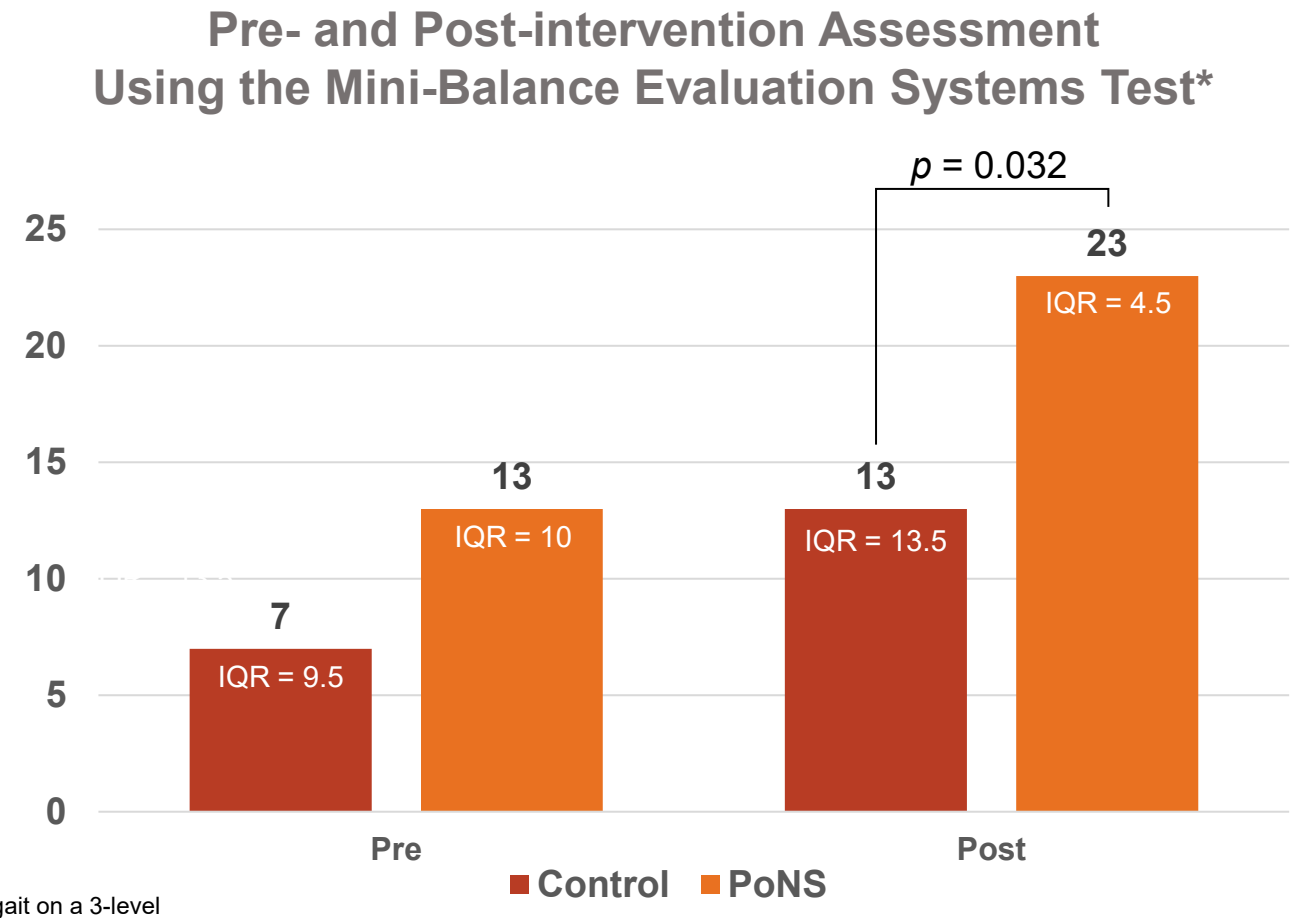
*Error on publication regarding EDSS Score
**One visit per week was in-clinic

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

# 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

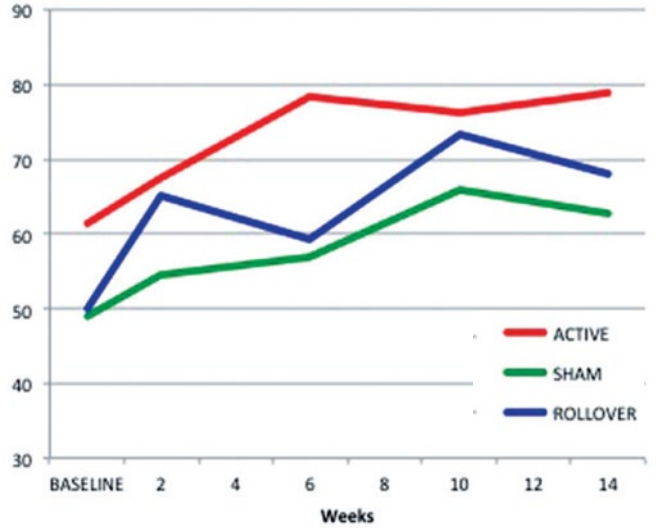



*Mini-BEST is a 14-item test that assesses measures dynamic balance, functional mobility, and gait on a 3-level ordinal scale (0–2).
IQR, interquartile range.

# Clinical Evidence[1]

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

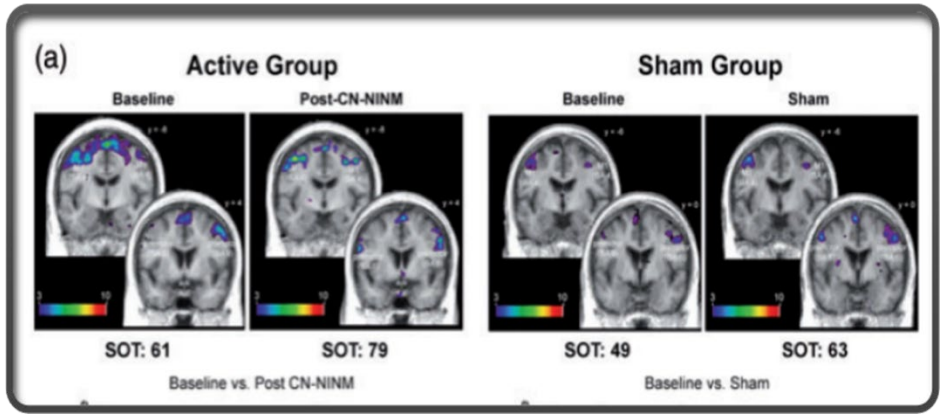
**Change over time for Sensory Organization Test (SOT) composite**



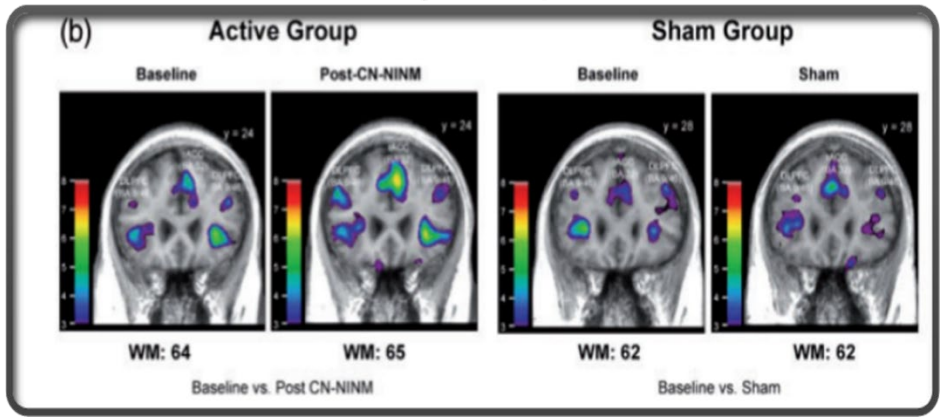

*Statistical analysis of SOT week 14 scores vs pre-training reveals that improvement in the active group is significant (p<0.001) whereas sham group difference did not reach statistical significance (p<0.06)*

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

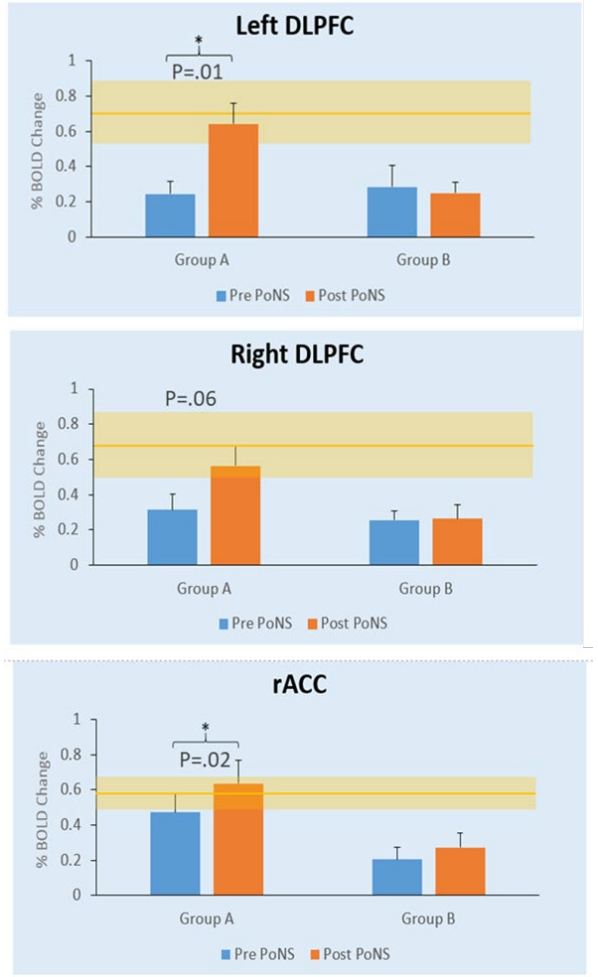
**Gait Imagery fMRI**




**Working Memory fMRI**




**VOIs BOLD signal vs. Healthy Controls**




*Error on publication regarding EDSS Score

# 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, 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

# Real-World Evidence Poster Presentation

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## Translingual Neurostimulation by Portable Neuromodulation Stimulator System as a New Rehabilitation Therapy for Improving Gait in People With Multiple Sclerosis

Antonella Favit-VanPelt, MD, PhD[1]; Kim Skinner, PT, DPT[1]; Greg Maislin, PhD[2]; Nicole Strachan, BHK, MSc. P.Kin[1]; and Lola Abhulimen, MBA[1] — [1]Helius Medical Technologies, Newtown, PA; [2]Biomedical Statistical Consulting, Wynnewood, PA

### Introduction

- Although gait impairment is a disabling symptom in MS leading to reduced mobility and impacting quality of life, current interventions (eg, rehabilitation therapy and pharmacological management) only marginally improve gait function.[1–3]
- Translingual neurostimulation (TLNS) delivered by a portable neuromodulation stimulator system promotes neuromodulation by stimulating the trigeminal (CN-V) and facial (CNVII) nerves exciting a natural flow of neural impulses to the brainstem (pons Varolii and medulla) and cerebellum.[4]
- Recent studies have shown that noninvasive activation of cranial nerves by TLNS when combined with therapeutic exercise programs can modulate neural pathways involved in gait and balance to improve function.[5–9]

### Objectives

- To assess the effect of TLNS (Portable Neuromodulation Stimulator [PoNS®] Therapy), in combination with a supervised therapeutic exercise program, to improve gait deficit in persons with MS—based on real-world evidence (RWE) data collected at clinical rehabilitation settings and pooled analysis of RWE data and data from 2 previous RCTs[5,10]

### Methods

*RWE Data*

- The RWE dataset was gathered from 4 Canadian rehabilitation clinics that integrated TLNS (PoNS therapy) as an adjunct to a supervised therapeutic exercise program to treat gait deficit in patients with MS between March 4, 2019 and December 31, 2019.
  - All patients treated within this date range are included in the analyses regardless of the completeness of the data in order to avoid selection bias.
- Gait performance assessment was determined using the Functional Gait Assessment (FGA),[11] a 10-item clinical gait test scored on a 4-level (0–3) ordinal scale; scores range from 0–30, with lower scores indicating greater impairment.
  - FGA measurements were made during patient care visits: Week 0 (baseline), Week 2, Week 8, and Week 14.
  - Values over time and changes from baseline are summarized by mean (SD), median, minimum, and maximum values and 95% confidence intervals (CI) for the mean score and mean improvements; primary endpoint is mean change from baseline to Week 14.
  - Paired t-tests were employed to evaluate the mean improvements from baseline at each subsequent time point based on observed data.

**TLNS (PoNS® Therapy): Rehabilitation Program**

| | Daily Training Schedule | |
|---|---|---|
| Morning Session | Warm-up Exercises without PoNS | 10 min |
| | Balance Training with PoNS | 20 min |
| | Gait Training with PoNS | 20 min |
| | Breathing and Awareness Training with PoNS | 20 min |
| Break | | 3–4 hours |
| Afternoon Session | Balance Training with PoNS | 20 min |
| | Movement Control Exercises without PoNS | 20 min |
| | Gait Training with PoNS | 20 min |
| Break | | |
| Evening Session | Breathing and Awareness Training with PoNS | 20 min |

*RWE Data*

- The primary analysis of the RWE was based on a mixed model for repeated measures (MMRM),[12] both to account for missing data over time and to ensure that variability in baseline FGA scores did not result in substantial bias.
  - The MMRM assumed an unstructured covariance matrix that allows variances and pairwise covariances to vary over time; parameters of the MMRM were estimated using SAS Proc Mixed.
  - MMRMs were used to evaluate values over time as well as changes from baseline including baseline as covariate.
  - For mean changes, t-tests derived from the MMRM were used to determine nominal significance levels; distributions of improvements were evaluated graphically using a cumulative distribution function.
- Heterogeneity of improvements in gait deficit in the real-world clinical setting were evaluated across a number of clinical factors (gender, age category, race/ethnicity, years with MS category, type of MS, Expanded Disability Status Scale (EDSS) category, prior physical therapy (PT), and medication use), with modeling approaches similar to those used in the overall analyses.

*Pooled Analysis of RWE and RCT Data*

- In the 2 previous RCTs, gait improvement was assessed using the Dynamic Gait Index (DGI),[13] an 8-item test scored on a 4-level (0–3) ordinal scale; scores range from 0–24, with lower scores indicating greater impairment.
  - Seven of the 8 items on the DGI are also included within the 10-item FGA.
- In order to pool the RWE data with data from the RCTs, an adjusted DGI score was derived by summing the 7 scores from the tasks the two measures have in common and multiplying by 8/7; this "adjusted" 7-item DGI, therefore, has the same overall scores range as the 8-item DGI.
- A similar MMRM model was used to characterize expected improvements in gait from baseline to Week 14 in order to provide a summary of expected improvements in DGI over time using the largest possible sample size.
- An additional responder analyses was performed to summarize the number and percentage of patients achieving improvement based on DGI categorical response.

### Results

*Demographic and Baseline Characteristics*

- The RWE analysis included 42 patients with a mean age of 55.4 years, mean duration of MS of 18.6 years, and mean EDSS score of 5.5. (**Table 1**)
  - Median age stratified by gender was 57.5 years (range: 39–72) for females (n = 28) and 51.0 years (range: 32–72) for males (n = 14).
- While the previous RCTs restricted eligible patients to those with EDSS scores ranging from 3.5 to 6.0, the RWE dataset included a broader ranger of EDSS scores.
  - Patients in the RWE sample had a mean EDSS score of 5.5 (range: 1.0–6.5), with a mean duration of MS of 18.6 years (range: 4–45 years).

**Table 1. Baseline and Disease Characteristics**

| Characteristics* | RWE Sample (N = 42) |
|---|---|
| **Gender** | |
| Female | 28 (66.7) |
| Male | 14 (33.3) |
| **Age** | |
| Total RWE sample, mean (SD) | 55.4 (11.0) |
| **Age Category** | |
| <50 | 14 (33.3) |
| 50 to 64 | 17 (40.5) |
| ≥65 | 11 (26.2) |
| **Race/Ethnicity** | |
| Caucasian | 38 (90.5) |
| Hispanic | 2 (4.8) |
| Afro-Caribbean | 1 (2.9) |
| Indian | 1 (2.9) |
| **Years with MS** | |
| Total RWE sample, mean (SD) | 18.6 (9.5) |
| 0–10 | 11 (26.2) |
| 11–20 | 16 (38.1) |
| 21–30 | 11 (26.2) |
| 31–45 | 4 (9.5) |
| **Type of MS, n (%)** | |
| Primary Progressive | 6 (20.7) |
| Relapsing/Remitting | 9 (31.0) |
| Secondary Progressive | 14 (48.3) |
| Missing | 13 |
| **EDSS** | |
| Total RWE, mean (SD) | 5.5 (1.3) |
| Mild | 2 (5.0) |
| Moderate | 21 (52.5) |
| Moderate Severe | 17 (42.5) |
| Missing | 2 |
| **Prior PT** | |
| Yes | 34 (85.0) |
| No | 6 (25.0) |
| Missing | 2 |
| **Medications†** | |
| Disease modifying | 7 (17.9) |
| Symptom moderating | 13 (33.3) |
| Gait dysfunction | 8 (20.5) |
| Neuropsychotropic | 3 (7.7) |
| Other medications | 18 (41.0) |
| Missing | 3 |

*Values are number (percent) unless otherwise noted.
†Subjects can have more than one type of medication. Thus, the sum of percentages can exceed 100%.

*Efficacy: FGA in RWE Dataset*

*MMRM for FGA Values Over Time*

- Using all available data from 42 MS patients, the MMRM estimated mean improvement from baseline to Week 14 in the FGA was 4.63 (95% CI: 3.61 to 5.65). (**Table 2**)
  - Estimated mean improvements from baseline in FGA score based on the random effects model were statistically significant at all subsequent time points (**Figure 1**) and were similar to mean improvements based on the observed data.
  - Notably, the estimated mean improvement at Week 14 of 4.63 is above the minimum detectable change (MDC) for stroke patients (4.2 points)[14] and people with other specific neurological disease (4 points)[15] and above the minimum clinically important difference (MCID) in community-dwelling older adults (4 points).[16] The MDC and MCID on the FGA have not been reported for patients with MS.
  - The percentage of patients who achieved at least a 4-point improvement in the FGA increased over time and was 58.3% at Week 14. (**Figure 2**)

**Table 2. MMRM for FGA Total Score Over Time and Change From Baseline**

Least Square Means from Random Effects Model for Repeated Measures

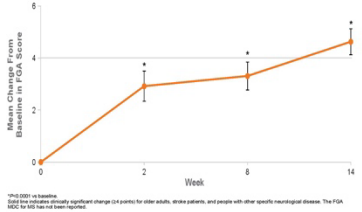
| Visit | Mean (Standard Error) | 95% CI | P-value |
|---|---|---|---|
| Week 0 (Baseline) | 10.19 (0.97) | 8.24–12.14 | <0.0001 |
| Week 2 (Progress) | 13.12 (1.07) | 10.96–15.28 | <0.0001 |
| Week 8 (BenchMark) | 13.49 (1.12) | 11.23–15.75 | <0.0001 |
| Week 14 (Discharge) | 14.88 (1.01) | 12.84–16.91 | <0.0001 |

Changes from Baseline Estimated from MMRM

| Visit | Estimate (Standard Error) | 95% CI | P-value |
|---|---|---|---|
| Week 2 (Progress) | 2.92 (0.58) | 1.74–4.10 | <0.0001 |
| Week 8 (BenchMark) | 3.31 (0.54) | 2.22–4.40 | <0.0001 |
| **Week 14 (Discharge)*** | **4.63 (0.69)** | **3.01–6.65** | **<0.0001** |

*Primary endpoint of RWE analysis.

**Figure 1. RWE Patients: Difference in Least Squares Means in FGA Score from Baseline**




*Efficacy: FGA in RWE Dataset*

*Observed Data for FGA Values Over Time*

- Mean improvements in FGA total scores based on observed data were highly statistically significantly at all follow-up time points (paired t-test $P<0.0001$). (**Table 3**)
- Mean improvement in FGA at Week 14 was 4.75 (95% CI: 3.66 to 5.84).
- Median improvement was 5 points, and 83% of patients an improvement of ≥2 points. (**Figure 3**)

*Stratified Analysis*

- Homogeneity of treatment effect was demonstrated for an extensive set of baseline characteristics including gender, age category (<50, 50 to 64, ≥65), years with MS category (0–10, 11–20, 21–30, 31–45), type of MS (primary progressive, relapsing/remitting, secondary progressive), prior PT status, and use of various medications.
  - Patients with an EDSS category of moderately severe appeared, on average, to have smaller, yet still statistically significant, improvements compared to subjects with an EDSS category of moderate disease; mean improvement from baseline to Week 14 was 2.33 (95% CI: 0.68 to 3.98; $P=0.007$) and 5.75 (95% CI: 4.48 to 7.01; $P<0.0001$) for patients in the moderately severe and moderate categories, respectively.

**Figure 2. Percentage of RWE Patients with FGA Improvements ≥4 Points Over Time**

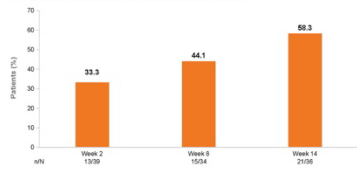



**Table 3. Observed FGA Total Scores Over Time and Change From Baseline**

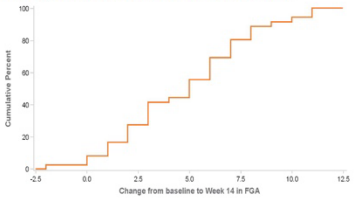
Observed FGA Total Scores Over Time

| Visit | N | Mean (SD) | Median | Minimum | Maximum | 95% CI |
|---|---|---|---|---|---|---|
| Week 0 (Baseline) | 42 | 10.19 (6.26) | 9.50 | 0.00 | 28.00 | 8.24–12.14 |
| Week 2 (Progress) | 39 | 13.10 (6.50) | 11.00 | 3.00 | 3.000 | 10.99–15.21 |
| Week 8 (BenchMark) | 34 | 13.79 (6.42) | 13.00 | 3.00 | 30.00 | 11.55–16.03 |
| Week 14 (Discharge) | 36 | 15.69 (6.28) | 15.50 | 7.00 | 29.00 | 13.57–17.82 |

Observed Changes from Baseline in FGA Total Scores

| Visit | N | Mean (SD) | Median | 95% CI | P-value |
|---|---|---|---|---|---|
| Week 2 (Progress) | 39 | 2.79 (3.69) | 3.00 | 1.60–3.99 | <0.0001 |
| Week 8 (BenchMark) | 34 | 3.24 (3.10) | 3.00 | 2.16–4.32 | <0.0001 |
| Week 14 (Discharge) | 36 | 4.75 (3.22) | 5.00 | 3.66–5.84 | <0.0001 |

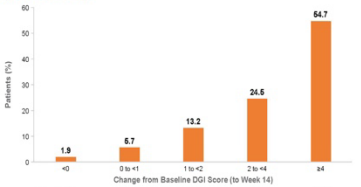
**Figure 3. Cumulative Distribution of Observed Changes from Baseline to Week 14 in FGA**




*Pooled Analysis of RWE Sample and RCT Active Cohorts*

- MMRM adjusted mean improvement in DGI from baseline to Week 14 was 4.58 (95% CI: 3.62 to 5.54) for the pooled RWE and RCT analysis including all possible data at all weeks.
- Among 53 patients with Week 14 data, 29 (55%) experienced ≥4 point improvement from baseline in DGI. (**Figure 4**)

**Figure 4. Pooled RWE/RCT Data: Summary of Categorical Response—DGI Improvements (to Week 14)**




*Safety*

- In the real-world data collected with use of TLNS (PoNS therapy) in patients with MS, minimal adverse events were reported, with all determined to be typical for this patient population with or without use of the device.
- No serious adverse events related to the PoNS device were reported in the MS RCTs or have occurred during its use in clinical rehabilitation settings to treat balance and gait disorders (>45,128 patient-use sessions since March 4, 2019).

### Conclusions

- In this evaluation of a real-world dataset of patients with MS with generally long duration of disease, translingual neurostimulation (PoNS therapy) combined with a therapeutic exercise program significantly improved gait deficit at Week 2, the earliest evaluated time point, and at every subsequent time point.
- At Week 14, 58.3% of patients had an FGA improvement of ≥4 points, surpassing the MDC for older adults, stroke patients, and persons with other neurological disease.
- Analysis of real-world data pooled with the 2 randomized clinical trials demonstrated, consistent with the RCT data, that translingual neurostimulation (PoNS therapy) combined with a therapeutic exercise program is safe and effective for improving gait deficit in individuals with mild and moderate symptoms from MS.

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**Disclosures:** **A. Favit-VanPelt, K. Skinner, N. Strachan, L. Abhulimen:** employees of Helius Medical Technologies; **G. Maslin:** statistical consulting for Helius Medical Technologies.

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Presented at the 2022 Consortium of Multiple Sclerosis Centers (CMSC) Annual Meeting, June 1–4, 2022, National Harbor, MD

Visit ponstherapy.com to view the poster online

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Slide 34

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