

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

Date of Report (Date of earliest event reported): November 12, 2020



**HELIUS MEDICAL TECHNOLOGIES, INC.**

(Exact name of Registrant as Specified in Its Charter)

**DELAWARE**  
(State or Other Jurisdiction  
of Incorporation)

**001-38445**  
(Commission File Number)

**36-4787690**  
(IRS Employer  
Identification No.)

**642 Newtown Yardley Road, Suite 100**  
**Newtown, PA**  
(Address of Principal Executive Offices)

**18940**  
(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 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
<b>Common Stock</b>	<b>HSDT</b>	<b>The Nasdaq Stock Market LLC</b>

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, 2020, Helius Medical Technologies, Inc. (the “**Registrant**”) issued a press release announcing its financial results for the quarter ended September 30, 2020, 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 9.01****Financial Statements and Exhibits.****(d) Exhibits**

<b>Exhibit Number</b>	<b>Exhibit Description</b>
99.1	<a href="#">Press Release, dated November 12, 2020.</a>

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**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, 2020

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



## **Helius Medical Technologies, Inc. Reports Third Quarter of Fiscal Year 2020 Financial Results**

NEWTOWN, Pa., November 12, 2020 (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, 2020.

### **Third Quarter and Recent Business Updates**

- The Company made a leadership change by appointing Dane C. Andreeff to the position of Interim President and Chief Executive Officer ("CEO"), and Blane Walter as Chairman of the Board of Directors. These moves followed the departure of Philippe Deschamps from his role as President, CEO and Chairman of the Board of Directors.
  - Following the receipt of Breakthrough Designation earlier this year, the Company submitted a request to the U.S. Food and Drug Administration ("FDA") for de novo classification and clearance of the Portable Neuromodulation Stimulator (PoNS™) device as a potential treatment for gait deficit due to symptoms of Multiple Sclerosis ("MS"). The Company received a request for additional information from the FDA which includes requests for additional analysis of clinical data and proposes certain labeling modifications.
  - Subsequent to quarter-end the Company closed a private placement for total gross proceeds of approximately \$3.4 million led by a syndicate consisting of current members of the management team and other current investors which the Company expects will be sufficient to fund our operations throughout most of the first quarter of 2021.
  - The Company expanded its authorized clinic network to a total of 27 Authorized PoNS Treatment™ Clinic locations spanning across Canada, up from 7 clinics at the beginning of the year.
  - The Company announced the publication of an important study, titled *Translingual Neural Stimulation with the Portable Neuromodulation Stimulator (PoNS™) Induces Structural Changes Leading to Functional Recovery in Patients with Mild-to-Moderate Traumatic Brain Injury*, in the peer-reviewed journal, EMJ Radiology.
  - The putative shareholder class action lawsuit against the Company in the Southern District of New York was dismissed without prejudice in July 2020.
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### **Third Quarter 2020 Financial Summary**

- Revenue of \$131 thousand, compared to revenue of \$150 thousand in third quarter of 2019.
- Operating loss of \$3.7 million, compared to operating loss of \$5.7 million in third quarter of 2019.
- Net loss of \$3.5 million, compared to net loss of \$5.6 million in third quarter of 2019.
- As of September 30, 2020, the Company had cash of \$2.7 million, compared to \$5.5 million at December 31, 2019. The Company had no debt outstanding at September 30, 2020.

“I’m very pleased by our team’s performance during the third quarter, especially given the challenging environment created by the COVID pandemic,” said Dane Andreeff, Interim President and Chief Executive Officer of Helius. “We continued to make strong progress in our strategy to obtain regulatory clearance in the U.S. and submitted our request for de novo classification and clearance to the FDA on August 4th. We look forward to working with the FDA within the context of our Breakthrough Device Designation to facilitate the review of our PoNS device, with the goal of making it available to the estimated 1 million U.S. MS patients as quickly as possible. While our sales performance in Canada continued to be impacted by the disruption due to COVID, our commercial team has done an impressive job of engaging and training Canadian clinics to provide PoNS Treatment, expanding our network to a total of 27 PoNS authorized clinics as of last week.”

“Looking ahead, Helius remains committed to driving continued progress with respect to the two primary aspects of our near-term strategy: pursuing regulatory clearance in the U.S. and advancing our commercialization in the Canadian market. By focusing on these priorities, and continuing to operate as efficiently as possible, we believe we are pursuing the best course to benefit our customers, patients and shareholders. We look forward to building on our recent successes and facilitating awareness, accessibility and adoption of our revolutionary PoNS Treatment to bring 2020 to a strong close.”

### **Third Quarter 2020 Financial Results**

Total revenue for the third quarter of 2020 was \$131 thousand, compared to \$150 thousand in the third quarter of 2019. Product sales represented approximately 95% of total revenue in the third quarter of 2020 compared to 100% of total revenue in the third quarter of 2019. Product sales in both periods were generated through sales of the PoNS device pursuant to supply agreements with PoNS Authorized clinic locations in Canada. License and fee revenue represented 5% of sales in the third quarter of 2020, compared to 0% of sales in the third quarter of 2019.

Gross profit for the third quarter of 2020 was \$109 thousand, compared to gross profit of \$61 thousand in the third quarter of 2019. Operating expenses for the third quarter of 2020 decreased \$2.0 million, or 35% year-over-year, to \$3.8 million, compared to \$5.8 million in the third quarter of 2019.

Operating loss for the third quarter of 2020 decreased \$2.1 million, or 36% year-over-year, to \$3.7 million, compared to \$5.7 million in the third quarter of 2019.

Total other income for the third quarter of 2020 was \$183 thousand, compared to \$148 thousand in the third quarter of 2019.

Net loss for the third quarter of 2020 was \$3.5 million, or \$(0.08) per basic and diluted common share, compared to a net loss of \$5.6 million, or \$(0.22) per basic and diluted common share, in the third quarter

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of 2019. Weighted average shares used to compute basic and diluted net loss per common share were 45.1 million and 25.9 million for the third quarters of 2020 and 2019, respectively.

### **Nine Months Ended September 30, 2020 Financial Results**

Total revenue for the nine months ended September 30, 2020 was \$0.5 million, compared to \$1.3 million in the prior year period. Product sales represented 94% of total revenue for the nine months ended September 30, 2020, compared to 96% of total revenue in the prior year period. Product sales in both periods were generated through sales of the PoNS device pursuant to supply agreements with PoNS Authorized clinic locations in Canada. License and fee revenue represented 6% of total revenue for the nine months ended September 30, 2020, compared to 4% of total revenue in the prior year period.

Gross profit for the nine months ended September 30, 2020 was \$0.3 million, compared to gross profit of \$0.8 million in the prior year period. Operating expenses for the nine months ended September 30, 2020 decreased \$7.5 million, or 39% year-over-year, to \$11.7 million, compared to \$19.2 million in the prior year period.

Operating loss the nine months ended September 30, 2020 decreased \$7.0 million, or 38% year-over-year, to \$11.4 million, compared to operating loss of \$18.4 million in the prior year period.

Total other expense for the nine months ended September 30, 2020 was \$211 thousand, compared to \$13.9 million of other income in the prior year period. The year-over-year change is driven primarily by the change in fair value of derivative instruments which is primarily attributable to the change in our stock price, volatility and the number of derivative financial instruments being measured during the period.

Net loss for the nine months ended September 30, 2020 was \$11.6 million, or \$(0.30) per basic and diluted common share, compared to net loss of \$4.5 million, or \$(0.17) 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 39.2 million and 25.9 million for the nine months ended September 30, 2020 and 2019, respectively.

Net cash provided by financing activities during the nine months ended September 30, 2020 was \$6.7 million.

As of September 30, 2020, the Company had cash of \$2.7 million, compared to \$5.5 million at December 31, 2019. The Company had no debt outstanding at September 30, 2020. Subsequent to quarter end, the Company raised \$3.4 million of gross proceeds in a private placement, which the Company expects will extend its cash runway throughout most of the first quarter of 2021.

### **Full Year 2020 Outlook**

On May 7, 2020, the Company withdrew its previously announced full year 2020 outlook. The Company is currently unable to estimate the duration and impact of the COVID-19 pandemic on its financial and operating results for the full year 2020.

### **Conference Call**

Management will host a conference call at 5:45 p.m. Eastern Time on November 12, 2020 to discuss the results of the quarter and business outlook. Those who would like to participate may dial 877-407-2988 (201-389-0923 for international callers) and provide access code 13711025. 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>.

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For those unable to participate, a replay of the call will be available for two weeks at 877-660-6853 (201-612-7415 for international callers); access code 13711025. 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 commercial product is the Portable Neuromodulation Stimulator (PoNSTM). For more information, visit [www.heliusmedical.com](http://www.heliusmedical.com).

#### **About the PoNS Device and PoNS Treatment**

The Portable Neuromodulation Stimulator (PoNSTM) is an authorized class II, non-implantable, medical device in Canada intended for use as a short term treatment (14 weeks) of gait deficit due to mild and moderate symptoms from multiple sclerosis (MS), and chronic balance deficit due to mild-to-moderate traumatic brain injury (mmTBI) and is to be used in conjunction with physical therapy. The PoNSTM is an investigational medical device in the United States, the European Union ("EU"), and Australia ("AUS"). The device is currently under review for de novo classification and clearance by the FDA. It is also under premarket review by the AUS Therapeutic Goods Administration. PoNSTM 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," "expect," "look forward," "will" and similar expressions. Such forward-looking statements include, among others, statements regarding the COVID-19 pandemic, including its impact on the Company, the Company's future growth and operational progress, including clinical and regulatory development plans for the PoNS device, the Company's expectations regarding the sufficiency of funds for anticipated future operations, potential receipt of regulatory clearance of the PoNS device in the United States, the success of the Company's planned study, business and commercialization initiatives and objectives, and expectations for full year 2020.

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 impact of the COVID-19 pandemic, 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

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Company's Annual Report on Form 10-K for the year ended December 31, 2019, its Quarterly Report on Form 10-Q for the quarter ended September 30, 2020 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](http://www.sec.gov) or [www.sedar.com](http://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.

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

	September 30, 2020	December 31, 2019
<b>ASSETS</b>		
Current assets		
Cash	\$ 2,680	\$ 5,459
Accounts receivable, net	80	210
Other receivables	138	364
Inventory, net of reserve	572	598
Prepaid expenses	666	610
<b>Total current assets</b>	<b>4,136</b>	<b>7,241</b>
Property and equipment, net	463	712
Other assets		
Goodwill	725	1,242
Intangible assets, net	579	582
Operating lease right-of-use asset, net	105	552
Other assets	18	18
<b>Total other assets</b>	<b>1,427</b>	<b>2,394</b>
<b>TOTAL ASSETS</b>	<b>\$ 6,026</b>	<b>\$ 10,347</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable	\$ 720	\$ 1,676
Accrued liabilities	1,399	1,519
Operating lease liability	107	172
Derivative financial instruments	—	5
Deferred revenue	339	430
<b>Total current liabilities</b>	<b>2,565</b>	<b>3,802</b>
Non-current liabilities		
Operating lease liability	47	465
Deferred revenue	217	245
<b>TOTAL LIABILITIES</b>	<b>2,829</b>	<b>4,512</b>
<b>STOCKHOLDERS' EQUITY</b>		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding as of September 30, 2020 and December 31, 2019	—	—
Class A common stock, \$0.001 par value; 150,000,000 shares authorized; 45,354,612 and 30,718,554 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	45	31
Additional paid-in capital	120,213	111,479
Accumulated other comprehensive loss	(693)	(902)
Accumulated deficit	(116,368)	(104,773)
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b>3,197</b>	<b>5,835</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 6,026</b>	<b>\$ 10,347</b>

**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,	
	2020	2019	2020	2019
<b>Revenue:</b>				
Product sales, net	\$ 124	\$ 150	\$ 441	\$ 1,295
Fee revenue	—	—	9	49
License revenue	7	—	20	—
<b>Total operating revenue</b>	<b>131</b>	<b>150</b>	<b>470</b>	<b>1,344</b>
<b>Cost of sales:</b>				
Cost of product sales	22	89	187	538
<b>Gross profit</b>	<b>109</b>	<b>61</b>	<b>283</b>	<b>806</b>
<b>Operating expenses:</b>				
Research and development	1,327	1,506	3,755	6,462
Selling, general and administrative	2,370	4,291	7,625	12,715
Amortization expense	72	—	287	—
<b>Total operating expenses</b>	<b>3,769</b>	<b>5,797</b>	<b>11,667</b>	<b>19,177</b>
<b>Operating loss</b>	<b>(3,660)</b>	<b>(5,736)</b>	<b>(11,384)</b>	<b>(18,371)</b>
<b>Other income (expense):</b>				
Other income	—	11	63	35
Change in fair value of derivative financial instruments	1	196	4	14,033
Foreign exchange gain (loss)	182	(59)	(278)	(147)
<b>Total other income (expense)</b>	<b>183</b>	<b>148</b>	<b>(211)</b>	<b>13,921</b>
<b>Net loss</b>	<b>(3,477)</b>	<b>(5,588)</b>	<b>(11,595)</b>	<b>(4,450)</b>
<b>Other comprehensive loss:</b>				
Foreign currency translation adjustments	(172)	68	209	(168)
<b>Comprehensive loss</b>	<b>\$ (3,649)</b>	<b>\$ (5,520)</b>	<b>\$ (11,386)</b>	<b>\$ (4,618)</b>
<b>Net loss per share</b>				
Basic	<b>\$ (0.08)</b>	<b>\$ (0.22)</b>	<b>\$ (0.30)</b>	<b>\$ (0.17)</b>
Diluted	<b>\$ (0.08)</b>	<b>\$ (0.22)</b>	<b>\$ (0.30)</b>	<b>\$ (0.17)</b>
<b>Weighted average shares outstanding</b>				
Basic	<b>45,137,995</b>	<b>25,903,544</b>	<b>39,187,370</b>	<b>25,869,039</b>
Diluted	<b>45,137,995</b>	<b>25,903,544</b>	<b>39,187,370</b>	<b>25,869,039</b>

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

	Nine Months Ended September 30,	
	2020	2019
<b>Cash flows from operating activities:</b>		
Net loss	\$ (11,595)	\$ (4,450)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of derivative financial instruments	(4)	(14,033)
Stock-based compensation expense	2,021	3,336
Unrealized foreign exchange loss	245	211
Depreciation expense	92	89
Amortization expense	287	—
Provision for doubtful accounts	160	—
Intangible asset impairment	182	—
Loss from disposal of property and equipment	110	—
Gain from lease modification	(56)	—
Changes in operating assets and liabilities:		
Accounts receivable	(30)	(380)
Other receivables	226	(123)
Inventory	26	(897)
Prepaid expenses	(56)	285
Other current assets	—	264
Operating lease liability	20	(9)
Accounts payable	(956)	(678)
Accrued liabilities	(120)	(75)
Deferred revenue	(119)	—
<b>Net cash used in operating activities</b>	<b>(9,567)</b>	<b>(16,460)</b>
<b>Cash flows from investing activities:</b>		
Purchase of property and equipment	(14)	(260)
Proceeds from sale of property and equipment	61	—
Internally developed software	(7)	—
<b>Net cash provided by (used in) investing activities</b>	<b>40</b>	<b>(260)</b>
<b>Cash flows from financing activities:</b>		
Proceeds from the issuance of common stock and accompanying warrants	7,233	—
Share issuance costs	(506)	(52)
Proceeds from the exercise of stock options and warrants	—	215
Proceeds from Paycheck Protection Program Loan	323	—
Repayment of Paycheck Protection Program Loan	(323)	—
<b>Net cash provided by financing activities</b>	<b>6,727</b>	<b>163</b>
<b>Effect of foreign exchange rate changes on cash</b>	<b>21</b>	<b>(7)</b>
<b>Net decrease in cash</b>	<b>(2,779)</b>	<b>(16,564)</b>
<b>Cash at beginning of period</b>	<b>5,459</b>	<b>25,583</b>
<b>Cash at end of period</b>	<b>\$ 2,680</b>	<b>\$ 9,019</b>

**Investor Relations Contact:**

Westwicke Partners on behalf of Helius Medical Technologies, Inc.

Mike Piccinino, CFA

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