

**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

March 28, 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 March 28, 2024, Heliuss Medical Technologies, Inc. (the “Registrant”) issued a press release announcing its financial results for the quarter and year ended December 31, 2023, 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 March 28, 2024.](#)

104 Cover Page Interactive Data File (embedded within Inline XBRL document)

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 28, 2024

By: /s/ Jeffrey S. Mathiesen
Jeffrey S. Mathiesen
Chief Financial Officer and Treasurer



Helius Medical Technologies, Inc. Reports Fourth Quarter and Full Year 2023 Financial Results

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

NEWTOWN, Pa., March 28, 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 and full year ended December 31, 2023.

Fourth Quarter and Recent Business Updates

- Secured Healthcare Common Procedure Coding System (“HCPCS”) Level II codes for the Portable Neuromodulation Stimulator (“PoNS®”) mouthpiece and controller from the Centers for Medicare & Medicaid Services (“CMS”), representing a significant step toward reimbursement.
- Further expanded the registrational program in stroke by adding a second site and initiating an open-label study; reached alignment with the U.S. Food and Drug Administration (“FDA”) on optimizing the stroke development plan.
- Signed a letter of intent (“LOI”) with the Québec Ministry of Health and Social Services (“MSSS”) to purchase up to 30 PoNS systems that will be distributed in five separate administrative regions within Québec as part of a government-funded initiative designed to evaluate the effectiveness of PoNS Therapy™ when used by patients suffering the effects of stroke.
- Released study results from collaborative project between Pacific Blue Cross (“PBC”) and HealthTech Connex (“HTC”), demonstrating that PoNS Therapy can drastically improve return-to-work (“RTW”) outcomes for patients suffering from traumatic brain injury (“TBI”).
- Q4 2023 revenue of \$134 thousand, compared to \$282 thousand in Q4 2022, primarily attributable to the June 30, 2023 expiration of PTAP in the United States and lower Canada product sales.

- Total operating expenses of \$2.3 million in Q4 2023, a decrease of \$0.5 million compared to Q4 2022.
- Generated \$1.3 million of net proceeds from the sale of shares of Company common stock under its At-The-Market (“ATM”) in Q1 2024, extending cash runway into Q3 2024.

“We are pleased to have reached a key milestone toward Medicare and broad third-party reimbursement last month when CMS assigned HCPCS codes for the PoNS mouthpiece and controller, effective April 1, 2024. We plan to engage with CMS in the coming months with the objective of securing Medicare reimbursement for the PoNS controller and mouthpiece to be effective as soon as October 1, 2024. In addition, these codes will facilitate our ability to concurrently pursue third-party payer coverage,” said Dane Andreeff, President and Chief Executive Officer of Helius.

“Delivering PoNS Therapy to stroke patients suffering from gait and balance deficit is one of our chief goals and I'm proud to report that we've made several meaningful strides toward potential U.S. authorization. In recent weeks, we've added a second site to our ongoing investigator-initiated, placebo-controlled study, begun enrollment of an open-label study at this same site, and met with the FDA to optimize our overall stroke development plan. We are now targeting an early 2025 regulatory submission with possible commercialization by the end of next year.”

“With \$1.3 million raised under our ATM program since year end, we now have the cash runway to take us into the third quarter of 2024 as we continue progressing our stroke registrational program and pursuing widespread reimbursement,” concluded Andreeff.

Fourth Quarter 2023 Financial Results

Total revenue for the fourth quarter of 2023 was \$134 thousand, a decrease of \$148 thousand compared to \$282 thousand in the fourth quarter of 2022 primarily attributable to the June 30, 2023 expiration of PTAP in the United States and lower Canada product sales.

Cost of revenues was \$90 thousand for the three months ended December 31, 2023, compared to \$150 thousand for the comparable period in 2022, primarily due to decreased revenues.

Gross profit for the fourth quarter of 2023 was \$44 thousand, compared to gross profit of \$132 thousand in the fourth quarter of 2022.

Selling, general, and administrative expenses for the fourth quarter of 2023 decreased to \$1.6 million, compared to \$2.0 million in the fourth quarter of 2022 due primarily to a decrease in compensation related expenses.

Research and development expenses for the fourth quarter of 2023 decreased to \$0.7 million compared to \$0.8 million in the fourth quarter of 2022, resulting primarily from a decrease in clinical and product development expenses in the current year period.

Operating loss for the fourth quarter of 2023 decreased to a loss of \$2.2 million, compared to an operating loss of \$2.7 million in the fourth quarter of 2022.

Net loss was \$1.0 million for the fourth quarter of 2023, compared to a net loss of \$4.9 million in the fourth quarter of 2022. The basic and diluted net loss per share for the fourth quarter 2023 was \$1.47, compared to net loss per share of \$8.66 in the fourth quarter 2022.

Full Year 2023 Financial Results

Total revenue for the full year 2023 was \$644 thousand, compared to \$787 thousand for the full year 2022, due to lower Canada product sales resulting from the prior year inclusion of approximately \$120 thousand of revenue recognized in connection with the delivery PoNS devices related to noncash consideration paid in the Company's acquisition of Heuro.

Cost of revenue for the full year 2023 increased \$120 thousand to \$583 thousand, compared to cost of revenue of \$463 thousand for the full year 2022, primarily attributable to fixed overhead costs, including salaries and benefits of employees involved in management of the supply chain and certain production costs.

Gross profit for the full year 2023 was \$61 thousand, compared to gross profit of \$324 thousand for the full year 2022.

Selling, general, and administrative expenses for the full year 2023 decreased to \$9.3 million, compared to \$10.6 million for the full year 2022, due primarily to a \$0.6 million decrease in stock-based compensation and a \$0.6 million decrease in payroll taxes including the \$0.5 million Employee Retention Credit claims we filed for the prior eligible periods.

Research and development expenses for the full year 2023 decreased to \$2.9 million, compared to \$4.3 million for the full year 2022, due primarily to decreases in product development expenses and clinical trial activities as we transitioned our focus from product development and clinical trials to U.S. commercialization activities beginning in 2022.

Operating loss for the full year 2023 decreased \$3.1 million to a loss of \$12.4 million, compared to a loss of \$15.5 million for the full year 2022.

Net loss for the full year 2023 was \$8.9 million, compared to \$14.1 million for the full year 2022. The basic and diluted net loss per share for the full year 2023 was \$14.56 per share, compared to \$52.13 per share, for the full year 2022.

Cash and Liquidity

Cash used in operating activities for the three months ended December 31, 2023, was \$2.0 million, compared to \$2.1 used in operating activities in the fourth quarter of 2022, reflecting the results of our continued focus on managing cash burn.

As of December 31, 2023, the Company had cash of \$5.2 million, compared to \$14.5 million at December 31, 2022. In Q1 2024, the Company generated \$1.3 million of net proceeds from the

sale of shares of its common stock under its ATM program at an average share price of \$9.27 per share, extending the cash runway into Q3 2024.

The Company had no debt outstanding at December 31, 2023.

Conference Call

Date: Thursday, March 28, 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 Company’s expected results for its business and financial performance in 2024, 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, 2023, 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

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

	Three Months Ended December 31,		Years Ended December 31,	
	2023	2022	2023	2022
Revenue				
Product sales, net	\$ 123	\$ 281	\$ 605	\$ 778
Other revenue	11	1	39	9
Total revenue	134	282	644	787
Cost of revenue	90	150	583	463
Gross profit	44	132	61	324
Operating expenses				
Selling, general and administrative expenses	1,632	1,967	9,271	10,640
Research and development expenses	650	794	2,942	4,262
Amortization expense	8	40	117	181
Goodwill and fixed asset impairment	—	—	159	757
Total operating expenses	2,290	2,801	12,489	15,840
Loss from operations	(2,246)	(2,669)	(12,428)	(15,516)
Nonoperating income (expense)				
Interest income (expense), net	—	85	257	(834)
Change in fair value of derivative liability	915	(2,462)	2,966	3,027
Foreign exchange (loss) gain	213	154	275	(756)
Other income (expense), net	73	6	80	7
Nonoperating income (expense), net	1,201	(2,217)	3,578	1,444
Loss before provision for income taxes	(1,045)	(4,886)	(8,850)	(14,072)
Provision for income taxes	—	—	—	—
Net loss	<u>\$ (1,045)</u>	<u>\$ (4,886)</u>	<u>\$ (8,850)</u>	<u>\$ (14,072)</u>
Loss per share				
Basic	<u>\$ (1.47)</u>	<u>\$ (8.66)</u>	<u>\$ (14.56)</u>	<u>\$ (52.13)</u>
Diluted	<u>\$ (1.47)</u>	<u>\$ (8.66)</u>	<u>\$ (14.56)</u>	<u>\$ (52.13)</u>
Weighted average number of common shares outstanding				
Basic	<u>708,603</u>	<u>564,014</u>	<u>607,890</u>	<u>269,929</u>
Diluted	<u>708,603</u>	<u>564,014</u>	<u>607,890</u>	<u>269,929</u>

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

	December 31, 2023	December 31, 2022
ASSETS		
Current assets		
Cash and cash equivalents	\$ 5,182	\$ 14,549
Accounts receivable, net	117	71
Other receivables	520	272
Inventory, net	457	589
Prepaid expenses and other current assets	1,162	1,216
Total current assets	<u>7,438</u>	<u>16,697</u>
Property and equipment, net	178	347
Intangible assets, net	24	140
Operating lease right-of-use asset, net	52	103
Total assets	<u>\$ 7,692</u>	<u>\$ 17,287</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 531	\$ 627
Accrued and other current liabilities	1,260	1,280
Current portion of operating lease liabilities	45	54
Current portion of deferred revenue	43	27
Total current liabilities	<u>1,879</u>	<u>1,988</u>
Operating lease liabilities, net of current portion	12	56
Deferred revenue, net of current portion	128	175
Derivative liability	3,323	6,917
Total liabilities	<u>5,342</u>	<u>9,136</u>
STOCKHOLDERS' EQUITY		
Class A common stock, \$0.001 par value; 150,000,000 shares authorized; 714,590 and 564,094 shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively	1	1
Additional paid-in capital	162,979	159,645
Accumulated deficit	(159,957)	(151,107)
Accumulated other comprehensive loss	(673)	(388)
Total stockholders' equity	<u>2,350</u>	<u>8,151</u>
Total liabilities and stockholders' equity	<u>\$ 7,692</u>	<u>\$ 17,287</u>