

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

August 8, 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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 8, 2019, Helius Medical Technologies, Inc. (the "**Registrant**") issued a press release announcing its financial results for the quarter ended June 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, 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 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Press Release, dated August 8, 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: August 8, 2019

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



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

NEWTOWN, Pa., August 8, 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 second quarter ended June 30, 2019.

Second Quarter 2019 Financial Summary

- Revenue of \$0.5 million, compared to no revenue in second quarter of 2018.
- Operating loss of \$5.8 million, compared to operating loss of \$11.8 million in second quarter of 2018.
- Net loss of \$0.2 million, compared to net loss of \$17.8 million in second quarter of 2018.

Second Quarter and Recent Business Updates

- On April 10, 2019, the Company announced that the U.S. Food and Drug Administration (the "FDA") had completed its review of the Company's request for de novo classification of the Portable Neuromodulation Stimulator (PoNS™) device and declined the Company's request. In reaching its conclusion, FDA noted that it did not have sufficient information to discern the relative independent contributions of the PoNS device and physical therapy on the improvements from baseline in the effectiveness endpoints observed in the Company's clinical studies. FDA noted that the Company could generate additional data to address its concerns and resubmit its application.
 - On May 6, 2019, the Company submitted an application to the Therapeutic Goods Administration for marketing authorization of the PoNS device in Australia.
 - On June 5, 2019, the Company reported that three new clinics have been authorized to provide PoNS Treatment™ in Canada, giving Canadians broader regional access to the Company's innovative treatment. The new clinics join the current roster of existing clinics authorized to provide the PoNS Treatment, including Neurotherapy Montreal and Surrey Neuroplasticity Clinic.
 - On June 11, 2019, the Company reported that a scientific paper entitled *Human Translingual Neurostimulation Alters Resting Brain Activity in High-density EEG* was published in the latest edition of the peer reviewed *Journal of NeuroEngineering and Rehabilitation*. This high-density array electroencephalograph study of the PoNS demonstrates brain activity changes following exposure to both the high and low frequency pulse versions of the PoNS device used in the Company's traumatic brain injury clinical trials.
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- On June 18, 2019, the Company provided an update on its strategy to resubmit an application for de novo clearance of its PoNS device with FDA. As part of its strategy, members of the Company's management participated in an informational discussion with FDA in June regarding the issues FDA raised in its April response letter. The Company has concluded that, while it will not finalize its resubmission protocol until after it engages with FDA in a pre-submission meeting, such a protocol will, at a minimum, need to include new data evaluating the effect of physical therapy alone, without use of the PoNS device. Additional data or analyses may also be required, subject to further input from FDA.

"We were pleased by our sales performance during the second quarter, which continues to reflect initial demand primarily from the first two Canadian clinics in Montreal and Surrey that are providing our PoNS Treatment to patients suffering from chronic balance disorder due to mild-to-moderate traumatic brain injury," said Philippe Deschamps, Chief Executive Officer of HeliUS. "In addition to our sales performance, we made important progress in advancing our commercial strategy in Canada during the second quarter, with three additional clinics authorized to provide our PoNS Treatment."

Mr. Deschamps continued: "In the United States, in connection with our pursuit of FDA clearance, we participated in an informational discussion with the Agency in June to clarify the results of prior interactions. Based on FDA's clarifications, in early August we submitted a request for a pre-submission meeting with the Agency focused on discussing our resubmission strategy to augment the clinical trial protocol of our registrational trial, TBI 001, in mmTBI, which is intended to support the resubmission of an application for de novo clearance of the PoNS device. We intend to finalize our resubmission protocol after engaging with FDA in this pre-submission meeting. Our resubmission strategy has been developed under the guidance of our expanded regulatory affairs team, which includes a regulatory counsel with extensive experience in de novo applications to the Neuromodulation division at FDA, a statistician who previously worked in a senior position at FDA for many years and several prominent clinical advisors. Additionally, we have also begun a data collection program to address questions regarding the relative contribution of physical therapy to the positive therapeutic outcomes of PoNS Treatment in our TBI trials."

"We are reaffirming our revenue guidance today based on the commercial progress we have made in Canada during the first half of 2019. Looking ahead to the balance of the year, we remain focused on expanding our commercial efforts in Canada by training and authorizing new clinics to administer our PoNS Treatment and raising awareness of its benefits, while working to obtain regulatory clearance in the United States, Australia and Europe in order to increase availability of this innovative therapy."

Second Quarter 2019 Financial Results

Revenue for the second quarter of 2019 was \$0.5 million. The Company's revenue was generated almost exclusively through sales of the PoNS device pursuant to supply agreements with two neuroplasticity clinics in Canada. The Company also generated \$49,000 in fee revenue from franchise agreements Heuro Canada, Inc. ("Heuro") executed with neuroplasticity clinics that have been engaged to provide the PoNS Treatment.

Gross profit for the second quarter of 2019 was \$0.3 million. Operating expenses for the second quarter of 2019 decreased 48% year-over-year, to \$6.1 million, compared to \$11.8 million in the second quarter of 2018. The year-over-year decrease in operating expenses in the second quarter was primarily driven by a decrease of \$5.0 million, or 57% year-over-year, in selling, general and administrative expenses. The decrease in selling, general and administrative expenses was primarily due to a \$5.2 million reduction in

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 second quarter of 2019 decreased approximately \$6.0 million, or 51% year-over-year, to \$5.8 million, compared to \$11.8 million in the second quarter of 2018.

Total other income for the second quarter of 2019 was \$5.6 million, compared an expense of \$6.0 million in the second quarter of 2018. 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 \$5.5 million for the second quarter of 2019, compared to a loss of \$6.2 million in the second 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 second quarter of 2019 was \$0.2 million, or \$(0.01) per basic and diluted common share, compared to a net loss of \$17.8 million, or \$(0.78) per basic and diluted common share, in the second quarter of 2018. Weighted average shares used to compute basic net loss per common share were 25.9 million and 22.9 million for the second quarters of 2019 and 2018, respectively. Weighted average shares used to compute diluted net income (loss) per common share were 25.9 million and 23.0 million for the second quarters of 2019 and 2018, respectively.

Six Months Ended June 30, 2019 Financial Results

Revenue for the six months ended June 30, 2019 was \$1.2 million. The Company's revenue was generated almost exclusively through sales of the PoNS device pursuant to supply agreements with two 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 six months ended June 30, 2019 was \$0.7 million. Operating expenses for the six months ended June 30, 2019 decreased \$3.1 million, or 19% year-over-year, to \$13.4 million, compared to \$16.5 million in the six months ended June 30, 2018. The decrease in operating expenses in the period was driven primarily by a decrease of \$2.6 million, or 24% year-over-year, in selling, general and administrative expenses. The decrease in selling, general and administrative expenses was primarily due to a \$4.8 million reduction in 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\$. This was partially offset by higher commercial operations expenses of \$2.2 million, including wages and salaries of \$0.6 million to support the Company's Canadian launch.

Operating loss for the six months ended June 30, 2019 decreased \$3.9 million, or 24% year-over-year, to \$12.6 million, compared to operating loss of \$16.5 million in the prior year period.

Total other income for the six months ended June 30, 2019 was \$13.8 million, compared to an expense of \$2.5 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 \$13.8 million for the six months ended June 30, 2019, compared to a loss of \$3.7 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 income for the six months ended June 30, 2019 was \$1.1 million, or \$0.04 per basic and diluted common share, compared to net loss of \$19.0 million, or \$(0.88) per basic common share and \$(0.90) per diluted common share, in the prior year period. Weighted average shares used to compute basic net income (loss) per share were 25.9 million and 21.6 million for the six months ended June 30, 2019 and 2018, respectively. Weighted average shares used to compute diluted net income (loss) per share were 26.0 million and 21.8 million for the six months ended June 30, 2019 and 2018, respectively.

As of June 30, 2019, the Company had cash of approximately \$14.3 million, compared to \$25.6 million at December 31, 2018. The Company had no debt outstanding at June 30, 2019.

The decrease in cash during the period was driven primarily by net cash used in operating activities of \$11.2 million and net cash used in investing activities of \$0.2 million, offset slightly by \$0.2 million of cash provided by financing activities.

Full Year 2019 Outlook

The Company today reaffirmed its revenue guidance for full year 2019. For the twelve months ending December 31, 2019, the Company continues to expect revenue in a range of \$1.6 million to \$2.0 million.

Conference Call

Management will host a conference call at 4:30 p.m. Eastern Time on August 8, 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 1354346. 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 1354346. 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 a licensed class II, noninvasive, medical device in Canada indicated for the treatment of chronic balance deficit due to mild-to-moderate traumatic brain injury when 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 by the EU Notified Body and 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, business and commercialization initiatives and objectives, the potential receipt of regulatory clearance of the PoNS device 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 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 June 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)

June 30, 2019

ASSETS		June 30, 2019
Current assets		
Cash	\$	14,31
Accounts receivable		72
Other receivables		29
Inventory		90
Prepaid expenses		30
Other current assets		-
Total current assets		16,52
Property and equipment, net		
71		71
Other assets		
Operating lease right-of-use asset, net		61
Non-current receivables		32
Other assets		1
Total other assets		95
TOTAL ASSETS	\$	18,19
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$	3,04
Accrued liabilities		1,37
Operating lease liability		15
Derivative financial instruments		28
Total current liabilities		4,86
Non-current liabilities		
Operating lease liability		55
TOTAL LIABILITIES		5,41
Commitments and contingencies		
STOCKHOLDERS' EQUITY		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding as of June 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 June 30, 2019 and December 31, 2018, respectively		2
Additional paid-in capital		107,43
Accumulated other comprehensive loss		(82)
Accumulated deficit		(93,85)
TOTAL STOCKHOLDERS' EQUITY		12,78
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$	18,19

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

	Three Months Ended		
	June 30,		
	2019	2018	2017
Revenue:			
Product sales, net	\$ 469	\$ —	\$ —
Fee revenue	49	—	—
Total operating revenue	518	—	—
Cost of sales:			
Cost of product sales	212	—	—
Gross profit	306	—	—
Operating expenses:			
Research and development	2,275	2,921	—
Selling, general and administrative	3,845	8,886	—
Total operating expenses	6,120	11,807	—
Operating loss	(5,814)	(11,807)	—
Other income (expense):			
Other income	13	1	—
Change in fair value of derivative financial instruments	5,548	(6,249)	—
Foreign exchange gain (loss)	67	229	—
Total other income (expense)	5,628	(6,019)	—
Net (loss) income	(186)	(17,826)	—
Other comprehensive (loss) income:			
Foreign currency translation adjustments	(124)	119	—
Comprehensive (loss) income	\$ (310)	\$ (17,707)	\$ —
Net (loss) income per share			
Basic	\$ (0.01)	\$ (0.78)	\$ —
Diluted	\$ (0.01)	\$ (0.78)	\$ —
Weighted average shares outstanding			
Basic	25,870,600	22,918,692	—
Diluted	25,870,600	23,045,565	—

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

Six

		2019
Cash flows from operating activities:		
Net income (loss)	\$	1,13
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Change in fair value of derivative financial instruments		(13,83)
Stock-based compensation expense		1,77
Unrealized foreign exchange loss (gain)		15
Depreciation expense		4
Changes in operating assets and liabilities:		
Accounts receivable		(54)
Other receivables		(20)
Inventory		(51)
Prepaid expenses		14
Other assets		26
Operating lease liability		(
Accounts payable		65
Accrued liabilities		(28)
Net cash used in operating activities		(11,21)
Cash flows from investing activities:		
Purchase of property and equipment		(20)
Net cash used in investing activities		(20)
Cash flows from financing activities:		
Proceeds from the issuance of common stock and accompanying warrants		-
Share issuance costs		(5)
Proceeds from the exercise of stock options and warrants		21
Net cash provided by financing activities		16
Effect of foreign exchange rate changes on cash		(1
Net (decrease) increase in cash		(11,27
Cash at beginning of period		25,58
Cash at end of period	\$	14,31

Investor Relations Contact:

Westwicke Partners on behalf of Helius Medical Technologies, Inc.

Mike Piccinino, CFA

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