

**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**

August 12, 2021

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)

**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
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 August 12, 2021, Helius Medical Technologies, Inc. (the “**Registrant**”) issued a press release announcing its financial results for the quarter ended June 30, 2021, 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 No.	Description
99.1	<a href="#">Press Release, dated August 12, 2021.</a>
104	Cover Page Interactive Data File (embedded within Inline XBRL document).





## **Helius Medical Technologies, Inc. Reports Second Quarter 2021 Financial Results**

NEWTOWN, Pa., August 12, 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 ended June 30, 2021.

### **Second Quarter and Recent Business Updates**

- Frederick Fantazzia appointed Vice President of Sales & Marketing, North America, June 1, 2021
- Dane Andreeff and Jeffrey Mathiesen appointed President & Chief Executive Officer and Chief Financial Officer, respectively, June 14, 2021
- Antonella Favit-Van Pelt, M.D., Ph.D. appointed Chief Medical Officer, July 7, 2021
- New website launched for U.S.-based patients and physicians: <https://ponstreatment.com>

### **Second Quarter 2021 Financial Summary**

- Revenue: \$71 thousand, vs. \$133 thousand in Q2 2020
- Operating loss: \$6.2 million vs. \$3.7 million in Q2 2020
  - Q2 2021 included \$1.9 million of increased non-cash stock-based compensation expense comprised of a one-time fully vested stock option grant valued at \$1.0 million and stock options granted to key management and sales executives
- Net loss: \$6.0 million vs. \$3.4 million in Q2 2020
- Cash balance: \$7.4 million at June 30, 2021 vs. \$3.3 million at December 31, 2020

“Helius made important progress during the second quarter and in recent weeks in preparing for U.S. commercialization, following the receipt of U.S. marketing authorization of our PoNS device for MS in late March,” said Dane Andreeff, President and Chief Executive Officer of Helius. “Most notably, we enhanced and expanded our senior leadership team with the appointment of several highly qualified individuals, including a Vice President of Sales and Marketing for North America who will inform and lead our strategy to commercialize in the U.S. We also secured many of the required state licenses that will enable us to distribute and sell our PoNS device, and are now cleared to sell in approximately 85% of states in the U.S.. Lastly, we continued to develop our go-to-market strategy, by refining our plan to initially target the estimated 130,000 MS patients with gait deficit who may require physical therapy. With respect to our operations in Canada, although the country remained severely impacted by the effects of the COVID-19 pandemic during the second quarter, with restrictions on both the clinics and patients we serve, we are cautiously optimistic that these headwinds will moderate in the second half of 2021 as the operating environment begins to recover.”

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Mr. Andreeff continued: “During the second half of this year, we will remain keenly focused on pursuing our pre-commercial activities in order to meet our goal of beginning U.S. commercialization of our PoNS Treatment during the first quarter of 2022. Specifically, we plan to begin building our commercial team and appropriately engage centers of excellence to allow them to gain experience with PoNS in the target population, with the goal that they will then disseminate their experience with PoNS to colleagues and health care providers. The focus of these efforts will include the 10 states we have identified that comprise more than 50% of the targeted MS patients. We will also begin engaging with payers in our pursuit to establish PoNS pricing in line with benchmark pricing for comparable devices used in the neurorehabilitation space. By executing on these near-term initiatives, we aim to bring our innovative PoNS technology to the aid of U.S. patients as quickly and efficiently as possible, which we believe represents the best path to creating value for our shareholders.”

### **Second Quarter 2021 Financial Results**

Total revenue for the second quarter of 2021 was \$71 thousand, compared to \$133 thousand in the second quarter of 2020. Product sales represented 89% of total revenue in the second quarter of 2021 compared to 95% 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 11% of sales in the second quarter of 2021, compared with 5% of sales in the prior year period.

Gross profit for the second quarter of 2021 was \$4 thousand, compared to gross profit of \$69 thousand in the second quarter of 2020.

Operating expenses for the second quarter of 2021 increased \$2.4 million, or 63% year-over-year, to \$6.2 million, compared to \$3.8 million in the second quarter of 2020. Operating expenses in the second quarter of 2021 included a \$1.9 million increase in non-cash stock-based compensation expense comprised of a one-time fully vested stock option grant valued at \$1.0 million and stock options granted in conjunction with the addition of key management and sales executives.

Operating loss for the second quarter of 2021 increased \$2.5 million, or 66% year-over-year, to \$6.2 million, compared to \$3.7 million in the second quarter of 2020.

Total other income for the second quarter of 2021 was \$185 thousand, compared to total other income of \$361 thousand in the second quarter of 2020.

Net loss for the second quarter of 2021 was \$6.0 million, or \$(2.58) per basic and diluted common share, compared to a net loss of \$3.4 million, or \$(2.90) per basic and diluted common share, in the second quarter of 2020. Weighted average shares used to compute basic and diluted net loss per common share were 2.3 million and 1.2 million for the second quarter of 2021 and 2020, respectively.

### **Six Months Ended June 30, 2021 Financial Results**

Total revenue for the six months ended June 30, 2021 was \$155 thousand, compared to \$339 thousand for the six months ended June 30, 2020. Product sales represented 90% of total revenue for the six months ended June 30, 2021, compared to 94% of total revenue for the six months ended June 30, 2020. 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 10% of total revenue for the six months ended June 30, 2021, compared to 6% of total revenue for the six months ended June 30, 2020.

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Gross profit for the six months ended June 30, 2021 was \$72 thousand, compared to gross profit of \$174 thousand for the six months ended June 30, 2020. Operating expenses for the six months ended June 30, 2021 increased \$1.8 million, or 23% year-over-year, to \$9.7 million, compared to \$7.9 million for the six months ended June 30, 2020.

Operating loss for the six months ended June 30, 2021 increased \$2.0 million, or 25% year-over-year, to \$9.7 million, compared to operating loss of \$7.7 million for the six months ended June 30, 2020. Operating expenses in the six months ended June 30, 2021 included a \$1.7 million increase in stock-based compensation expense comprised of a one-time fully vested stock option grant valued at \$1.0 million and stock options granted in conjunction with the addition of key management and sales executives.

Total other income for the six months ended June 30, 2021 was \$324 thousand, compared to \$394 thousand of total other expense for the six months ended June 30, 2020.

Net loss for the six months ended June 30, 2021 was \$9.3 million, or \$(4.29) per basic and diluted common share, compared to net loss of \$8.1 million, or \$(7.85) per basic and diluted common share, for the six months ended June 30, 2020. Weighted average shares used to compute basic and diluted net per share were 2.2 million and 1.0 million for the six months ended June 30, 2021 and the six months ended June 30, 2020, respectively.

Net cash provided by financing activities during the six months ended June 30, 2021 was \$10.8 million.

As of June 30, 2021, the Company had cash of \$7.4 million, compared to \$3.3 million at December 31, 2020. The Company had no debt outstanding at June 30, 2021.

### **Conference Call**

Management will host a conference call at 5:00 p.m. Eastern Time on August 12, 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 13721027. 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 13721027. 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 PoNSTM Device and PoNS Treatment™**

The Portable Neuromodulation Stimulator (PoNSTM) is an innovative non-surgical device, inclusive of a controller and mouthpiece, which delivers electrical stimulation to the surface of the tongue to provide treatment of gait deficit. The PoNS device is indicated for use in the United States as a short term treatment

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of gait deficit due to mild-to-moderate symptoms from multiple sclerosis (“MS”) and is to be used as an adjunct to a supervised therapeutic exercise program in patients 22 years of age and over by prescription only. It is authorized for sale in Canada as a class II, non-implantable, medical device intended as a short term treatment (14 weeks) of gait deficit due to mild and moderate symptoms from 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 PoNS™ is an investigational medical device in the European Union (“EU”) and Australia (“AUS”). It is currently under premarket review by the AUS Therapeutic Goods Administration.

**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,” “will,” “goal,” “aim to” 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 pre-commercial activities for the PoNS device, and expected time to begin commercialization of the PoNS device in the U.S..

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 Company’s capital requirements to achieve its business objectives, the impact of the COVID-19 pandemic, the Company’s ability to train physical therapists in the supervision of the use of the PoNS Treatment, the Company’s ability to secure contracts with rehabilitation clinics, the Company’s ability to obtain national Medicare coverage and to obtain a reimbursement code so that the PoNS device is covered by Medicare and Medicaid, the Company’s ability to build internal commercial infrastructure, secure state distribution licenses, build a commercial team and build relationships with Key Opinion Leaders, neurology experts and neurorehabilitation centers, market awareness of the PoNS device, future clinical trials and the clinical development process, manufacturing and supply chain risks, potential changes to the MCIT program resulting from the 60-day deferral of the program implementation, the product development process and FDA regulatory submission review and approval process, other development activities, ongoing government regulation, and other risks detailed from time to time in the “Risk Factors” section of the Company’s Annual Report on Form 10-K for the year ended December 31, 2020, its Quarterly Report on Form 10-Q for the quarter ended June 30, 2021 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)

	June 30, 2021	December 31, 2020
<b>ASSETS</b>		
Current assets		
Cash	\$ 7,425	\$ 3,331
Accounts receivable, net	51	74
Other receivables	169	156
Inventory, net	507	389
Prepaid expenses	833	735
Total current assets	8,985	4,685
Property and equipment, net	449	486
Other assets		
Goodwill	783	759
Intangible assets, net	438	527
Operating lease right-of-use asset, net	62	90
Total other assets	1,283	1,376
<b>TOTAL ASSETS</b>	<b>\$ 10,717</b>	<b>\$ 6,547</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable	\$ 912	\$ 747
Accrued liabilities	873	1,337
Operating lease liability	62	59
Deferred revenue	290	281
Total current liabilities	2,137	2,424
Non-current liabilities		
Operating lease liability	—	32
Deferred revenue	213	220
<b>TOTAL LIABILITIES</b>	<b>2,350</b>	<b>2,676</b>
<b>STOCKHOLDERS' EQUITY</b>		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding as of June 30, 2021 and December 31, 2020	—	—
Class A Common stock, \$0.001 par value; 150,000,000 shares authorized; 2,317,772 and 1,484,362 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively	2	1
Additional paid-in capital	138,023	123,872
Accumulated other comprehensive loss	(1,412)	(1,099)
Accumulated deficit	(128,246)	(118,903)
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b>8,367</b>	<b>3,871</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 10,717</b>	<b>\$ 6,547</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		Six Months Ended	
	June 30,		June 30,	
	2021	2020	2021	2020
<b>Revenue:</b>				
Product sales	\$ 63	\$ 126	\$ 140	\$ 317
Fee revenue	—	—	—	9
License revenue	8	7	15	13
<b>Total operating revenue</b>	<b>71</b>	<b>133</b>	<b>155</b>	<b>339</b>
<b>Cost of sales:</b>				
Cost of product sales	67	64	83	165
<b>Gross profit</b>	<b>4</b>	<b>69</b>	<b>72</b>	<b>174</b>
<b>Operating expenses:</b>				
Research and development	1,377	1,308	2,694	2,428
Selling, general and administrative	4,744	2,394	6,939	5,255
Amortization expense	49	89	106	215
<b>Total operating expenses</b>	<b>6,170</b>	<b>3,791</b>	<b>9,739</b>	<b>7,898</b>
<b>Operating loss</b>	<b>(6,166)</b>	<b>(3,722)</b>	<b>(9,667)</b>	<b>(7,724)</b>
<b>Other income (expense):</b>				
Other income	—	56	—	63
Change in fair value of derivative financial instruments	—	(1)	—	3
Foreign exchange gain (loss)	185	306	324	(460)
<b>Total other income (expense)</b>	<b>185</b>	<b>361</b>	<b>324</b>	<b>(394)</b>
<b>Net loss</b>	<b>(5,981)</b>	<b>(3,361)</b>	<b>(9,343)</b>	<b>(8,118)</b>
<b>Other comprehensive loss:</b>				
Foreign currency translation adjustments	(185)	(255)	(313)	381
<b>Comprehensive loss</b>	<b>\$ (6,166)</b>	<b>\$ (3,616)</b>	<b>\$ (9,656)</b>	<b>\$ (7,737)</b>
<b>Net loss per share</b>				
Basic	\$ (2.58)	\$ (2.90)	\$ (4.29)	\$ (7.85)
Diluted	\$ (2.58)	\$ (2.90)	\$ (4.29)	\$ (7.85)
<b>Weighted average shares outstanding</b>				
Basic	2,317,389	1,160,661	2,179,878	1,033,692
Diluted	2,317,389	1,160,661	2,179,878	1,033,692

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

	Six Months Ended June 30,	
	2021	2020
<b>Cash flows from operating activities:</b>		
Net loss	\$ (9,343)	\$ (8,118)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of derivative financial instruments	—	(3)
Stock-based compensation expense	3,156	1,571
Unrealized foreign exchange (gain) loss	(323)	433
Depreciation expense	56	67
Amortization expense	106	215
(Recovery of) provision for doubtful accounts	(11)	153
Non-cash lease expense	30	196
Intangible asset impairment	—	181
Loss from disposal of property and equipment	—	110
Gain from lease modification	—	(56)
Changes in operating assets and liabilities:		
Accounts receivable	34	1
Other receivables	(13)	226
Inventory	(118)	28
Prepaid expenses	(98)	(105)
Operating lease liability	(31)	(126)
Accounts payable	229	(1,288)
Accrued liabilities	(366)	(381)
Deferred revenue	2	(83)
<b>Net cash used in operating activities</b>	<b>(6,690)</b>	<b>(6,979)</b>
<b>Cash flows from investing activities:</b>		
Purchase of property and equipment	(19)	(3)
Proceeds from sale of property and equipment	—	61
Internally developed software	(2)	(7)
<b>Net cash (used in) provided by investing activities</b>	<b>(21)</b>	<b>51</b>
<b>Cash flows from financing activities:</b>		
Proceeds from the issuance of common stock and accompanying warrants	11,037	7,233
Share issuance costs	(1,523)	(506)
Proceeds from the exercise of warrants	1,320	—
Proceeds from Paycheck Protection Program Loan	—	323
Repayment of Paycheck Protection Program Loan	—	(323)
<b>Net cash provided by financing activities</b>	<b>10,834</b>	<b>6,727</b>
<b>Effect of foreign exchange rate changes on cash</b>	<b>(29)</b>	<b>6</b>
<b>Net increase (decrease) in cash</b>	<b>4,094</b>	<b>(195)</b>
<b>Cash at beginning of year</b>	<b>3,331</b>	<b>5,459</b>
<b>Cash at end of year</b>	<b>\$ 7,425</b>	<b>\$ 5,264</b>

**Investor Relations Contact:**

Westwicke on behalf of Helius Medical Technologies, Inc.

Jack Powell, Vice President

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