

**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): March 10, 2021

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:

<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 March 10, 2021, Heliuss Medical Technologies, Inc. (the “**Registrant**”) issued a press release announcing its financial results for the quarter ended December 31, 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**

Exhibit Number	Exhibit Description
99.1	Press Release, dated March 10, 2021.

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 10, 2021

By: /s/ Joyce LaViscount
Joyce LaViscount
Chief Financial Officer, Chief Operating Officer and Secretary



Helius Medical Technologies, Inc. Reports Fourth Quarter and Full Year 2020 Financial Results

NEWTOWN, Pa., March 10, 2021 (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 and full year ended December 31, 2020.

Fourth Quarter and Recent Business Updates

- The Company closed a private placement for total net proceeds of approximately \$3.2 million and an underwritten public offering of units for net proceeds of approximately \$9.6 million.
 - Helius expects its existing capital, including net proceeds from the public offering that closed and net proceeds raised through the exercise of warrants in the first quarter of 2021, will be sufficient to fund the Company's operations into the first quarter of 2022.
- The Company announced on January 11, 2021 that it submitted its formal response to the U.S. Food and Drug Administration's (the "FDA") request for additional information, related to Helius' request for de novo classification and clearance of the PoNS device.
- The Company received written notice from The Nasdaq Stock Market LLC on January 19, 2021 that Helius is in compliance with all applicable listing standards.
- The Centers for Medicare & Medicaid Services ("CMS") announced that it is finalizing a new coverage pathway, Medicare Coverage of Innovative Technology, or "MCIT," for FDA-designated breakthrough medical devices cleared by FDA.
 - The MCIT rule will provide national Medicare coverage as early as the same day as FDA market authorization for breakthrough devices and coverage would last for four years.

Fourth Quarter 2020 Financial Summary

- Revenue of \$191 thousand, compared to revenue of \$152 thousand in fourth quarter of 2019.
- Operating loss of \$3.0 million, compared to operating loss of \$5.6 million in fourth quarter of 2019.
- Net loss of \$2.5 million, compared to net loss of \$5.3 million in fourth quarter of 2019.

Full Year 2020 Financial Summary

- Revenue of \$0.7 million, compared to revenue of \$1.5 million in 2019.
 - Operating loss of \$14.4 million, compared operating loss of \$24.0 million in 2019.
 - Net loss of \$14.1 million, compared to net loss of \$9.8 million in 2019.
 - As of December 31, 2020, the Company had cash of \$3.3 million, compared to \$5.5 million at December 31, 2019. The Company had no debt outstanding at December 31, 2020.
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“During the fourth quarter, we were pleased with our pace of progress and the commitment our employees have shown in view of the continued headwinds created by the COVID-19 pandemic,” said Dane Andreeff, Interim President and Chief Executive Officer of Heliu. “Our regulatory team focused on preparing a thorough response to FDA’s request for additional information related to our request for U.S. de novo classification and clearance in MS. As a result of their efforts, we were pleased to announce the submission of our response on January 11th, and we hope to receive de novo classification and clearance during the first half of 2021. In Canada, while we continued to see the impacts of COVID on the clinics we serve and their patients, our commercial team successfully expanded our network of authorized PoNS clinics from 7 to 31 locations by year-end, exceeding our goal. Subsequent to quarter-end, we also secured approximately \$11 million to strengthen our balance sheet and support our operations going forward.”

“As we enter 2021, Heliu is focused on securing regulatory clearance and coverage for our breakthrough PoNS device in the U.S. while supporting our recently expanded network of Canadian clinics. With our U.S. de novo submission in MS under review, a network of 31 clinics in Canada and an enhanced balance sheet, we believe we are well-positioned to weather the continued effects of the pandemic and expand the availability of our PoNS Treatment going forward. We remain committed to executing on our regulatory and commercial strategies as effectively and efficiently with the ultimate goal of bringing our innovative PoNS Treatment to the aid of as many patients as possible.”

Fourth Quarter 2020 Financial Results

Total revenue for the fourth quarter of 2020 was \$191 thousand, compared to \$152 thousand in the fourth quarter of 2019. Product sales represented approximately 96% of total revenue in the fourth quarter of 2020 compared to 100% of total revenue in the fourth 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 4% of sales in the fourth quarter of 2020, compared to 0% of sales in the fourth quarter of 2019.

Gross loss for the fourth quarter of 2020 was \$10 thousand, compared to gross loss of \$156 thousand in the fourth quarter of 2019. Operating expenses for the fourth quarter of 2020 decreased \$2.5 million, or 45% year-over-year, to \$3 million, compared to \$5.5 million in the fourth quarter of 2019.

Operating loss for the fourth quarter of 2020 decreased \$2.6 million, or 47% year-over-year, to \$3.0 million, compared to \$5.6 million in the fourth quarter of 2019.

Total other income for the fourth quarter of 2020 was \$468 thousand, compared to \$294 thousand in the fourth quarter of 2019.

Net loss for the fourth quarter of 2020 was \$2.5 million, or \$(1.77) per basic and diluted common share, compared to a net loss of \$5.3 million, or \$(6.71) per basic and diluted common share, in the fourth quarter of 2019. Weighted average shares used to compute basic and diluted net loss per common share were 1.4 million and 0.8 million for the fourth quarter of 2020 and 2019, respectively.

Full Year 2020 Financial Results

Total revenue for the full year 2020 was \$0.7 million, compared to \$1.5 million for full year 2019. Product sales represented 95% of total revenue for full year 2020, compared to 97% of total for full year 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 total revenue for full year 2020, compared to 3% of total revenue for the full year 2019.

Gross profit for full year 2020 was \$0.3 million, compared to gross profit of \$0.7 million for full year 2019. Operating expenses for full year 2020 decreased \$9.9 million, or 41% year-over-year, to \$14.7 million, compared to \$24.6 million for full year 2019.

Operating loss full year 2020 decreased \$9.6 million, or 40% year-over-year, to \$14.4 million, compared to operating loss of \$24.0 million for full year 2019.

Total other income for full year 2020 was \$0.3 million, compared to \$14.2 million of other income for full year 2019. 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 full year 2020 was \$14.1 million, or \$(11.80) per basic and diluted common share, compared to net loss of \$9.8 million, or \$(12.99) per basic and diluted common share, for full year 2019. Weighted average shares used to compute basic and diluted net loss per share were 1.2 million and 0.8 million for full year 2020 and full year 2019, respectively.

Net cash provided by financing activities during the twelve months ended December 31, 2020 was \$9.6 million.

As of December 31, 2020, the Company had cash of \$3.3 million, compared to \$5.5 million at December 31, 2019. The Company had no debt outstanding at December 31, 2020.

Full Year 2021 Outlook

The Company is not providing a formal financial outlook for the full year 2021 at this time, given the continued uncertainty on the duration and impact of the COVID-19 pandemic on its financial and operating results.

Conference Call

Management will host a conference call at 5:00 p.m. Eastern Time on March 10, 2021 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 13715793. 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 877-660-6853 (201-612-7415 for international callers); access code 13715793. 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.

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 (mTBI) 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 2021.

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 uncertainties associated with the clinical development process and FDA regulatory submission and approval process, including that the Company’s request for de novo classification and clearance may be declined by the FDA, that the FDA is not required to and may not respond to the Company’s request in the timeframe indicated by its de novo review goals or in the time the Company expects, whether the Company’s response will be satisfactory to the FDA, whether the FDA will require additional information, whether the Company will be able to provide it in a timely manner and whether such additional information will be satisfactory to the FDA, 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 Company’s Annual Report on Form 10-K for the year ended December 31, 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 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)

	December 31, 2020	December 31, 2019
ASSETS		
Current assets		
Cash	\$ 3,331	\$ 5,459
Accounts receivable, net	74	210
Other receivables	156	364
Inventory, net	389	598
Prepaid expenses	735	610
Total current assets	4,685	7,241
Property and equipment, net	486	712
Other assets		
Goodwill	759	1,242
Intangible assets, net	527	582
Operating lease right-of-use asset, net	90	552
Other assets	—	18
Total other assets	1,376	2,394
TOTAL ASSETS	\$ 6,547	\$ 10,347
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 747	\$ 1,676
Accrued liabilities	1,337	1,519
Operating lease liability	59	172
Derivative financial instruments	—	5
Deferred revenue	281	430
Total current liabilities	2,424	3,802
Non-current liabilities		
Operating lease liability	32	465
Deferred revenue	220	245
TOTAL LIABILITIES	2,676	4,512
STOCKHOLDERS' EQUITY		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding as of December 31, 2020 and December 31, 2019	—	—
Class A Common stock, \$0.001 par value; 150,000,000 shares authorized; 1,484,362 and 877,672 shares issued and outstanding as of December 31, 2020 and December 31, 2019, respectively	1	1
Additional paid-in capital	123,872	111,509
Accumulated other comprehensive loss	(1,099)	(902)
Accumulated deficit	(118,903)	(104,773)
TOTAL STOCKHOLDERS' EQUITY	3,871	5,835
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 6,547	\$ 10,347

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

	Three Months Ended		Year Ended	
	December 31,		December 31,	
	2020	2019	2020	2019
Revenue:				
Product sales, net	\$ 184	\$ 159	\$ 625	\$ 1,454
Fee revenue	—	(12)	9	37
License revenue	7	5	27	5
Total operating revenue	191	152	661	1,496
Cost of sales:				
Cost of product sales	201	308	388	846
Gross profit	(10)	(156)	273	650
Operating expenses:				
Research and development	827	1,599	4,582	8,061
Selling, general and administrative	2,089	3,806	9,714	16,521
Amortization expense	76	64	363	64
Total operating expenses	2,992	5,469	14,659	24,646
Operating loss	(3,002)	(5,625)	(14,386)	(23,996)
Other income:				
Other income	—	60	63	95
Change in fair value of derivative financial instruments	—	80	4	14,113
Foreign exchange gain	468	154	189	7
Total other income	468	294	256	14,215
Net loss	(2,534)	(5,331)	(14,130)	(9,781)
Other comprehensive loss:				
Foreign currency translation adjustments	(406)	(143)	(197)	(311)
Comprehensive loss	\$ (2,940)	\$ (5,474)	\$ (14,327)	\$ (10,092)
Net loss per share				
Basic	\$ (1.77)	\$ (6.71)	\$ (11.80)	\$ (12.99)
Diluted	\$ (1.77)	\$ (6.71)	\$ (11.80)	\$ (12.99)
Weighted average shares outstanding				
Basic	1,430,504	793,934	1,197,774	752,932
Diluted	1,430,504	793,934	1,197,774	752,932

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

	Year Ended December 31,	
	2020	2019
Cash flows from operating activities:		
Net loss	\$ (14,130)	\$ (9,781)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of derivative financial instruments	(4)	(14,113)
Stock-based compensation expense	2,529	4,691
Unrealized foreign exchange (gain) loss	(182)	70
Depreciation expense	119	127
Amortization expense	363	64
Provision for doubtful accounts	140	220
Provision for inventory reserve	205	50
Intangible asset impairment	184	—
Loss from disposal of property and equipment	110	—
Gain from lease modification	(56)	—
Changes in operating assets and liabilities:		
Accounts receivable	(4)	(438)
Other receivables	226	(278)
Inventory	4	(256)
Prepaid expenses	(125)	(163)
Other current assets	—	264
Operating lease liability	(28)	(13)
Accounts payable	(635)	(1,116)
Accrued liabilities	(280)	(327)
Deferred revenue	(174)	—
Net cash used in operating activities	(11,738)	(20,999)
Cash flows from investing activities:		
Purchase of property and equipment	(63)	(278)
Proceeds from sale of property and equipment	61	—
Business acquisitions, net of cash acquired	—	(416)
Internally developed software	(7)	(75)
Net cash used in investing activities	(9)	(769)
Cash flows from financing activities:		
Proceeds from the issuance of common stock and accompanying warrants	10,653	1,685
Share issuance costs	(1,015)	(247)
Proceeds from the exercise of stock options and warrants	—	215
Proceeds from Paycheck Protection Program Loan	323	—
Repayment of Paycheck Protection Program Loan	(323)	—
Net cash provided by financing activities	9,638	1,653
Effect of foreign exchange rate changes on cash	(19)	(9)
Net decrease in cash	(2,128)	(20,124)
Cash at beginning of year	5,459	25,583
Cash at end of year	\$ 3,331	\$ 5,459

Investor Relations Contact:

Westwicke Partners on behalf of Helius Medical Technologies, Inc.

Jack Powell, Vice President

investorrelations@heliusmedical.com