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): April 30, 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 April 30, 2020, Helius Medical Technologies, Inc. (the " *Company* ") issued a press release announcing the publication of its PoNS ™ registrational clinical trial (TBI-001) in mild-to-moderate traumatic brain injury. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Forward- Looking Statements

This Current Report on Form 8-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and Private Securities Litigation Reform Act, as amended, and Canadian securities laws, including those relating to the Company's product development, clinical trials, clinical and regulatory timelines, market opportunity, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statements that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which the Company operates and management's current beliefs and assumptions.

These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential," "predict," "project," "should," "would" and similar expressions and the negatives of those terms. These statements relate to future events or our financial performance and involve known and unknown risks, uncertainties, and other factors which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in the Company's filings with the SEC. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Press release, dated April 30, 2020, issued by the Company.

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 30, 2020

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

Helius Medical Technologies, Inc. Announces Publication of its PoNS ™ Registrational Clinical Trial (TBI-001) in TBI

122 Subject, Multicenter, Double-Blind, Randomized, Clinical Trial Finds PoNS Treatment ™ found Significant Improvement in Balance and Gait Deficits for Individuals Who Have Experienced a Mild-to-Moderate Traumatic Brain Injury

NEWTOWN, PA. | April 30, 2020— Helius Medical Technologies, Inc. (NASDAQ:HSDT) (TSX:HSM) ("Helius" or the "Company"), a neurotech company focused on neurological wellness, today announced that its registrational clinical trial, TBI-001, was published on April 29, 2020 in *Neuromodulation: Technology at the Neural Interface* . The TBI-001 trial found that PoNS Treatment ™ provided significant improvement in balance in patients with a chronic balance deficit following a mild-to-moderate traumatic brain injury ("mmTBI").

This newly-published, 122 subject, multicenter, double-blind randomized clinical trial, found that the PoNS Treatment, which pairs translingual neurostimulation using the Portable Neuromodulation Stimulator (PoNS ™) device with therapeutic activities, significantly improves balance and gait. Conducted by researchers at 7 clinical sites across the US and Canada, this trial, which was completed in 2017, is the second double-blind, randomized clinical trial to demonstrate the level of balance improvement PoNS Treatment provides to patients suffering from chronic balance deficit as a result of a mild-to-moderate traumatic brain injury. For more information on the TBI-001 trial and its results, see the published journal article .

"Whether traumatic brain injuries are mild, moderate or severe, the devastating effects can last a lifetime," said Philippe Deschamps, Chief Executive Officer of Helius Medical Technologies. "We are excited to announce the publication of this 122 subject, multicenter, double-blind, randomized, clinical trial in a peer-reviewed journal and believe that it provides important clinical support for the PoNS Treatment as new, novel, valuable treatment option for patients suffering from the effects of mmTBI."

The PoNS Treatment involves the use of the PoNS device in conjunction with therapeutic activities. The PoNS device sits on the surface of a patient's tongue and delivers mild, gentle electrical impulses to the surface of the tongue. These impulses excite the neural network flowing to the brain. This neural activity, combined with therapeutic activities, is believed to enable "neuroplasticity" which may restore lost function.

The TBI-001 trial evaluated subjects who had experienced a mild-to-moderate traumatic brain injury at least one year prior to receiving the PoNS Treatment and had reached a plateau in recovery (according to their healthcare providers) with physical therapy alone. Subjects used the PoNS device for 5 weeks in conjunction with therapeutic activities. At the end of the 5-week treatment program, patients demonstrated improved balance and gait. Researchers found that 67.2 percent of

the pooled patient population who completed 5 weeks of PoNS Treatment experienced a clinically and statistically significant improvement in balance, as indicated in their mean SOT (Sensory Organizational Test) scores at 2 weeks and 5 weeks compared to baseline. Mean DGI (Dynamic Gait Index) scores were significantly increased from baseline at weeks 2 and 5.

Exploratory endpoints, such as the headache disability index, sleep quality index and quality of life measure index were also observed as part of the trial. While further analysis and research is needed, there was an indication of improvements in these exploratory endpoints. Demonstrated improvements in balance and gait, coupled with potential improvements in the exploratory endpoints, may allow treated individuals to experience improved quality of life.

Mr. Deschamps continued: “We are very encouraged by the results of the clinical trial. As a result of their improvements in balance and gait, many of our patients reported being able to perform independent self-care tasks, like dressing and showering, that were once beyond their reach prior to receiving PoNS Treatment.”

Katherine Webb, a patient enrolled in the study described her experience during the study. “It had been 4 and a half years since my injury when I first started the study. For those 4 and a half years, I had not been able to put one foot in tandem in front of the other and walk with my feet in a row without tipping or falling over due to loss of balance. It was early February of 2017, and with the device in my mouth, I walked the line. The Physiotherapist FaceTimed my husband and daughter who were flooded with tears as they watched. As a result of my improved balance throughout the study I experienced many more firsts since my TBI, like washing my hair without having to balance against the shower walls for stability,” said Katherine Webb.

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 class II, non-implantable medical device authorized for sale in Canada. PoNS is intended as a short term treatment (14 weeks) of chronic balance deficit due to mild-to-moderate traumatic brain injury and is to be used in conjunction with physical therapy and indicated as a short term treatment (14 weeks) of gait deficit due to mild and moderate symptoms from MS and is to be used in conjunction with physical therapy. The PoNS is an investigational medical device in the United States, the European Union, and Australia, and is currently under review for clearance by the AUS Therapeutic Goods Administration. PoNS Treatment is currently not commercially available in the United States, the European Union or Australia.

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, the success of the Company’s planned study, business and commercialization initiatives and objectives, the potential receipt of regulatory clearance of the PoNS device in the United States, the European Union and Australia and the Company’s revenue guidance.

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 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, 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.

Investor Relations Contact:

Westwicke Partners on behalf of Helius Medical Technologies, Inc.
Mike Piccinino, CFA
443-213-0500
investorrelations@heliusmedical.com