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): April 27, 2022

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 (*see* General Instruction A.2. below):

☐ 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	**HDST**	**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 April 27, 2022, Helius Medical Technologies, Inc. (the "Company") issued a press release announcing that the first patients have purchased the Company's Portable Neuromodulation Stimulator ("PoNS") devices to initiate PoNS therapy. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated April 27, 2022.
104	Cover Page Interactive Data File (embedded within Inline XBRL document).

SIGNATURES

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.

Date: April 27, 2022

By: /s/ Jeffrey S. Mathiesen

Jeffrey S. Mathiesen
Chief Financial Officer and Treasurer

Exhibit 99.1

Helius Medical Technologies, Inc. Fulfills First U.S. Prescriptions for PoNS®

-- First patients have purchased PoNS devices to initiate PoNS Therapy --
-- Nineteen PoNS device prescriptions have been written in the U.S. since recent commercial launch --

NEWTOWN, Pa., April 27, 2022 (GLOBE NEWSWIRE) -- Helius Medical Technologies, Inc. (Nasdaq:HSDT) ("Helius" or the "Company"), a neurotech company focused on neurological wellness, today announced the fulfillment of the first United States prescriptions of Portable Neuromodulation Stimulator ("PoNS") therapy for use in multiple sclerosis ("MS") patients with gait deficit. PoNS has been sold in Canada since 2019.

"We are extremely excited that the first patients in the United States have purchased the PoNS device on a cash pay basis to begin treatment. Production of the first run of the U.S. commercial version of PoNS systems completed earlier this month and we've already received nineteen prescriptions. Two patients have received their PoNS devices to start therapy and we expect to be fulfilling additional prescriptions in the coming days and weeks," stated Dane Andreeff, President and Chief Executive Officer of Helius. "This is a tremendous milestone for the Company as well as the nearly one million people in the U.S. suffering from MS, and we look forward to bringing this important treatment to patients who need it. As previously disclosed, we expect prescriptions in the U.S. to remain on a cash pay basis for the foreseeable future as we pursue reimbursement from third-party payers and CMS. We are pleased with the reception we are receiving during the launch."

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 non-surgical 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. Helius is advancing PoNS post-approval research in MS through a recently launched Therapeutic Experience Program (TEP) designed to partner with neurologists and neurorehabilitation therapists at 10-12 US centers of excellence, who express an interest in becoming "early adopters" of PoNS therapy.

PoNS is also authorized for sale in Canada for two 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. 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.

Cautionary Disclaimer Statement

This press release does not and shall not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or other jurisdiction. Any offer, if at all, will be made only by means of a prospectus, including a prospectus supplement, forming a part of the effective registration 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,” “continue,” “expect,” “will,” “goal,” “aim to” and similar expressions. Such forward-looking statements include, among others, statements regarding the Company’s future growth and operational progress, including commercial activities for the PoNS device, our revenue from sales of our products, receipt and fulfillment of prescriptions and progress of commercialization of the PoNS device in the U.S.,, expectations for the Therapeutic Experience Program, and our future expenses and cash flow.

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 ability to find additional sources of funding, the impact of the COVID-19 pandemic, manufacturing, labor shortage and supply chain risks, 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, market awareness of the PoNS device, future clinical trials and the clinical development process, ongoing government regulation and other factors, 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, 2021 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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