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

September 17, 2021
Date of Report (Date of earliest event reported)

HELIUS MEDICAL TECHNOLOGIES, INC.

(Exact name of Registrant as Specified in Its Charter)

DELAWARE	**001-38445**	**36-4787690**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
642 Newtown Yardley Road, Suite 100 **Newtown, PA** **(Address of Principal Executive Offices)**		**18940** **(Zip Code)**

Registrant's Telephone Number, Including Area Code: (215) 944-6100

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 September 17, 2021, 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 September 2021.
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: September 17, 2021

By: /s/ Jeffrey S. Mathiesen

Jeffrey S. Mathiesen
Chief Financial Officer and Treasurer

Exhibit 99.1

Helius
MEDICAL TECHNOLOGIES

Empowering Neuroplasticity
Disruptive Technology for Healthcare

NASDAQ:HSDT

Legal Disclaimers

This presentation contains forward-looking statements, including statements about: 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, 2020, its Quarterly Report on Form 10-Q for the quarter ended June 30, 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 an investigational medical device in the European Union ("EU") and Australia ("AUS"). It is currently under premarket review by the AUS Therapeutic Goods Administration.

The Portable Neuromodulation Stimulator "PoNS™" Device

The first and only patented treatment combining trigeminal nerve neurostimulation via the tongue with physical therapy to reduce symptoms of neurological disease or trauma.

- Authorized in the US for gait deficit due to mild to moderate symptoms of multiple sclerosis ("MS")
- FDA Breakthrough Designation granted for the treatment of gait deficit due to symptoms of MS
- FDA Breakthrough Designation granted for the treatment of dynamic gait and balance deficits following a stroke
- Authorized in Canada 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")

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

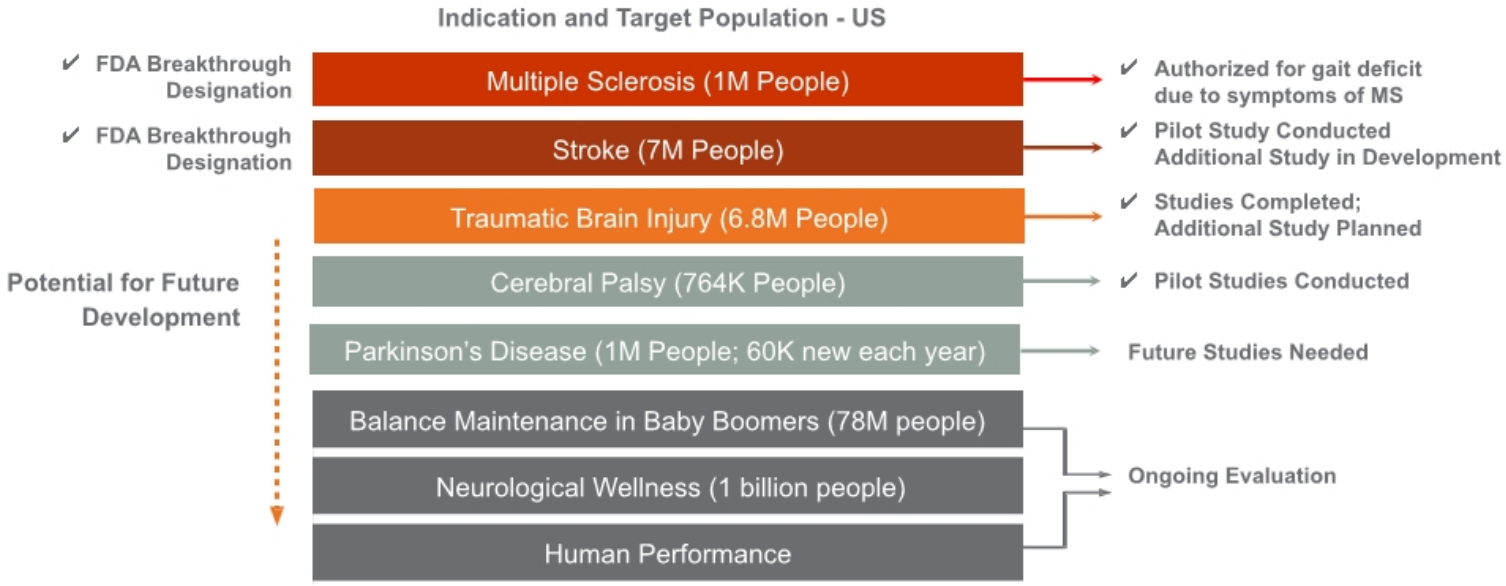
August 2021

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

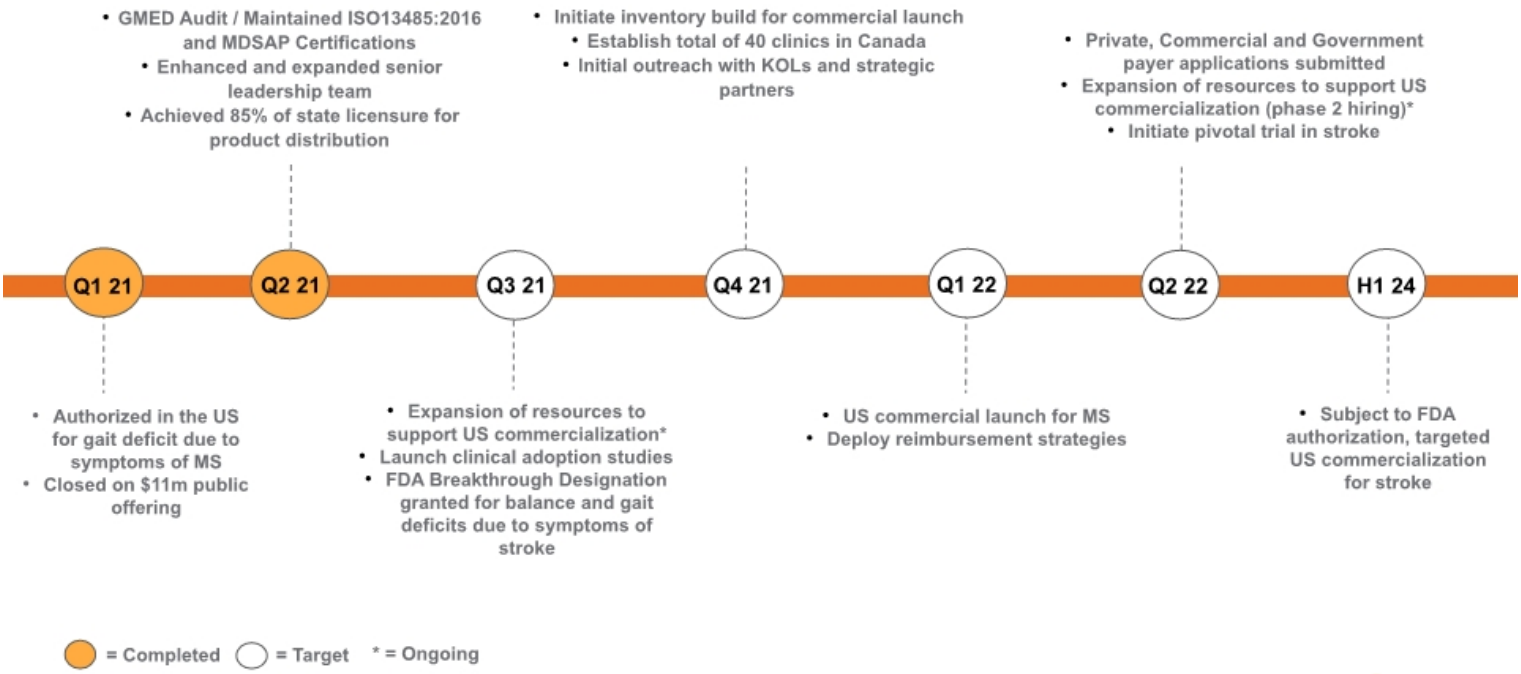
Next Milestones

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

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



Recent Milestones and Anticipated Value Creation Events



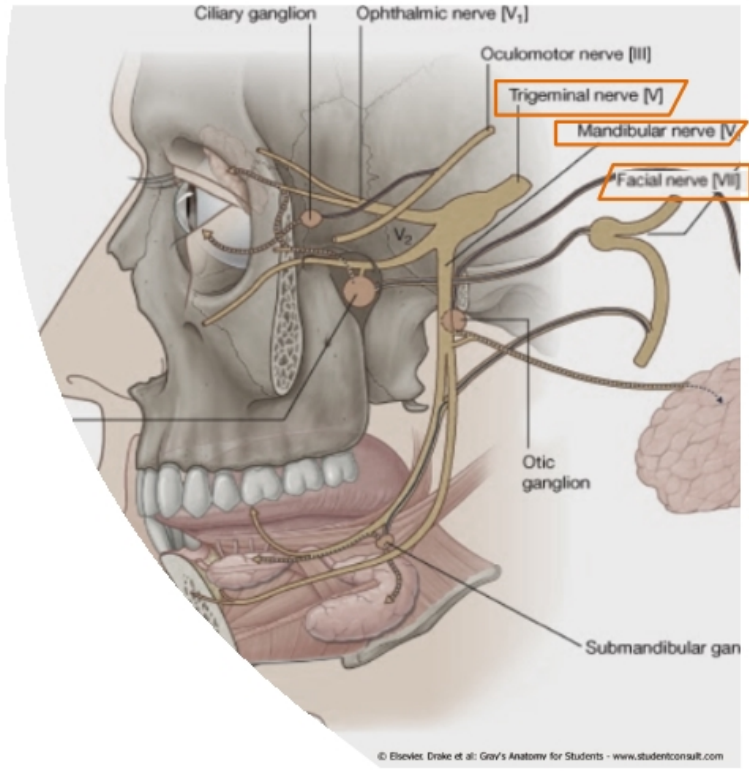
PoNS Treatment™

PoNS Treatment™ Mechanism of Action

Neuromodulation: modification of the nervous system by targeted stimuli

PoNS device designed to induce *Trans lingual Neurostimulation*: trigeminal nerve neuromodulation via the tongue

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



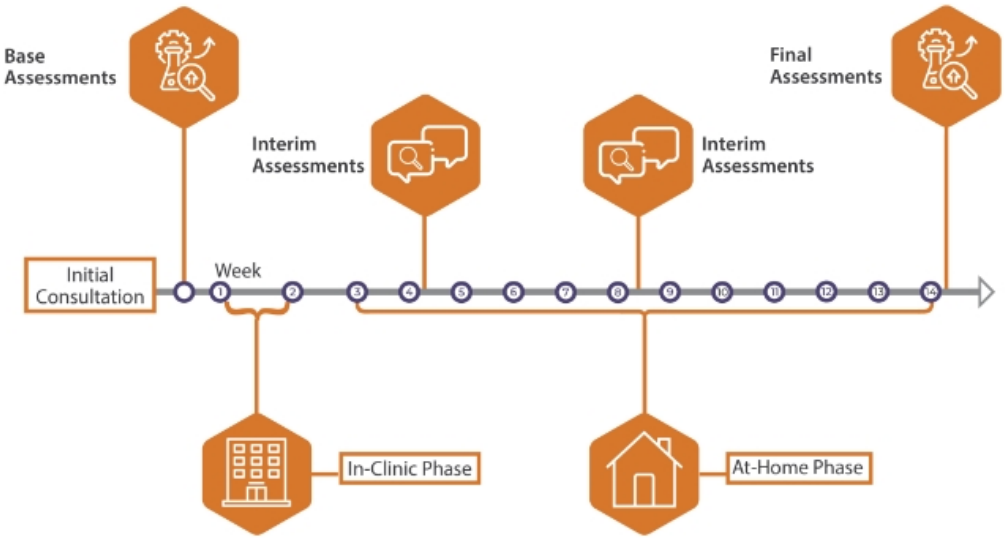
PoNS™ Device

Empowering the brain and improvement during PoNS Treatment™

- 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 Treatment™

Comprehensive 14 Week PoNS Treatment™ Program



PoNS Treatment™ for Symptoms Due to Stroke

*PoNS is not authorized to treat individuals with 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 Treatment to be used as an adjunct to a supervised therapeutic exercise program in patients 22 years of age and over

*PoNS is not authorized to treat individuals with stroke

Potential Addressable U.S. Opportunity in Stroke

7 million

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

80%

Of those individuals have a gait impairment[2]

*PoNS is not authorized to treat individuals with stroke

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.

PoNS Treatment™ 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

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

(approx. 16,000 in USA[1])

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

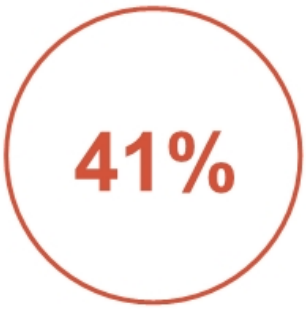
MS patients are vocal and connected on social media

MS patients actively seek out new and promising treatments

1. American Academy of Neurology

Potential Addressable U.S. Opportunity in Multiple Sclerosis

Americans estimated to be affected by MS



Report having difficulties walking, including 13% with an inability to walk at least 2x/week[1]

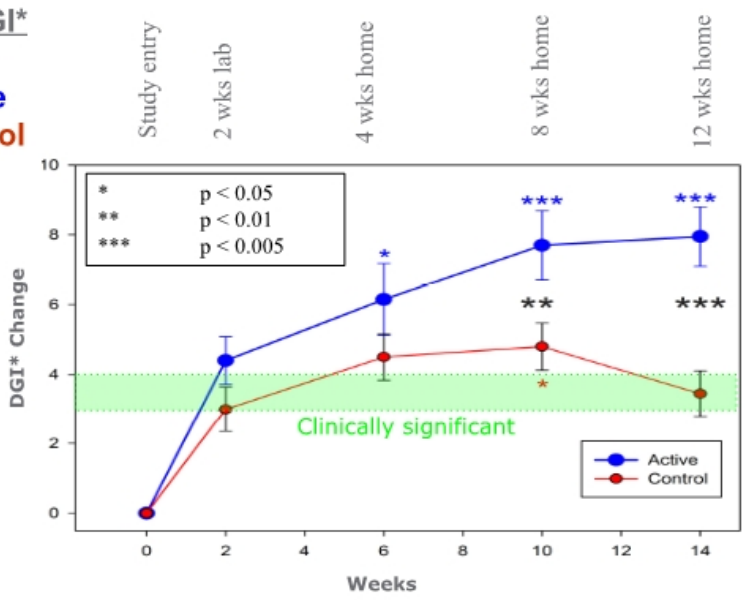
1. Acorda Therapeutics Announces Pricing and Patient Assistance Programs for AMPYRA®; Exhibit 99.1; February 3, 2010

Clinical Evidence

Multiple Sclerosis Study – Mild and Moderate MS (EDSS score 3.5-6)

Mean DGI*

10 Active
10 Control



Two groups (10 each):

1. **"Active" PoNS + exercises**
2. **Placebo PoNS + exercises**

100%
Improvement in Dynamic Gait Index scores for the Active Group

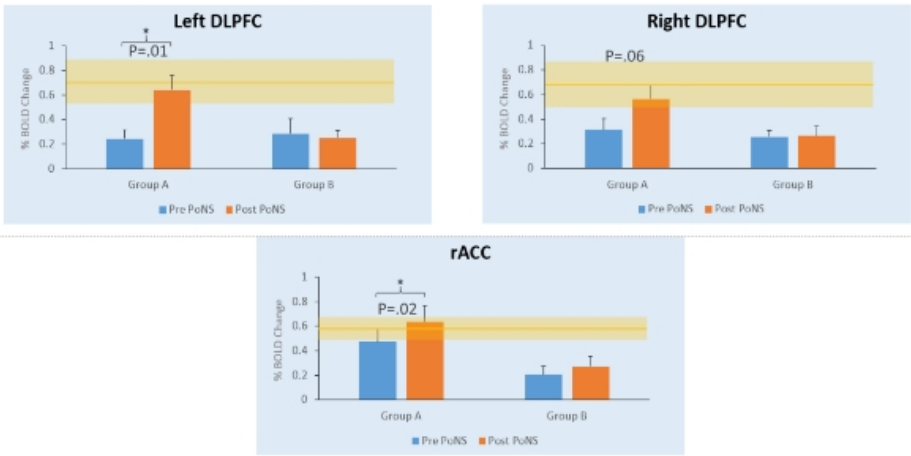
- All 10 subjects in the active treatment group experienced at least a 4 point improvement from baseline to Week 14 in DGI. Mean average of 7.95.
- Only 3 of 10 (30%) subjects in the placebo control group experienced an improvement in DGI of at least 4 points from baseline to week 14. Mean average of 3.45.

Tyler et al. Journal of NeuroEngineering and Rehabilitation 2014, 11:79
*DGI = Dynamic Gait Index, a measure of the ability to walk

Clinical Evidence

fMRI Changes in Patients Treated with Active PoNS and PT vs non-stimulating Placebo PoNS and PT

VOIs BOLD signal vs. Healthy Controls



Group A: Active Arm
Group B: Placebo Arm

Mean and 95% quantile of healthy control's BOLD signal change

[1]Multiple Sclerosis Journal Experimental, Translational and Clinical January-March 2017: 19 DOI: 10.1177/ 2055217317690561

PoNS™ Device

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 HC and FDA regulatory submissions

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

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

Health Insight

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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Current Strategies for Managing Neurological Disorders

Prescription Drugs

Therapy

Surgery

Medical Devices

Commercialization and Reimbursement

Therapeutic Experience Program

- Helius sponsored open-label, interventional, observational, clinical study
- Evaluating PoNS on-label treatment in target population (Multiple Sclerosis) aiming to investigate patients' adherence and compliance to PoNS therapy regimen
- Enrolling ~ 50-60 subjects with gait deficit due to mild-moderate MS at Centers of Excellence across the US (10-12 sites)
- Expected to start enrollment in Q4' 21 and continue through Q2' 22.

U.S. Pre-Commercial Activities

- Building out go-to-market strategy (including licensing, territory identification, KOL engagement, etc.) and supporting infrastructure
- Finalizing distribution model of the PoNS device
- Targeting commercial launch in Q1’22 with initial cash pay customers, while pursuing commercial and government reimbursement programs
- Creating Patient Access Programs
- Identifying and onboarding neuro rehab clinics currently treating MS patients to provide treatment

Capitalization & Ownership

Capitalization & Ownership

As of June 30, 2021

Capitalization	Common Stock Equivalents
Common Stock	2,317,772
U.S. Warrants (WAEP $16.32)	593,924
Options (WAEP $38.92)	631,015
RSUs	8,290
Total Fully Diluted	3,551,001

Ownership	# Common Shares	% of Common Outstanding
Executive Officers and Directors	376,941	16.3%
Columbus Capital Management	160,805	6.9%
Maple Leaf Funds	116,366	5.0%
AIGH Capital Management, LLC	77,429	3.3%
A&B (HK) Company, Ltd.	71,306	3.1%

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 (OTCQB: 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

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

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

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.

Non-Executive Directors

Experienced Leadership With Healthcare and Commercialization Expertise

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

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

Helius MS Scientific Advisory Board and Key Opinion Leaders

Extensive IP Portfolio

Exclusively licensed from inventors (4% royalty):

- 9 US Medical Method Patents Issued
- Patents expire between 2029 and 2031

Patents owned by Helius (no royalty):

- 29 US Patents Issued
- 41 Foreign Patents Issued
- Patents expire between 2026 and 2040

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 treatment authorized to improve impaired function by stimulating cranial nerves via the tongue, supported by an extensive IP portfolio
- US authorization in gait deficit due to MS
- MS launch targeted Q1’22 in US
- FDA Breakthrough Designation granted for the treatment of balance and gait deficits due to symptoms of stroke

Thank you

NASDAQ:HSDT