

**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): December 23, 2024**



**HELIUS MEDICAL TECHNOLOGIES, INC.**

(Exact name of registrant as specified in its charter)

<b>Delaware</b> (State or other jurisdiction of incorporation)	<b>001-38445</b> (Commission File Number)	<b>36-4787690</b> (IRS Employer Identification No.)
<b>642 Newtown Yardley Road, Suite 100</b> <b>Newtown, PA</b> (Address of principal executive offices)		<b>18940</b> (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 8.01 Other Events.**

On December 23, 2024, Helius Medical Technologies, Inc. (the “Company”) announced the first PoNS System sale to the VA Healthcare System. The PoNS System sale through our distributor, Lovell Government Services, was at the contracted price of \$23,844, comprised of \$16,499 for the PoNS Controller and \$7,345 for the PoNS Mouthpiece. The full text of the press release issued in conjunction with the announcement is included in Exhibit 99.1 to this Current Report on Form 8-K.

**Item 9.01 Financial Statements and Exhibits.**

**(d) Exhibits**

Exhibit No.	Description
99.1	<a href="#">Company Press Release dated December 23, 2024.</a>
104	Cover Page Interactive Data File (embedded within Inline XBRL document)





## **Helius Announces First Portable Neuromodulation Stimulator (PoNS®) System Sale to the Veterans Affairs (VA) Healthcare System**

*Initial order placed with Company's distributor at contracted price and represents operational implementation through VA Federal Supply Schedule (FSS) Contract*

NEWTOWN, Pa., Dec. 23, 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 the first PoNS System sale to the VA Healthcare System. The PoNS System sale through our distributor, Lovell Government Services ("Lovell"), was at the contracted price of \$23,844, comprised of \$16,499 for the PoNS Controller and \$7,345 for the PoNS Mouthpiece.

"We are excited to announce the first PoNS System sale to the VA and are proud to support advancing the treatment of gait deficit for Veterans with MS," said Dane Andreeff, Helius President and Chief Executive Officer. "Since the approval of PoNS for inclusion on the Federal Supply Schedule contract, we have worked hard to integrate with the VA as an approved vendor to streamline future operations. This sale to one of the larger VA Centers of Excellence in MS, serves as a launching point for further penetration into this patient population of up to 70,000 veterans with MS as we continue to expand our sales coverage which currently extends across many of the VAs on the east coast and southeast. Additionally, this order provides valuable market pricing evidence that supports our efforts to advance discussions for broader Medicare reimbursement with CMS."

PoNS is indicated in the U.S. for use as a short-term treatment of gait deficit in adults with mild-to-moderate symptoms from MS when used in conjunction with physical therapy. The VA estimates that between 55,000 and 70,000 veterans in the U.S. are living with MS. The Company is committed to supporting this community as demonstrated in a recent spotlight on KATU that featured veteran and PoNS user Kevin Byrne, whose inspiring journey underscores the potential of PoNS Therapy®. The Company now has a team of independent sales professionals covering many VA locations along the east coast and in the southeast and is working to further expand coverage to all VA MS Centers of Excellence ("MSCoE") network facilities across the U.S.

The PoNS device was approved for inclusion on Lovell's Veterans Affairs (VA) Federal Supply Schedule (FSS) and General Services Administration (GSA) Advantage contracts earlier in 2024.

The contract award number #V797D- 50450 enables the VA and other federal entities to purchase PoNS at pre- approved pricing via the VA's FSS Medical Equipment and Surgical (Med/Surg) Contract at VA National Acquisition Center MedSurg Catalog and via the GSA Advantage online catalog at GSA Advantage. The PoNS system, Item # S1-001-02, is priced at \$23,843.72 and the PoNS mouthpiece, Item # M1-001 is priced at \$7,344.97.

### **About Lovell® Government Services**

Lovell Government Services has been a trusted SDVOSB vendor since 2013 with a proven track record of successfully introducing suppliers to the government market. Lovell is a two-time Inc. 5,000 honoree and leader in the federal space. They partner with medical and pharmaceutical companies looking to better serve Veteran and military patient populations, increase their federal revenue stream, and win government contracts. Learn more at [www.lovellgov.com](http://www.lovellgov.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 ("mmTBI") 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](http://www.ponstherapy.com).

### **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](http://www.heliusmedical.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 PoNS System sales to the VA, the Company’s future communications with CMS and the results of such communications, 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](http://www.sec.gov) or [www.sedar.com](http://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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