

**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

November 14, 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

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:

- 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>
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 November 14, 2022, Helius Medical Technologies, Inc. (the “Registrant”) issued a press release announcing its financial results for the quarter ended September 30, 2022, as well as information regarding a conference call to discuss these financial results and the Registrant’s recent corporate highlights. 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, 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 [Press Release dated November 14, 2022.](#)

104 Cover Page Interactive Data File (embedded within Inline XBRL document)



Helius Medical Technologies, Inc. Reports Third Quarter 2022 Financial Results

- Total Q3 revenue up 80% over prior year --
- Cash on hand expected to fund operations through 2023 --
- Company to host call at 8:30am today --

NEWTOWN, Pa., November 14, 2022 (GLOBE NEWSWIRE) -- Helius Medical Technologies, Inc. (Nasdaq:HSDT) ("Helius" or the "Company"), a neurotech company focused on neurological wellness, today reported financial results for the quarter ended September 30, 2022.

Third Quarter and Recent Business Updates

- First full quarter of commercial availability of PoNS® in the U.S.
- Introduced online, on-demand training module to standardize and streamline the training of physical therapists who wish to use PoNS Therapy to treat patients suffering gait impairment due to multiple sclerosis (MS).
- Added MGH Institute of Health Professions and Oregon Health & Science University as a Therapeutic Experience Program (TEP) centers of excellence joining Shepard Center in Atlanta and NYU Langone already enrolling patients.
- Closed an \$18 million public offering, raising net proceeds of approximately \$16.3 million.
- Q3 2022 revenue increased by 80% to \$196 thousand compared to \$109 thousand in Q3 2021, and by 65% compared to Q2 2022.
- \$16.7 million of cash on hand to fund operations through 2023.

"It was the first full quarter of commercial sales and the market response to PoNS Therapy remained strong, as demonstrated by the quarter over quarter increase in US sales. The Patient Therapy Access Program we introduced in June has been well received, and a significant percentage of patients have used PTAP to access on-label PoNS Therapy at a reduced price. We also addressed another major impediment to access by introducing an online training module which has allowed us to greatly accelerate the training of physical therapists. In the US, we have gone from less than half a dozen to close to 100 PTs trained over the past three months, with the large majority occurring since we kicked off the program. Because physical therapists can now receive PoNS Therapy training on-demand in three hours or less, instead of through an in-person, multi-day course, patients can have readily available access to PoNS trained therapist," said Dane Andreeff, President and Chief Executive Officer of Helius.

"We also made progress with TEP, an important program that will help us gather information about the effectiveness of PoNS Therapy in a real-world environment. During the quarter, we began enrollment at the previously announced TEP locations and, more recently, added Mass General and OSHU as a Centers of Excellence. We are energized by all the Company has accomplished in 2022 so far and, fortified by our recent equity raise, look forward to continuing the momentum into next year and beyond, bringing relief to as many patients as possible who suffer from gait impairment," concluded Mr. Andreeff.

Third Quarter 2022 Financial Results

Total revenue for the third quarter of 2022 was \$196 thousand, an increase of 80% compared to \$109 thousand in the third quarter of 2021 and was comprised primarily of product sales in both periods. Product sales in the U.S. during the third quarter totaling \$139 thousand more than doubled over the second quarter 2022 levels.

For the three months ended September 30, 2022, cost of sales was \$101 thousand as compared to \$86 thousand for the three months ended September 30, 2021. The increase was primarily attributable to overhead costs, including salaries and benefits of employees involved in management of the supply chain and, to a lesser extent, higher product sales in the current period. Gross profit for the third quarter of 2022 was \$95 thousand, compared to gross profit of \$23 thousand in the third quarter of 2021.

Operating expenses for the third quarter of 2022 increased to \$4.9 million, compared to \$4.4 million in the third quarter of 2021. The increase was primarily due to a net increase in stock-based compensation expense, including \$1.2 million attributable to performance-based options that vested during current year quarter, partially offset by lower research and development costs following the U.S. commercial launch.

Operating loss for the third quarter of 2022 increased \$0.5 million to a loss of \$4.9 million, compared to an operating loss of \$4.4 million in the third quarter of 2021.

Net loss was \$1.0 million for the third quarter of 2022, compared to a net loss of \$4.7 million, in the corresponding prior year period. The basic and diluted net loss per share for the third quarter 2022 was \$0.12, compared to net loss per share of \$2.01 in the third quarter 2021.

As of September 30, 2022, the Company had cash of \$16.7 million, compared to \$11.0 million at December 31, 2021. The Company had no debt outstanding at September 30, 2022.

Fourth Quarter and Near-Term Guidance

The Company currently expects fourth quarter revenue to be modestly above the third quarter levels, factoring in the timing required to pair patients with trained physical therapists. In addition, as we near the end of the fourth quarter, we may experience some patients delaying PoNS treatment until after the holidays, which could temper sales growth as we expand our U.S. market penetration. As we continue to build momentum and expand our sales coverage, the Company expects future quarterly revenue to continue increasing sequentially quarter over quarter throughout 2023 as the U.S. commercialization of PoNS develops.

Conference Call

As previously announced, management will host a conference call as follows:

Date: Monday, November 14, 2022

Time: 8:30 AM ET

Register* (Audio Only): [Click Here](#)

Webcast: <https://edge.media-server.com/mmc/p/k92nxahw>

The webcast will be archived under the Newsroom 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 promote neuroplasticity, improving 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. For more information visit www.ponstherapy.com.

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 ("mTBI") 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:

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, projected revenue from sales of our products, progress of commercialization of the PoNS device in the U.S., the ability and timing of our customers' ability to seek reimbursement for the PoNS device in the U.S., expectations for the Therapeutic Experience Program, clinical development plans, and product development activities.

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, 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, 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, its Quarterly Reports on Form 10-Q for the quarters ended March 31, 2022 and June 30, 2022 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:

Lisa M. Wilson, In-Site Communications, Inc.
T: 212-452-2793
E: lwilson@insitecony.com

Unaudited Condensed Consolidated Statements of Operations

(Amounts in thousands except shares and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue				
Product sales, net	\$ 195	\$ 102	\$ 497	\$ 242
Other revenue	1	7	8	22
Total revenue	196	109	505	264
Cost of revenue	101	86	313	169
Gross profit	95	23	192	95
Operating expenses				
Selling, general and administrative	3,393	2,859	8,673	9,800
Research and development	751	1,489	3,468	4,182
Amortization expense	47	48	141	153
Goodwill impairment	757	—	757	—
Total operating expenses	4,948	4,396	13,039	14,135
Loss from operations	(4,853)	(4,373)	(12,847)	(14,040)
Nonoperating income (expense)				
Interest expense, net	(919)	—	(919)	—
Change in fair value of derivative liability	5,489	—	5,489	—
Foreign exchange (loss) gain	(747)	(314)	(910)	10
Other income, net	—	—	1	—
Nonoperating income (expense), net	3,823	(314)	3,661	10
Loss before provision for income taxes	(1,030)	(4,687)	(9,186)	(14,030)
Provision for income taxes	—	—	—	—
Net loss	\$ (1,030)	\$ (4,687)	\$ (9,186)	\$ (14,030)
Net loss per share				
Basic	\$ (0.12)	\$ (2.01)	\$ (0.52)	\$ (6.29)
Diluted	\$ (0.12)	\$ (2.01)	\$ (0.52)	\$ (6.29)
Weighted average number of common shares outstanding				
Basic	8,543,303	2,326,893	17,761,752	2,229,422
Diluted	8,543,303	2,326,893	17,761,752	2,229,422

Helius Medical Technologies, Inc.
Unaudited Condensed Consolidated Balance Sheets
(Except for share data, amounts in thousands)

	<u>September 30, 2022</u>	<u>December 31, 2021</u>
ASSETS		
Current assets		
Cash	\$ 16,658	\$ 11,005
Accounts receivable, net	21	66
Other receivables	196	185
Inventory, net	609	476
Prepaid expenses and other current assets	733	862
Total current assets	18,217	12,594
Property and equipment, net	348	409
Goodwill	—	763
Intangible assets, net	178	333
Operating lease right-of-use asset, net	116	3
Total assets	<u>\$ 18,859</u>	<u>\$ 14,102</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 570	\$ 1,069
Accrued liabilities	551	1,433
Operating lease liabilities	53	3
Deferred revenue	26	148
Total current liabilities	1,200	2,653
Operating lease liabilities	70	—
Deferred revenue	173	193
Derivative liability	4,455	—
Total liabilities	5,898	2,846
STOCKHOLDERS' EQUITY		
Class A common stock, \$0.001 par value; 150,000,000 shares authorized; 28,201,282 and 3,780,674 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	28	4
Additional paid-in capital	159,386	149,412
Accumulated deficit	(146,221)	(137,035)
Accumulated other comprehensive loss	(232)	(1,125)
Total stockholders' equity	12,961	11,256
Total liabilities and stockholders' equity	<u>\$ 18,859</u>	<u>\$ 14,102</u>