

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

July 13, 2021
Date of Report (Date of earliest event reported)



HELIUS MEDICAL TECHNOLOGIES, INC.

(Exact name of Registrant as Specified in Its Charter)

DELAWARE
(State or Other Jurisdiction
of Incorporation)

001-38445
(Commission File Number)

36-4787690
(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.

Regulation FD Disclosure.

Item 7.01

On July 13, 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 July 2021.



Empowering the Neuroplasticity of the Brain
Disruptive Technology for Healthcare

(NASDAQ:HSDT | TSX:HSM)

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. 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 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 March 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 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



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 (“mTBI”)

PoNS™ Device

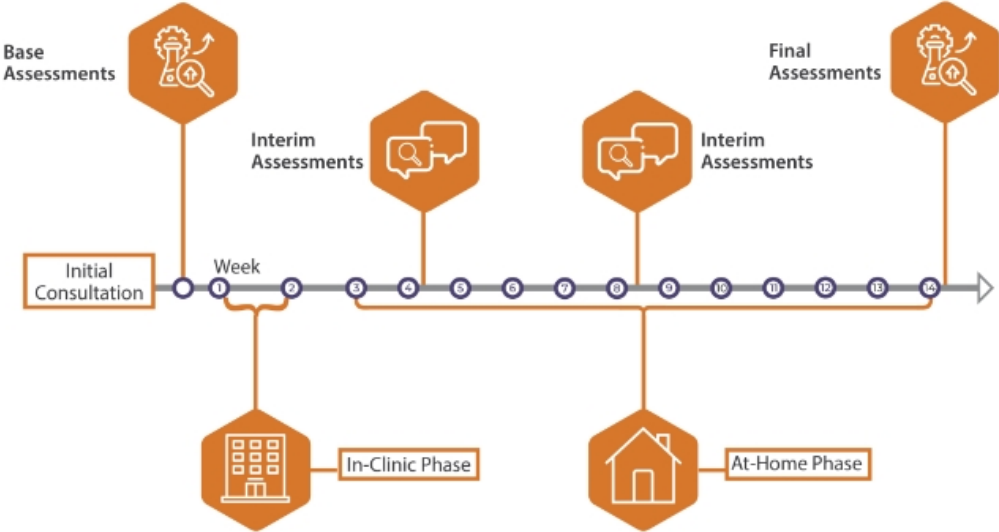
Empowering the brain and improvement during PoNS Treatment™



- 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

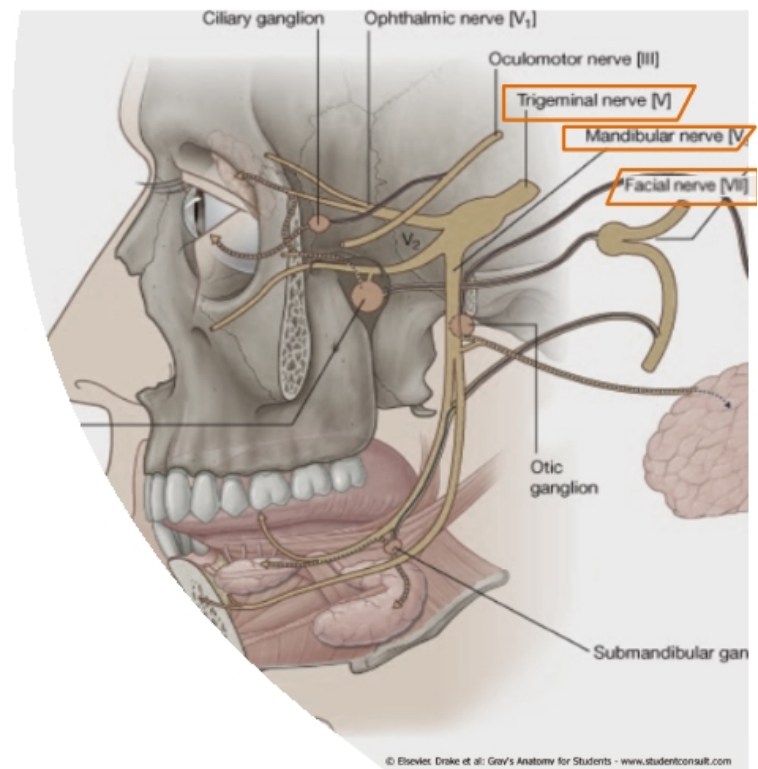


PoNS Treatment™ Mechanism of Action

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

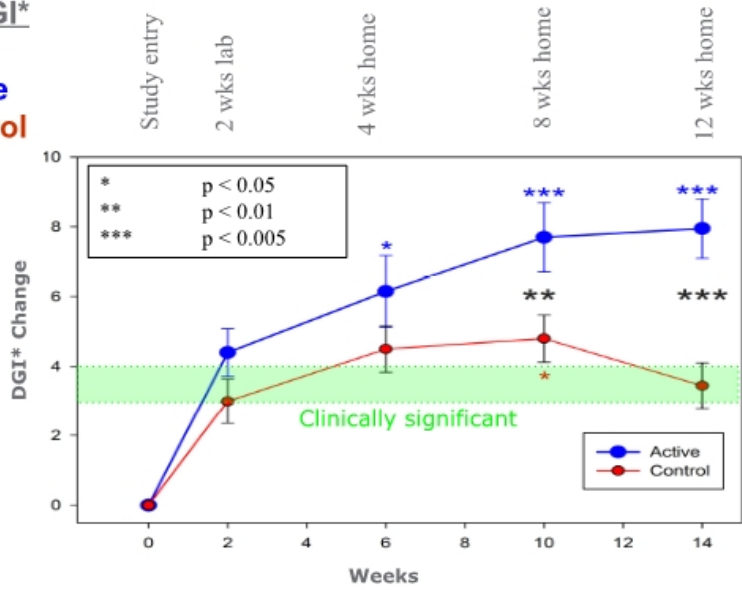


Clinical Evidence

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



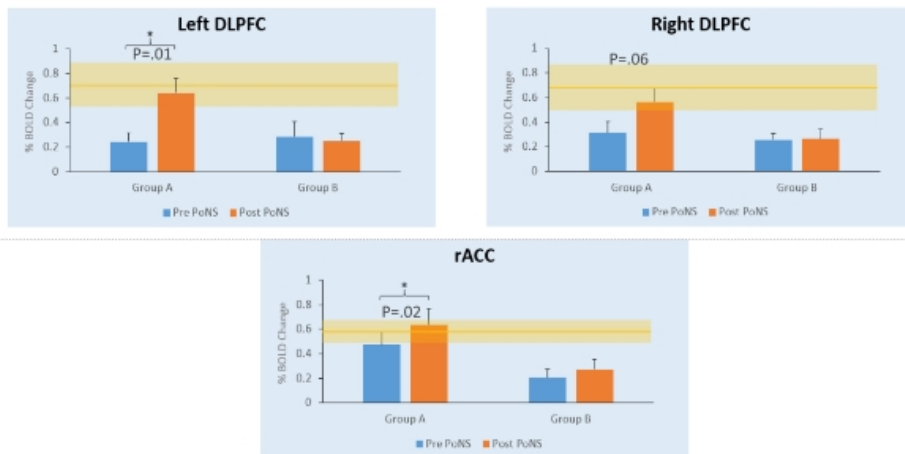
- All 10 subjects in the active treatment group experienced at least a 4 point improvement from baseline to Week 14 in DGI. Mean average of 7.95.
- Only 3 of 10 (30%) subjects in the placebo control group experienced an improvement in DGI of at least 4 points from baseline to week 14. Mean average of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

PoNS™ Device

Approved 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

Home > Managing Diseases > The Restorative Power of Neuroplasticity in People with MS

SPONSORED

The Restorative Power of Neuroplasticity in People with MS



PoNS therapy helps Ontario woman recover from brain injury

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



Home > Managing Diseases > 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



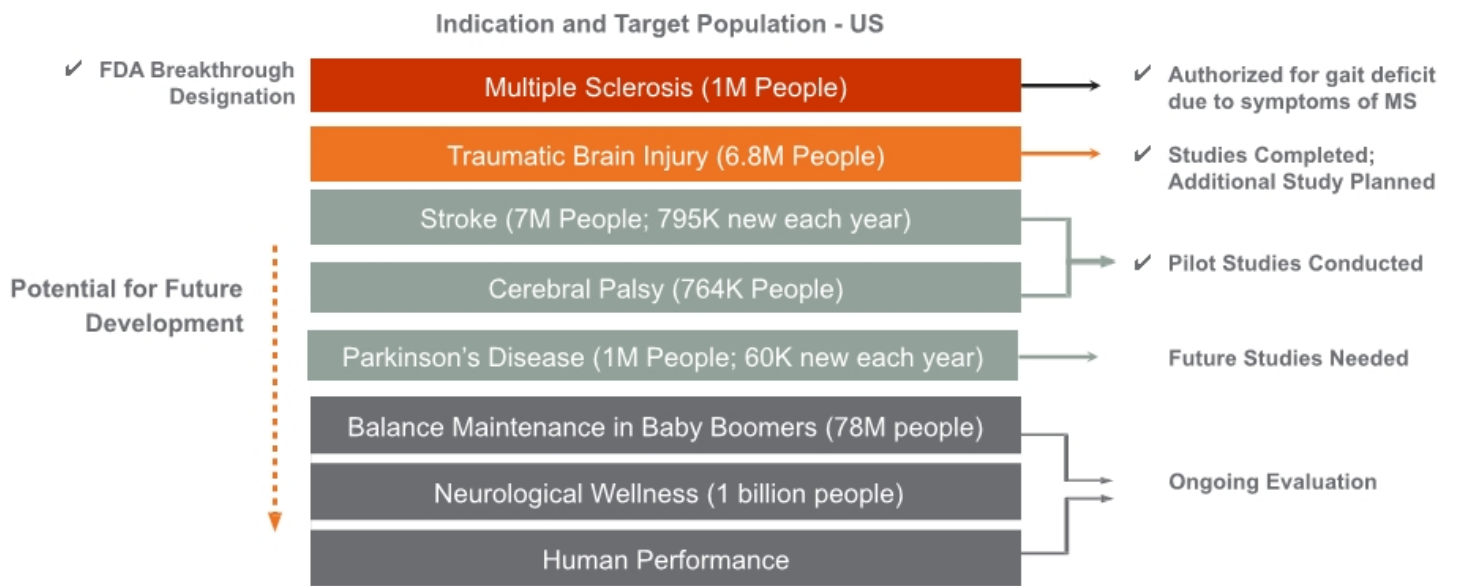
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MS PATIENT BENEFITS FROM NEW DEVICE

Large Potential Addressable Markets

U.S. Clinical Progress and Future Opportunities



Current Strategies for Managing Neurological Disorders



Prescription Drugs



Therapy



Surgery

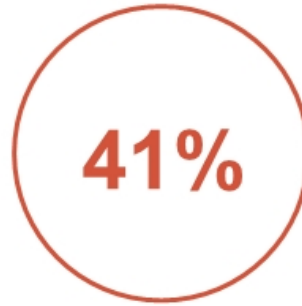


Medical Devices

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/week¹

1. 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 USA¹)



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

- **FDA program to address unmet medical needs. Provides interactive and timely communications with the FDA**
- **Achieved Breakthrough Designation and worked interactively with the FDA under the program to achieve market authorization**
- **Potential expedited reimbursement pathway under MCIT rule for breakthrough designation products with FDA clearance**
- **Potential to use this pathway for other indications in the future**





- MCIT – Medicare Coverage for Innovative Technologies – accelerated coverage pathway for innovative products
- 4 years CMS reimbursement for products with a breakthrough designation and FDA clearance
- Alignment of coverage with launch date

60 million

people in the US are covered under **Medicare**.

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
- Continuing to pursue Medicare Coverage for Innovative Technologies ("MCIT") Pathway - accelerated coverage that allows for 4 years CMS reimbursement for products with a breakthrough designation and FDA clearance (CMS target ruling date Dec 2021)
- Creating Patient Access Programs
- Identifying and onboarding neuro rehab clinics currently treating MS patients to provide treatment

Helius MS Scientific Advisory Board and Key Opinion Leaders



International Opportunities

EUROPE:

- Evaluating appropriate timing for submission

AUSTRALIA:

- Awaiting decision from Therapeutic Goods Administration (TGA)

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
- Based on our clearance in the U.S., CMS can use relevant documentation used for U.S. approval to apply for Chinese approval

Next Neurological Market Opportunity

Stroke

795k
US individuals
have a stroke
each year¹

50%
of stroke survivors
65 and over suffer
from reduced
mobility²

Walking is the
most frequently
reported activity at
the time of a fall in
stroke survivors³

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).

*PoNS is not authorized to treat individuals with stroke

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

Extensive IP Portfolio

Exclusively licensed from inventors (4% royalty):

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

Patents owned by Heliuss (no royalty):

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

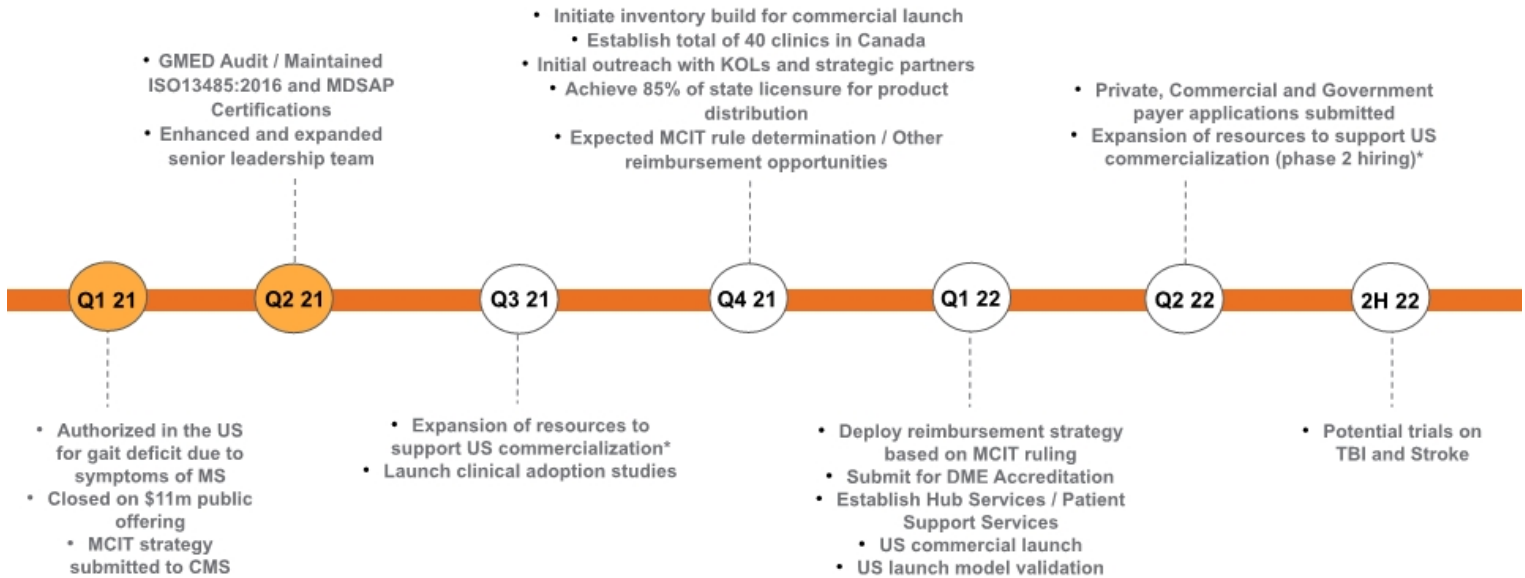
Heliuss Patents Transferred to China Medical System Holdings (CMS):

- 3 Chinese Design Patents

Independent Verification of Patents and Freedom to Operate Opinion:

- September 2017

Recent Milestones and Anticipated Value Creation Events



● = Completed ○ = Target * = Ongoing

Capitalization & Ownership

As of June 30, 2021

Capitalization	Common Stock Equivalents
Common Stock	2,317,772
U.S. Warrants	593,924
Canadian Warrants	0
Options	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%

First-in-Class Neurotech

- First and only treatment authorized to improve lost 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
- Potential CMS reimbursement for 4 years with FDA clearance for breakthrough designation for MS
- Potential Stroke and TBI label expansion



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 Heliuss 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



Joyce LaViscount
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
Medical Advisor

- 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

*Antonella Favitt-Van Pelt, M.D., Ph.D. was appointed as Chief Medical Officer on July 7, 2021



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



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



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.



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



Thank you

(NASDAQ:HSDT | TSX:HSM)

