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): July 21, 2025

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	**18940**
(Address of principal executive offices)	**(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 July 21, 2025, Helius Medical Technologies, Inc. (the "Company") announced the positive outcome of the Portable Neuromodulation Stimulator ("PoNS") Stroke Registrational Program ("SRP") and planned upcoming FDA submission seeking an indication for gait and balance deficit in patients with chronic symptoms of stroke under the current Breakthrough Device Designation. The key primary outcomes from the SRP indicate that (i) a double-blind randomized clinical trial met the primary endpoint of demonstrating statistically significant greater improvements in gait and/or balance deficit due to stroke with active PoNS therapy with and without including additional data from an open label study using statistical methods to balance baseline characteristics and (ii) the studies confirmed a minimal incidence of adverse events and good treatment tolerability.

Helius started the SRP in March 2024 after a positive interaction with the FDA on the data development program, study design, and endpoints. The SRP includes two pivotal Sponsor-initiated clinical studies: a double-blind, randomized controlled trial and a single-arm trial, which began in April 2024. The SRP is also supported by a pilot investigator-initiated, double-blind randomized controlled trial by Dr. Steve Kautz and Dr. Mark Bowden of MUSC (SC) and Brook Rehabilitation (FL) respectively, which began late in the fall of 2023. All three clinical trials enrolled patients from the same patient population and shared the same study structure/endpoints aimed at establishing the efficacy and safety of PoNS in people with gait deficit due to chronic stroke.

A total of 159 patients were enrolled across the three studies, with 130 patients completing both the 12-week study treatment phase and the 12-week post treatment follow-up period, at 10 clinical sites including centers of excellence for stroke rehabilitation across the US and Canada. Study participants received the (active or sham) study treatment in combination with physical therapy according to the current guidelines for functional rehabilitation of people with chronic stroke.

The primary endpoints for all three studies included improvement of gait and/or balance deficit after 12 weeks of study treatment with two key multiplicity-controlled secondary endpoints assessing risk of falling and 12-week durability of effect. The double-blind randomized clinical trial met the primary endpoint of demonstrating statistically significant greater improvements in gait and/or balance deficit due to stroke with active PoNS therapy with and without including additional data from an open label study using statistical methods to balance baseline characteristics. The studies also demonstrated minimal incidence of adverse events and confirmed good treatment tolerability.

Cautionary Disclaimer Statement

Certain statements in this Current Report on Form 8-K 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 Company's product development, clinical trials, clinical and regulatory timelines, and other statements that are predictive in nature.

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 capital requirements to achieve the Company's business objectives, the impact on the Company of global macroeconomic conditions including effects from supply chain constraints, logistics challenges, labor shortages, disruptions in the banking system and financial markets, high levels of inflation and increased interest rates on the Company's ability to operate its business and access capital markets, the

success of the Company's business plan, including the Company's ability to secure contracts with rehabilitation clinics, obtain national Medicare coverage at an acceptable rate so that the PoNS device is covered by Medicare and Medicaid, 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, 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, and the Company's ability to achieve significant revenues, 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, 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.

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.

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: July 21, 2025

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