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): August 6, 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 2.02 Results of Operations and Financial Condition.

On August 6, 2020, the Helius Medical Technologies, Inc. (the "***Registrant***") issued a press release that announced its preliminary results of operations for the quarter ended June 30, 2020. A copy of this press release, which is incorporated herein by reference, is furnished (with respect to the information contained in this Item 2.02) as Exhibit 99.1 to this Current Report on Form 8-K.

In accordance with General Instruction B.2. of Form 8-K, the information in this Item 2.02, and Exhibit 99.1 hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "***Exchange Act***"), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any of the Registrant's filings under the Securities Act of 1933, as amended (the "***Securities Act***"), or the Exchange Act, whether made before or after the date hereof, regardless of any incorporation language in such a filing, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

Preliminary Second Quarter 2020 Financial Results

Preliminary revenue for the second quarter of 2020 is expected to be approximately $0.1 million, compared to $0.5 million in the second quarter of 2019. The Company's revenue was generated almost exclusively through sales of the PoNS device pursuant to supply agreements with neuroplasticity clinics in Canada.

Gross profit for the second quarter of 2020 is expected to be approximately $0.1 million, compared to gross profit of $0.3 million in the second quarter of 2019. Operating expenses for the second quarter of 2020 are expected to be approximately $3.7 million, compared to $6.1 million in the second quarter of 2019. The year-over-year decrease in operating expenses was primarily driven by an expected decrease of approximately $1.5 million, or 39%, in selling, general and administrative expenses. The decrease in selling, general and administrative expenses was primarily due to a reduction in commercial operations expenses coupled with a reduction in wages and salaries.

Six Months Ended June 30, 2020 Financial Results

Preliminary revenue for the six months ended June 30, 2020 is expected to be approximately $0.3 million, compared to $1.2 million in the prior year period. The Company's revenue was generated almost exclusively through sales of the PoNS device pursuant to supply agreements with neuroplasticity clinics in Canada.

Gross profit for the six months ended June 30, 2020 is expected to be approximately $0.2 million, compared to gross profit of $0.7 million in the prior year period. Operating expenses for the six months ended June 30, 2020 are expected to be approximately $7.8 million, compared to $13.4 million in the prior year period.

The Company has not completed the preparation of its financial statements for the quarter ended June 30, 2020 and additional details with respect to the quarter ended June 30, 2020 results of operations are not yet available. The Company plans to release quarter ended June 30, 2020 actual results after the completion of its quarterly review.

Cash Position

As of June 30, 2020, the Company had cash of $5.3 million, compared to $5.5 million at December 31, 2019. The Company had no debt outstanding at June 30, 2020.

Regulatory Update

On August 4, 2020, the Company submitted a request to the U.S. Food and Drug Administration ("FDA") for de novo classification and clearance of the Portable Neuromodulation Stimulator (PoNS™) device for the treatment of gait deficit due to symptoms of Multiple Sclerosis ("MS"), to be used as an adjunct to a supervised therapeutic exercise program.

Forward-Looking Statements

The second quarter 2020 financial results contained in this Current Report on Form 8-K are subject to finalization in connection with the preparation of the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020. This Current Report on Form 8-K may contain forward-looking statements made in reliance upon the safe harbor provisions of Section 27A of the Securities Act and

Section 21E of the Exchange Act. 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 about Registrant's preliminary second quarter 2020 financial information, future clinical and regulatory development plans for the PoNS device, the success of the Registrant's planned study and the potential receipt of regulatory clearance of the PoNS device in the United States. These forward-looking statements are based on information currently available to the Registrant and its current plans or expectations, and are subject to a number of uncertainties and risks that could significantly affect current plans. Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors, including the uncertainties associated with the clinical development process and FDA regulatory submission and approval process, including the Registrant's capital requirements to achieve its business objectives and other risks detailed from time to time in the filings made by the Registrant with securities regulators, and including the risks and uncertainties about the Registrant's business described in the "Risk Factors" sections of the Registrant's Annual Report on Form 10-K for the year ended December 31, 2019, its Quarterly Report on Form 10-Q for the quarter ended March 31, 2020 filed on May 11, 2020 and its other filings with the United States Securities and Exchange Commission. The Registrant is under no obligation to (and expressly disclaims any such obligation to) update or alter its forward-looking statements, 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 August 6, 2020.

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: August 6, 2020

By: /s/ Joyce LaViscount

Joyce LaViscount
Chief Financial Officer

Exhibit 99.1

Helius Medical Technologies, Inc. Submits Request for FDA Clearance for PoNS™ Device; Reports Preliminary Financial Results for the Second Quarter and Six Months Ended June 30, 2020

NEWTOWN, PA, | August 6, 2020 - 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 a request to the U.S. Food and Drug Administration ("FDA") for de novo classification and clearance of the Portable Neuromodulation Stimulator (PoNS™) device and reported preliminary financial results for the second quarter and six months ended June 30, 2020. The PoNS device was granted Breakthrough Designation by FDA on May 7, 2020.

"Helius is excited to announce the submission of our request for de novo classification and clearance of the PoNS device for the treatment of gait deficit due to symptoms from Multiple Sclerosis ("MS"), to be used as an adjunct to a supervised therapeutic exercise program in patients over 18 years of age," said Philippe Deschamps, Helius' President, CEO and Chairman. "The achievement of this important milestone reflects our strong pace of progress since the first quarter of this year, when we made the strategic decision to prioritize an MS indication as the regulatory pathway to pursue our first U.S. breakthrough designation and regulatory clearance. Most importantly, our submission brings us a step closer to making our novel PoNS Treatment available for the 1 million U.S. patients estimated to be living with MS, a disease with a significant unmet medical need, particularly in addressing associated gait dysfunction. We look forward to the FDA's review of our submission, as we strive to provide patients with gait deficit due to MS symptoms a non-drug, non-implantable treatment that has the potential to significantly improve their ability to walk."

Mr. Deschamps continued: "As anticipated, our second quarter financial performance was impacted by the disruption caused by the COVID-19 pandemic – with our clinics in Canada affected by government mandates enacted to slow the spread of the virus. However, we were pleased by the efforts and progress made by our team, who worked diligently during the quarter to help mitigate the impact of this pandemic on our business and continue pursuing our commercial and regulatory priorities. We remain focused on expanding access to our novel PoNS technology in Canada as efficiently and effectively as possible for the benefit of our patients and shareholders and look forward to discussing our recent progress in more detail on our second quarter earnings call."

Second Quarter 2020 Preliminary Financial Results

Preliminary revenue for the second quarter of 2020 is expected to be approximately $0.1 million, compared to $0.5 million in the second quarter of 2019. The Company's revenue was generated almost exclusively through sales of the PoNS device pursuant to supply agreements with neuroplasticity clinics in Canada.

Gross profit for the second quarter of 2020 is expected to be approximately $0.1 million. Operating expenses for the second quarter of 2020 are expected to be approximately $3.7 million, compared to $6.1 million in the second quarter of 2019. The year-over-year decrease in operating expenses was primarily

driven by an expected decrease of approximately $1.5 million, or 39%, in selling, general and administrative expenses. The decrease in selling, general and administrative expenses was primarily due to a reduction in commercial operations expense coupled with a reduction in wages and salaries.

Operating loss for the second quarter of 2020 is expected to be $3.7 million, compared to $5.8 million in the second quarter of 2019.

Six Months Ended June 30, 2020 Preliminary Financial Results

Preliminary revenue for the six months ended June 30, 2020 is expected to be approximately $0.3 million, compared to $1.2 million in the prior year period. The Company's revenue was generated almost exclusively through sales of the PoNS device pursuant to supply agreements with neuroplasticity clinics in Canada.

Gross profit for the six months ended June 30, 2020 is expected to be approximately $0.2 million, compared to gross profit of $0.7 million in the prior year period. Operating expenses for the six months ended June 30, 2020 are expected to be approximately $7.8 million, compared to $13.4 million in the six months ended June 30, 2019.

Operating loss for the six months ended June 30, 2020 is expected to be $7.6 million, compared to operating loss of $12.6 million in the prior year period.

The Company has not completed the preparation of its financial statements for the quarter ended June 30, 2020 and additional details with respect to the quarter ended June 30, 2020 results of operations are not yet available. The Company plans to release quarter ended June 30, 2020 actual results after the completion of its quarterly review.

Cash Position

As of June 30, 2020, the Company had cash of $5.3 million, compared to $5.5 million at December 31, 2019. The Company had no debt outstanding at June 30, 2020.

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 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:

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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, 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 Form 10-Q for the quarter ended March 31, 2020 filed on May 11, 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.