

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

May 12, 2022  
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 May 12, 2022, Helius Medical Technologies, Inc. (the “*Registrant*”) issued a press release announcing its financial results for the quarter ended March 31, 2022, 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 No.	Description
<a href="#"><u>99.1</u></a>	Press Release, dated May 12, 2022.





## **Helius Medical Technologies, Inc. Reports First Quarter 2022 Financial Results and Provides Update on U.S. Commercial Launch of PoNS®**

*-- Company to host call at 9:00am today with CEO, CFO, CMO and VP Sales & Marketing --*

NEWTOWN, Pa., May 12, 2022 (GLOBE NEWSWIRE) -- Helius Medical Technologies, Inc. (Nasdaq:HSDT) ("Helius" or the "Company"), a neurotech company focused on neurological wellness, today reported financial results for the quarter ended March 31, 2022.

### **First Quarter and Recent Business Updates**

- U.S. commercial launch of PoNS® for multiple sclerosis ("MS") commenced with 23 prescriptions written and 2 filled.
- Finalizing activities for participation of several clinical trial sites for the Company-sponsored Therapeutic Experience Program ("TEP"), an open label observational interventional trial designed to evaluate the impact of subjects' adherence on PoNS Therapy outcomes in patients with MS.
- Increased to 41 clinic locations in Canada.
- Q1 2022 revenue increased by 126% to \$190 thousand compared to \$84 thousand in Q1 2021.
- Projected cash flow positive operations by Q4 2023

"The U.S. commercial launch of PoNS for multiple sclerosis is officially under way. PoNS is an important therapy, and we are energized by the strong reception in the marketplace, with 23 prescriptions written as of today and therapy actively being scheduled. Regarding our TEP program, we plan to soon provide PoNS devices to NYU-Langone Health and we are completing setup activities to enroll several highly regarded centers of excellence, which we expect to announce soon. In Canada, our authorized sites grew to 41 clinic locations under our commercial expansion plan. It's a busy and exciting time at Helius, and we are confident there is much more to come," said Dane Andreeff, President and Chief Executive Officer of Helius.

### **First Quarter 2022 Financial Results**

Total revenue for the first quarter of 2022 was \$190 thousand, an increase of 126% compared to \$84 thousand in the first quarter of 2021 and was comprised primarily of product sales in both periods.

Gross profit for the first quarter of 2022 was \$66 thousand, compared to gross profit of \$69 thousand in the first quarter of 2021, reflecting increased fixed costs in the current year period in preparation for our anticipated revenue growth.

Operating expenses for the first quarter of 2022 increased to \$4.6 million, compared to \$3.6 million in the first quarter of 2021. The planned increase was primarily due to increased compensation expenses related to personnel additions in late 2021 and the first quarter 2022 to support the U.S. commercial launch.

Operating loss for the first quarter of 2022 increased \$1.1 million to a loss of \$4.6 million, compared to an operating loss of \$3.5 million in the first quarter of 2021.

Net loss was \$4.3 million for the first quarter of 2022, compared to a net loss of \$3.4 million in the corresponding prior year period. The basic and diluted net loss per share for the first quarter was \$1.15 per share, compared to a net loss of \$1.65 per share for the first quarter of 2021.

### **Cash and Liquidity**

Cash used in operating activities for the three months ended March 31, 2022, was \$4.7 million compared to \$2.9 million in the first quarter of 2021. The increase year over year resulted primarily from the increased operating expenses as well as the amount and timing of bonus and franchise tax payments in 2022.

As of March 31, 2022, the Company had cash of \$6.3 million, compared to \$11.0 million at December 31, 2021.

No shares were sold under the Lincoln Park Capital Purchase Agreement during the first quarter of 2022 and approximately \$14.4 million remained available for sale under the agreement at March 31, 2022. The Company had no debt outstanding as of March 31, 2022.

### **Second Quarter and Near-Term Guidance**

The Company currently expects second quarter revenue to be modestly above the first quarter levels, factoring in potential delays for some portion of U.S. patients to pursue insurance coverage prior to filling their prescriptions. As we continue to build momentum and expand our sales coverage, the Company expects future quarterly revenue to continue increasing sequentially quarter over quarter throughout the year and through 2023 as the U.S. commercialization of PoNS develops. Based upon its current pricing structure, projected prescription rates and anticipated reimbursement timeline in the U.S., the Company believes it can be cash flow positive by the fourth quarter 2023.

### **Conference Call**

As previously announced, management will host a conference call as follows:

Date:	Thursday, May 12, 2022
Time:	9:00 AM ET
Toll-free (U.S.)	(866) 374-5140
International	(404) 400-0571
Conference ID	33919561
Webcast:	<a href="https://edge.media-server.com/mmc/p/4ew556jx">https://edge.media-server.com/mmc/p/4ew556jx</a>

The webcast will be archived under the Newsroom section of the Company's investor relations website.

## **About Helius Medical Technologies, Inc.**

Helius Medical Technologies is a leading neurotech company in the medical device field focused on neurologic deficits using non-implantable platform technologies that amplify the brain's ability to compensate and promotes neuroplasticity, aiming to improve the lives of people dealing with neurologic diseases. The Company's first commercial product is the Portable Neuromodulation Stimulator (PoNS). For more information, visit [www.heliusmedical.com](http://www.heliusmedical.com).

## **About the PoNS Device and PoNS Therapy**

The Portable Neuromodulation Stimulator (PoNS) is an innovative non-surgical medical device, inclusive of a controller and mouthpiece, which delivers electrical stimulation to the surface of the tongue to improve balance and gait. The PoNS device is indicated for use in the United States as a short-term treatment 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. Helius is advancing PoNS post-approval research in MS through a recently launched Therapeutic Experience Program (TEP) designed to partner with neurologists and neurorehabilitation therapists at 10-12 US centers of excellence, who express an interest in becoming "early adopters" of PoNS therapy.

PoNS is also authorized for sale in Canada for two indications: (i) for use as a short-term treatment (14 weeks) of chronic balance deficit due to mild-to-moderate traumatic brain injury ("mTBI") and is to be used in conjunction with physical therapy; and (ii) for use as a short term treatment (14 weeks) of gait deficit due to mild and moderate symptoms from MS and is to be used in conjunction with physical therapy. PoNS is also authorized for sale in Australia for short term use by healthcare professionals as an adjunct to a therapeutic exercise program to improve balance and gait.

## **Cautionary Disclaimer Statement:**

This press release does not and shall not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or other jurisdiction. Any offer, if at all, will be made only by means of a prospectus, including a prospectus supplement, forming a part of the effective registration 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," "will," "goal," "aim to" and similar expressions. Such forward-looking statements include, among others, statements regarding the Company's future growth and operational progress, including commercial activities for the PoNS device, projected revenue from sales of our products, progress of commercialization of the PoNS device in the U.S., the ability and timing of our customers' ability to seek reimbursement for the PoNS device in the U.S., expectations for the Therapeutic Experience Program, clinical development plans, product development activities, and our future expenses and cash flow, including our ability to have cash flow positive operations by Q4 2023.

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, availability of funds, including that funding from our purchase agreement with Lincoln Park Capital Fund, LLC may be limited or be insufficient to fund our operations, the ability to find additional sources of funding, the impact of the COVID-19 pandemic, manufacturing, labor shortage and supply chain risks, 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, ongoing government regulation and other factors, 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, 2021, its Quarterly Report on Form 10-Q for the quarter ended March 31, 2022 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.

**Investor Relations Contact:**

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Unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss  
(Amounts in thousands except shares and per share data)

	Three Months Ended March 31,	
	2022	2021
<b>Revenue:</b>		
Product sales	\$ 183	\$ 77
License revenue	7	7
<b>Total operating revenue</b>	<b>190</b>	<b>84</b>
<b>Cost of sales:</b>		
Cost of product sales	124	15
<b>Gross profit</b>	<b>66</b>	<b>69</b>
<b>Operating expenses:</b>		
Research and development	1,764	1,316
Selling, general and administrative	2,819	2,197
Amortization expense	47	57
<b>Total operating expenses</b>	<b>4,630</b>	<b>3,570</b>
<b>Operating loss</b>	<b>(4,564)</b>	<b>(3,501)</b>
<b>Other income:</b>		
Other income	1	—
Foreign exchange gain	217	139
<b>Total other income</b>	<b>218</b>	<b>139</b>
<b>Net loss</b>	<b>(4,346)</b>	<b>(3,362)</b>
<b>Other comprehensive loss:</b>		
Foreign currency translation adjustments	(202)	(128)
<b>Comprehensive loss</b>	<b>\$ (4,548)</b>	<b>\$ (3,490)</b>
<b>Net loss per share</b>		
Basic	<b>\$ (1.15)</b>	<b>\$ (1.65)</b>
Diluted	<b>\$ (1.15)</b>	<b>\$ (1.65)</b>
<b>Weighted average shares outstanding</b>		
Basic	<b>3,787,871</b>	<b>2,040,839</b>
Diluted	<b>3,787,871</b>	<b>2,040,839</b>



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

	<u>March 31, 2022</u>	<u>December 31, 2021</u>
<b>ASSETS</b>		
Current assets		
Cash	\$ 6,310	\$ 11,005
Accounts receivable, net	60	66
Other receivables	185	185
Inventory, net	520	476
Prepaid expenses	951	862
Total current assets	<u>8,026</u>	<u>12,594</u>
Property and equipment, net	380	409
Other assets		
Goodwill	777	763
Intangible assets, net	291	333
Other non-current assets	4	—
Operating lease right-of-use asset, net	140	3
Total other assets	<u>1,212</u>	<u>1,099</u>
<b>TOTAL ASSETS</b>	<b><u>\$ 9,618</u></b>	<b><u>\$ 14,102</u></b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable	\$ 1,111	\$ 1,069
Accrued liabilities	1,008	1,433
Operating lease liability	51	3
Deferred revenue	29	148
Total current liabilities	<u>2,199</u>	<u>2,653</u>
Non-current liabilities		
Operating lease liability	99	—
Deferred revenue	190	193
<b>TOTAL LIABILITIES</b>	<b><u>2,488</u></b>	<b><u>2,846</u></b>
Commitments and contingencies		
<b>STOCKHOLDERS' EQUITY</b>		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding as of March 31, 2022 and December 31, 2021	—	—
Class A common stock, \$0.001 par value; 150,000,000 shares authorized; 3,794,797 and 3,780,674 shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	4	4
Additional paid-in capital	149,834	149,412
Accumulated deficit	(141,381)	(137,035)
Accumulated other comprehensive loss	(1,327)	(1,125)
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b><u>7,130</u></b>	<b><u>11,256</u></b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b><u>\$ 9,618</u></b>	<b><u>\$ 14,102</u></b>