

**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 18, 2024



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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 7.01 Regulation FD Disclosure.

On November 18, 2024, Helius Medical Technologies, Inc. (the “Company”) issued two press releases. Copies of these press releases are attached as Exhibit 99.1 and Exhibit 99.2, respectively, to this Current Report. The information in Item 7.01 of this Current Report, including Exhibits 99.1 and 99.2 hereto, is furnished pursuant to Item 7.01 and shall not be deemed “filed” for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as expressly set forth by specific reference in such a filing. The Company’s submission of this Current Report shall not be deemed an admission as to the materiality of any information required to be disclosed solely to satisfy the requirements of Regulation FD.

This Current Report and Exhibits 99.1 and 99.2 hereto contain forward-looking statements within the meaning of the federal securities laws. These forward-looking statements are based on current expectations and are not guarantees of future performance. Further, the forward-looking statements are subject to the limitations listed in Exhibits 99.1 and 99.2 and in the other reports of the Company filed with the Securities and Exchange Commission, including that actual events or results may differ materially from those in the forward-looking statements.

Item 8.01 Other Events.

On November 18, 2024, the Company issued a press release announcing that it has initiated a process to explore a range of strategic alternatives focused on maximizing stockholder value and that the Company has engaged B. Riley Securities to act as a financial advisor in connection with such process.

Also on November 18, 2024, the Company issued a press release announcing updates from its participation in the November 8, 2024 Centers for Medicare & Medicaid Services (“CMS”) HCPCS Level 2 Public Meeting relating to the CMS preliminary pricing determination for the PoNS Controller. At such meeting, the Company rebutted the CMS determination by articulating, among other things, that the PoNS Controller pricing should be based on gap-filling using recent market pricing.

As previously disclosed, in October 2024, CMS issued its final pricing determination of \$2,963.30 for the PoNS Mouthpiece to be effective January 1, 2025. Helius has requested a meeting with CMS prior to the January 1, 2025 effective date for the PoNS Mouthpiece pricing in an attempt to revisit such pricing determination.

Item 9.01 Financial Statements and Exhibits.**(d) Exhibits**

Exhibit No.	Description
99.1	Company Press Release dated November 18, 2024.
99.2	Company Press Release dated November 18, 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: November 18, 2024

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



Helius Medical Technologies, Inc. Announces Exploration of Strategic Alternatives

NEWTOWN, Pa., Nov. 18, 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 it has initiated a process, in consultation with its financial and legal advisors, to explore a range of strategic alternatives focused on maximizing stockholder value.

The deferral of a reimbursement payment determination for the PoNS Controller and inadequate PoNS Mouthpiece pricing issued by CMS in October has limited the Company’s ability to advance its operations and impeded its access to traditional financing avenues.

Helius has engaged B. Riley Securities to act as a financial advisor in connection with the strategic review process. All potential strategic alternatives to maximize value, including an acquisition, merger, reverse merger, other business combination, sale of assets, licensing, and other strategic transactions, will be explored. No updates on the process are expected to be provided during the evaluation period unless and until the Board of Directors has concluded that disclosure is appropriate or required.

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 strategic alternative exploration process and outcome and the Company’s future operating results.

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

Philip Trip Taylor
Gilmartin Group
investorrelations@heliusmedical.com



Helius Medical Technologies, Inc. Provides Updates on Efforts to Achieve Fair Market Access for its Portable Neuromodulation Stimulator (PoNS®) Device

Management to host business update call today at 9:00am ET

NEWTOWN, Pa., Nov. 18, 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 provided updates on its efforts to achieve fair market access for its Portable Neuromodulation Stimulator (PoNS) device and announced plans to host a business update call today at 9:00am ET.

“We disagree with the proposed pricing for the PoNS Mouthpiece and are disappointed CMS has once again mapped the Controller pricing to a code for fundamentally different technology,” said Dane Andreeff, Helius’ President and Chief Executive Officer. “In the face of this challenge our team’s response has been impressive as we continue to pursue fair market access for Medicare’s Multiple Sclerosis (MS) patients with balance and gait deficit. At the November 8th HCPCS Level 2 Public meeting we again refuted CMS’ methodology and presented compelling evidence in support of fair pricing for the PoNS device. Our diligent response and extensive evidence, outlined here today, has been successfully understood by the VA and a private payor. We are hopeful CMS can reach the same conclusions, and we will continue to support their reassessment.”

Recent Reimbursement Updates

- CMS issued pricing determinations for both the PoNS Controller and Mouthpiece that the Company believes reflect incomplete information and erroneous assessments of the technology, which currently preclude market access to PoNS device prescriptions for Medicare’s (MS) patients with balance and gait deficits
 - Mouthpiece pricing to take effect January 1, 2025 does not reflect recent market pricing in the gap-filling analysis. Helius has requested a meeting with CMS to occur prior to the effective date in an attempt to correct the pricing
 - Proposed Controller pricing incorrectly maps to a TENS device code as PoNS does not involve peripheral stimulation, and acts through neural plasticity and therefore is not grounded on the gate control theory of pain
 - Timing for the pricing determination and reimbursement implementation of the Controller on April 1st, three months after the Mouthpiece, an accessory required

for use of the device. Helius plans to request the Controller pricing to be set in tandem with the Mouthpiece on January 1st

- Enduring a third review cycle for PoNS Controller pricing and the uncertain timeline has delayed access to PoNS Therapy® for qualified MS patients and delayed Helius' commercial launch
- Process has impacted the Company's market value and impeded its ability to access public markets to finance its operations thus leading to the pursuit of strategic alternatives

Business Update Call

Helius management plans to host a conference call to discuss recent business updates and its efforts to achieve fair market access for the PoNS device at 9:00am ET today, November 18, 2024. Interested parties may access the live and recorded webcast here or on the "Events" page under "News & Events" on the Helius investor relations website.

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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, its Form 10-Q for the quarter ended September 30, 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.

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