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): March 2, 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 March 2, 2020, the Helius Medical Technologies, Inc. (the "***Registrant***") issued a press release that announced its preliminary unaudited results of operations for the quarter and year ended December 31, 2019. 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 Fourth Quarter 2019 Financial Results (Unaudited)

Preliminary revenue for the fourth quarter of 2019 was approximately $0.1 million. The Company's revenue was generated exclusively through sales of the PoNS device pursuant to supply agreements with five neuroplasticity clinics in Canada.

Gross loss for the fourth quarter of 2019 is expected to be approximately $0.2 million. Operating expenses for the fourth quarter of 2019 are expected to be approximately $5.4 million, compared to $5.7 million in the fourth quarter of 2018. The year-over-year decrease in operating expenses in the fourth quarter was primarily driven by an expected decrease of approximately $0.6 million, or 26%, in research and development expenses. The decrease in research and development expenses was primarily due to a reduction in product development costs.

Full Year 2019 Financial Results (Unaudited)

Preliminary revenue for the twelve months ended December 31, 2019 was approximately $1.5 million. The Company's revenue was generated almost exclusively through sales of the PoNS device pursuant to supply agreements with seven neuroplasticity clinics in Canada. In addition, the Company generated approximately $37,000 in fee revenue from franchise agreements its wholly owned subsidiary, Heuro Canada, Inc., or Heuro, executed with neuroplasticity clinics that have been engaged to provide the PoNS Treatment.

Gross profit for the twelve months ended December 31, 2019 is expected to be approximately $0.6 million. Operating expenses for the twelve months ended December 31, 2019 are expected to be approximately $24.6 million, compared to $27.2 million in the twelve months ended December 31, 2018.

The Company has not completed the preparation of its financial statements for the fourth quarter and the full year 2019 and additional details with respect to the fourth quarter and full year 2019 results of operations are not yet available. The Company plans to release fourth quarter and full year 2019 actual results after the completion of its annual audit.

Cash Position

As of December 31, 2019, the Company had cash of $5.5 million, compared to $25.6 million at December 31, 2018. The Company had no debt outstanding at December 31, 2019.

Regulatory Update

On February 27, 2020, the Company submitted a Canadian Class II license amendment application for the treatment of gait deficit in patients with mild and moderate Multiple Sclerosis ("MS"). This is an important new clinical indication for the PoNS device, given the approximately 100,000 individuals living with MS in Canada. The Company believes this label expansion will significantly expand its addressable market opportunity in Canada to include a patient population that is motivated to pursue treatment options which may resolve or delay the progression of MS symptoms.

Based on the quality of the data included in its MS submission package to Health Canada, the Company is prioritizing the MS indication as the pathway to pursue for its first US clearance of the PoNS device. The Company believes the existing published data and clinical experience with use of the PoNS for the treatment of gait disorder in patients with mild and moderate MS are sufficient to demonstrate

a favorable risk/benefit profile, as required for de novo clearance. The Company plans to submit to the FDA for this high unmet medical need in the second half of 2020.

The Company will continue to pursue its TBI indication with a new trial, called TBI-002, which will be used to support its new request for de novo classification and clearance of the PoNS device for the treatment of chronic balance deficit due to mild to moderate traumatic brain injury ("mmTBI"). The design of TBI-002 incorporates specific recommendations that the Company received from the FDA in January 2020. The Company expects the trial to cost $6 million and to begin enrollment in April 2020 and the Company is targeting submission to the FDA in the second quarter of 2021.

Forward-Looking Statements

The 2019 financial results contained in this Current Report on Form 8-K are subject to finalization in connection with the preparation of the Company's Annual Report on Form 10-K for the year ended December 31, 2019. 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 2019 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, 2018, its Quarterly Report on Form 10-Q for the quarter ended September 30, 2019 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 March 2, 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: March 2, 2020

By: /s/ Joyce LaViscount

Joyce LaViscount
Chief Financial Officer

Exhibit 99.1

Helius Medical Technologies Reports Preliminary Unaudited Fourth Quarter and Full Year Unaudited 2019 Financial Results, Provides Commercial and Regulatory Update and Announces Submission to Health Canada for Multiple Sclerosis (MS) Label Expansion and New US Regulatory Prioritization for MS

NEWTOWN, Pa. | March 2, 2020 - Helius Medical Technologies, Inc. (NASDAQ:HSDT) (TSX:HSM) ("Helius" or the "Company"), a neurotech company focused on neurological wellness, today reported preliminary unaudited financial results for the fourth quarter and full year ended December 31, 2019, provided an update on its commercial and regulatory activities and announced it has submitted a Canadian Class II license amendment application for the treatment of gait deficit in patients with mild and moderate Multiple Sclerosis ("MS").

"We are pleased to provide an update today on our recent financial and operational progress in advance of our earnings call on March 12th," said Philippe Deschamps, Chief Executive Officer of Helius. "In 2019, our first year as a commercial stage company in Canada, preliminary total revenue was approximately $1.5 million, within our guidance range of $1.5 million to $1.6 million. Overall, 2019 was a year marked by important progress in advancing and refining our commercial strategy in Canada and regulatory strategy in the U.S."

Mr. Deschamps continued: "In Canada, we developed and expanded our authorized clinic network to include six clinics and one satellite clinic by the end of the year, exceeding our goal for 2019. Beginning in the third quarter of 2019, we also made important changes to our commercial strategy in Canada, acquiring the Heuro Canada operating entity and establishing an internal team to lead our commercial efforts going forward. During the fourth quarter of 2019, and in recent months, we enhanced our targeting criteria for the clinics with which we engage and authorize to provide PoNS Treatment, prioritizing clinics that have established commercial operations, strong referral networks with local neurological hospitals and reimbursement and an exclusive focus on neurorehabilitation. We have authorized 7 new clinics with 9 locations in the first two months of 2020 for a total of 16 clinics to provide PoNS Treatment across Canada."

Preliminary Fourth Quarter 2019 Financial Results (Unaudited)

Preliminary revenue for the fourth quarter of 2019 was approximately $0.1 million. The Company's revenue was generated exclusively through sales of the PoNS device pursuant to supply agreements with five neuroplasticity clinics in Canada.
Gross loss for the fourth quarter of 2019 is expected to be approximately $0.2 million. Operating expenses for the fourth quarter of 2019 are expected to be approximately $5.4 million, compared to $5.7 million in the fourth quarter of 2018. The year-over-year decrease in operating expenses in the fourth quarter was primarily driven by an expected decrease of approximately $0.6 million, or 26%, in research and

development expenses. The decrease in research and development expenses was primarily due to a reduction in product development costs.

Full Year 2019 Financial Results (Unaudited)

Preliminary revenue for the twelve months ended December 31, 2019 was approximately $1.5 million. The Company's revenue was generated almost exclusively through sales of the PoNS device pursuant to supply agreements with seven neuroplasticity clinics in Canada. In addition, the Company generated approximately $37,000 in fee revenue from franchise agreements its wholly owned subsidiary, Heuro Canada, Inc., or Heuro, executed with neuroplasticity clinics that have been engaged to provide the PoNS Treatment.

Gross profit for the twelve months ended December 31, 2019 is expected to be approximately $0.6 million. Operating expenses for the twelve months ended December 31, 2019 are expected to be approximately $24.6 million, compared to $27.2 million in the twelve months ended December 31, 2018.

The Company has not completed the preparation of its financial statements for the fourth quarter and the full year 2019 and additional details with respect to the fourth quarter and full year 2019 results of operations are not yet available. The Company plans to release fourth quarter and full year 2019 actual results after the completion of its annual audit.

Cash Position

As of December 31, 2019, the Company had cash of $5.5 million, compared to $25.6 million at December 31, 2018. The Company had no debt outstanding at December 31, 2019.

Regulatory Update

On February 27, 2020, the Company submitted a Canadian Class II license amendment application for the treatment of gait deficit in patients with mild and moderate Multiple Sclerosis ("MS"). This is an important new clinical indication for the PoNS device, given the approximately 100,000 individuals living with MS in Canada. The Company believes this label expansion will significantly expand its addressable market opportunity in Canada to include a patient population that is motivated to pursue treatment options which may resolve or delay the progression of MS symptoms.

Based on the quality of the data included in its MS submission package to Health Canada, the Company is prioritizing the MS indication as the pathway to pursue for its first US clearance of the PoNS device. The Company believes the existing published data and clinical experience with use of the PoNS for the treatment of gait disorder in patients with mild and moderate MS are sufficient to demonstrate a favorable risk/benefit profile, as required for de novo clearance. The Company plans to submit to the FDA for this high unmet medical need in the second half of 2020.

The Company will continue to pursue its TBI indication with a new trial, called TBI-002, which will be used to support its new request for de novo classification and clearance of the PoNS device for the treatment of chronic balance deficit due to mild to moderate traumatic brain injury ("mmTBI"). The design of TBI-002 incorporates specific recommendations that the Company received from the FDA in January 2020. The Company expects the trial to cost $6 million and to begin enrollment in April 2020 and the Company is targeting submission to the FDA in the second quarter of 2021.

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 an authorized class II, non-implantable, medical device in Canada intended for use as a short term treatment (14 weeks) of 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"), and it is currently under review for clearance from 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.
Mike Piccinino, CFA
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Cautionary Disclaimer Statement:

The 2019 financial results contained in this news release are subject to finalization in connection with the preparation of the Company's Annual Report on Form 10-K for the year ended December 31, 2019. 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, such as the Company's preliminary 2019 financial information contained in this press release. 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.

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 regulation of commercially available medical devices in Canada, including Health Canada's ongoing assessment of post-market data, the clinical development, regulatory submission and approval process in the United States, the European Union and Australia, as well as the Company's capital requirements needed 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, its Quarterly Report on Form 10-Q for the quarter ended September 30, 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.