

**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 13, 2024

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

Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

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 13, 2024, Helius Medical Technologies, Inc. (the “Registrant”) issued a press release announcing its financial results for the quarter ended March 31, 2024, 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
99.1	Press Release dated May 13, 2024.
104	Cover Page Interactive Data File (embedded within Inline XBRL document)



Helius Medical Technologies, Inc. Reports First Quarter 2024 Financial Results

-- Company to host call at 4:30pm today --

NEWTOWN, Pa., May 13, 2024 (GLOBE NEWSWIRE) -- Helius Medical Technologies, Inc. (Nasdaq:HSDT) (“Helius” or the “Company”), a neurotech company focused on delivering a novel therapeutic neuromodulation approach for balance and gait deficits, today announced results for the quarter ended March 31, 2024.

First Quarter and Recent Business Updates

- Received Healthcare Common Procedure Coding System (“HCPCS”) codes and preliminary determination for reimbursement for the Portable Neuromodulation Stimulator (“PoNS®”) mouthpiece and controller from the Centers for Medicare & Medicaid Services (“CMS”), paving the way toward final price determination on October 1, 2024.
- Added six more sites to the stroke registrational program in the U.S. and Canada; reached alignment with the U.S. Food and Drug Administration (“FDA”) on optimizing the stroke development plan.
- Announced partnership with Lovell® Government Services to make PoNS available to federal healthcare systems, including the U.S. Department of Veterans Affairs (“VA”) and Department of Defense (“DoD”).
- Q1 2024 revenue of \$135 thousand, compared to \$111 thousand in Q1 2023, reflecting increased product sales in both the U.S. and Canada.
- Closed on \$6.4 million public offering, raising net proceeds of approximately \$5.6 million.

“We marched one step closer to an important milestone when CMS released its preliminary Medicare payment determinations for the PoNS Controller and Mouthpiece earlier this month. This was a significant achievement for Helius, and at the HCPCS public meeting later this month, we will present arguments to support higher reimbursement rates than those established in the preliminary determinations. Once the reimbursement amount is finalized, the payment rates are expected to be effective October 1,” stated Helius’ President and Chief Executive Officer, Dane Andreeff.

“We believe the establishment of Medicare payment rates will make it easier to expand reimbursement across third-party payers, creating a pathway to positive cash flow as we continue pursuing stroke authorization in the U.S. We remain on track for an early 2025 regulatory submission for stroke, and we added several new sites to our registrational program during the quarter to advance this objective. It’s an exciting time at Helius with the achievement of two monumental goals in sight and the cash that will help us get there,” concluded Andreeff.

First Quarter 2024 Financial Results

Total revenue for the first quarter of 2024 was \$135 thousand, an increase of \$24 thousand compared to \$111 thousand in the first quarter of 2023, primarily attributable to higher product sales in the U.S. and Canada.

Cost of revenue was \$123 thousand for the three months ended March 31, 2024, compared to \$122 thousand for the comparable period in 2023, remaining relatively flat due to fixed overhead costs.

Operating expenses for the first quarter of 2024 decreased to \$3.4 million, compared to \$3.8 million in the first quarter of 2023. The decrease was driven primarily by a decrease in professional fees and payroll related expenses as well as in product development expenses and clinical trial activities as we transitioned our focus in the U.S. to commercialization activities. This decrease was partially offset by an increase in contract manufacturer expense associated with the transition to a new contract manufacturer during the current year period.

Operating loss for the first quarter of 2024 decreased \$0.4 million to a loss of \$3.4 million, compared to an operating loss of \$3.8 million in the first quarter of 2023.

Net loss was \$2.5 million in the first quarter of 2024 and in the corresponding prior year period. The basic and diluted net loss per share for the first quarter was \$3.08 per share compared to a net loss of \$4.42 per share for the first quarter of 2023.

Cash and Liquidity

Cash used in operating activities for the three months ended March 31, 2024, was \$3.0 million compared to \$3.2 million in the first quarter of 2023.

As of March 31, 2024, the Company had cash of \$3.6 million and no debt outstanding. On May 9, 2024, the Company raised \$5.6 million in net proceeds in a public offering, extending the cash runway into 2025.

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Conference Call

Date: **Monday, May 13, 2024**

Time: **4:30 p.m. Eastern Time**

Register (Audio only): [Click here](#)

Webcast: [Click here](#)

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 orally applied technology platform that amplifies the brain's ability to engage physiologic compensatory mechanisms and promote neuroplasticity, improving the lives of people dealing with neurologic diseases. The Company's first commercial product is the Portable Neuromodulation Stimulator. For more information about the PoNS® or Helius Medical Technologies, visit www.heliusmedical.com.

About the PoNS Device and PoNS Therapy

The Portable Neuromodulation Stimulator (PoNS) is an innovative, non-implantable, orally applied therapy that delivers neurostimulation through a mouthpiece connected to a controller and it's used, primarily at home, with physical rehabilitation exercise, to improve balance and gait. The PoNS device, which delivers mild electrical impulses to the tongue, 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.

PoNS has shown effectiveness in treating gait or balance and a significant reduction in the risk of falling in stroke patients in Canada, where it received authorization for sale in three indications: (i) for use as a short-term treatment (14 weeks) of gait deficit due to mild and moderate symptoms from stroke and is to be used in conjunction with physical therapy; (ii) 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 (iii) 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. For more information visit www.ponstherapy.com.

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,” “expect,” “continue,” “will,” “goal,” “aim” and similar expressions. Such forward-looking statements include, among others, statements regarding the sufficiency of the Company’s future cash position, the development, commercialization and success of the Company’s PoNS and PoNS Treatment, future decisions and approvals from applicable regulatory entities in the U.S. and Canada, the Company’s strategic operating plans, and the uses and effectiveness of PoNS and PoNS Therapy.

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, the Company’s ability to find additional sources of funding, manufacturing, labor shortage and supply chain risks, including risks related to manufacturing delays, the Company’s ability to obtain national Medicare insurance coverage and to obtain a reimbursement code, the Company’s ability to continue to build internal commercial infrastructure, secure state distribution licenses, market awareness of the PoNS device, future clinical trials and the clinical development process, the product development process and the 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, 2024, 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.

Investor Relations Contact

Lisa M. Wilson, In-Site Communications, Inc.
T: 212-452-2793
E: lwilson@insitecony.com

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

	Three Months Ended	
	March 31,	
	2024	2023
Revenue		
Product sales, net	\$ 124	\$ 106
Other revenue	11	5
Total revenue	135	111
Cost of revenue	123	122
Gross profit (loss)	12	(11)
Operating expenses		
Selling, general and administrative expenses	2,633	2,874
Research and development expenses	788	886
Amortization expense	7	39
Total operating expenses	3,428	3,799
Loss from operations	(3,416)	(3,810)
Nonoperating income (expense)		
Interest income (expense), net	(8)	100
Change in fair value of derivative liability	1,142	1,221
Foreign exchange loss	(288)	(5)
Other income, net	54	—
Nonoperating income, net	900	1,316
Loss before provision for income taxes	(2,516)	(2,494)
Provision for income taxes	—	—
Net loss	(2,516)	(2,494)
Other comprehensive income (loss)		
Foreign currency translation adjustments	288	5
Comprehensive loss	\$ (2,228)	\$ (2,489)
Loss per share		
Basic	\$ (3.08)	\$ (4.42)
Diluted	\$ (3.08)	\$ (4.42)
Weighted average number of common shares outstanding		
Basic	817,327	564,134
Diluted	817,327	564,134

Helius Medical Technologies, Inc.
Consolidated Balance Sheets
(in thousands, except share and per share data)

	March 31, 2024	December 31, 2023
ASSETS		
Current assets		
Cash and cash equivalents	\$ 3,638	\$ 5,182
Accounts receivable, net	49	117
Other receivables	513	520
Inventory, net	384	457
Prepaid expenses and other current assets	940	1,162
Total current assets	5,524	7,438
Property and equipment, net	174	178
Intangible assets, net	17	24
Operating lease right-of-use asset, net	42	52
Total assets	<u>\$ 5,757</u>	<u>\$ 7,692</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 814	\$ 531
Accrued and other current liabilities	674	1,260
Current portion of operating lease liabilities	46	45
Current portion of deferred revenue	42	43
Total current liabilities	1,576	1,879
Operating lease liabilities, net of current portion	—	12
Deferred revenue, net of current portion	115	128
Derivative liability	2,080	3,323
Total liabilities	<u>3,771</u>	<u>5,342</u>
Commitments and contingencies (Note 9)		
Stockholders' equity		
Class A common stock, \$0.001 par value; 150,000,000 shares authorized; 887,847 and 714,590 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively		
	1	1
Additional paid-in capital	164,843	162,979
Accumulated deficit	(162,473)	(159,957)
Accumulated other comprehensive loss	(385)	(673)
Total stockholders' equity	<u>1,986</u>	<u>2,350</u>
Total liabilities and stockholders' equity	<u>\$ 5,757</u>	<u>\$ 7,692</u>