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

October 24, 2019
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 or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

642 Newtown Yardley Road, Suite 100
Newtown, Pennsylvania, 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 Exchange 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 24, 2019, Helius Medical Technologies, Inc. issued a press release announcing a U.S. regulatory update following its meeting with the U.S. Food and Drug Administration. 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 No.	Description
99.1	Press Release, dated October 24, 2019.

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: October 24, 2019

By: /s/ Joyce LaViscount
Joyce LaViscount
Chief Financial Officer

Exhibit 99.1

Helius Medical Technologies, Inc. Announces Update on US Regulatory Strategy Following Pre-Submission Meeting with FDA

NEWTOWN, PA., October 24, 2019 (GLOBE NEWSWIRE) -- Helius Medical Technologies, Inc. (Nasdaq:HSDT) (TSX:HSM) ("Helius" or the "Company"), a neurotech company focused on neurological wellness, today is providing an update outlining the Company's US regulatory strategy following its pre-submission meeting with the U.S. Food and Drug Administration ("FDA").

"The pre-submission meeting was built upon Helius' prior clinical work and experience gained through ongoing interactions with FDA," said Philippe Deschamps, Chief Executive Officer of Helius. "The discussion during the course of the meeting focused on supporting FDA's request for a study that demonstrates the benefit of PoNS Treatment® compared to physical therapy alone in a way that can be generalized to the intended population of patients with balance deficits following mild-to-moderate traumatic brain injury. FDA indicated that additional data are required to support the new de novo submission. Study design, endpoints, eligible patient population and the duration of the investigation were discussed. Two analysis methods were proposed and will be implemented to maximize the information gained in the study while allowing for efficient enrollment and study execution. Overall, the meeting provided the information needed to help finalize the design of the new study in accordance with FDA's current recommendations. Helius has already incorporated FDA's new feedback in its plans, and estimates that it will be able to submit a new request for de novo classification based on the results of our new study in the third quarter of 2020."

Mr. Deschamps continued, "We thank FDA for their feedback on our plans during the recent pre-submission meeting and look forward to further collaboration with the Agency as we prepare our new de novo submission. We intend to provide further updates on our US regulatory strategy during our third quarter earnings call on November 12, 2019."

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 a licensed class II, noninvasive, medical device in Canada intended for use as a short term treatment (14 weeks) of 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"), and it is currently under review for clearance by an EU Notified Body and the AUS Therapeutic Goods Administration. PoNS Treatment™ 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" and similar expressions. Such forward-looking statements include, among others, statements regarding the Company's future clinical and regulatory development plans for the PoNS device and the potential regulatory clearance of the PoNS device.

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 uncertainties associated with finalizing the study protocol for the proposed study, the uncertainties associated with clinical trial enrollments and the results of the planned study, uncertainties regarding the FDA regulatory submission and approval process, the regulation of commercially available medical devices in Canada, including Health Canada's ongoing assessment of post-market data, the clinical development, regulatory submission and approval process in the United States, the European Union and Australia, as well as the Company's capital requirements needed 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, 2018, its Quarterly Report on Form 10-Q for the quarter ended June 30, 2019 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.