Helius
MEDICAL TECHNOLOGIES

Empowering Neuroplasticity

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

October 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, manufacturing, labor shortage and supply chain risks including risks related to manufacturing delays, the Company's ability to obtain national Medicare coverage at an acceptable rate and negotiate reimbursement with other third-party payers, the Company's ability to build internal commercial infrastructure, secure state distribution licenses, market awareness of the PoNS device, future clinical trials and the clinical development process, the product development process and the 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, 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.

About Helius Medical Technologies

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; 51 foreign patents issued) expiring between 2026 and 2041

March 2021 - 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 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

$64.5k

Average cost of a fall[5]

$50B

Cost to the healthcare system each year[5]

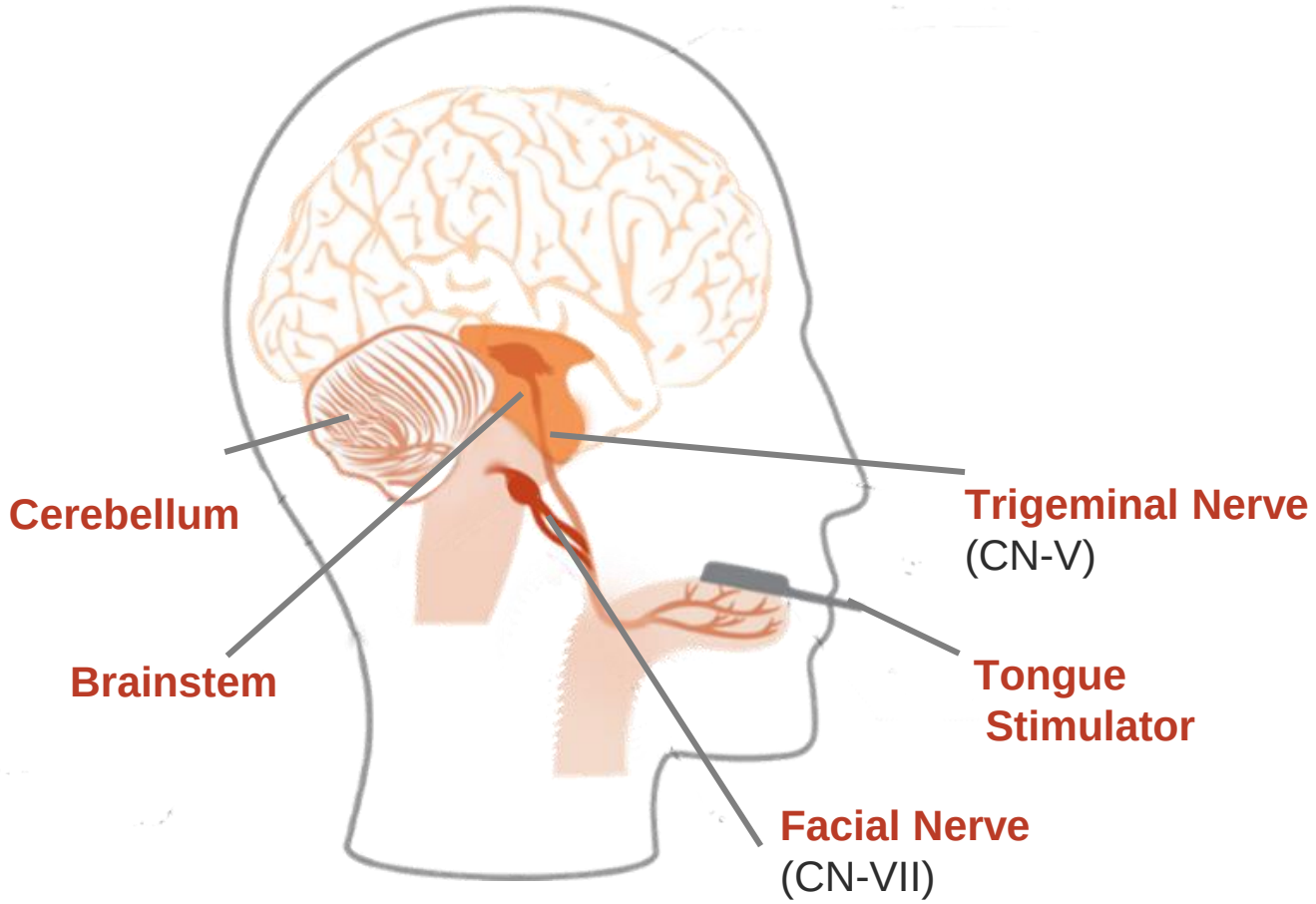
PoNS Therapy®

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]

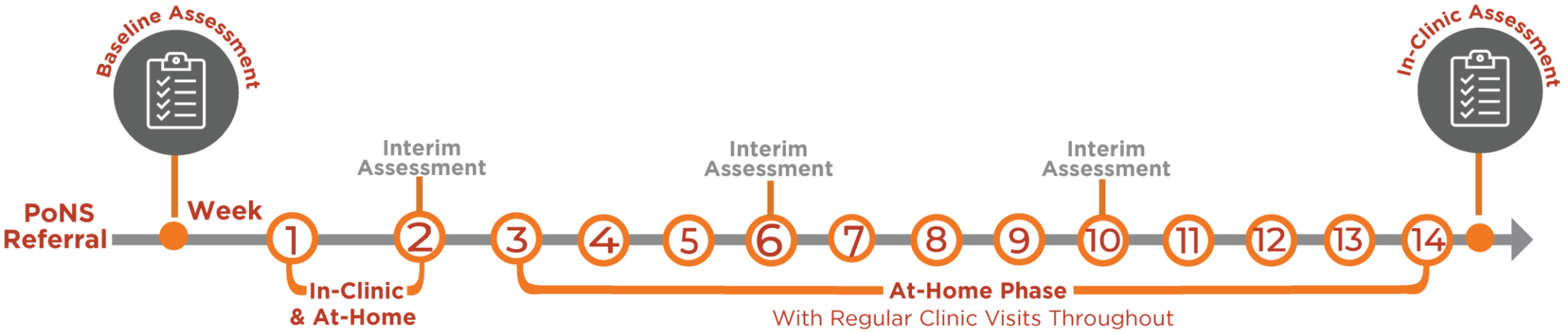


~25MM pulses per 20-minute session
Feels like champagne or carbonated water bubbles

- 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%
average improvement

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]

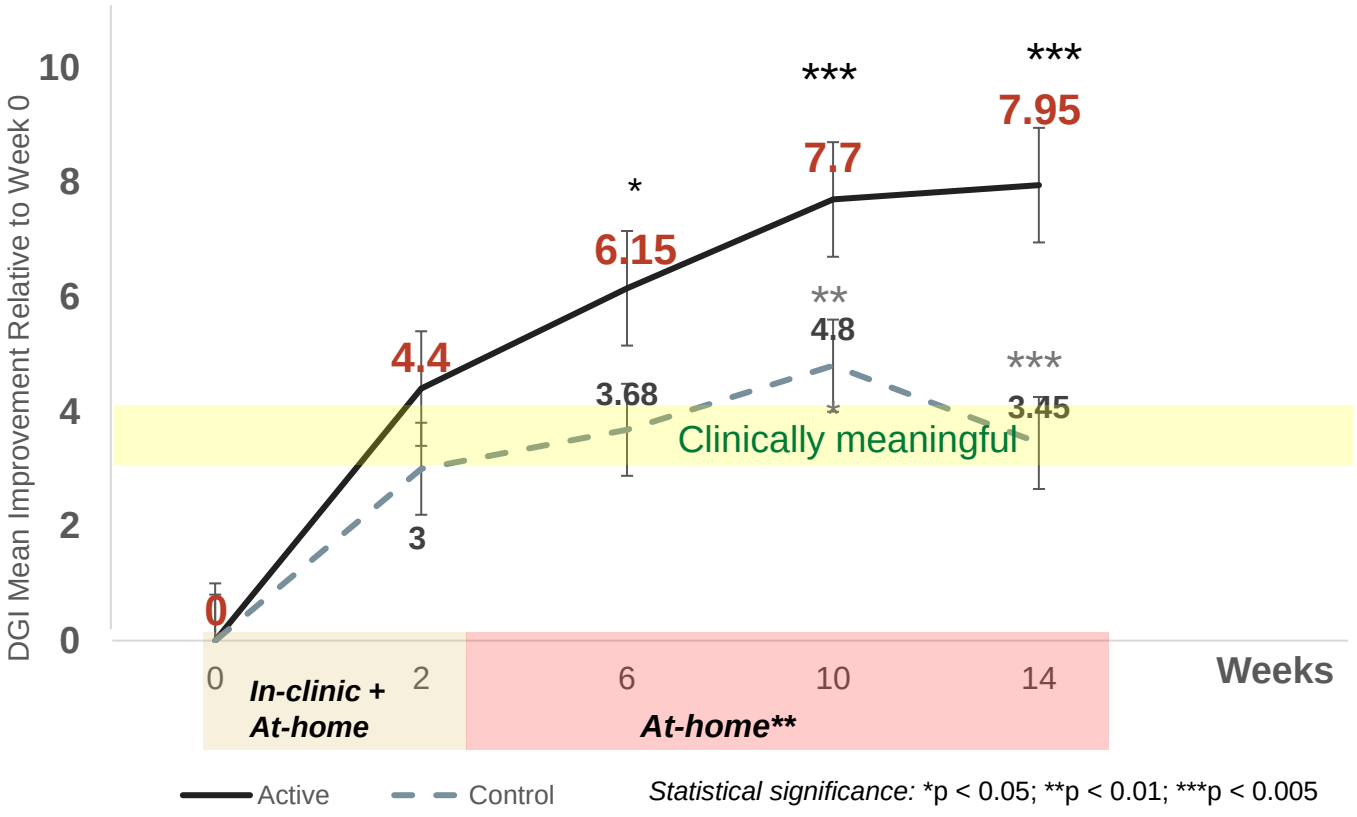
100% of multiple sclerosis patients in the active group experienced a **clinically meaningful improvement** in gait*[3]

Over 200k full patient sessions have been successfully performed on PoNS without an adverse event

*Study results from randomized placebo-controlled clinical trial
**Study results from real-world database analysis

Clinical Evidence[1] (May 2014, University of Wisconsin-Madison)

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

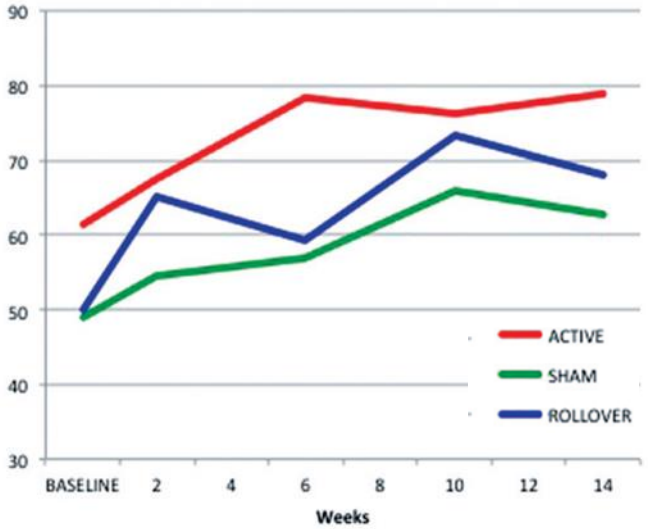
*Error on publication regarding EDSS Score
**One visit per week was in-clinic

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

Clinical Evidence[1]

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

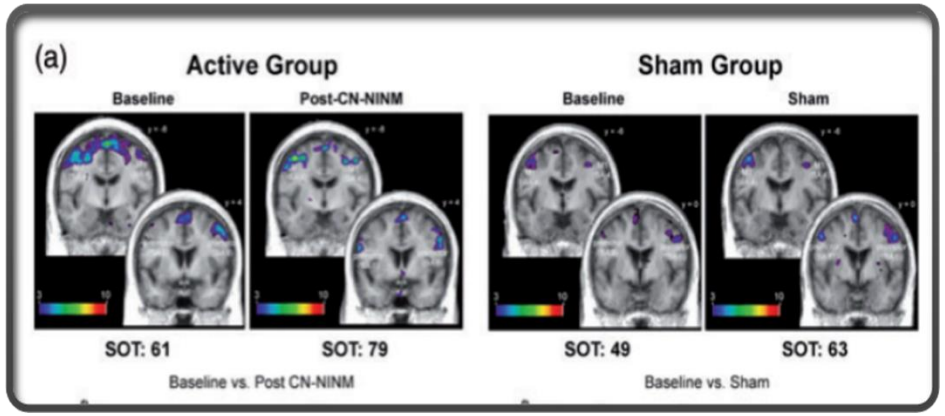
Change over time for Sensory Organization Test (SOT) composite



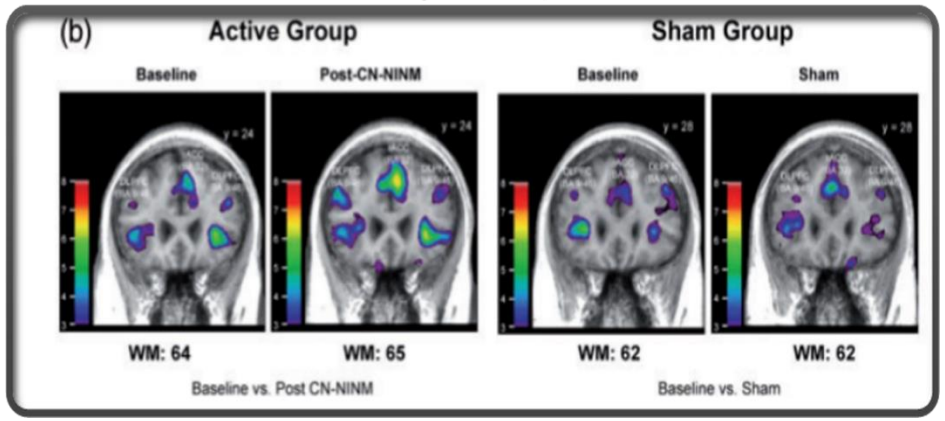
Statistical analysis of SOT week 14 scores vs pre-training reveals that improvement in the active group is significant (p<0.001) whereas sham group difference did not reach statistical significance (p<0.06)

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

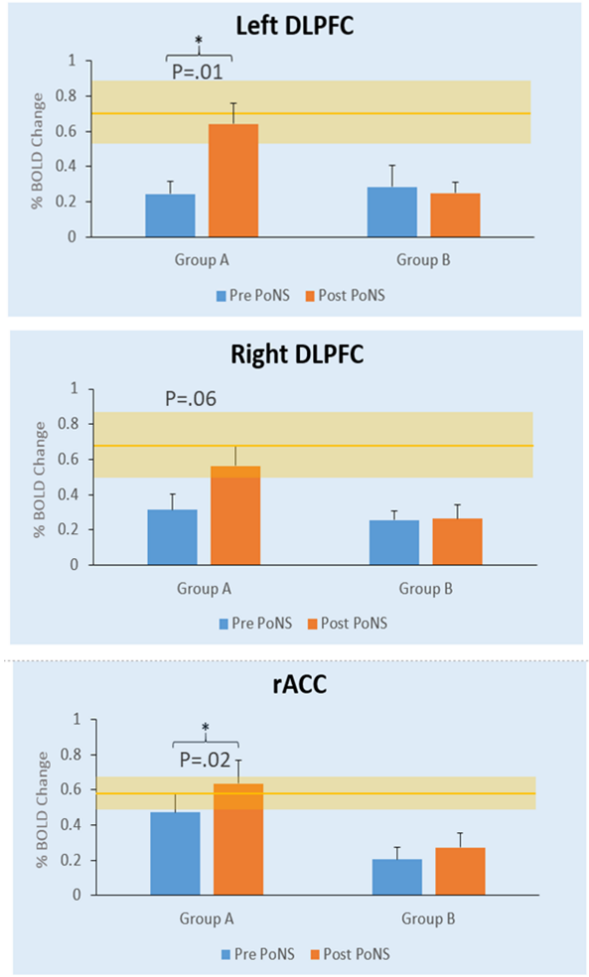
Gait Imagery fMRI



Working Memory fMRI



VOIs BOLD signal vs. Healthy Controls



*Error on publication regarding EDSS Score

Preliminary Results From PoNSTEP Study[1]

- Explores the relationship between treatment adherence and therapeutic outcomes over 14-week period and the 6-month post-treatment follow-up
- 6 participating Centers of Excellence
    - NCNE, Shepherd Center, Montefiore Medical Center, OHSU, MGH Institute, and NYU Langone Health
- Preliminary results confirm the benefit of PoNS Therapy on gait rehabilitation and the importance of treatment compliance
- Treatment adherence was directly linked to the level of improvement

74%
Of participants
(70% adherence)

4 point
Improvement in DGI

50%
Of participants
(85-100% adherence)

Nearly 7 point
Improvement in DGI

- Post-treatment durability follow-up to be completed by end of the year, with full results expected early 2025

Commercialization and Reimbursement

Large Potential Addressable Markets

U.S. Market

Affected by MS

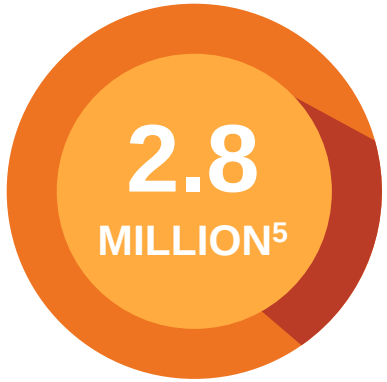
70% report difficulty walking[2]

Authorized for gait deficit due to symptoms of MS

Affected by stroke

Impaired walking affects about **80%** of survivors[4]

Pilot Study Conducted
Additional RCT/OL Studies Ongoing



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

Authorized Treatments for Walking Difficulty Due to MS

	PoNS Therapy	Bioness	Cionic	Ampyra	Physical Therapy
Indication	• Treats gait deficit due to mild to moderate symptoms from MS • (Currently authorized also in TBI and stroke in Canada. Expected expansion into stroke and TBI in the US)	• Improves mobility for patients with foot drop and/or knee instability caused by an upper motor neuron disease or injury	• Improves walking or lower extremity weakness due to neurological conditions	• Improves walking speed in adults with MS	• Helps with balance and gait disorders caused by neurological disease through a variety of techniques
Efficacy	• In an RCT, 100% of individuals with MS treated with active PoNS and consistently using PoNS with physical therapy ("PT") for 14 weeks, improved gait scores by more than >2x vs individuals with MS using a sham device and PT • 14 weeks of PoNS Therapy increases blood flow and activates specific areas of the brain responsible for functional gait and balance rehabilitation • In a real-world analysis, almost 60% of individuals in the study achieved at least a 4-point improvement in the FGA by the end of 14 weeks of therapy	• 40% improvement in walking speed • 15% improvement on critical balance measures (decreased fall risk) • 30% improvement in distance walked	• 94% of participants experienced increased ankle dorsiflexion at heel strike • 9º average improvement to dorsi+inversion across all participants • 88% of participants experienced reduced ankle inversion during swing	• Patients responding to AMPYRA increased walking speed by an average of approximately 25% from baseline in two clinical studies	• PT is the standard of care for mobility deficits across neurological disorders • Short-term PT can improve mobility and some other symptoms of MS and other neurological disorders associated with physical disability • Long-term PT has not been proven to maintain improvement gained with the initial PT rehabilitation
Price	• List Price: $25,700	• ~$6,000	• Year 1: $260 down, then $260 per month ($3,380) • Year 2: $120/month ($1,440)	• $4,256 per 30-day supply à ~51K per year (prior to generic)	• The national average per session can range from $30 - $400

U.S. Commercialization Launch Initiatives

Driving Awareness and Building Experience

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 Therapy 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

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
- Enrollment closed in Q2, study still ongoing
- Preliminary treatment endpoint analysis in 2H 24
- 6 participating Centers of Excellence (NYU Langone Health, Shepherd Center, OHSU, MGH Institute, NCNE, Montefiore Medical Center)

Well Positioned to Scale After Reimbursement

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

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

- Pursuing commercial and government reimbursement programs with initial cash pay option
- Dual path for reimbursement
- DME
  - Secured HCPCs codes for both Controller and Mouthpiece
  - CMS final price determination of $2,963.30 for Mouthpiece to be challenged
  - CMS final price determination for Controller deferred

	List Price	VA FSS	3rd Party Payer
Controller	$17,800	$16,499	$16,554
Mouthpiece	$ 7,900	$7,345	$ 7,347
Complete PoNS System	$25,700	$23,844	$23,900

- NDC/UPC/HRI
  - Codes established for both PoNS System and PoNS Mouthpiece
  - Listed in Medi-Span and FDB databases
- Partnered with Lovell Government Services to establish distribution and reimbursement pathways with the U.S. Department of Veterans Affairs (“VA”)
  - Contracted with the VA and other Government Services through the FSS and GSA
  - Establish regional sales rep relationships for VA & DoD
- Registry program to generate evidence for coverage
  - Designed to gather important health economic information (over 36-month period) to establish the value of PoNS on key therapeutic outcomes

Reimbursement with the Veterans Administration

- Partnered with Lovell Government Services to establish distribution and reimbursement pathways with the VA
  - Approved federal contractor with access to federal markets
    - VA
    - Department of Defense
  - Procurement and reimbursement solution
  - VA is the largest integrated healthcare system

Veterans currently diagnosed with MS[1]

Veterans living with complications from a stroke[2-3]

Veterans currently under VA care who have been diagnosed with at least one TBI[4]

"After living with MS since 1999, gait difficulties took away my most valued treasure: quality adventures with my 13-year-old daughter. My focused PoNS Therapy helped me improve my walking, and as a result of my improved walking I experienced freedoms such as increased walking speed, endurance, and distance. As a reward for her support and motivation, Rogue and I will vacation in New York City to walk the streets of Manhattan and enjoy our favorite Broadway musicals! Thank you for the experiences I thought were lost forever." – Kevin Byrne

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 PT 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 registrational program that streamlines cost and timeline
- Program includes randomized control studies as well as open-label study. Nine participating sites in North America, including Medical University of South Carolina ("MUSC"), Brooks Rehabilitation, Shepherd Center, The MGH Institute of Health Professions, and five large rehabilitation centers in US and Canada
- Reducing the risk of falls – key secondary endpoint
- Targeting regulatory submission for stroke indication in 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)
- 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]

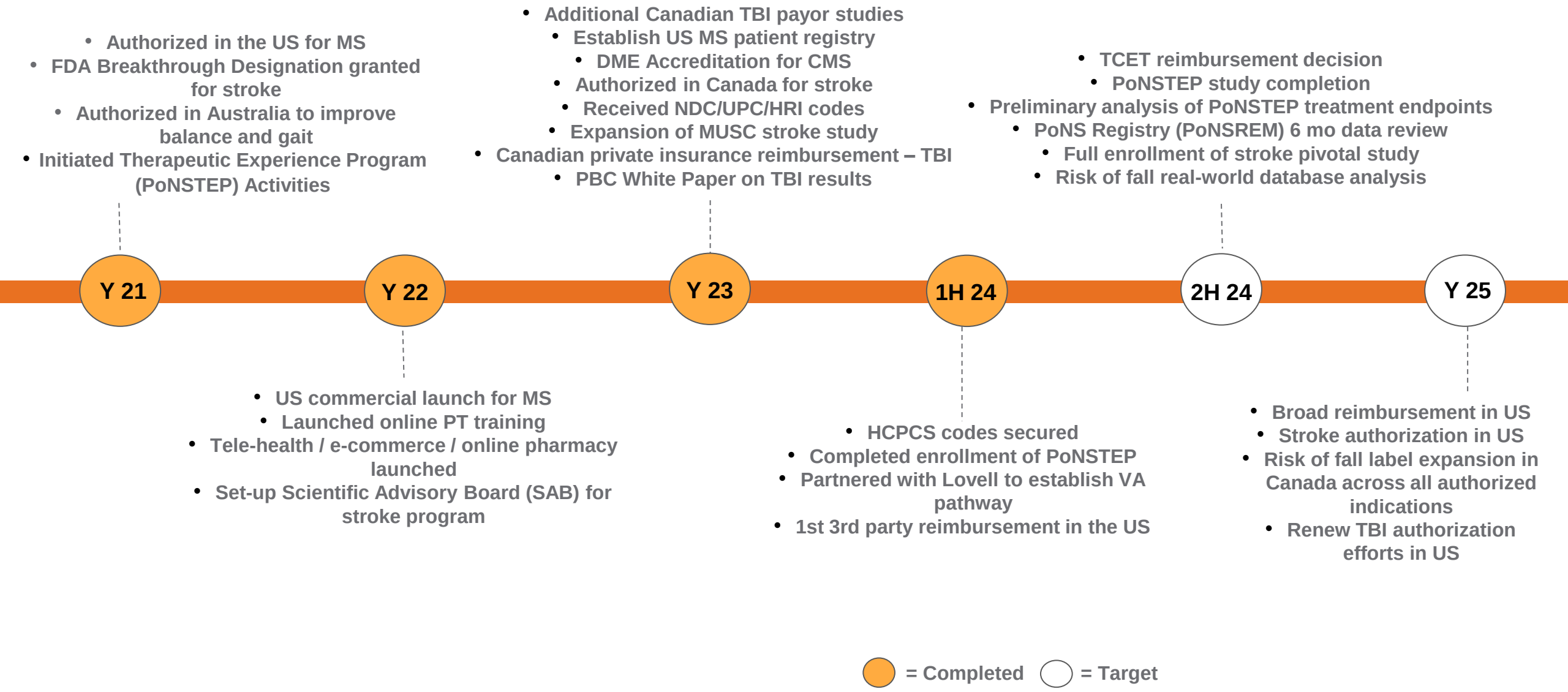
Return to Work Outcomes

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 TBI

- 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

Financial Update

Summary Operations and Cash Flows	Q2 2024	Q2 2023	Six Months Ended 6/30/2024	Six Months Ended 6/30/2023
Total Revenue	$182K	$256K	$317K	$367K
Operating Loss	$(3.3M)	$(3.2M)	$(6.7M)	$(7.0M)
Net Loss	$(1.6M)	$(1.6M)	$(4.1M)	$(4.1M)
Cash Used in Operations	$(2.9M)	$(2.7M)	$(5.9M)	$(5.9M)

($ in millions)

Summary Balance Sheet	6/30/2024	12/31/2023
Cash and Cash Equivalents	$6.4	$5.2
Long-term Debt	$ --	$ --

Capitalization & Cash Position

Nasdaq	
Symbol	HSDT
Market Cap*	$1.9M
Price Per Share*	$0.51
Shares Outstanding*	3,741
50 Day Avg Volume	274K
Cash at 6/30/24	$6.4M
* Based upon shares and PFWs outstanding at August 7, 2024, and closing price on October 7, 2024	

Capitalization (in thousands)	6/30/24
Common Stock (incl. 164k prefunded warrants)	3,741
Legacy Warrants**	613
12 month warrants @ $2.25 exercise price	2,852
5 year warrants @ $2.25/$2.475 exercise price	2,995
Options	246
Total Fully Diluted	10,447
**Includes 604K warrants @ $1.6163 strike price	

HSDT Analyst Coverage
MAXIM GROUP, LLC
Anthony Vendetti

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, Inc. for 4 years and HDL Therapeutics, Inc. for over 15 years

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, Inc. and its affiliate Thera Neuropharma, Inc.
- Served as Senior Director and Global Medical Lead at Shire Pharmaceuticals Group PLC, Director of Medical Strategy at Bristol-Myers Squibb Company, and as Global Clinical Development Lead at GE Healthcare

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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