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

January 11, 2021
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)	**(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.

On January 11, 2021, Helius Medical Technologies, Inc. (the "Company") issued a press release announcing its submission of a response to the U.S. Food and Drug Administration in pursuit of de novo classification and clearance of the Portable Neuromodulation Stimulator (PoNS™) device for the treatment of gait deficit due to symptoms of Multiple Sclerosis. A copy of the press release is attached hereto as Exhibit 99.1.

The information in this Item 7.01, including Exhibit 99.1 attached hereto, is being furnished, shall not be deemed "filed" for any purpose, and shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On January 11, 2021, the Company announced that it has submitted its formal response to the U.S. Food and Drug Administration's request for additional information received in October 2020, which related to the Company's request for de novo classification and clearance of the PoNS™ device as a potential treatment for gait deficit due to symptoms of Multiple Sclerosis, to be used as an adjunct to a supervised therapeutic exercise program in patients over 18 years of age.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit	Description
99.1	Press Release, dated January 11, 2021.

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: January 11, 2021

By: /s/ Joyce LaViscount

Joyce LaViscount
Chief Financial Officer, Chief Operating Officer and Secretary

Helius Medical Technologies, Inc. Submits Response to U.S. FDA in Pursuit of De Novo Classification and Clearance of the PoNS™ Device for the Treatment of Gait Deficit Due to Symptoms of Multiple Sclerosis

Submits formal response to the U.S. Food and Drug Administration's request for additional information

NEWTOWN, Pa., January 11, 2021 (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 submitted its formal response to the U.S. Food and Drug Administration's (the "FDA" or "Agency") request for additional information.

The FDA's request for additional information was 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.

"The Helius team is very excited to announce the timely submission of our response to the FDA's request for additional information," said Dane Andreeff, Interim President and Chief Executive Officer of Helius. "The achievement of this important milestone was made possible by the diligent efforts of our regulatory and clinical affairs team, and I would like to thank them for their hard work and dedication in recent months."

Mr. Andreeff continued: "Looking ahead, we expect that the FDA's receipt of our response will enable the FDA to resume its review of our request for de novo classification and clearance. We remain committed to our goal of bringing our PoNS technology to the aid of U.S. patients suffering with gait deficit due to MS-related symptoms as expeditiously as possible, and hope to receive the FDA's decision on our request for de novo classification and clearance during the first half of this year."

Additional Background Information:

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. On October 19, 2020, the Company announced the receipt of the FDA's request for additional information, which was received approximately 75 days following the submission date and placed the FDA's review on hold until receipt by the FDA of the requested information.

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:
Westwicke Partners on behalf of Helius Medical Technologies, Inc.
Jack Powell
investorrelations@heliusmedical.com

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,” “goal,” “expect,” “remain,” “hope” and similar expressions. Such forward-looking statements include, among others, statements regarding the Company’s future growth and operational progress, clinical and regulatory development plans for the PoNS device, and potential regulatory clearance of the PoNS device, including expected timing for the FDA to resume its review of our request for de novo classification and clearance and expected timing for receipt of the FDA’s decision on such request.

These statements involve substantial known and unknown risks and uncertainties. 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 uncertainties associated with the clinical development process and FDA regulatory submission and approval process, including that the Company’s request for de novo classification and clearance may be declined by the FDA, that the FDA is not required to and may not respond to the Company’s request in the timeframe indicated by its de novo review goals or in the time the Company expects, whether the Company’s response will be satisfactory to the FDA, whether the FDA will require additional information, whether the Company will be able to provide it in a timely manner and whether such additional information will be satisfactory to the FDA, uncertainties regarding the Company’s capital requirements to achieve its business objectives, the impact of the COVID-19 pandemic, uncertainties associated with future clinical trials and other development activities, and other risks detailed from time to time in the filings made by the Company with securities regulators, including the risks and uncertainties 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 September 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.