

**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

May 9, 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))

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Class A Common stock	HSDT	The Nasdaq Stock Market LLC

Item 2.02**Results of Operations and Financial Condition.**

On May 9, 2019, Helius Medical Technologies, Inc. (the “**Registrant**”) issued a press release announcing its financial results for the quarter ended March 31, 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 May 9, 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: May 9, 2019

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



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

NEWTOWN, Pa., May 9, 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 first quarter ended March 31, 2019.

First Quarter 2019 Financial Summary

- Revenue of \$0.7 million, compared to no revenue in first quarter 2018.
- Operating loss of \$6.8 million, compared to operating loss of \$4.7 million in first quarter 2018.
- Net income of \$1.3 million, compared to net loss of \$1.2 million in first quarter 2018.

First Quarter and Recent Business Highlights

- On March 5, 2019, the Company announced the first patients in Canada have begun PoNS Treatment.
 - 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 and 510(k) clearance of the Portable Neuromodulation Stimulator (PoNS) device and declined the Company's request. In reaching its conclusion, the 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. The 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 our PoNS device in Australia.
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“This was an important quarter for Heliuss Medical Technologies, as it represents our first as a commercial-stage company,” said Philippe Deschamps, Chief Executive Officer of Heliuss. “Our team worked diligently to prepare for the commercialization of our PoNS Treatment in Canada, which enabled us to make the first commercial shipments of our PoNS device in February and March. Our first quarter sales performance benefitted from strong initial demand from two Canadian neuroplasticity clinics that began treating their first patients during the quarter.”

Mr. Deschamps continued: “While we were disappointed with the FDA’s recent decision regarding our PoNS device, our commercialization in Canada is off to a great start for the year and we are reaffirming our revenue guidance for 2019. Looking ahead, we will continue to expand our commercial efforts in Canada with the goal of providing relief to the more than 350,000 Canadians suffering from chronic balance deficit due to mild-to-moderate traumatic brain injury. Importantly, we also remain committed to securing regulatory clearance of our PoNS device in the U.S., Australia and Europe, in order to provide our innovative PoNS Treatment to as many patients as possible.”

First Quarter 2019 Financial Results

Revenue for the first quarter of 2019 was \$0.7 million, representing the first revenue from commercial sales of the PoNS device. The Company’s revenue was generated through sales of the PoNS device pursuant to supply agreements with two neuroplasticity clinics in Canada.

Operating expenses for the first quarter of 2019 increased 54% year-over-year, to \$7.3 million, compared to \$4.7 million in the first quarter of 2018. The year-over-year increase in operating expenses in the first quarter was driven by an increase of \$2.4 million, or 112% year-over-year, in selling, general and administrative expenses, which was primarily due to increased headcount and commercial operations expenses.

Operating loss for the first quarter of 2019 increased approximately \$2.1 million, or 45% year-over-year, to \$6.8 million, compared to \$4.7 million in the first quarter of 2018.

Total other income for the first quarter of 2019 increased \$4.6 million, or 129% year-over-year, to \$8.1 million, compared to \$3.6 million in the first 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 \$8.3 million for the first quarter of 2019, compared to a gain of \$2.5 million in the first 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 income for the first quarter of 2019 was \$1.3 million, or \$0.05 per basic common share, compared to a net loss of \$1.2 million, or \$(0.06) per basic common share, in the first quarter of 2018. Diluted loss per common share was \$(0.06) and \$(0.08) for the quarters ended March 31, 2019 and 2018, respectively. Weighted average shares used to compute basic net income (loss) per common share were 25.8 million and 20.3 million for the first quarters of 2019 and 2018, respectively. Weighted average shares used to compute diluted net loss per common share were 26.8 million and 20.5 million for the first quarters of 2019 and 2018, respectively.

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 May 9, 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 5261919. 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 5261919. 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 and the potential receipt of 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 clinical development process and the 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 March 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.

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

	March 31, 2019	December 31, 2018
ASSETS		
Current assets		
Cash	\$ 18,656	\$ 25,583
Accounts receivable	910	177
Other receivables	182	98
Inventory	731	392
Prepaid expenses	352	447
Other current assets	—	264
Total current assets	20,831	26,961
Property and equipment, net	693	554
Other assets		
Operating lease right-of-use asset, net	650	—
Non-current receivables	306	294
Other non-current assets	18	18
Total other assets	974	312
TOTAL ASSETS	\$ 22,498	\$ 27,827
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 2,474	\$ 2,392
Accrued liabilities	1,518	1,812
Operating lease liability	148	—
Derivative financial instruments	5,743	13,769
Total current liabilities	9,883	17,973
Non-current liabilities		
Operating lease liability	597	—
TOTAL LIABILITIES	10,480	17,973
Commitments and contingencies (Note 6)		
STOCKHOLDERS' EQUITY		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized, no shares issued and outstanding as of March 31, 2019 and December 31, 2018	—	—
Class A common stock, \$0.001 par value; 150,000,000 shares authorized; 25,844,180 and 25,827,860 shares issued and outstanding as of March 31, 2019 and December 31, 2018, respectively	26	26
Additional paid-in capital	106,363	105,411
Accumulated other comprehensive loss	(703)	(591)
Accumulated deficit	(93,668)	(94,992)
TOTAL STOCKHOLDERS' EQUITY	12,018	9,854
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 22,498	\$ 27,827

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

	Three Months Ended March 31,	
	2019	2018
Revenue:		
Product sales, net	\$ 677	\$ —
Cost of sales:		
Cost of product sales	236	—
Gross profit	441	—
Operating expenses:		
Research and development	2,681	2,552
Selling, general and administrative	4,581	2,165
Total operating expenses	7,262	4,717
Operating loss	(6,821)	(4,717)
Other income (expense):		
Other income	11	59
Change in fair value of derivative financial instruments	8,289	2,525
Foreign exchange gain (loss)	(155)	968
Total other income	8,145	3,552
Net income (loss)	1,324	(1,165)
Other comprehensive income (loss):		
Foreign currency translation adjustments	(112)	(953)
Comprehensive income (loss)	\$ 1,212	\$ (2,118)
Net income (loss) per share		
Basic	\$ 0.05	\$ (0.06)
Diluted	\$ (0.06)	\$ (0.08)
Weighted average shares outstanding		
Basic	25,832,190	20,334,929
Diluted	26,785,708	20,460,656

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

	Third Months Ended March 31,	
	2019	2018
Cash flows from operating activities:		
Net Income (loss)	\$ 1,324	\$ (1,165)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Change in fair value of derivative financial instruments	(8,289)	(2,525)
Stock-based compensation expense	835	387
Unrealized foreign exchange loss (gain)	176	(993)
Depreciation expense	22	10
Changes in operating assets and liabilities:		
Accounts receivable	(740)	—
Other receivables	(84)	7
Inventory	(339)	—
Prepaid expenses	95	94
Other current assets	264	(105)
Operating lease liability	(3)	—
Accounts payable	83	(886)
Accrued liabilities	(144)	316
Net cash used in operating activities	(6,800)	(4,860)
Cash flows from investing activities:		
Purchase of property and equipment	(161)	(27)
Net cash used in investing activities	(161)	(27)
Cash flows from financing activities:		
Share issuance costs	(52)	(73)
Proceeds from the exercise of stock options and warrants	92	3,753
Net cash provided by financing activities	40	3,680
Effect of foreign exchange rate changes on cash	(6)	40
Net decrease in cash	(6,927)	(1,167)
Cash at beginning of period	25,583	5,562
Cash at end of period	\$ 18,656	\$ 4,395

Investor Relations Contact:

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