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 19, 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 8.01 Other Events.

On October 19, 2020, Helius Medical Technologies, Inc. issued a press release announcing an update on the U.S. Food and Drug Administration's review of the Company's request for de novo classification and clearance of the PoNS device for the treatment of gait deficit due to symptoms from Multiple Sclerosis, to be used as an adjunct to a supervised therapeutic exercise program in patients over 18 years of age. The full text of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Press Release, dated October 19, 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 19, 2020

By: /s/ Joyce LaViscount

Joyce LaViscount
Chief Financial Officer

Exhibit 99.1

Helius Medical Technologies, Inc. Provides Update on FDA's Review of its Request for De Novo Classification and Clearance of the PoNS™ Device for the Treatment of Gait Deficit Due to Symptoms of Multiple Sclerosis

NEWTOWN, Pa., October 19, 2020 (GLOBE NEWSWIRE) -- Helius Medical Technologies, Inc. (Nasdaq:HSDT) (TSX:HSM) ("Helius" or the "Company"), a neurotech company focused on neurological wellness, today announced that it has received a request for additional information from the U.S. Food and Drug Administration (the "FDA" or "Agency") related to the Company's request for de novo classification and clearance of the Portable Neuromodulation Stimulator (PoNS™) device as a potential treatment for gait deficit due to symptoms of Multiple Sclerosis ("MS"), to be used as an adjunct to a supervised therapeutic exercise program in patients over 18 years of age.

During the substantive review phase of a request for de novo classification and clearance, FDA may request additional information in order to obtain information necessary for the Agency to continue or complete its review and, in such instances, places its review on hold until the requested information is submitted.

Helius submitted its request for de novo classification and clearance of the PoNS device for the treatment of gait deficit due to symptoms from MS on August 4, 2020, following the receipt of Breakthrough Designation by FDA in early May. The FDA's request for additional information was received approximately 75 days from the submission date, which is consistent with FDA's expected timing for review of a Breakthrough Designated product, such as the PoNS device. The FDA's request for additional information includes requests for additional analysis of clinical data and proposes certain labeling modifications.

"As we continue to work towards our goal of bringing our PoNS technology to the aid of U.S. patients suffering with gait deficit due to MS-related symptoms, Helius is committed to preparing and submitting our response to the FDA's request for additional information as thoroughly and efficiently as possible, so that the Agency can resume its review process," said Dane Andreeff, Interim President and Chief Executive Officer of Helius. "Importantly, we believe the PoNS device's Breakthrough Designation status will provide Helius with the opportunity to work efficiently with the Agency as we address the request and plan our formal response."

About Helius Medical Technologies, Inc.

Helius Medical Technologies is a neurotech company focused on neurological wellness. The Company's purpose is to develop, license and acquire unique and non-invasive platform technologies that amplify the brain's ability to heal itself. The Company's first commercial

product is the Portable Neuromodulation Stimulator (PoNS™). For more information, visit www.heliusmedical.com.

About the PoNS™ Device and PoNS Treatment™

The Portable Neuromodulation Stimulator (PoNS™) 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 multiple sclerosis (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™ is an investigational medical device in the United States, the European Union ("EU"), and Australia ("AUS"). The device is currently under review for de novo classification and clearance by the FDA. It is also under premarket review by the AUS Therapeutic Goods Administration. PoNS™ is currently not commercially available in the United States, the European Union or Australia.

Investor Relations Contact:

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Cautionary Disclaimer Statement:

Certain statements in this news release are not based on historical facts and constitute forward-looking statements or forward-looking information within the meaning of the U.S. Private Securities Litigation Reform Act of 1995 and Canadian securities laws. All statements other than statements of historical fact included in this news release are forward-looking statements that involve risks and uncertainties. Forward-looking statements are often identified by terms such as "believe," "continue," "look forward," "will," "committed to" and similar expressions. Such forward-looking statements include, among others, statements regarding the Company's future growth and operational progress, including clinical and regulatory development plans for the PoNS device, potential regulatory clearance of the PoNS device, the success of the Company's partnership with Breakthrough and the ability of such research to impact the Company's launch plans.

There can be no assurance that such statements will prove to be accurate and actual results and future events could differ materially from those expressed or implied by such statements. Important factors that could cause actual results to differ materially from the Company's expectations 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 FDA regulatory submission and approval process, including the Company's capital requirements to achieve its business objectives, and other risks detailed from time to time in the filings made by the Company with securities regulators, and 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, which can be obtained from either at www.sec.gov or www.sedar.com.
The reader is cautioned not to place undue reliance on any forward-looking statement. The forward-looking statements contained in this news release are made as of the date of this news release and the Company assumes no obligation to update any forward-looking statement or to update the reasons why actual results could differ from such statements except to the extent required by law.
The Toronto Stock Exchange has not reviewed and does not accept responsibility for the adequacy or accuracy of the content of this news release.