

**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

January 26, 2022

Date of Report (Date of earliest event reported)



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

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
Common Stock	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 January 26, 2022, Helius Medical Technologies, Inc. (the “**Registrant**”) issued a press release providing a corporate update, which includes certain preliminary unaudited financial results as of and for the quarter ended December 31, 2021. A copy of this press release is furnished herewith as Exhibit 99.1 to this Current Report 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 (the “**Securities Act**”), 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	Company Press Release, dated January 26, 2022.
104	Cover Page Interactive Data File (embedded within Inline XBRL document).



Helius Medical Technologies, Inc. Provides Corporate Update

-- Fourth Quarter 2021 Revenue Projected to Range from \$250,000 to \$260,000 --

-- Unaudited Year End Cash Balance of \$11 million --

-- Continued Progress Toward U.S. Commercial Launch of PoNS® for Multiple Sclerosis --

-- Initiation of Pivotal and Investigator Initiated Trials for Use of PoNS in Stroke Patients Targeted for First Half of 2022 --

NEWTOWN, Pa., January 26, 2022 – (GLOBE NEWSWIRE) -- Helius Medical Technologies, Inc. (Nasdaq: HSDT) (“Helius” or the “Company”), a neurotech company focused on neurological wellness, today provided a corporate update.

2021 Corporate Highlights and Achievements

- Received marketing authorization from the U.S. Food and Drug Administration (“FDA”) for use of PoNS for short term treatment of gait deficit due to mild-to-moderate symptoms from multiple sclerosis (“MS”)
 - Granted a second FDA Breakthrough Designation for PoNS for the treatment of dynamic gait and balance deficits resulting from a stroke
 - Received authorization from the Australian Therapeutic Goods Administration (“TGA”) for the sale of PoNS as a Class IIa medical device to improve balance and gait
 - Contracted with NYU-Langone Health, the first of a targeted ten to twelve Centers of Excellence in a multi-center, company-sponsored Therapeutic Experience Program (“TEP”), an open label observational interventional trial designed to evaluate the impact of subjects’ adherence to PoNS therapy
 - Launched collaboration with the Medical University of South Carolina (“MUSC”) in an Investigator Initiated Trial (“IIT”) to evaluate the effects of PoNS therapy on the recovery of gait and postural stability in chronic stroke survivors
 - Appointed several highly qualified individuals to restructure senior leadership team including President & Chief Executive Officer, Chief Financial Officer, Chief Medical Officer, and Vice President of Sales & Marketing, North America
 - Enhanced the Board of Directors with the appointment of industry veterans Sherrie Perkins and Paul Buckman
 - Raised \$24.0 million gross proceeds from equity financings to fund Company through several critical milestones including the US commercial launch of PoNS for the treatment of gait deficit due to MS
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Canadian Commercial Activities

- Total of 37 authorized PoNS clinics at the end of 2021, up from 31 at the end of 2020, despite the impact of COVID-19
- Expected 4th quarter 2021 revenue increased more than 30% year over year compared to Q4 2020, and more than doubled compared to Q3 2021
- Revenue uncertainty due to COVID-19 will continue into 2022, due in part to the potential impact of the recent reinstatement of some COVID-19 restrictions in certain parts of Canada

Key 2022 Targeted Milestones

- Initial prescriptions for PoNS for the treatment of gait deficit due to MS related to the U.S. commercial launch projected in the first quarter 2022
- Conduct IIT stroke trial at MUSC, which will allow for observation of PoNS therapy in a real-world clinical setting; expect to enroll twelve participants during the first half of 2022
- Full expansion of TEP, with the goal of enrolling ten to twelve Centers of Excellence and fifty to sixty MS patients by mid-2022
- Initiation of pivotal clinical trial in stroke patients in the first half of 2022

Year End 2021 Financial Updates

- Unaudited 2021 year-end cash balance of \$11.0 million
- Estimated unaudited fourth quarter 2021 revenues between \$250 thousand and \$260 thousand

“The past year was a period of great transformation for HeliUS and validation of the PoNS therapy” said Dane Andreeff, President and Chief Executive Officer of HeliUS. “We enter 2022 poised to capitalize on our efforts and success, beginning with the U.S. commercialization of PoNS for MS, with initial prescriptions expected in the first quarter of this year. Along with achieving this significant milestone, we’ll continue to advance our study of PoNS in stroke patients, as well as open more TEP Centers of Excellence. Both initiatives will offer valuable insight into the functional outcomes of PoNS therapy in MS and stroke patients. I am very excited about what 2022 holds as we take another step closer to our goal of unlocking the full potential of neuromodulation and becoming the standard of care for gait deficit.”

Our closing procedures for our fiscal quarter and year ended December 31, 2021 are not yet complete. The preliminary financial information presented in this press release reflects our current expectations based solely on information available to us as of the date of this press release and is subject to change as a result of the completion of the Company’s financial and operating closing procedures, customary audit procedures and other developments that may occur before the completion of these procedures. Accordingly, you should not place undue reliance on this preliminary financial information, which may differ materially from actual results. See “Cautionary Disclaimer Statement” below for a discussion of certain factors that could result in differences between the estimated unaudited financial information reported in this press release and actual results.

Conference Call

Dane C. Andreeff, President and Chief Executive Officer, and Jeffrey S. Mathiesen, Chief Financial Officer, will host a conference call to discuss fourth quarter and full year 2021 results and provide a business update as follows:

Date: Monday, March 14, 2022

Time: 5:00 PM ET

Toll-free (U.S.) (844) 348-4652

International (213) 358-0895

Conference ID 2995141

A live webcast of the call will also be provided on the Events section of the Company's investor relations website at:

<https://edge.media-server.com/mmc/p/mtbio3ko>.

A replay of the call will be available for one week at (855) 859-2056 (U.S.) or (404) 537-3406 (international). The conference ID for the replay is 2995141. The webcast will be archived on the Events 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 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) PoNS is authorized 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 (ii) PoNS is authorized 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

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,” “future,” “goal,” “target,” “milestone,” “project,” “preliminary,” “on track,” “estimate,” “continue,” “aim” and similar expressions.

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, the impact of the COVID-19 pandemic, inflation, supply chain disruptions and labor shortages, 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, future clinical trials and the clinical development process, manufacturing and supply chain risks, the product development process and 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, 2020, its Quarterly Report on Form 10-Q for the quarter ended September 30, 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.

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