

**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

Date of Report (Date of earliest event reported): November 02, 2023



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

N/A

(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
Class A Common Stock, \$0.001 par value	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 November 2, 2023, Helius Medical Technologies, Inc. (the “Registrant”) issued a press release which includes certain preliminary unaudited consolidated financial results as of and for the quarter ended September 30, 2023. A copy of this press release is furnished herewith as Exhibit 99.1 to this current report on Form 8-K 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 November 2, 2023.
104	Cover Page Interactive Data File (embedded within Inline XBRL document).



Helius Medical Technologies, Inc. to Release Third Quarter 2023 Financial Results on November 9, 2023; Announces Extended Cash Runway into Q2 2024

- Expects to report Q3 revenues in range of \$140 - \$150 thousand, reflecting the expected decrease in U.S. sales with the conclusion of the Patient Therapy Access Program (PTAP) on June 30, 2023 --
- Expects to report approximately \$7.0 million in cash, cash equivalents and proceeds receivable from warrant exercises, extending cash runway into Q2 2024 --
- Expects to report cash used in operating activities for the first nine months of 2023, ranging from \$8.3 - \$8.4 million, and for Q3, \$2.4 - \$2.5 million, reflecting continued focus on cash management --

NEWTOWN, PA., November 2, 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 that the Company will release its third quarter 2023 financial results on Thursday, November 9, 2023, after the market closes.

Dane C. Andreeff, President and Chief Executive Officer, and Jeffrey S. Mathiesen, Chief Financial Officer will host a conference call to discuss the results and provide an expanded business update regarding Helius' progress and plans surrounding the U.S. commercialization of PoNS® as follows:

Date: Thursday, November 9, 2023
Time: 4:30 p.m. Eastern Time
Toll free: 800-225-9448
International: 203-518-9708
Conference ID: HSDTQ323
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 <https://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 is 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 <https://www.ponstherapy.com/>.

Preliminary Results

The Company has not yet completed its financial and operating closing procedures for the third quarter 2023. Additionally, the preliminary financial data above has not been subject to review or other procedures by the Company’s independent registered public accounting firm. As a result, actual results may differ materially from the preliminary results shown above and will not be publicly available until the Company reports its third quarter 2023 results.

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, the potential impact of UPC code assignment on the success of the commercialization of PoNS system, the availability of Medicare reimbursement for the PoNS system, Helius’ ability to negotiate reimbursement with third party payers, and the strategic plans of the Company and the effectiveness of those 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, the Company's ability to maintain and enforce its intellectual property rights, clinical trials and the clinical development process, the product development process, the regulatory submission review and approval process, the Company's operating costs and use of cash, including cash runway, and the Company's 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
