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 15, 2021 Date of Report (Date of earliest event reported)



HELIUS MEDICAL TECHNOLOGIES, INC.

(Exact name of Registrant as Specified in Its Charter)

DELAWARE (State or Other Jurisdiction of Incorporation) 001-38445

(Commission File Number)

642 Newtown Yardley Road, Suite 100 Newtown, PA (Address of Principal Executive Offices) 36-4787690 (IRS Employer Identification No.)

> 18940 (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))

D 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:

	Trading	
Title of each class	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 \Box

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. \Box

Item 8.01 Other Events

As previously disclosed, on March 23, 2020, Helius Medical Technologies, Inc. (the "Company"), received notice from the Listing Qualifications Staff (the "Staff") of The Nasdaq Stock Market LLC ("Nasdaq") that the bid price for the Company's common stock had closed below \$1.00 per share for the prior 30-consecutive business day period and that the Company had been granted a 180-day grace period, through September 21, 2020, to regain compliance with Nasdaq Marketplace Rule 5550(a)(2) (the "Minimum Bid Price Rule"). Thereafter, on April 17, 2020, the Company received an additional notice from the Staff indicating that Nasdaq had temporarily stayed enforcement of the Minimum Bid Price Rule through June 30, 2020 and, accordingly, the 180-day grace period applicable to the Company would not expire until December 3, 2020. On December 4, 2020, the Company received notice from the Staff indicating that the Company was not eligible for an additional 180 day extension to meet the Minimum Bid Price Rule. As a result, the Staff determined that the Company's securities would be subject to delisting unless the Company timely requests a hearing before the Nasdaq Hearings Panel (the "Panel"). The Company timely requested a hearing before the Panel, which stayed the delisting pending the Panel's decision.

On January 15, 2021, the Company received a letter from the Nasdaq Office of General Counsel notifying the Company that the minimum bid price deficiency had been cured and that the Company was in compliance with all applicable listing standards. Accordingly, the hearing was considered moot and cancelled, and Nasdaq has determined to continue the listing of the Company's Class A common stock on The Nasdaq Capital Market.

On January 19, 2021, the Company issued a press release with respect to the foregoing, a copy of which is filed as Exhibit 99.1 hereto.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Description

99.1 Press Release, dated January 19, 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.

By:

HELIUS MEDICAL TECHNOLOGIES, INC.

Date: January 19, 2021

/s/ Joyce LaViscount

Joyce LaViscount Chief Financial Officer, Chief Operating Officer and Secretary

2

Helius Medical Technologies, Inc. Regains Compliance with Nasdaq Listing Standards

The Company's Stock Will Continue to be Listed and Trade on The Nasdaq Stock Market

NEWTOWN, Pa., January 19, 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 received written notice from The Nasdaq Stock Market LLC that the Company's minimum bid price deficiency has been cured, and that the Company is in compliance with all applicable listing standards. Accordingly, the scheduled hearing before the Hearings Panel to appeal the previous determination of non-compliance has been cancelled, and shares of the Company's Class A common stock will continue to be listed and trade on The Nasdaq Capital Market under the ticker "HSDT."

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 (PoNSTM). For more information, visit <u>www.heliusmedical.com</u>.

About the PoNSTM Device and PoNS TreatmentTM

The Portable Neuromodulation Stimulator (PoNSTM) 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 PoNSTM 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. PoNSTM 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 ability to remain listed on The Nasdaq Capital Market, the Company's 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 Company's ability to meet the continued listing requirements of The Nasdaq Capital Market, 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.