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 10, 2023
Date of Report (Date of earliest event reported)

HELIUS MEDICAL TECHNOLOGIES, INC.

(Exact name of Registrant as Specified in Its Charter)

DELAWARE	**001-38445**	**36-4787690**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(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 August 10, 2023, Helius Medical Technologies, Inc. (the "Registrant") issued a press release announcing its financial results for the quarter ended June 30, 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 August 10, 2023.
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: August 10, 2023

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

Exhibit 99.1

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

-- Total Q2 revenue up 115% over prior year; 131% over Q1 2023 --
-- Company to host call at 4:30pm today --

NEWTOWN, Pa., August 10, 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 June 30, 2023.

Second Quarter and Recent Business Updates

- Q2 2023 revenue of $256 thousand, compared to $119 thousand in Q2 2022, an increase of 115%; up $145 thousand compared to Q1 2023, or 131%.
- Operating cash burn of $2.7 million in Q2 2023 decreased by $0.9 million compared to Q2 2022.
- Expanded stroke trial at the Medical University of South Carolina (MUSC) from 12 to 60 patients. The trial is designed to evaluate the effects of cranial-nerve non-invasive neuromodulation (CN-NINM), delivered using PoNS Therapy™, on gait and dynamic balance in chronic stroke survivors and is an important step toward pursuing United States Food and Drug Administration (FDA) authorization for stroke in the U.S.
- Added Montefiore Medical Center to the PoNS® Therapeutic Experience Program (PoNSTEP), a multi-center, company-sponsored, open label observational interventional trial to evaluate the impact of adherence to PoNS Therapy in patients with multiple sclerosis (MS).
- PoNS device awarded Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) accreditation by The Compliance Team (TCT), which is authorized by the Centers for Medicare & Medicaid Services (CMS) to accredit all DMEPOS products and services – an important milestone towards reimbursement by CMS.
- Patient Therapy Access Program (PTAP) concluded on June 30, 2023. PTAP enabled qualified Americans with MS to have early access to PoNS Therapy™ at a significantly reduced price, while the Company initiated efforts to pursue reimbursement by third party payers and CMS.

- Established an at-the-market (ATM) offering program, under which the Company may offer and sell shares having an aggregate offering price of up to $2.0 million, providing Helius the ability to access additional cash opportunistically, and on an as-needed basis.

“We saw a significant increase in sales during the second quarter of 2023, with revenue up 115% over the second quarter of 2022, and up 131% compared to the first quarter of 2023. This growth was due in part to patients purchasing PoNS prior to the expiration of PTAP at the end of June. We were pleased by the success of PTAP in creating access to PoNS in the early stages of our U.S. launch,” said Dane Andreeff, President and Chief Executive Officer of Helius.

“Going into the second half of the year, securing CMS and third-party payer reimbursement remains the Company’s chief objectives. Through PTAP we added important health economic information to our MS patient registry, which will help establish the value of PoNS on key clinical and therapeutic outcomes. In June, PoNS was awarded DMEPOS accreditation, a necessary step for Medicare coverage. With these critical components of our U.S. reimbursement strategy in place as well as a growing number of sites offering PoNS Therapy and a healthy balance sheet, we are well on our way toward achieving our goals in 2023 and beyond,” concluded Andreeff.

Second Quarter 2023 Financial Results

Total revenue for the second quarter of 2023 was $256 thousand, an increase of $137 thousand compared to $119 thousand in the second quarter of 2022, resulting from increased U.S. sales of PoNS systems under the favorable pricing offered through the PTAP, which terminated on June 30, 2023.

Cost of revenue increased to $184 thousand for the three months ended June 30, 2023, compared to $88 thousand for the comparable period in 2022, primarily attributable to higher sales compared to the same period in the prior year.

Selling, general and administrative expenses for the second quarter of 2023 were $2.6 million, comparable to the $2.5 million reported in the second quarter of 2022.

Research and development expenses for the second quarter of 2023 decreased to $0.7 million, compared to $1.0 million in the second quarter of 2022, driven primarily by a decrease in product development expenses and clinical trial activities as the Company transitioned to U.S. commercialization activities.

Total operating expenses for the second quarter of 2023 decreased to $3.3 million, compared to $3.5 million in the second quarter of 2022.

Operating loss for the second quarter of 2023 decreased $0.2 million to a loss of $3.2 million, compared to an operating loss of $3.4 million in the second quarter of 2022.

Net loss was $1.6 million for the second quarter of 2023, compared to a net loss of $3.8 million in the corresponding prior year period. The basic and diluted net loss per share for the second quarter was $0.06 per share, compared to a net loss of $0.97 per share for the second quarter of 2022.

Cash and Liquidity

Cash used in operating activities for the three months ended June 30, 2023 was $2.7 million, a decrease of $0.9 million compared to the second quarter of 2022, reflecting the results of our focus on managing cash burn and extending our cash runway further into 2024.

As of June 30, 2023, the Company had cash of $8.6 million, compared to $14.5 million as of December 31, 2022.

The Company had no debt outstanding as of June 30, 2023.

Third Quarter and Near-Term Guidance

The Company currently expects third quarter 2023 and full year 2023 revenue to be above comparable periods in the prior year with a shift in sales mix to be more heavily weighted to Canada, offsetting an anticipated decrease in the U.S following the end of the PTAP. Future U.S. sales of PoNS are expected to be at our cash-pay price until we gain reimbursement by CMS and third-party payers.

Conference Call

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

Date:	Thursday, August 10, 2023
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 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 orally-applied, non-implantable 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 ("mmTBI") 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 sufficiency of the Company's future cash position, the development, commercialization and 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

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Helius Medical Technologies, Inc.
Unaudited Condensed Consolidated Statement of Operations
(in thousands, except shares and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenue				
Product sales, net	$ 244	$ 119	$ 350	$ 302
Other revenue	12	—	17	7
Total revenue	256	119	367	309
Cost of revenue	184	88	306	212
Gross profit (loss)	72	31	61	97
Operating expenses				
Selling, general and administrative expenses	2,569	2,461	5,443	5,280
Research and development expenses	684	953	1,570	2,717
Amortization expense	38	47	77	94
Total operating expenses	3,291	3,461	7,090	8,091
Loss from operations	(3,219)	(3,430)	(7,029)	(7,994)
Nonoperating income (expense)				
Interest income (expense), net	89	—	189	—
Change in fair value of derivative liability	1,223	—	2,444	—
Foreign exchange (loss) gain	259	(380)	254	(163)
Other income (expense), net	—	—	—	1
Nonoperating income (expense), net	1,571	(380)	2,887	(162)
Loss before provision for income taxes	(1,648)	(3,810)	(4,142)	(8,156)
Provision for income taxes	—	—	—	—
Net loss	$ (1,648)	$ (3,810)	$ (4,142)	$ (8,156)
Loss per share				
Basic	$ (0.06)	$ (0.97)	$ (0.15)	$ (2.11)
Diluted	$ (0.06)	$ (0.97)	$ (0.15)	$ (2.11)
Weighted average number of common shares outstanding				
Basic	28,219,824	3,928,704	28,216,641	3,858,676
Diluted	28,219,824	3,928,704	28,216,641	3,858,676

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

	June 30, 2023	December 31, 2022
ASSETS		
Current assets		
Cash and cash equivalents	$ 8,599	$ 14,549
Accounts receivable, net	144	71
Other receivables	41	272
Inventory, net	563	589
Prepaid expenses and other current assets	918	1,216
Total current assets	10,265	16,697
Property and equipment, net	345	347
Intangible assets, net	65	140
Operating lease right-of-use asset, net	78	103
Total assets	$ 10,753	$ 17,287
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 576	$ 627
Accrued and other current liabilities	856	1,280
Current portion of operating lease liabilities	49	54
Current portion of deferred revenue	43	27
Total current liabilities	1,524	1,988
Operating lease liabilities, net of current portion	35	56
Deferred revenue, net of current portion	149	175
Derivative liability	4,473	6,917
Total liabilities	6,181	9,136
STOCKHOLDERS' EQUITY		
Class A common stock, $0.001 par value; 150,000,000 shares authorized; 28,270,762 and 28,207,330 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	28	28
Additional paid-in capital	160,443	159,618
Accumulated deficit	(155,249)	(151,107)
Accumulated other comprehensive loss	(650)	(388)
Total stockholders' equity	4,572	8,151
Total liabilities and stockholders' equity	$ 10,753	$ 17,287