

**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 8, 2018

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 November 8, 2018, Helius Medical Technologies, Inc. (the “**Registrant**”) issued a press release announcing its financial results for the quarter and nine months ended September 30, 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

<u>Exhibit Number</u>	<u>Exhibit Description</u>
99.1	Press Release, dated November 8, 2018

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 hereunto duly authorized.

HELIUS MEDICAL TECHNOLOGIES, INC.

By: /s/ Joyce LaViscount

Joyce LaViscount
Chief Financial Officer

Date: November 8, 2018



Helius Medical Technologies, Inc. Reports Third Quarter 2018 Financial Results

NEWTOWN, Pa., November 8, 2018 (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 third quarter and nine months ended September 30, 2018.

Third Quarter 2018 Financial Summary

- Operating loss of \$4.9 million, compared to operating loss of \$6.0 million in third quarter 2017.
- Net loss of \$4.5 million, compared to net loss of \$12.9 million in third quarter 2017.
- Cash of \$12.4 million as of September 30, 2018, compared to \$5.6 million as of December 31, 2017.

Third Quarter Highlights

- Effective July 9, 2018, the Company appointed Jennifer Laux as Chief Commercial Officer. Ms. Laux brings to Helius extensive experience in leading successful global commercialization strategies and new product launches.
- On September 4, 2018, the Company announced the submission of its request to the U.S. Food and Drug Administration ("FDA") for de novo classification and 510(k) clearance of the Portable Neuromodulation Stimulator (PoNS™), an investigational medical device. The Company is pursuing de novo classification and 510(k) clearance of the PoNS device for the treatment of balance deficit due to mild- to moderate traumatic brain injury ("TBI").
- On September 19, 2018, the Company announced that it has partnered with The Ohio State University Wexner Medical Center, a leading U.S. neurorehabilitation center located in Columbus, Ohio, to establish its first Clinical Experience Program for the PoNS Treatment.

Highlights Subsequent to Quarter End

- On October 2, 2018, the Company announced it has entered into an agreement with HealthTech Connex, Inc. to develop and manage neuroplasticity clinics in Canada.
 - On October 22, 2018, the Company announced that its wholly owned subsidiary, NeuroHabilitation Corporation, received authorization from Health Canada to market its PoNS device, 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 balance deficit in patients with mild-to-moderate TBI.
 - On October 24, 2018, the Company announced that its wholly owned subsidiary, NeuroHabilitation Corporation, has partnered with Northwell Health's Feinstein Institute for Medical Research in
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- Manhasset, New York. This partnership will enable the Company to implement its second Clinical Experience Program for its investigational PoNS Treatment.

“During the third quarter, Heliuss made exciting progress on our regulatory strategy with the goal of bringing our innovative PoNS Treatment to market for the treatment of balance deficit in patients with mild-to-moderate TBI,” said Heliuss’ CEO, Philippe Deschamps. “Most importantly, we submitted our request for de novo classification and 510(k) clearance of our PoNS device to the FDA and submitted an application to Health Canada for a Class II Medical Device License. We received our Health Canada Class II Medical Device License in October 2018, enabling us to market the PoNS device as an adjunct to physical therapy for balance deficit in patients with mild-to-moderate TBI.”

Mr. Deschamps continued, “In tandem with our regulatory strategy, we are focused on key activities to prepare for the launch of our PoNS Treatment, including the establishment of our commercial infrastructure in Canada and the pursuit of our pre-regulatory clearance activities in the U.S. By executing on these key activities, we aim to bring our innovative PoNS Treatment to market as efficiently and effectively as possible, improve the lives of patients and their loved ones and address the large global unmet need for balance deficit due to TBI in addition to delivering long-term value to our shareholders.”

Third Quarter 2018 Financial Results

Operating expenses for the third quarter of 2018 decreased \$1.1 million, or 18% year-over-year, to \$4.9 million, compared to \$6.0 million in the third quarter of 2017. The year-over-year decrease in operating expenses in the third quarter was driven by a decrease of \$1.5 million, or 39% year-over-year, in research and development expenses, due to reduced clinical trial expenses and product development costs, offset partially by an increase of \$0.4 million, or 19% year-over-year, in general and administrative expenses, primarily due to higher wages and salaries as well as increased consulting expenses relating to the Company’s commercial infrastructure build out.

Operating loss for the third quarter of 2018 decreased \$1.1 million, or 18% year-over-year, to \$4.9 million, compared to \$6.0 million in the third quarter of 2017.

Total other income (expense) for the third quarter of 2018 increased \$7.3 million year-over-year to an income of \$0.4 million, compared to an expense of \$7.0 million in the third quarter of 2017. The year-over-year increase in total other income (expense) was driven primarily by the change in fair value of derivative financial instruments, which was a gain of \$0.4 million for the third quarter of 2018, compared to a loss of \$6.0 million in the third quarter of 2017. The change in fair value of the Company’s derivative financial instruments was primarily attributable to the change in our stock price, volatility and the number of derivative financial instruments being measured during the period, as the Company reclassified non-employee stock options previously recorded as derivative financial instruments to equity.

The increase in total other income (expense) was also driven by the change in foreign exchange gain (loss), which resulted in a gain of \$1,000 for the third quarter of 2018, compared to a loss of \$1.0 million in the third quarter of 2017. The change in foreign exchange gain (loss) was primarily due to the amount of Canadian dollars held at the end of each reporting period, coupled with the change in the Company’s functional currency from the Canadian Dollar to the U.S. Dollar. The change in functional currency was accounted for prospectively from April 1, 2018 and financial statements prior to and including the period ended March 31, 2018 have not been restated for the change in functional currency.

Net loss for the third quarter of 2018 decreased \$8.4 million, or 65% year-over-year, to \$4.5 million, or \$0.19 per basic and diluted common share, compared to net loss of \$12.9 million, or \$0.67 per basic and diluted common share, in the third quarter of 2017. Weighted average shares used to compute basic net loss per share were 23.4 million and 19.2 million for the third quarters of 2018 and 2017, respectively. Weighted average shares used to compute diluted net loss per share were 23.8 million and 19.2 million for the third quarters of 2018 and 2017, respectively.

Nine Months 2018 Financial Results

Operating expenses for the nine months ended September 30, 2018 increased \$4.4 million, or 26% year-over-year, to \$21.4 million, compared to \$17.0 million in the nine months ended September 30, 2017. The increase in operating expenses in the period was driven primarily by an increase of \$7.8 million, or 133% 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, along with increased legal and other professional services expenses. The year-over-year increase in operating expenses was offset partially by a decrease of \$3.3 million, or 30% year-over-year, in research and development expenses, primarily due to reduced clinical trial expenses.

Operating loss for the nine months ended September 30, 2018 increased \$4.4 million, or 26% year-over-year, to \$21.4 million, compared to operating loss of \$17.0 million in the prior year period.

Total other expense for the nine months ended September 30, 2018 decreased \$5.2 million, or 71% year-over-year, to \$2.1 million, compared to \$7.3 million in the prior year period. 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 \$3.4 million for the nine months ended September 30, 2018, compared to a loss of \$5.5 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 our stock price, volatility and the number of derivative financial instruments being measured during the period. The year-over-year decrease in total other expense was also driven by the change in foreign exchange gain (loss), which resulted in a gain of \$1.2 million for the nine months ended September 30, 2018, compared to a loss of \$1.9 million in the prior year period.

Net loss for the nine months ended September 30, 2018 decreased approximately \$0.8 million, or 3% year-over-year, to \$23.5 million, or \$1.06 per basic and diluted common share, compared to net loss of \$24.3 million, or \$1.32 per basic and diluted common share, in the prior year period. Weighted average shares used to compute basic and diluted net loss per share were 22.2 million and 18.4 million for the nine months ended September 30, 2018 and 2017, respectively.

As of September 30, 2018, the Company had cash of approximately \$12.4 million, compared to \$5.6 million at December 31, 2017. The Company had no debt outstanding at September 30, 2018.

The increase in cash during the period was driven primarily by \$21.7 million of cash provided by financing activities, which was comprised of \$17.1 million in net proceeds received in connection with the sale of common stock and accompanying warrants in a public offering in April 2018 and \$4.6 million in proceeds from the exercise of stock options and warrants. The increase in cash during the period was partially offset by net cash used in operating activities of \$14.5 million and net cash used in investing activities of \$0.4 million.

Conference Call

Management will host a conference call at 4:30 p.m. Eastern Time on November 8 to discuss the results of the quarter. Those who would like to participate may dial 866-393-4306 (734-385-2616 for international callers) and provide access code 6767726. 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 6767726. 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 (PoNS). For more information, visit www.heliusmedical.com.

About the PoNS Device and PoNS Treatment

The Portable Neuromodulation Stimulator (PoNS) is an investigational, non-invasive, medical device in the US currently under review by the US Food & Drug Administration for clearance to improve balance in patients following a mild-to-moderate traumatic brain injury (mTBI) when combined with targeted physical therapy. PoNS is currently not commercially available in the US. PoNS is a licensed class II medical device in Canada.

PoNS Treatment is the first and only tongue-delivered neuromodulation that combines stimulation of cranial nerves with physical and cognitive therapy to restore lost neurological function. The Company's trials investigating the PoNS in traumatic brain injury are more fully discussed in the Company's disclosure materials, including its Annual Report on Form 10-K and other filings with the United States Securities and Exchange Commission.

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. Such forward-looking statements include, among others, statements regarding the potential regulatory approval and commercial launch of the PoNS Treatment.

Forward-looking statements are often identified by terms such as "believe", "will", "may", "should", "anticipate", "expects", "estimate", "intend" and similar expressions.

There can be no assurance that such statements will prove to be accurate and actual results and future events could differ materially from those anticipated in such statements. Important factors that could cause actual results to differ materially from the Company's expectations include the uncertainties

associated with the FDA regulatory submission and approval process, including the possibility that the FDA may not find the Company's regulatory submission sufficient to support clearance, the process of negotiating with rehabilitation centers to implement CEPs, the uncertainty of the health outcomes data to be generated by the CEPs, uncertainties associated with commercial contracting process, the Company's need to raise additional capital to achieve its business objectives and other risks detailed from time to time in the filings made by the Company with securities regulators.

The reader is cautioned that assumptions used in the preparation of any forward-looking statements may prove to be incorrect. Events or circumstances may cause actual results to differ materially from those predicted, as a result of numerous known and unknown risks, uncertainties, and other factors, many of which are beyond the control of the Company. The reader is cautioned not to place undue reliance on any forward-looking statement. Such information, although considered reasonable by management at the time of preparation, may prove to be incorrect and actual results may differ materially from those anticipated. Forward-looking statements contained in this news release are expressly qualified by this cautionary statement. Risks and uncertainties about the Company's business are more fully discussed in the Company's disclosure materials, including its Annual Report on Form 10-K for the year ended December 31, 2017, its Quarterly Report on Form 10-Q for the quarter ended September 30, 2018 and its other filings with the United States Securities and Exchange Commission and the Canadian securities regulators and which can be obtained from either at www.sec.gov or www.sedar.com.

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 Condensed Consolidated Balance Sheets
(Except for share data, amounts in thousands)

	September 30, 2018	December 31, 2017
ASSETS		
Current assets		
Cash	\$ 12,397	\$ 5,562
Receivables	41	704
Inventory	197	—
Prepaid expenses	100	352
Total current assets	12,735	6,618
Property and equipment, net	558	173
Other assets	18	18
TOTAL ASSETS	\$ 13,311	\$ 6,809
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities		
Accounts payable	\$ 2,186	\$ 3,479
Accrued liabilities	1,304	1,242
Derivative financial instruments	14,278	9,578
Total current liabilities	17,768	14,299
TOTAL LIABILITIES	17,768	14,299
Commitments and contingencies		
STOCKHOLDERS' DEFICIT		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized as of September 30, 2018; no preferred stock authorized as of December 31, 2017	—	—
Class A common stock, \$0.001 par value; 150,000,000 shares authorized; 23,378,246 shares issued and outstanding as of September 30, 2018	23	—
Class A common stock, no par value; unlimited shares authorized; 20,178,226 shares issued and outstanding as of December 31, 2017	—	52,230
Additional paid-in capital	86,280	6,602
Accumulated other comprehensive (loss) income	(883)	47
Accumulated deficit	(89,877)	(66,369)
TOTAL STOCKHOLDERS' DEFICIT	(4,457)	(7,490)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	\$ 13,311	\$ 6,809

Helius Medical Technologies, Inc.
Unaudited Condensed 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,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	\$ 2,309	\$ 3,798	\$ 7,781	\$ 11,121
General and administrative	2,581	2,172	13,632	5,862
Total operating expenses	<u>4,890</u>	<u>5,970</u>	<u>21,413</u>	<u>16,983</u>
Operating loss	<u>(4,890)</u>	<u>(5,970)</u>	<u>(21,413)</u>	<u>(16,983)</u>
Other income (expense):				
Other income	4	—	63	—
Change in fair value of derivative financial instruments	368	(5,960)	(3,356)	(5,452)
Foreign exchange gain (loss)	1	(1,008)	1,198	(1,860)
Total other income (expense)	<u>373</u>	<u>(6,968)</u>	<u>(2,095)</u>	<u>(7,312)</u>
Net loss	<u>(4,517)</u>	<u>(12,938)</u>	<u>(23,508)</u>	<u>(24,295)</u>
Other comprehensive loss:				
Foreign currency translation adjustments	(96)	1,266	(930)	1,916
Comprehensive loss	<u>\$ (4,613)</u>	<u>\$ (11,672)</u>	<u>\$ (24,438)</u>	<u>\$ (22,379)</u>
Net loss per share				
Basic	<u>\$ (0.19)</u>	<u>\$ (0.67)</u>	<u>\$ (1.06)</u>	<u>\$ (1.32)</u>
Diluted	<u>\$ (0.19)</u>	<u>\$ (0.67)</u>	<u>\$ (1.06)</u>	<u>\$ (1.32)</u>
Weighted average shares outstanding				
Basic	<u>23,377,941</u>	<u>19,225,057</u>	<u>22,221,667</u>	<u>18,368,973</u>
Diluted	<u>23,845,498</u>	<u>19,225,057</u>	<u>22,221,667</u>	<u>18,368,973</u>

Helius Medical Technologies, Inc.
Condensed Consolidated Statements of Cash Flows
(unaudited)

	Nine Months Ended September 30,	
	2018	2017
Cash flows from operating activities:		
Net loss	\$ (23,508)	\$ (24,295)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of derivative financial instruments	3,356	5,452
Stock-based compensation expense	7,245	1,464
Unrealized foreign exchange (gain) loss	(1,262)	1,758
Depreciation expense	40	7
Changes in operating assets and liabilities:		
Receivables	663	(530)
Inventory	(197)	—
Prepaid expenses	252	366
Other assets	—	(18)
Accounts payable	(1,274)	1,471
Accrued liabilities	209	86
Net cash used in operating activities	(14,476)	(14,239)
Cash flows from investing activities:		
Purchase of property and equipment	(425)	(181)
Net cash used in investing activities	(425)	(181)
Cash flows from financing activities:		
Proceeds from the issuance of common stock and accompanying warrants	18,400	14,547
Share issuance costs	(1,345)	(1,248)
Proceeds from the exercise of stock options and warrants	4,637	911
Net cash provided by financing activities	21,692	14,210
Effect of foreign exchange rate changes on cash	44	158
Net increase (decrease) in cash	6,835	(52)
Cash at beginning of period	5,562	2,669
Cash at end of period	\$ 12,397	\$ 2,617

Investor Relations Contact:

Westwicke Partners on behalf of Helius Medical Technologies, Inc.
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