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

April 1, 2022
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		**18940**
(Address of Principal Executive Offices)		**(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 7.01 Regulation FD Disclosure.

On April 1, 2022, Helius Medical Technologies, Inc. (the "Company") posted an updated corporate presentation to its website at http://heliusmedical.com/index.php/investor-relations/overview, which the Company may use from time to time in communications or conferences. A copy of the corporate presentation is attached as Exhibit 99.1 to this Current Report on Form 8-K (this "Report").

The information in this Report, including Exhibit 99.1 hereto, is furnished pursuant to Item 7.01 and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (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 of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing. The Company's submission of this 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 Report and Exhibit 99.1 hereto contain forward-looking statements within the meaning of the federal securities laws. These forward looking statements are based on current expectations and are not guarantees of future performance. Further, the forward-looking statements are subject to the limitations listed in Exhibit 99.1 and in the other reports of the Company filed with the Securities and Exchange Commission, including that actual events or results may differ materially from those in the forward-looking statements.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Corporate Presentation, dated April 2022.
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: April 1, 2022

By: /s/ Jeffrey S. Mathiesen

Jeffrey S. Mathiesen
Chief Financial Officer and Treasurer

Exhibit 99.1

Helius
MEDICAL TECHNOLOGIES

Empowering Neuroplasticity

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

April 2022

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, and the timing and success of the Company's commercialization efforts in the United States. 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 reduce symptoms of neurological disease or trauma.

Authorized for the treatment of gait deficit due to mild to moderate symptoms from multiple sclerosis ("MS")

FDA Breakthrough Designation granted for the treatment of gait deficit due to symptoms of 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 mild and moderate symptoms of MS and chronic balance deficit due to mild and moderate traumatic brain injury ("mmTBI")

Authorized for use by healthcare professionals as an adjunct to a therapeutic exercise program to improve balance and gait.

A Path to Commercialization: FDA Breakthrough Designation

MULTIPLESCLEROSIS

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*

STROKE

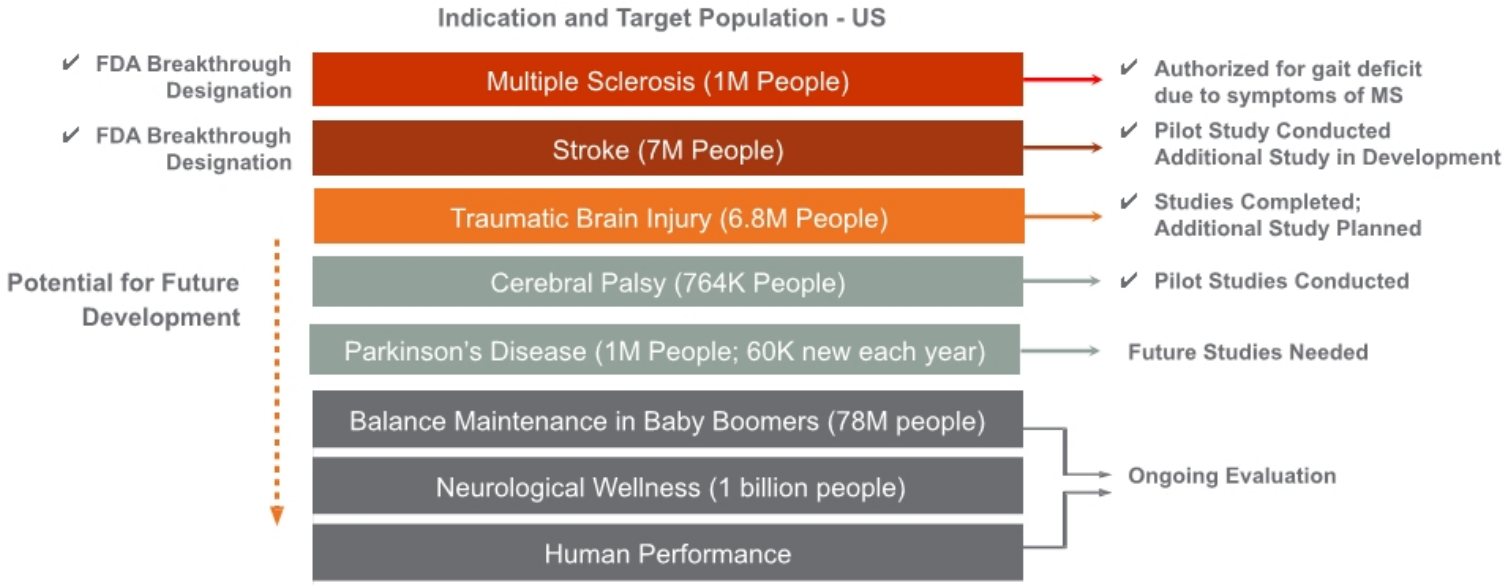
August 2021

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

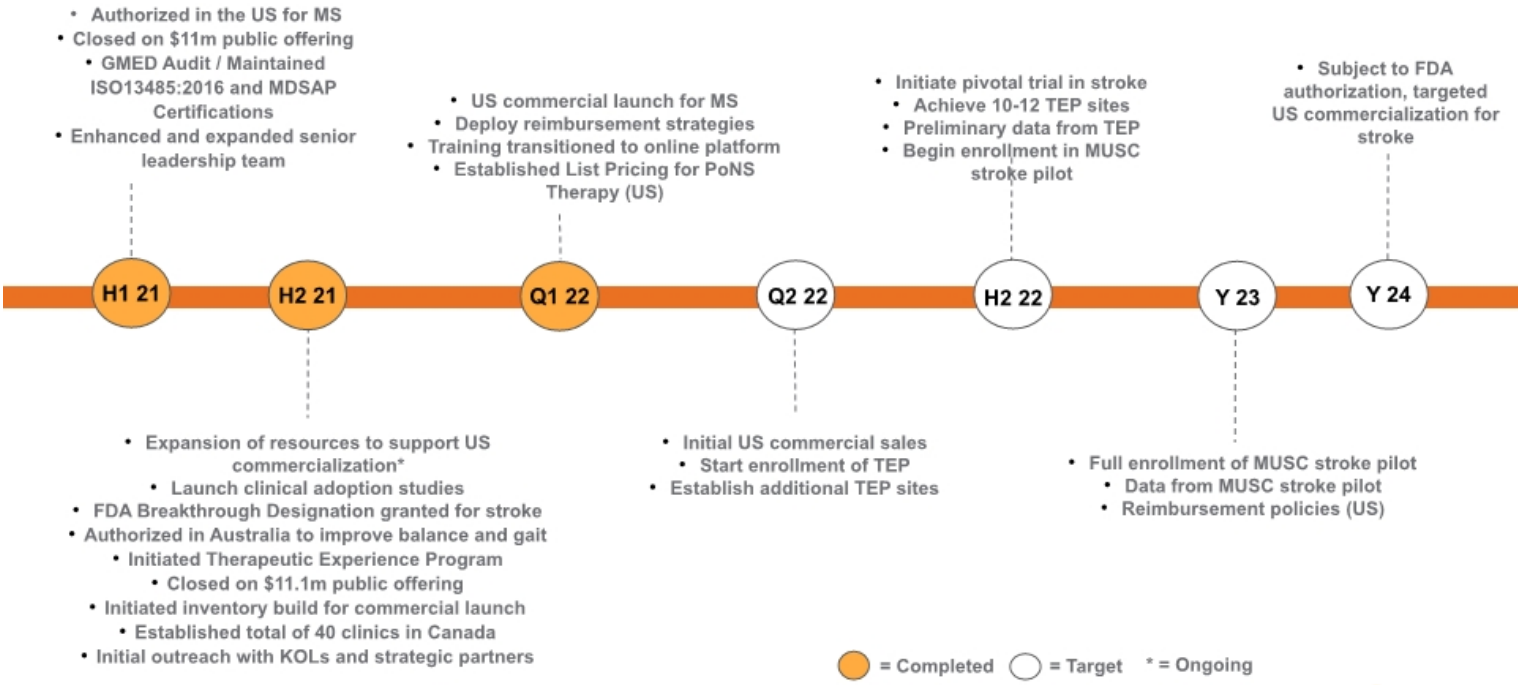
Next Milestones

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

Large Potential Addressable Markets
U.S. Clinical Progress and Future Opportunities

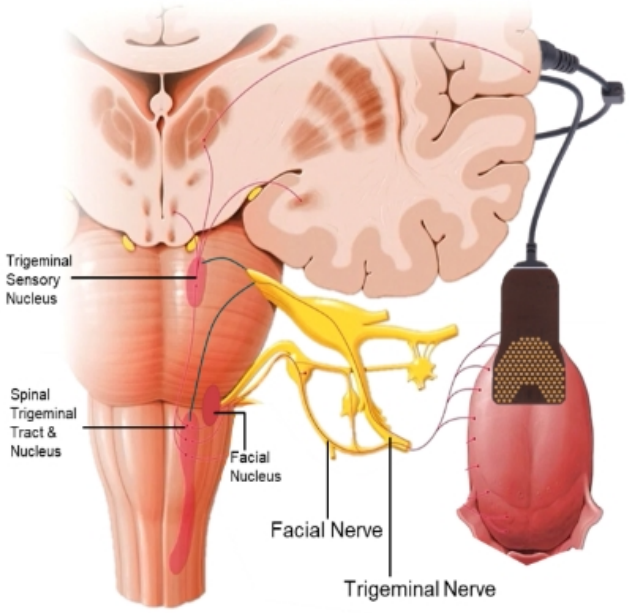


Recent Milestones and Anticipated Value Creation Events



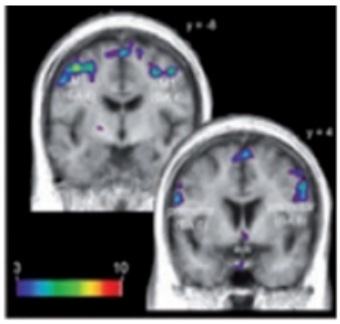
PoNS Therapy™

PoNS Therapy™
Mechanism of Action



Adapted from https://www.kenhub.com/en/study/anatomy-of-taste-patway

Blood oxygen level-dependent (BOLD) signal



Neuromodulation:
modification of the nervous system by targeted stimuli

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

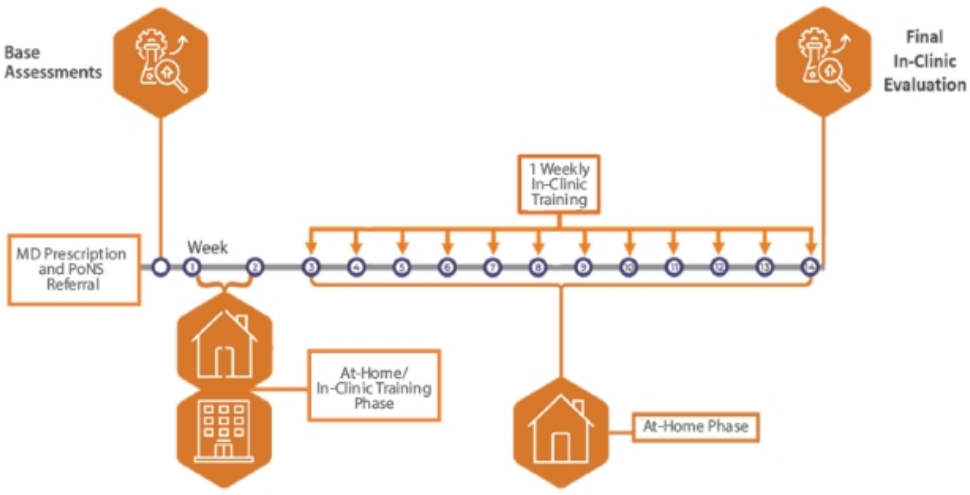
~25MM pulses per 20-minute session
Feels like champagne or carbonated water bubbles

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

PoNS Therapy™



Current Strategies for Managing Neurological Disorders

Prescription Drugs

Therapy

Surgery

Medical Devices

PoNS Therapy™ for Symptoms of Multiple Sclerosis

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

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

Commercialization and Reimbursement

Therapeutic Experience Program

- Helius sponsored open-label, interventional, observational, clinical 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)
- Expected to start enrollment in Q2' 22 and continue through Q4' 22
- 1st Center of Excellence announced (NYU Langone Health)

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
- Pursuing commercial and government reimbursement programs with initial cash pay option
  - Ongoing CMS engagement to obtain HCPCS codes and coverage
- Prescriptions received in March with initial shipments anticipated in April
- Exploring tele-medicine / prescription fulfillment
- Implement key marketing strategies to generate awareness
  - Advocacy engagement
  - Social and digital presence
  - Conference attendance (ACTRIMS, CMSC, ACRM)

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

Addressable Market

G35 Diagnosis and one of the following: R26, R260, R261, R262, R263, R268, R2681, R2689, R269 (Primary) New Patient Count					
State Code	2016	2017	2018	2019	2020
NY	10,340	10,769	10,943	10,959	10,158
OH	8,709	8,965	9,286	8,900	8,459
FL	8,549	8,839	9,050	8,793	8,090
CA	7,417	8,272	8,457	8,513	8,187
MI	7,208	7,863	8,009	8,191	7,644
NJ	6,714	6,815	6,867	6,379	5,822
TX	5,529	5,949	6,139	6,247	6,009
PA	5,992	6,007	5,925	5,690	5,217
IL	5,360	5,478	5,211	4,750	4,393
GA	3,784	3,980	4,214	4,065	3,549
Top 10 States	69,602	72,937	74,101	72,487	67,528
All States	124,953	130,525	132,231	129,668	120,282

Abnormalities of gait and mobility R26

Codes:

- R26.0 Ataxic gait
- R26.1 Paralytic gait
- R26.2 Difficulty in walking, not elsewhere classified
- R26.8 Other abnormalities of gait and mobility
- R26.81 Unsteadiness on feet
- R26.89 Other abnormalities of gait and mobility
- R26.9 Unspecified abnormalities of gait and mobility

5 Year Avg All States: ≈ 127,532 patients

5 Year Avg Top 10 States: ≈ 71,331 patients

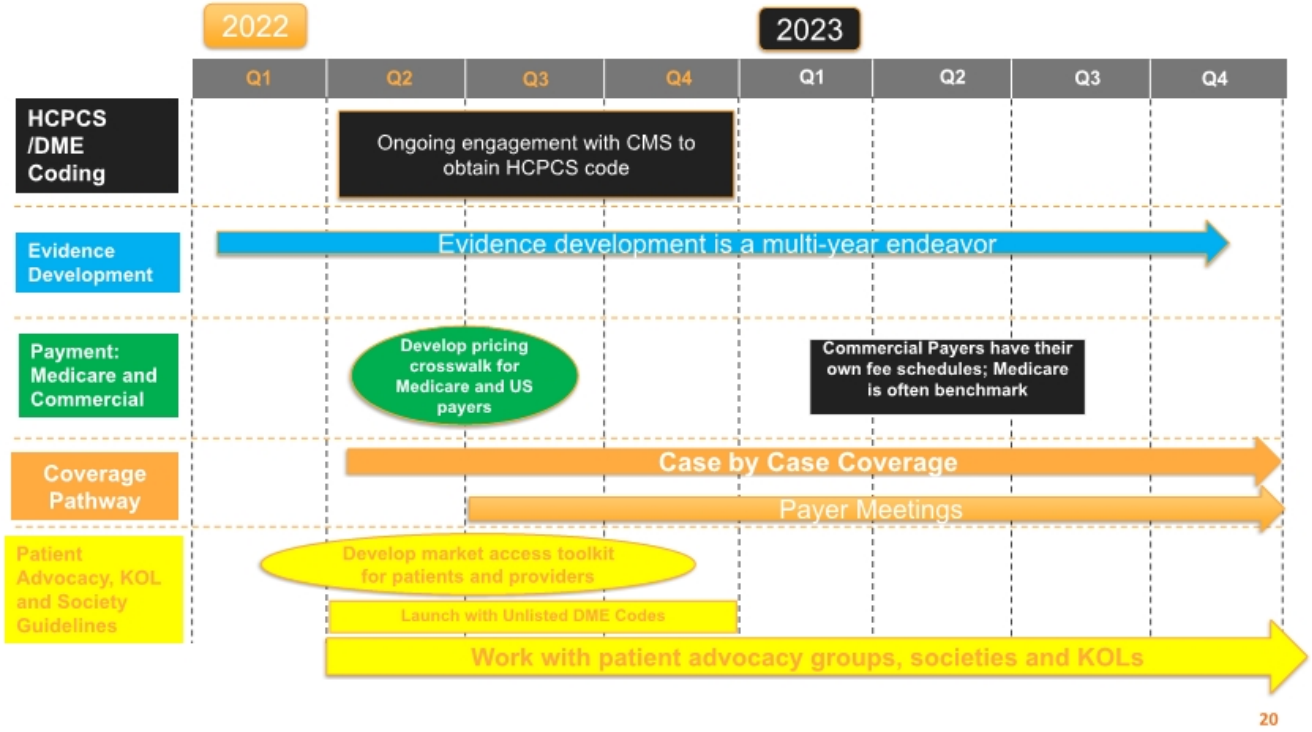
* Data Source = Purple Labs Patient Data

PoNS Established US List Pricing

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

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

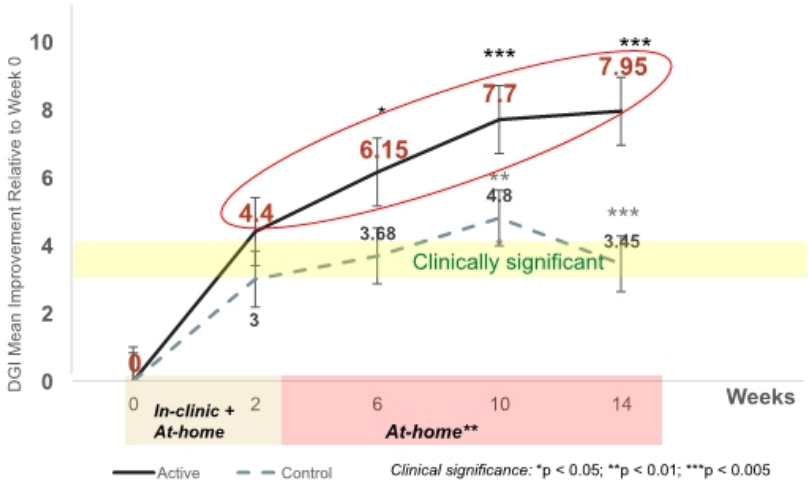
US Market Access Key Coding & Payment Milestones and Timelines



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

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

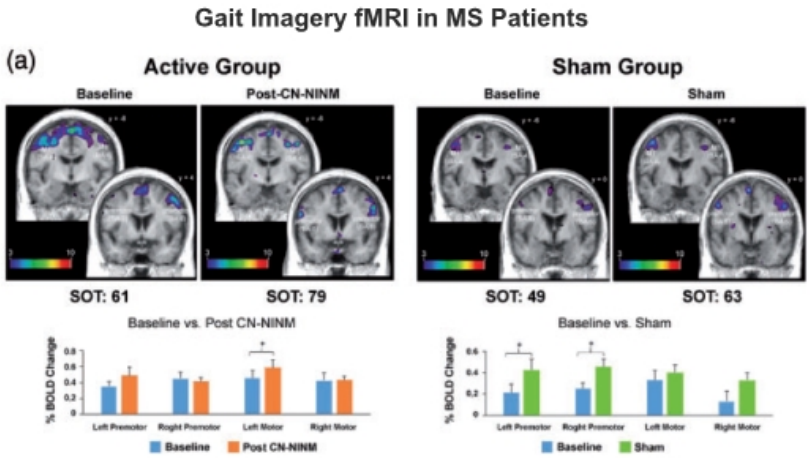
*Error on publication regarding EDSS Score[3]
**One visit per week was in-clinic

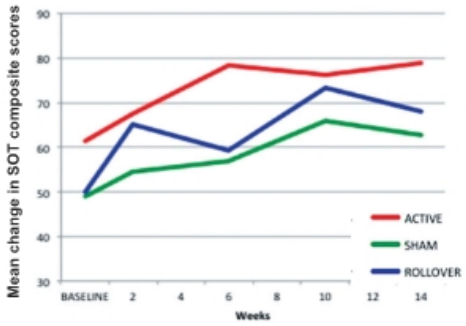
1. Tyler, Mitchell E et al. "Non-invasive neuromodulation to improve gait in chronic multiple sclerosis: a randomized double blind controlled pilot trial." Journal of neuroengineering and rehabilitation vol. 11 79. 1 May. 2014, doi:10.1186/1743-0003-11-79

PoNS Therapy: Imaging Data[1]

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

Gait Imagery task revealed task-related activations in bilateral premotor and motor regions





*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 which was used in FDA regulatory submission

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. Data on file: 001_Helius Medical Inc_PoNS_Direct DeNovo Request_08042020.pdf. August 2020.

Health Insight

Advocacy Industry News Innovations Managing Illnesses Wellness More

Home » Managing Illnesses » The Restorative Power of Neuroplasticity in People with MS

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The Restorative Power of Neuroplasticity in People with MS

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Advocacy Industry News Innovations Managing Illnesses Wellness More

Home » Managing Illnesses » PoNS Treatment™ Could Help Canadian MS Patients with Chronic Gait Deficit

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PoNS Treatment™ Could Help Canadian MS Patients with Chronic Gait Deficit

Global NEWS

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HEALTH

PoNS therapy helps Ontario woman recover from brain injury

By Aaron Streck - Global News
Posted October 15, 2020 6:03 pm

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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

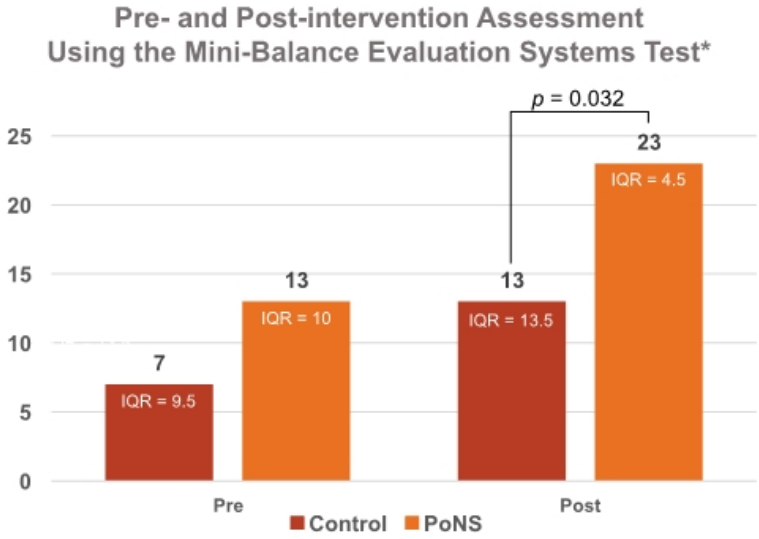
Americans estimated to be living with complications of stroke[1]

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*	$13.5M
Price Per Share*	$3.57
Shares Outstanding	3.8M
50 Day Avg Volume	16K
Cash at 12/31/21	$11.0M
Cash Used in Operations 12 months 12/31/21	$13.4M
* Based upon Mar 30, 2022 closing price	

Capitalization	As Reported
Common Stock	3,780,674
Warrants (WAEP $16.32)	593,924
Options (WAEP $38.54)	669,117
RSUs	2,359
Total Fully Diluted	5,046,074

Ownership at December 31, 2021	As Reported	
	# Common Shares	% of Common Outstanding
Executive Officers and Directors	433,150	11.5%
Columbus Capital Management L.L.C.	324,684	8.6%
AIGH Capital Management LLC	255,400	6.8%
Maple Leaf Funds	189,416	5.0%
Kepos Capital LP	100,304	2.7%
The Vanguard Group	79,586	3.3%
A&B (HK) Company, Ltd.*	71,306	1.9%
Altium Capital Management LP	48,862	1.3%
* Based upon latest reported holdings		

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
- ~8.8% 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

Dr. Antonella Favit-Van Pelt
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

Frederick Fantazzia
VP, Sales & Marketing North America

- 25+ years combined experience in Medical Device and Pharmaceutical Sales
- 16+ years in the medical devices industry with extensive commercialization expertise in neuromodulation sales and marketing
- Former VP of North America Sales and Marketing, LivaNova and legacy Cyberonics (Cyberonics experience included global responsibility)
- Pharma Experience - Launched and sold multiple pharmaceuticals including Tiazac, Celexa, Monourol, and Lexapro

Lawrence Picciano
Senior VP, Engineering, Quality & Regulatory Affairs

- 25+ years experience in Medical Device industry
- 20+ years experience in Quality and Regulatory with Philips, Animas Corporation, a J &J Company, CircuLite Corp, and International Technidyne Corporation
- Over 10 US Medical Device submissions and clearances
- BS in electrical engineering

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

Mitch Tyler

Director

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

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

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 40 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