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

Date of Report (Date of earliest event reported): October 27, 2020

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

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 October 27, 2020, Helius Medical Technologies, Inc. (the "Company") posted an updated corporate fact sheet 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 fact sheet 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 Number	Exhibit Description
99.1	Corporate Fact Sheet, dated October 27, 2020.

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: October 27, 2020

By: /s/ Joyce LaViscount

Joyce LaViscount
Chief Financial Officer

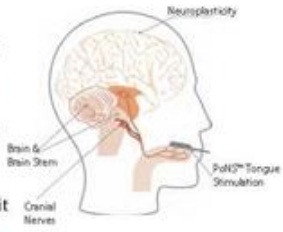
Helius
MEDICAL TECHNOLOGIES
NASDAQ: HSDT
TSX: HSM

FACT SHEET
October 2020

Platform Technology

Portable Neuromodulation Stimulator (PoNS™) Device

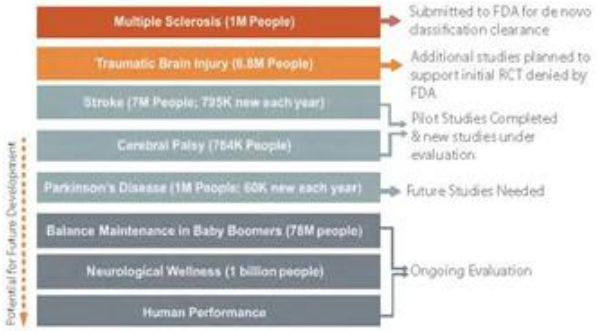
Helius Medical Technologies is a US-based medical device company developing and commercializing the PoNS™ technology. This first-in-class, non-implantable device is built on the scientific principals and decades of evidence-based research in neuromodulation and neurorehabilitation. Used in conjunction with physical therapy, PoNS™ is authorized in Canada for the treatment of gait deficit due to mild and moderate symptoms of Multiple Sclerosis (MS) and for the treatment of chronic balance deficit due to mild-to-moderate Traumatic Brain Injury (mmTBI). Following the 2019 FDA denial of PoNS™ for the treatment of chronic balance deficit due to mmTBI, in Q1 2020, PoNS™ achieved FDA Breakthrough Device Designation and is currently under FDA review for the treatment of gait deficit due to mild or moderate symptoms of MS.



COMPANY HIGHLIGHTS

- ✓ "First Mover Advantage" in non-surgical tongue-based neuromodulation
- ✓ Large global addressable lifetime markets
- ✓ Smart device uploads to cloud to provide compliance data for clinician, payer review
- ✓ Robust clinical and safety evidence in over 300 patients
- ✓ US Scientific Advisory Board comprised of experts with 150+ years in MS neurorehabilitation research
- ✓ Canadian sales and marketing success generating revenue and real-world evidence
- ✓ International commercialization strategies in play
- ✓ Scale manufacturing with KeyTronic (Oakdale, MN)
- ✓ Robust patent portfolio with 38 US and 41 int'l expiring 2026 through 2040
- ✓ Experienced management team with 80+ years in life sciences scale-ups, launches and commercialization.

POTENTIAL ADDRESSABLE MARKETS IN THE US



THE PoNS™ DEVICE

- Non-implantable device comprised of a mouthpiece and controller
- Electrodes on the mouthpiece deliver mild electrical signals to the surface of the tongue that stimulate direct pathways to the brain (Translingual Neurostimulation or "TLNS")
- TLNS combined with physical therapy may enhance neuroplasticity
- PoNS™ is a smart device that tracks frequency, duration & intensity of use
- Protected by 79 US & international patents including medical methods & design/utility of therapeutic delivery mechanisms

642 Newtown Yardley Road, Suite 100, Newtown PA 18940 1 877-564-0008 www.heliusmedical.com

PoNS™ is not available for sale in the United States. It is limited to investigational use only.

Helius
MEDICAL TECHNOLOGIES

FACT SHEET
OCTOBER 2020

ROBUST CLINICAL AND SAFETY EVIDENCE

- ✓ 20 patient Pilot study showed TLNS with targeted PT improved clinical symptoms of gait dysfunction in MS by 130% vs. those who received the same therapy with control device
- ✓ In a 143 patient study to assess the safety & efficacy of PoNS™ plus PT for the treatment of chronic balance deficit due to mmTBI showed significant improvement in balance and gait. Response rate of 71.2% w/ 57.4% attaining a normal range for balance at end of 5-week study.
- ✓ Published sub study of data showed notable differences in brain structure in mmTBI patients after PoNS™ + PT. The most prominent grey matter changes were in the area associated with gait, balance, motor control, and visual motion.
- ✓ Additional studies in stroke and cerebral palsy under evaluation

GLOBAL REGULATORY PROGRESS

- US FDA Breakthrough Device Designation; FDA submission for de novo classification and clearance related to MS pending
- Pending proposed HHS ruling, potential with CMS for 4 years reimbursement upon clearance with Breakthrough Device Designation
- Health Canada authorization to treat gait deficit due to mild and moderate symptoms of MS in March 2020
- Health Canada authorization to treat balance deficit due to mmTBI in Oct 2018
- Australian Therapeutic Goods Administration under review for chronic balance deficit due to mmTBI and gait deficit due to mild or moderate symptoms of MS
- Chinese licensee, China Medical Systems leading pathway
- ISO 13485: 2016 Quality System Certification / MDSAP

COMMERCIAL

- "First mover advantage" in non-surgical tongue-based treatment for chronic balance and gait disorders, where limited treatment options exist
- Canadian commercial infrastructure established with direct sales force
- 27 PoNS™ Authorized Treatment Centers throughout Canada
- Emerging reimbursement as Canadian insurers begin to recognize PoNS™ in the treatment of balance/gait deficits in mmTBI and MS
- Collaboration with renown research institutions such as Toronto Rehab for ongoing TBI clinical insight
- China Medical Systems licensed rights for market development and commercialization in China
- US reimbursement and commercialization planning underway; development of strategies related to direct sales, distribution and strategic partners for implementation if clearance is achieved
- ISO 13485 certified scale manufacturer (KeyTronic) and global supply chain with capacity to meet demand across all markets

EXPERIENCED AND COMMITTED LEADERSHIP TEAM

Dane Andreeff
Interim CEO, Board Member

- 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 under management.
- Board Member and trusted advisor to Helius Inc for over 3 yrs and HDL Therapeutics for over 15 yrs
- Owns approx 3.2% of HSDT through Maple Leaf and affiliates

Joyce LaViscount
COO and CFO

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

Dr. Jonathan Sackier
Chief Medical Officer

- 30+ years in the health sciences industry
- Trained surgeon and leader of laparoscopic surgery
- Developed and launched robotic surgery with computer motion
- Invented tools for minimally invasive procedures and training
- Published over 120 peer-reviewed articles, 7 books & 50 chapters

Mark Leno
VP & GM Canada

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

•Continued from the prior page• Forward-looking statements are necessarily based on a number of estimates and assumptions reflecting management's current views with respect to future events. Such statements are inherently subject to risks and uncertainties that could cause actual results, performance or achievements to be materially different from the Company's expectations, including the impact of the COVID-19 pandemic, uncertainties associated with clinical trial enrollments and results, uncertainties associated with the clinical development, regulatory submission and approval processes and uncertainties associated with capital requirements to achieve management's business objectives, as well as other risks and uncertainties detailed from time to time in the filings made by the Company with securities regulators, including the risks and uncertainties about the Company's business described in the "Risk Factors" sections of the Company's Annual Report on Form 10-K for the year ended December 31, 2019, Quarterly Report on Form 10-Q for the quarter ended June 30, 2020 and its other filings with the United States Securities and Exchange Commission and the Canadian securities regulators available at www.sec.gov or www.sedar.com. This fact sheet speaks as of its date and the Company assumes no obligation to update any forward-looking statement except to the extent required by law.
This fact sheet contains industry and market data obtained from independent industry publications. Management has not independently confirmed this data and, although we believe it is generally reliable, it involves a number of assumptions and limitations, it is inherently imprecise, and you are cautioned not to place undue reliance on it.

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