

**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 11, 2023

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 11, 2023, Heliuss Medical Technologies, Inc. (the "Registrant") issued a press release announcing its financial results for the quarter ended March 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 May 11, 2023.
104	Cover Page Interactive Data File (embedded within Inline XBRL document)



Helius Medical Technologies, Inc. Reports First Quarter 2023 Financial Results

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

NEWTOWN, Pa., May 11, 2023 (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, 2023.

First Quarter and Recent Business Updates

- Q1 2023 revenue of \$111 thousand, compared to \$190 thousand in Q1 2022, the decrease due to revenue of \$120 thousand recognized in the prior year quarter resulting from a one-time delivery of Portable Neuromodulation Stimulator (PoNS®) systems under our previous Canadian distribution agreement, partially offset by an increase in product sales in the U.S., which commenced in April 2022
- Operating cash burn of \$3.2 million during the quarter, a decrease of \$1.5 million compared to Q1 2022, reflecting ongoing efforts to extend cash runway into 2024
- Introduced UpScriptHealth telehealth e-commerce site, allowing Americans with balance and gait deficits to access online health evaluations, fulfill PoNS Therapy™ prescriptions through a network of licensed providers, and order home delivery of PoNS devices
- Received authorization from Health Canada to market PoNS for the treatment of gait deficit due to mild and moderate symptoms from stroke
- Signed exclusive distribution agreement with HealthTech Connex Inc. (“HTC”), granting HTC the exclusive right to purchase, market, sell, and distribute PoNS throughout the metropolitan Vancouver and Fraser Valley regions of British Columbia, Canada

“One year ago, we launched PoNS Therapy in the United States, and our innovative product continues to resonate in the marketplace. Neurologists, physical therapists, and those suffering from MS are seeing how PoNS treatment can improve balance and gait and we’ve implemented several programs to eliminate barriers and delays to access, including our ponstherapy.com e-commerce site and an online training portal for therapists,” said Dane Andreeff, President and Chief Executive Officer of Helius.

“Although our quarterly revenue came in below expectations due primarily to a combination of timing differences, the transition to e-commerce, and cannibalization of sales by our Therapeutic Experience Program (PoNSTEP) at certain sites, we remain positive about our momentum both in the U.S. and in Canada, where the broadened set of authorizations and HTC distribution agreement

have greatly expanded the total addressable market. With our strong cash position, reduced expenses, and foothold in the market, we are confident that we can achieve our 2023 goals.”

First Quarter 2023 Financial Results

Total revenue for the first quarter of 2023 was \$111 thousand, a decrease of \$79 thousand compared to \$190 thousand in the first quarter of 2022, primarily attributable to lower Canada product sales, partially offset by increased net product sales in the United States. Commercial product sales in the United States commenced in April 2022. Canada product sales for the three months ended March 31, 2022 included approximately \$120 thousand of revenue recognized in connection with the delivery of PoNS devices under our prior distribution agreement with HTC.

Cost of revenue was \$122 thousand for the three months ended March 31, 2023, compared to \$124 thousand for the comparable period in 2022, remaining relatively flat due to fixed overhead costs.

Operating expenses for the first quarter of 2023 decreased to \$3.8 million, compared to \$4.6 million in the first quarter of 2022. The decrease was driven primarily by a decrease in product development expenses and clinical trial activities as we transitioned our focus in the U.S. from product development and clinical trials to commercialization activities.

Operating loss for the first quarter of 2023 decreased \$0.8 million to a loss of \$3.8 million, compared to an operating loss of \$4.6 million in the first quarter of 2022.

Net loss was \$2.5 million for the first quarter of 2023, compared to a net loss of \$4.3 million in the corresponding prior year period. The basic and diluted net loss per share for the first quarter was \$0.09 per share, compared to a net loss of \$1.15 per share for the first quarter of 2022.

Cash and Liquidity

Cash used in operating activities for the three months ended March 31, 2023, was \$3.2 million compared to \$4.7 million in the first quarter of 2022, reflecting the results of our focus on reducing cash burn and extending our cash runway beyond 2023.

As of March 31, 2023, the Company had cash of \$11.3 million, compared to \$14.5 million at December 31, 2022.

The Company had no debt outstanding as of March 31, 2023.

Second Quarter and Near-Term Guidance

The Company currently expects second quarter 2023 revenue to be above the prior year quarter and first quarter levels, factoring in potential delays for some portion of U.S. patients to pursue insurance coverage prior to filling their prescriptions. The Company also expects 2023 revenues to exceed prior year levels, though we may experience additional quarterly fluctuations as we make refinements to the U.S. commercial roll-out of PoNS.

Conference Call

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

Date: Thursday, May 11, 2023

Time: 4:30 PM ET

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 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.

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.

PoNS is also authorized for sale in Canada for three 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; and (iii) for use as a short-term treatment (14 weeks) of gait deficit due to mild and moderate symptoms from stroke, 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 the Company's business and financial performance in 2023, the success of the Company's PoNS device and related treatment, and the Company's strategic operating plans.

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, disruptions in the banking system and financial markets, lingering impacts of the COVID-19 pandemic, the effect of macroeconomic conditions and the Company's ability to access capital markets, 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, availability of funds, manufacturing, labor shortage and supply chain risks, our ability to maintain and enforce our intellectual property rights, clinical trials and the clinical development process, the product development process, the regulatory submission review and approval process, our operating costs and use of cash, and our ability to achieve significant revenues, 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, 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 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.
Unaudited Condensed Consolidated Statement of Operations
(in thousands, except shares and per share data)

	Three Months Ended March 31,	
	2023	2022
Revenue		
Product sales, net	\$ 106	\$ 183
Other revenue	5	7
Total revenue	111	190
Cost of revenue	122	124
Gross profit (loss)	(11)	66
Operating expenses		
Selling, general and administrative	2,874	2,819
Research and development	886	1,764
Amortization expense	39	47
Total operating expenses	3,799	4,630
Loss from operations	(3,810)	(4,564)
Nonoperating income (expense)		
Interest income (expense), net	100	—
Change in fair value of derivative liability	1,221	—
Foreign exchange (loss) gain	(5)	217
Other income (expense), net	—	1
Nonoperating income (expense), net	1,316	218
Loss before provision for income taxes	(2,494)	(4,346)
Provision for income taxes	—	—
Net loss	<u>\$ (2,494)</u>	<u>\$ (4,346)</u>
Net loss per share		
Basic	<u>\$ (0.09)</u>	<u>\$ (1.15)</u>
Diluted	<u>\$ (0.09)</u>	<u>\$ (1.15)</u>
Weighted average number of common shares outstanding		
Basic	<u>28,209,346</u>	<u>3,787,871</u>
Diluted	<u>28,209,346</u>	<u>3,787,871</u>

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

	<u>March 31, 2023</u>	<u>December 31, 2022</u>
ASSETS		
Current assets		
Cash and cash equivalents	\$ 11,340	\$ 14,549
Accounts receivable, net	11	71
Other receivables	156	272
Inventory, net	617	589
Prepaid expenses and other current assets	1,085	1,216
Total current assets	<u>13,209</u>	<u>16,697</u>
Property and equipment, net	354	347
Intangible assets, net	101	140
Operating lease right-of-use asset, net	91	103
Total assets	<u>\$ 13,755</u>	<u>\$ 17,287</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 840	\$ 627
Accrued liabilities	856	1,280
Operating lease liabilities	51	54
Deferred revenue	42	27
Total current liabilities	<u>1,789</u>	<u>1,988</u>
Operating lease liabilities	46	56
Deferred revenue	157	175
Derivative liability	5,696	6,917
Total liabilities	<u>7,688</u>	<u>9,136</u>
STOCKHOLDERS' EQUITY		
Class A common stock, \$0.001 par value; 150,000,000 shares authorized; 28,213,378 and 28,207,330 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	28	28
Additional paid-in capital	160,023	159,618
Accumulated deficit	(153,601)	(151,107)
Accumulated other comprehensive loss	(383)	(388)
Total stockholders' equity	<u>6,067</u>	<u>8,151</u>
Total liabilities and stockholders' equity	<u>\$ 13,755</u>	<u>\$ 17,287</u>