

**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

November 12, 2019

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 or organization)

001-38445

(Commission
File Number)

36-4787690

(I.R.S. Employer
Identification No.)

642 Newtown Yardley Road, Suite 100

Newtown, Pennsylvania, 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 14a12 under the Exchange Act (17 CFR 240.14a12)
- Precommencement communications pursuant to Rule 14d2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Precommencement communications pursuant to Rule 13e4(c) under the Exchange Act (17 CFR 240.13e4(c))

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of each class

Common stock

Trading Symbol(s)

HSDT

Name of each exchange on which registered

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 November 12, 2019, Heliuss Medical Technologies, Inc. (the “**Registrant**”) issued a press release announcing its financial results for the quarter ended September 30, 2019, as well as information regarding a conference call to discuss these financial results and the Registrant’s recent corporate highlights. A copy of this press release is furnished herewith as Exhibit 99.1 to this Current Report and is incorporated herein by reference.

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.**

On November 12, 2019, the Registrant announced its proposed plan to conduct a single arm clinical study as opposed to a new randomized study in order to support the its planned submission of a new request to the U.S. Food and Drug Administration (“**FDA**”) for de novo classification of its Portable Neuromodulation Stimulator (“**PoNSTM**”). This study is designed to provide patients with 5 weeks of physical therapy (“**PT**”) alone and compare these results to the existing results from the active arm of the Registrant’s registrational trial TBI 001 protocol. In accordance with the recommendations of the FDA, the Registrant plans to extend the study of PT alone patients for an additional 5 weeks of treatment involving PT and treatment with the PoNS device. This will allow the Registrant to compare the effects of 5 weeks of PT alone to the effects of an additional treatment of 5 weeks of PT + PoNS with the same patients. The Registrant estimates that it will be able to submit a new request for de novo classification based on the results of this 42-patient study in the third quarter of 2020.

Forward-Looking Statements

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 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 November 12, 2019.](#)

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: November 12, 2019

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



Helius Medical Technologies, Inc. Reports Third Quarter 2019 Financial Results and Provides Business Update; Updates Full Year 2019 Outlook

NEWTOWN, Pa., November 12, 2019 (GLOBE NEWSWIRE) -- Helius Medical Technologies, Inc. (Nasdaq:HSDT) (TSX:HSM) ("Helius" or the "Company"), a neurotech company focused on neurological wellness, today reported financial results for the quarter ended September 30, 2019.

Third Quarter 2019 Financial Summary

- Revenue of \$0.2 million, compared to no revenue in third quarter of 2018.
- Operating loss of \$5.7 million, compared to operating loss of \$4.9 million in third quarter of 2018.
- Net loss of \$5.6 million, compared to net loss of \$4.5 million in third quarter of 2018.

Third Quarter and Recent Business Updates

- On August 28, 2019, the Company provided an update from early Canadian clinical experience with PoNS™.
- On September 13, 2019, the Company reported that Clinique Cortex has been authorized to provide PoNS Treatment™ in Quebec City Canada, giving residents of Quebec City local access to the PoNS Treatment. Clinique Cortex will operate as a satellite clinic in partnership with Neurotherapy Montreal.
- On October 24, 2019, the Company provided an update outlining the Company's U.S. regulatory strategy following its pre-submission meeting with the U.S. Food and Drug Administration ("FDA")
- On October 30, 2019, the Company entered into an agreement with HealthTech Connex Inc, ("HTC"), the Company's commercial development partner in Canada, to purchase Heuro Canada, Inc. ("Heuro").

"During the third quarter, we continued to make important progress in advancing our commercialization and regulatory strategy in Canada and our regulatory strategy in the United States, with the overarching goal of expanding access to our PoNS Treatment™ for patients suffering from chronic balance disorder due to mild-to-moderate traumatic brain injury," said Philippe Deschamps, Chief Executive Officer of Helius. "We reported total revenue of \$150,000 during the third quarter of 2019 from sales to clinics that have been authorized to provide PoNS Treatment in Canada. We continue to see consistency in the demand for our devices on a quarter to quarter basis in that the number of patients who have begun treatment in each quarter,

beginning with the first quarter of this year, have been 23, 38, and 32 respectively. We are pleased with the progress on the PoNS Treatment and look forward to continued growth.”

Mr. Deschamps continued: “We made significant progress towards optimizing our early commercial efforts in Canada in the third quarter: we expanded our patient and caregiver-focused digital marketing efforts, we continued to utilize our Medical Affairs team to raise awareness among physiatrists and physical therapists and most importantly, we made the strategic decision to change our business model in Canada in order to accelerate the adoption of our novel technology by signing an agreement to acquire Heuro from HTC. In addition, we hired a Vice President and General Manager to lead our marketing and sales activities in Canada with the support of four other commercial professionals. We are very pleased with the way the new team has stepped into driving our commercial activities,” said Deschamps.

“In the United States, we continued to engage with FDA to discuss our resubmission strategy by participating in a pre-submission meeting with the Agency. The pre-submission meeting was held in October and provided us with important feedback needed to help finalize the design of a new study intended to support a request for de novo classification of the PoNS device,” said Deschamps.

“FDA accepted the Company’s proposed plan to conduct a single arm clinical study as opposed to a new randomized study. This study is designed to provide patients with 5 weeks of physical therapy (“PT”) alone and compare these results to the existing results from the active arm of the registrational trial TBI 001 protocol. FDA also recommended extending the study to PT alone patients for an additional 5 weeks of treatment involving PT and PoNS. This will allow us to compare the effects of 5 weeks of PT alone to the effects of additional treatment of 5 weeks of PT + PoNS with the same patients. We believe this strategy will maximize the probability of a successful trial to answer FDA’s questions. We estimate that we will be able to submit a new request for de novo classification based on the results of this 42-patient study in the third quarter of 2020,” said Dr. Jonathan Sackier, Chief Medical Officer of Helius.

“We are updating our revenue guidance to accommodate for lower revenue contributions from one of the founding PoNS clinics in Surrey, British Columbia. Specifically, our prior guidance range of \$1.6 million to \$2.0 million had assumed contributions from sales to the Surrey clinic, during the second half of 2019, of approximately \$500,000. The expected demand from the Surrey clinic in the second half of 2019 was included in the total consideration for our new agreement with HTC, and thus will not be recognized in our revenue in 2019, as our original guidance had contemplated. Partially offsetting the impact from lower than expected Surrey revenue in the second half of 2019, is the incremental contribution from the three new clinics that became fully operational during the third quarter. Looking ahead, we remain focused on driving strong sales performance and delivering progress with respect to our commercial and regulatory strategies to establish PoNS Treatment in the marketplace.”

Third Quarter 2019 Financial Results

Revenue for the third quarter of 2019 was \$0.2 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 profit for the third quarter of 2019 was \$0.1 million. Operating expenses for the third quarter of 2019 increased 19% year-over-year, to \$5.8 million, compared to \$4.9 million in the third quarter of 2018. The year-over-year increase in operating expenses in the third quarter was primarily driven by an increase of \$1.7 million, or 66%, in selling, general and administrative expenses. The increase in selling, general and administrative expenses was primarily due to a \$1.0 million increase in stock-based compensation expense

as well as an increase of \$0.6 million due to severance expense combined with a higher headcount to support the Company's commercial launch in Canada.

Operating loss for the third quarter of 2019 increased \$0.8 million, or 17%, to \$5.7 million, compared to \$4.9 million in the third quarter of 2018.

Total other income for the third quarter of 2019 was \$0.1 million, compared to \$0.4 million in the third quarter of 2018. The year-over-year decrease in total other income was driven primarily by the change in fair value of derivative financial instruments, which was a gain of \$0.2 million in the third quarter of 2019, compared to a gain of \$0.4 million in the third quarter of 2018. The change in fair value of the Company's derivative financial instruments was primarily attributable to the change in the Company's stock price, volatility and the number of derivative financial instruments being measured during the period.

Net loss for the third quarter of 2019 was \$5.6 million, or \$(0.22) per basic and diluted common share, compared to a net loss of \$4.5 million, or \$(0.19) per basic and diluted common share, in the third quarter of 2018. Weighted average shares used to compute basic net loss per common share were 25.9 million and 23.4 million for the third quarters of 2019 and 2018, respectively. Weighted average shares used to compute diluted net loss per common share were 25.9 million and 23.8 million for the third quarters of 2019 and 2018, respectively.

Nine Months Ended September 30, 2019 Financial Results

Revenue for the nine months ended September 30, 2019 was \$1.3 million. The Company's revenue was generated almost exclusively through sales of the PoNS device pursuant to supply agreements with five neuroplasticity clinics in Canada. In addition, the Company generated \$49,000 in fee revenue from franchise agreements Heuro executed with neuroplasticity clinics that have been engaged to provide the PoNS Treatment.

Gross profit for the nine months ended September 30, 2019 was \$0.8 million. Operating expenses for the nine months ended September 30, 2019 decreased \$2.2 million, or 10%, to \$19.2 million, compared to \$21.4 million in the nine months ended September 30, 2018. The decrease in operating expenses in the period was driven primarily by a decrease of \$1.3 million, or 17%, in research and development expenses, due primarily to a reduction in product development costs, and a decrease of \$0.9 million, or 7%, in selling, general and administrative expenses. The decrease in selling, general and administrative expenses was primarily due to lower stock-based compensation expense, which was impacted by the change in the Company's functional currency in the second quarter of 2018. During the second quarter of 2018, the Company revalued its outstanding stock options in connection with the change in its functional currency from CAD\$ to USD\$.

Operating loss for the nine months ended September 30, 2019 decreased \$3.0 million, or 14%, to \$18.4 million, compared to operating loss of \$21.4 million in the prior year period.

Total other income for the nine months ended September 30, 2019 was \$13.9 million, compared to an expense of \$2.1 million in the prior year period. The year-over-year increase in total other income was driven primarily by the change in fair value of derivative financial instruments, which was a gain of \$14.0 million for the nine months ended September 30, 2019, compared to a loss of \$3.4 million in the prior year period. The change in fair value of the Company's derivative financial instruments was primarily attributable to the change in the Company's stock price, volatility and the number of derivative financial instruments being measured during the period.

Net loss for the nine months ended September 30, 2019 was \$4.5 million, or \$(0.17) per basic and diluted common share, compared to net loss of \$23.5 million, or \$(1.06) per basic and diluted common share, in the prior year period. Weighted average shares used to compute basic net loss per share were 25.9 million and 22.2 million for the nine months ended September 30, 2019 and 2018, respectively. Weighted average shares used to compute diluted net loss per share were 25.9 million and 22.2 million for the nine months ended September 30, 2019 and 2018, respectively.

As of September 30, 2019, the Company had cash of \$9.0 million, compared to \$25.6 million at December 31, 2018. The Company had no debt outstanding at September 30, 2019.

The decrease in cash during the period was driven primarily by net cash used in operating activities of \$16.5 million and net cash used in investing activities of \$0.3 million, offset by \$0.2 million of cash provided by financing activities.

Full Year 2019 Outlook

The Company today updated its revenue guidance for full year 2019.

For the twelve months ending December 31, 2019, the Company now expects revenue in a range of \$1.5 million to \$1.6 million. This compares to the Company's prior revenue guidance range of \$1.6 million to \$2.0 million.

Conference Call

Management will host a conference call at 8:00 a.m. Eastern Time on November 12, 2019 to discuss the results of the quarter and business outlook. Those who would like to participate may dial 877-702-1173 (647-689-4067 for international callers) and provide access code 1274587. A live webcast of the call will also be provided on the Events section of the Company's investor relations website at:

<https://heliusmedical.com/index.php/investor-relations/events/upcoming-events>.

For those unable to participate, a replay of the call will be available for two weeks at 800-585-8367 (416-621-4642 for international callers); access code 1274587. The webcast will be archived on the Events section of the Company's investor relations website.

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 (PoNSTM). For more information, visit www.heliusmedical.com.

About the PoNS Device and PoNS Treatment

The Portable Neuromodulation Stimulator (PoNS) is an active, therapeutic, class II medical device authorized for sale in Canada 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 therapeutic activities. 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 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 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 the planned study, 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, 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.

Helius Medical Technologies, Inc.
Unaudited Consolidated Balance Sheets
(Except for share data, amounts in thousands)

	September 30, 2019	December 31, 2018
ASSETS		
Current assets		
Cash	\$ 9,019	\$ 25,583
Accounts receivable	557	177
Other receivables	201	98
Inventory	1,289	392
Prepaid expenses	162	447
Other current assets	—	264
Total current assets	11,228	26,961
Property and equipment, net	725	554
Other assets		
Operating lease right-of-use asset, net	586	—
Non-current receivables	323	294
Other assets	18	18
Total other assets	927	312
TOTAL ASSETS	\$ 12,880	\$ 27,827
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 1,714	\$ 2,392
Accrued liabilities	1,586	1,812
Operating lease liability	164	—
Derivative financial instruments	83	13,769
Total current liabilities	3,547	17,973
Non-current liabilities		
Operating lease liability	511	—
TOTAL LIABILITIES	4,058	17,973
Commitments and contingencies		
STOCKHOLDERS' EQUITY		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding as of September 30, 2019 and December 31, 2018	—	—
Class A common stock, \$0.001 par value; 150,000,000 shares authorized; 25,903,544 and 25,827,860 shares issued and outstanding as of September 30, 2019 and December 31, 2018, respectively	26	26
Additional paid-in capital	108,997	105,411
Accumulated other comprehensive loss	(759)	(591)
Accumulated deficit	(99,442)	(94,992)
TOTAL STOCKHOLDERS' EQUITY	8,822	9,854
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 12,880	\$ 27,827

Helius Medical Technologies, Inc.
Unaudited Consolidated Statements of Operations and Comprehensive Loss
(Amounts in thousands except share and per share data)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2019	2018	2019	2018
Revenue:				
Product sales, net	\$ 150	\$ —	\$ 1,295	\$ —
Fee revenue	—	—	49	—
Total operating revenue	150	—	1,344	—
Cost of sales:				
Cost of product sales	89	—	538	—
Gross profit	61	—	806	—
Operating expenses:				
Research and development	1,506	2,309	6,462	7,781
Selling, general and administrative	4,291	2,581	12,715	13,632
Total operating expenses	5,797	4,890	19,177	21,413
Operating loss	(5,736)	(4,890)	(18,371)	(21,413)
Other income (expense):				
Other income	11	4	35	63
Change in fair value of derivative financial instruments	196	368	14,033	(3,356)
Foreign exchange (loss) gain	(59)	1	(147)	1,198
Total other income (expense)	148	373	13,921	(2,095)
Net loss	(5,588)	(4,517)	(4,450)	(23,508)
Other comprehensive loss:				
Foreign currency translation adjustments	68	(96)	(168)	(930)
Comprehensive loss	\$ (5,520)	\$ (4,613)	\$ (4,618)	\$ (24,438)
Net loss per share				
Basic	\$ (0.22)	\$ (0.19)	\$ (0.17)	\$ (1.06)
Diluted	\$ (0.22)	\$ (0.19)	\$ (0.17)	\$ (1.06)
Weighted average shares outstanding				
Basic	25,903,544	23,377,941	25,869,039	22,221,667
Diluted	25,903,544	23,845,498	25,869,039	22,221,667

Helius Medical Technologies, Inc.
Unaudited Condensed Consolidated Statements of Cash Flows
(Amounts in thousands)

	Nine Months Ended September 30,	
	2019	2018
Cash flows from operating activities:		
Net loss	\$ (4,450)	\$ (23,508)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of derivative financial instruments	(14,033)	3,356
Stock-based compensation expense	3,336	7,245
Unrealized foreign exchange loss (gain)	211	(1,262)
Depreciation expense	89	40
Changes in operating assets and liabilities:		
Accounts receivable	(380)	—
Other receivables	(123)	663
Inventory	(897)	(197)
Prepaid expenses	285	252
Other assets	264	—
Operating lease liability	(9)	—
Accounts payable	(678)	(1,274)
Accrued liabilities	(75)	209
Net cash used in operating activities	(16,460)	(14,476)
Cash flows from investing activities:		
Purchase of property and equipment	(260)	(425)
Net cash used in investing activities	(260)	(425)
Cash flows from financing activities:		
Proceeds from the issuance of common stock and accompanying warrants	—	18,400
Share issuance costs	(52)	(1,345)
Proceeds from the exercise of stock options and warrants	215	4,637
Net cash provided by financing activities	163	21,692
Effect of foreign exchange rate changes on cash	(7)	44
Net (decrease) increase in cash	(16,564)	6,835
Cash at beginning of period	25,583	5,562
Cash at end of period	\$ 9,019	\$ 12,397

Investor Relations Contact:

Westwicke Partners on behalf of Helius Medical Technologies, Inc.

Mike Piccinino, CFA

investorrelations@heliusmedical.com