

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

March 14, 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 240.14d2(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

Item 2.02 Results of Operations and Financial Condition.

On March 14, 2019, Helius Medical Technologies, Inc. (the “**Registrant**”) issued a press release announcing its financial results for the quarter and full year ended December 31, 2018, 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 March 14, 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: March 14, 2019

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

Helius Medical Technologies, Inc. Reports Fourth Quarter and Full Year 2018 Financial Results and Introduces Full Year 2019 Outlook

NEWTOWN, Pa., March 14, 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 fourth quarter and full year ended December 31, 2018.

Full Year 2018 Financial Summary

- Revenue of \$0.5 million, compared to no revenue in 2017.
- Operating loss of \$26.7 million, compared to operating loss of \$22.9 million in 2017.
- Net loss of \$28.6 million, compared to net loss of \$28.0 million in 2017.
- Cash of \$25.6 million as of December 31, 2018, compared to \$5.6 million as of December 31, 2017.

Fourth Quarter 2018 Financial Summary

- Revenue of \$0.5 million, compared to no revenue in fourth quarter 2017.
- Operating loss of \$5.3 million, compared to operating loss of \$5.9 million in fourth quarter 2017.
- Net loss of \$5.1 million, compared to net loss of \$3.7 million in fourth quarter 2017.

Fourth Quarter Highlights

- On October 2, 2018, the Company announced it entered into a strategic alliance agreement with Health Tech Connex, Inc. and Heuro Canada Inc., to develop and manage neuroplasticity clinics in Canada.
 - On October 22, 2018, the Company announced it received authorization from Health Canada to market its PoNS device as a Class II medical device in Canada. The Health Canada Medical Device License certifies that the PoNS device meets all Canadian safety, effectiveness, and quality requirements. The Company may now market its PoNS Treatment as an adjunct to physical therapy for chronic balance deficit in patients with mild-to-moderate traumatic brain injury ("mmTBI").
 - On October 24, 2018, the Company announced it partnered with Northwell Health's Feinstein Institute for Medical Research in Manhasset, New York. This partnership enabled the Company to implement its second Clinical Experience Program ("CEP") for its PoNS Treatment.
 - In November 2018, the Company completed an underwritten public offering of 2,439,394 shares of its Class A common stock at a public offering price of \$8.25 per share, raising net proceeds of approximately \$18.3 million. BTIG, LLC and Oppenheimer & Co. Inc. acted as joint book-running managers for the offering, and Haywood Securities Inc. acted as a co-manager for the offering.
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- On December 12, 2018, the Company announced that it submitted an application for a CE Mark.

Highlights Subsequent to Year-End

- On January 3, 2019, the Company announced it partnered with Oregon Health & Science University (OHSU) in Oregon and with Kessler Institute for Rehabilitation and Kessler Foundation in New Jersey to launch its third and fourth CEPs for its PoNS Treatment. Subsequently, the Company entered its fifth CEP partnership with Baylor Research Institute in Dallas, Texas.
- On January 25, 2019, the Company announced it received a request for additional information letter from the U.S. Food and Drug Administration (FDA) related to the Company's request for de novo classification and 510(k) clearance of the PoNS device. The Company submitted its response to the information requested by the FDA, which the Company expects will enable the FDA to resume its review.
- On March 5, 2019, the Company announced the first patients in Canada have begun PoNS Treatment.

"2018 was an incredibly productive year for Heliu," said Philippe Deschamps, Chief Executive Officer of Heliu. "Among our most important accomplishments this year, we submitted our PoNS device for regulatory clearance and marketing authorization in the U.S. and Canada, the two primary markets where Heliu is initially focused, as well as in the European Union. In Canada, we received a Medical Device License allowing us to market PoNS Treatment to patients with chronic balance deficit due to mmTBI. Following this important regulatory milestone, we continued our rapid pace of progress during the fourth quarter by establishing the requisite support systems and agreements that enabled us to treat our first Canadian patients earlier this month, which marked our transition to a commercial-stage company."

Mr. Deschamps continued: "In 2019, we will continue to advance through the initial stages of our commercialization in Canada, with the ultimate goal of addressing the substantial opportunity that exists in this market of more than 350,000 Canadians suffering from chronic balance deficit due to mmTBI. I'm also pleased to announce that we have submitted our response to the additional information requested by the FDA. We will continue to work closely with the FDA to facilitate its review of our submission for de novo classification and 510(k) clearance of the PoNS device. We look forward to a year of continued progress and exciting new developments as we bring our PoNS Treatment to the aid of patients whose lives have been impacted by the effects of traumatic brain injury."

Fourth Quarter 2018 Financial Results

Revenue for the fourth quarter of 2018 was \$0.5 million, which represents the Company's first revenue since its inception. In the fourth quarter of 2018, Company recognized license fee revenue of \$0.5 million in connection with the satisfaction of its performance obligation related to the strategic alliance agreement with Health Tech Connex, Inc. and Heuro Canada, Inc.

Operating expenses for the fourth quarter of 2018 decreased 2% year-over-year, to \$5.7 million, compared to \$5.9 million in the fourth quarter of 2017. The year-over-year decrease in operating expenses in the fourth quarter was driven by a decrease of \$1.1 million, or 34% year-over-year, in research and development expenses, which was due to reduced product development costs. The year-over-year decrease in research and development expenses was offset almost entirely by an increase of \$1.0 million, or 38% year-over-

year, in general and administrative expenses, primarily due to increased expenses related to the buildout of the Company's commercial operations infrastructure.

Operating loss for the fourth quarter of 2018 decreased approximately \$0.6 million, or 10% year-over-year, to \$5.3 million, compared to \$5.9 million in the fourth quarter of 2017.

Total other expense for the fourth quarter of 2018 decreased \$2.0 million, or 93% year-over-year, to \$0.1 million, compared to \$2.1 million in the fourth quarter of 2017. The year-over-year decrease in total other expense was driven primarily by the change in fair value of derivative financial instruments, which was a loss of \$0.2 million for the fourth quarter of 2018, compared to a gain of \$2.0 million in the fourth quarter of 2017. 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 fourth quarter of 2018 increased \$1.4 million, or 37% year-over-year, to \$5.1 million, or \$0.21 per basic common share, compared to net loss of \$3.7 million, or \$0.19 per basic common share, in the fourth quarter of 2017. Diluted loss per common share was \$0.22 and \$0.26 for the quarters ended December 31, 2018 and 2017, respectively. Weighted average shares used to compute basic net loss per common share were 24.5 million and 19.4 million for the fourth quarters of 2018 and 2017, respectively. Weighted average shares used to compute diluted net loss per common share were 24.8 million and 19.9 million for the fourth quarters of 2018 and 2017, respectively.

Full Year 2018 Financial Results

Revenue for the full year ended December 31, 2018 was \$0.5 million, which represents the Company's first revenue since its inception. In 2018, the Company recognized license fee revenue of \$0.5 million in connection with the satisfaction of its performance obligation related to the strategic alliance with Health Tech Connex, Inc. and Heuro Canada, Inc.

Operating expenses for the full year ended December 31, 2018 increased \$4.3 million, or 19% year-over-year, to \$27.2 million, compared to \$22.9 million for the full year ended December 31, 2017. The increase in operating expenses in the period was driven primarily by an increase of \$8.7 million, or 103% year-over-year, in general and administrative expenses. The increase in general and administrative expenses was largely due to higher stock-based compensation expense, which was primarily the result of the change in the Company's functional currency. The increase in general and administrative expenses was also driven, in part, by increased expenses related to the buildout of the Company's commercial operations infrastructure and higher headcount compared to the prior year period. The year-over-year increase in operating expenses was offset partially by a decrease of \$4.4 million, or 31% year-over-year, in research and development expenses, primarily due to reduced clinical trial and product development expenses.

Operating loss for the full year ended December 31, 2018 increased \$3.8 million, or 17% year-over-year, to \$26.7 million, compared to operating loss of \$22.9 million in the prior year period.

Total other expense for the full year ended December 31, 2018 decreased \$3.2 million, or 62% year-over-year, to \$1.9 million, compared to \$5.2 million in the prior year period. The year-over-year decrease in total other expense was driven primarily by the change in foreign exchange gain (loss), which resulted in a gain of \$1.6 million for the full year ended December 31, 2018, compared to a loss of \$1.7 million in the prior year period.

Net loss for the full year ended December 31, 2018 increased approximately \$0.6 million, or 2% year-over-year, to \$28.6 million, or \$1.26 per basic and diluted common share, compared to net loss of \$28.0 million, or \$1.50 per basic and diluted common share, in the prior year period. Weighted average shares used to compute net loss per basic and diluted common share were 22.8 million and 18.6 million for the full years ended December 31, 2018 and 2017, respectively.

As of December 31, 2018, the Company had cash of approximately \$25.6 million, compared to \$5.6 million at December 31, 2017. The Company had no outstanding debt at December 31, 2018 and 2017.

Full Year 2019 Outlook

For the twelve months ending December 31, 2019, the Company expects total 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 March 14, 2019 to discuss the results of the quarter and the full year. Those who would like to participate may dial 866-393-4306 (734-385-2616 for international callers) and provide access code 8929969. 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 855-859-2056 (404-537-3406 for international callers); access code 8929969. 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 and the European Union ("EU"), and it is currently under review for clearance by the FDA and EU Notified Body. PoNS Treatment is currently not commercially available in the United States or the European Union.

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 projected financial results, the success of the Company’s commercial launch in Canada, expected future development timelines, regulatory approvals, 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 commercial launch of a new therapeutic treatment, 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 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.
Consolidated Balance Sheets
(Except for share data, amounts in thousands)

	As of December 31,	
	2018	2017
ASSETS		
Current assets		
Cash	\$ 25,583	\$ 5,562
Receivables	275	704
Inventory	392	—
Prepaid expenses	447	352
Other current assets	264	—
Total current assets	26,961	6,618
Property and equipment, net	554	173
Other assets		
Non-current receivables	294	—
Other non-currents assets	18	18
Total other assets	312	18
TOTAL ASSETS	\$ 27,827	\$ 6,809
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities		
Accounts payable	\$ 2,392	\$ 3,479
Accrued liabilities	1,812	1,242
Derivative financial instruments	13,769	9,578
Total current liabilities	17,973	14,299
TOTAL LIABILITIES	17,973	14,299
Commitments and contingencies (Note 7)		
STOCKHOLDERS' EQUITY (DEFICIT)		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized, 0 shares issued and outstanding as of December 31, 2018; no preferred stock authorized as of December 31, 2017	—	—
Class A common stock, \$0.001 par value; 150,000,000 shares authorized; 25,827,860 shares issued and outstanding as of December 31, 2018	26	—
Common stock (Unlimited Class A common shares authorized); 20,178,226 shares issued and outstanding as of December 31, 2017	—	52,230
Additional paid-in capital	105,411	6,602
Accumulated other comprehensive income (loss)	(591)	47
Accumulated deficit	(94,992)	(66,369)
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	9,854	(7,490)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	\$ 27,827	\$ 6,809

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

	Three Months Ended			20
	December 31,			
	2018	2017	Unaudited	
Revenue:				
License revenue	\$ 478	\$ -	\$	
Operating expenses:				
Research and development	2,159	3,266		
General and administrative	3,582	2,604		
Total operating expenses	5,741	5,870		
Operating loss	(5,263)	(5,870)		
Other income (expense):				
Other income	—	—		
Change in fair value of derivative financial instruments	(221)	2,009		
Foreign exchange gain (loss)	368	132		
Total other income (expense)	147	2,141		
Net loss	(5,116)	(3,729)		
Other comprehensive (loss) gain:				
Foreign currency translation adjustments	292	(141)		
Comprehensive loss	\$ (4,824)	\$ (3,870)	\$	
Net loss per share				
Basic	\$ (0.21)	\$ (0.19)	\$	
Diluted	\$ (0.22)	\$ (0.26)	\$	
Weighted average shares outstanding				
Basic	24,461,357	19,416,708		
Diluted	24,826,566	19,948,971		

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

	Year Ended December 31,	
	2018	2017
Cash flows from operating activities		
Net loss	\$ (28,623)	\$ (28,024)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	59	17
Change in fair value of derivative financial instruments	3,577	3,443
Stock-based compensation expense	8,095	1,818
Unrealized foreign exchange (gain) loss	(1,711)	1,585
Changes in operating assets and liabilities:		
Receivables	135	(479)
Prepaid expenses	(95)	186
Inventory	(392)	—
Other assets	(264)	—
Account payable	(1,087)	1,318
Accrued liabilities	685	811
Net cash used in operating activities	(19,621)	(19,325)
Cash flows from investing activities		
Purchase of property and equipment	(440)	(190)
Net cash used in investing activities	(440)	(190)
Cash flows from financing activities		
Proceeds from the issuances of common stock and warrants	38,526	20,878
Share issuance costs	(3,161)	(1,248)
Proceeds from the exercise of stock options and warrants	4,663	2,588
Net cash provided by financing activities	40,028	22,218
Effect of foreign exchange rate changes on cash	54	190
Net increase in cash	20,021	2,893
Cash at beginning of year	5,562	2,669
Cash at end of year	\$ 25,583	\$ 5,562
Supplemental disclosure of non-cash cash activities		
Cash paid for interest	\$ —	\$ —
Cash paid for income taxes	—	—
Supplemental schedule of non-cash investing and financing activities		
Share issuance costs included in accounts payable and accrued liabilities	\$ 52	\$ 73

Investor Relations Contact:

Westwicke Partners on behalf of Helius Medical Technologies, Inc.

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