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

April 10, 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 14a12 under the Exchange Act (17 CFR 240.14a12)
- ☐ Precommencement communications pursuant to Rule 14d2(b) under the Exchange Act (17 CFR 240.14d2(b))
- ☐ Precommencement communications pursuant to Rule 13e4(c) under the Exchange Act (17 CFR 240.13e4(c))

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 April 10, 2019, Helius Medical Technologies, Inc. (the "***Company***") issued a press release providing an update on the U.S. Food and Drug Administration's review of the Company's request for de novo classification and 510(k) clearance of its Portable Neuromodulation Stimulator (PoNS™) device in the United States. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Press Release, dated April 10, 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: April 10, 2019

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 510(k) Clearance of the PoNS™ Device

NEWTOWN, PA., April 10, 2019 - (GLOBE NEWSWIRE) -- Helius Medical Technologies, Inc. (Nasdaq:HSDT) (TSX:HSM) ("Helius" or the "Company"), a neurotech company focused on neurological wellness, today announced that the U.S. Food and Drug Administration (the "FDA" or the "Agency") has completed its review of the Company's request for De Novo classification and 510(k) clearance of the Portable Neuromodulation Stimulator (PoNS™) device and has declined the Company's request. In reaching its conclusion, the Agency noted that it did not have sufficient information to discern the relative independent contributions of the PoNS Device and physical therapy on the improvements from baseline in the effectiveness endpoints observed in the Company's clinical studies. The FDA noted that the Company could generate additional data to address its concerns and resubmit its application.

In the course of its review of the Company's submission, the Agency recognized that there were no device-related serious adverse events in either of the Company's two clinical trials, and that patients in both the treatment and the sham control arms demonstrated improvements from baseline for all the pre-specified clinical endpoints, including the primary endpoint of responder rate based on Sensory Organization Test score.

"We are understandably disappointed by the Agency's decision to decline our request for De Novo classification and 510(k) clearance, but Helius remains committed to generating the data to pursue a De Novo classification and 510(k) clearance of our PoNS device in the future for the treatment of patients with chronic balance deficit due to mmTBI, in order to bring our innovative therapy to more than 1.5 million Americans suffering from this condition," said Philippe Deschamps, Chief Executive Officer of Helius. "In addition to working on generating this new data, we will continue to focus on expanding our commercial efforts and treating patients in Canada, where we do currently have regulatory clearance" added Mr. Deschamps.

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 product in development 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 indicated for the treatment of chronic balance deficit due to mild-to-moderate traumatic brain injury when used in conjunction with physical therapy. The PoNS is an investigational medical device in

the United States and the European Union (“EU”), and it is currently under review for clearance by the EU Notified Body. PoNS Treatment is currently not commercially available in the United States or the European Union.

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, business and commercialization initiatives and objectives and the potential receipt of 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 the clinical development process and the 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, 2018 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.

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