UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

January 5, 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 January 5, 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	Description
99.1	Corporate Presentation, dated January 2021.

SIGNATURES

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 thereunto duly authorized.

HELIUS MEDICAL TECHNOLOGIES, INC.

Date: January 5, 2021

By: /s/ Joyce LaViscount

Joyce LaViscount
Chief Financial Officer

Exhibit 99.1

Helius
MEDICAL TECHNOLOGIES

Empowering the Healing Process of the Brain

Disruptive Technology for Healthcare

(NASDAQ:HSDT | TSX:HSM)

Legal Disclaimers

This presentation contains forward-looking statements, including statements about: uncertainties regarding the FDA regulatory approval process (including the FDA Breakthrough Designation), uncertainties regarding the regulatory approval process in China and Australia, whether the results of our clinical trials will be sufficient to support an FDA, CE Mark or TGA approval of the PoNS™ device for marketing or whether the agencies may require that the Company conduct future clinical trials; future economic, competitive, reimbursement and regulatory conditions; new product introductions; ability to commercialize its PoNS Treatment™; demographic trends; the intellectual property landscape; financial market conditions; continued availability of capital and financing, including its ability to continue as a going concern; and future business and strategic decisions made by the Company and its competitors. 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. Factors that may cause actual results to differ materially from any future results expressed or implied by any forward looking statements include the impact of the COVID-19 pandemic, uncertainties associated with clinical trial enrollments and the results of clinical trials, uncertainties associated with the clinical development process and regulatory submission and approval process, and other risks described in the "Risk Factors" section of Company's Annual Report on Form 10-K for the year ended December 31, 2019 and the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, 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 an authorized class II, non-implantable medical device authorized for sale in Canada. PoNS is intended as a short term treatment (14 weeks) of gait deficit due to symptoms from multiple sclerosis ("MS") and balance deficit due to mild-to-moderate traumatic brain injury ("mmTBI") and is to be used in conjunction with physical therapy ("PoNS Treatment"™). It is an investigational medical device in the United States, the European Union ("EU"), and Australia ("AUS"), and it is currently under review for clearance by the FDA for use in gait dysfunction due to MS and AUS Therapeutic Goods Administration. PoNS Treatment™ is not currently commercially available in the United States, the EU or Australia.

The Portable Neuromodulation Stimulator "PoNS" Device

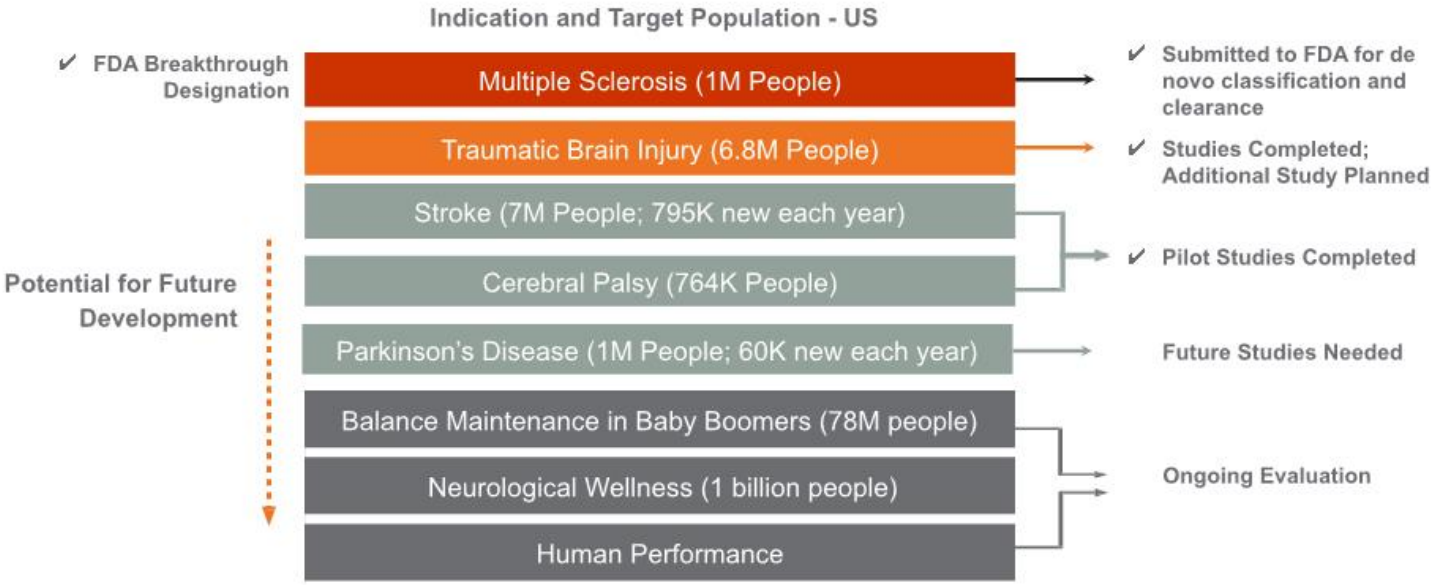
The first and only patented treatment combining trigeminal nerve neurostimulation via the tongue with physical therapy to reduce symptoms of neurological disease or trauma.

Submitted to FDA for de novo classification and clearance

FDA Breakthrough Designation granted for the treatment of gait deficit due to symptoms of multiple sclerosis

Authorized in Canada for chronic balance deficit due to mmTBI and gait deficit due to symptoms of MS

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



Breakthrough Designation Program

Helius is working interactively with the FDA under the program

Advantages

- Focused on addressing **high unmet needs** in gait deficit for MS patients
- **Prioritized** review of the submission under Breakthrough Designation
- **Interacting** with FDA to efficiently address topics as they arise during the premarket review phase
- **Interacting and utilizing leading industry experts**

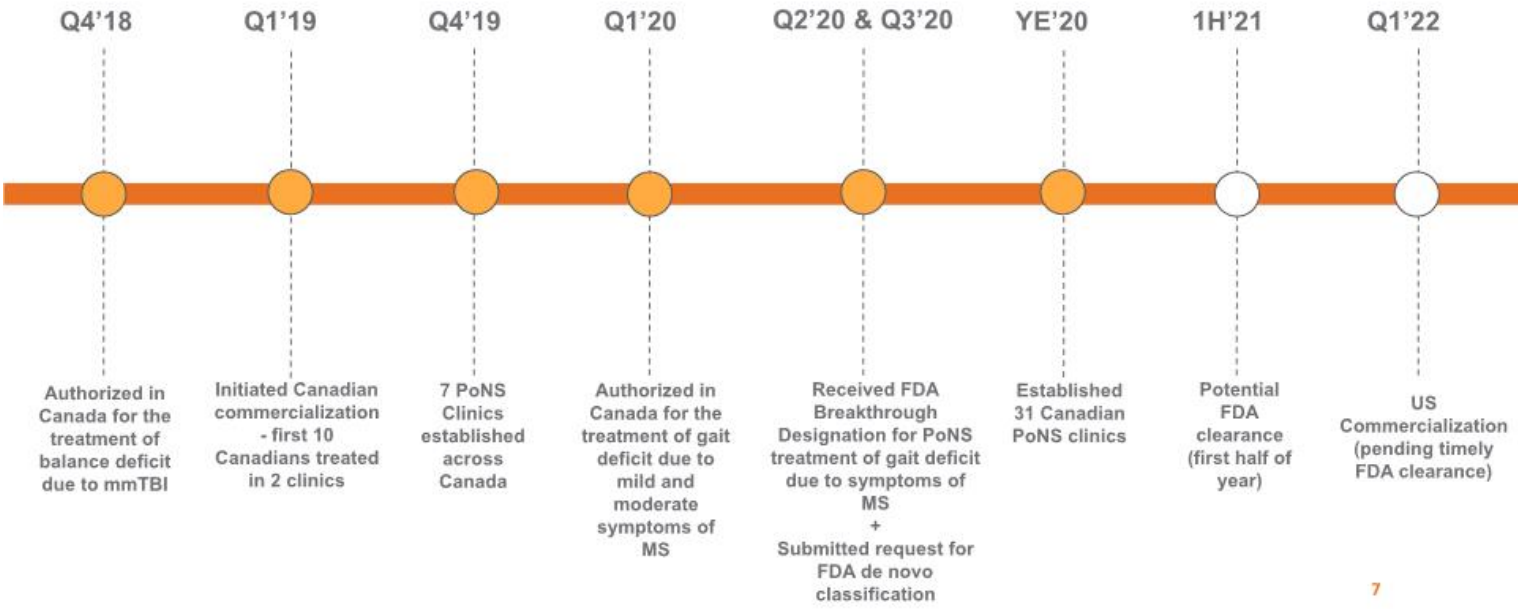
Potential first 4 years reimbursement under the *pending* CMS policy for companies with a breakthrough designation and FDA clearance.

70 million

people in the US are covered under **Medicare and Medicaid**, which PoNS will have access to if qualified.

Recent Milestones and Anticipated Value Creation Events

● = Completed ○ = Target



Executive Team

Experienced Leadership With Healthcare and Commercialization Expertise

Dane Andreeff

Interim CEO and Member, Board of Directors

- 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
- ~6.3% ownership of the company

Joyce LaViscount

Chief Financial Officer & Chief Operating Officer

- 30+ years in the health sciences industry
- Accomplished pharmaceutical/healthcare public company CAO
- Former COO and CFO at MM Pharmaceutical Solutions
- Former Executive Director/Group Controller at Aptalis Pharmaceuticals

Dr. Jonathan Sackier

Chief Medical Officer

- 30+ years in the health sciences industry
- Trained surgeon and pioneer of new medical technologies
- Has helped build several companies including medical technology, research and product-design and medical contract sales organizations

Mark Leno

VP, General Manager, Canadian Operations

- 17+ years in the medical devices industry
- Sales and Marketing Director, Boston Scientific Canada
- National Sales Manager, Canada Johnson & Johnson
- Former Media Relations and Marketing executive for Blue Jays & NHL

Board of Directors

Experienced Leadership With Healthcare and Commercialization Expertise

Blane Walter

Chairman of the Board

- Partner, Talisman Capital Partners
- Vice Chair of InVentive Health
- Chair of the Governor of Ohio's Executive Workforce Board
- Former CEO of InVentive 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

Jeff Mathiesen, CPA

Director

- 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

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

PoNS™ Device

Empowering the brain and recovery during PoNS Treatment

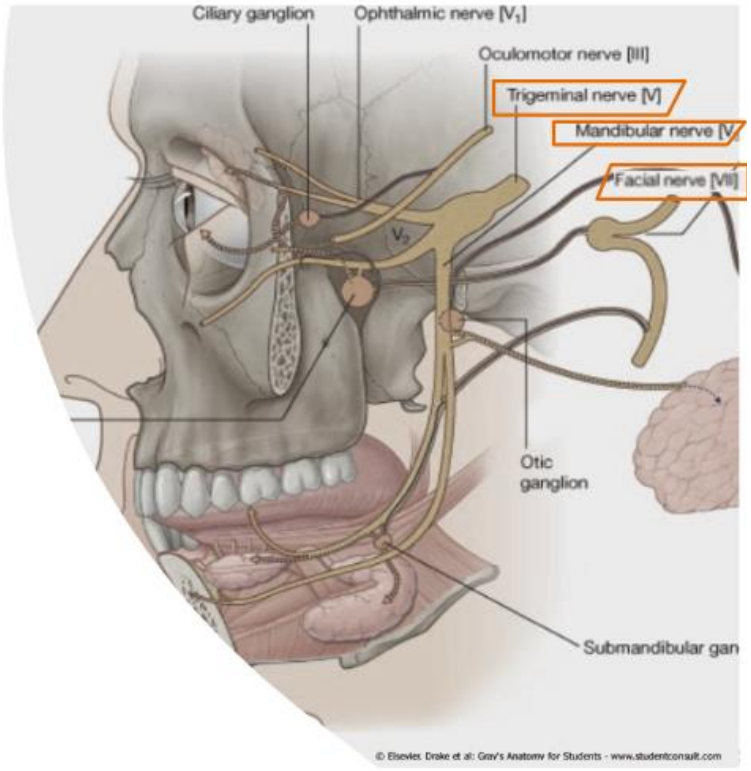
- PoNS controller and mouthpiece are connected by a cord
- Mouthpiece electrodes stimulate the tongue surface, sending signals to the brain

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

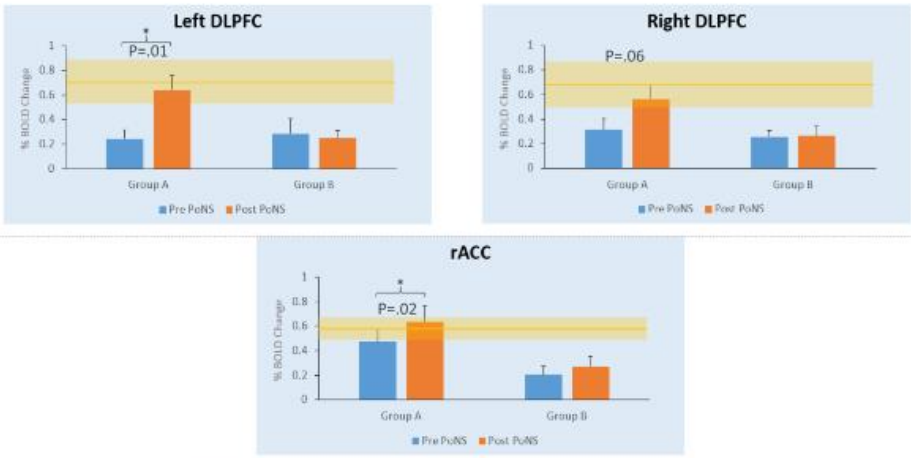
~25MM pulses per 20-minute session
Feels like champagne or carbonated water bubbles



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

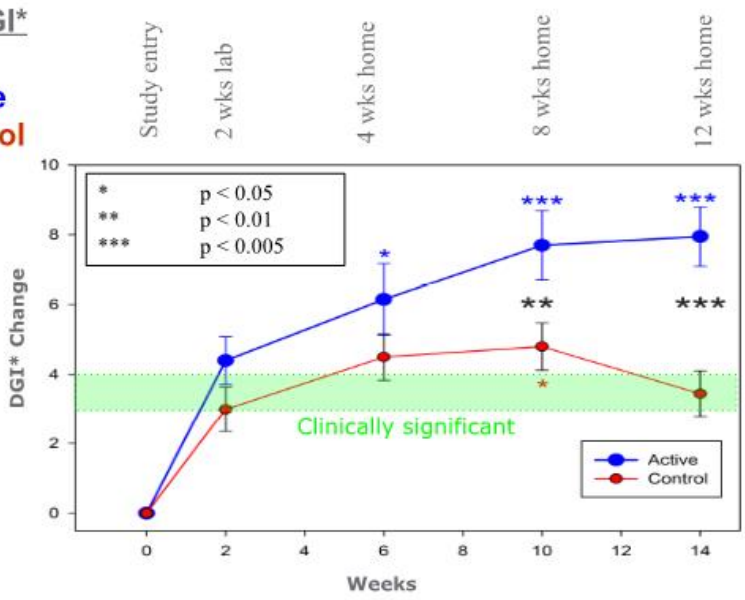
[1]Multiple Sclerosis Journal Experimental, Translational and Clinical January-March 2017: 19 DOI: 10.1177/ 2055217317690561

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

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

Current Strategies for Managing Neurological Disorders

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]

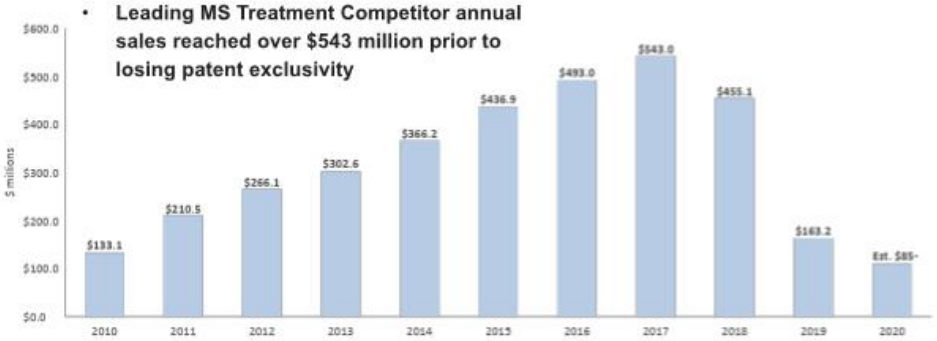
1. "Impact of Walking Impairment in Multiple Sclerosis Perspectives of Patients and Care Partners". https://www.researchgate.net/publication/51500060_Impact_of_Walking_Impairment_in_Multiple_Sclerosis_Perspectives_of_Patients_and_Care_Partners

The Current MS Gait Deficit Care in US
Competitive Landscape

	Leading MS Treatment Competitor
Treatment	First approved drug to improve walking in adults with MS
U.S. FDA Approval	2010
Total Sales Since Approval	$3.4B (2010 – 2019)[1]
Most Common Side Effects	Urinary tract infection Insomnia Dizziness Headache Nausea
Cost at Launch	$1,056 per 30-day supply[2]

Leading MS Treatment Competitor Annual Sales

- **Leading MS Treatment Competitor annual sales reached over $543 million prior to losing patent exclusivity**



1. Acorda Therapeutics Annual 10K (2010 – 2019)
2. "Acorda Therapeutics Announces Pricing and Patient Assistance Programs for AMPYRA"; Exhibit 99.1; February 3, 2010

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 even with little data

1. American Academy of Neurology

PoNS Device - Health Canada approved 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 an overall average improvement in their functional gait assessment (FGA)

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

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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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Multiple Sclerosis “MS” Opportunity

- 93,500 patients
- MS Society of Canada

- 1,000,000 patients
- National MS Society

BOTH

- MS patients are highly motivated and linked on social media
- High urgency to treat
- High Patient awareness
- Specialty clinic system

Helius MS Scientific Advisory Board

International Strategy

CHINA:

- **Strategic Agreement** with China Medical Systems ("CMS") for development and commercialization of PoNS in China plus 4 territories
- Transferred ownership of Asian patents, patent applications and granted exclusive license to market, promote distribute and sell the technology
- CMS assumed all development, patent (both application and defense), future manufacturing, clinical trial, and regulatory clearance costs for the territories
- **Upon clearance in the U.S., CMS can use relevant documentation used for U.S. approval to apply for Chinese approval**

AUSTRALIA:

- Awaiting decision from Therapeutic Goods Administration (TGA)

Next Neurological Market Opportunity

Stroke

795k
US individuals have a stroke each year[1]

50%
of stroke survivors 65 and over suffer from reduced mobility[2]

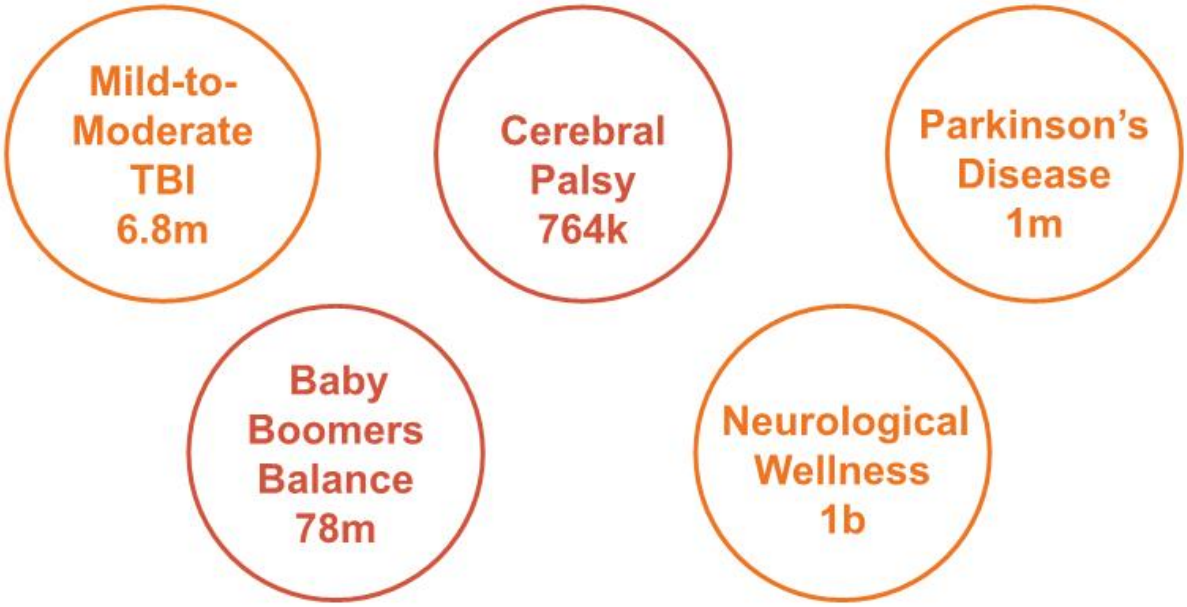
Walking is the most frequently reported activity at the time of a fall in stroke survivors[3]

In post-stroke patients, the cerebral cortex becomes impaired while the spinal cord is preserved. The ability to generate information from the spinal cord required for walking can be utilized through specific movements to reorganize the cortex (neuroplasticity)

Falls are the leading cause of injury related deaths among elderly people in the U.S.

1. Center for Disease Control and Prevention: Stroke Facts
2. "Walking Adaptability after a Stroke and Its Assessment in Clinical Settings"; Stroke Res Treat.; August 28, 2014
3. Verma R, Arya KN, Sharma P, Garg RK: Understanding gait control in post-stroke: Implications for management. *Journal of Bodywork and Movement Therapies* 2010, 1-8

Next Neurological Market Opportunity Continued



Capitalization & Ownership
As of January 4, 2021

Capitalization	Common Stock Equivalents
Common Stock	1,484,362
U.S. Warrants	273,553
Canadian Warrants	68,350
Options	111,074
RSUs	168
Total Fully Diluted	1,937,507

Ownership	# common shares	% of common outstanding
Columbus Capital Management	146,520	9.9%
Executive Officers and Directors	182,684	12.3%
A&B (HK) Company Limited	71,306	4.8%

We are a neurotech company in the medical device industry focused on neurological wellness.

- FDA Breakthrough Designation and pending US clearance in MS
- Potential to obtain CMS reimbursement for 4 years – 70M covered lives
- Building on success/knowledge/infrastructure developed in two years of commercialization in Canada for mild-to-moderate TBI and one year for MS
- US commercialization would leverage existing Canadian commercialization infrastructure
- First and only treatment to restore lost function by stimulating cranial nerves via the tongue, supported by an extensive IP portfolio

Helius
MEDICAL TECHNOLOGIES

Thank you

(NASDAQ:HSDT | TSX:HSM)