

**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**

March 9, 2023

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:

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 March 9, 2023, Helius Medical Technologies, Inc. (the “Company”) issued a press release announcing its financial results for the quarter and year ended December 31, 2022, as well as information regarding a conference call to discuss these financial results and the Company’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 Company’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	<a href="#">Press Release, dated March 9, 2023</a>
104	Cover Page Interactive Data File (embedded within Inline XBRL document)





## Helius Medical Technologies, Inc. Reports Fourth Quarter and Full Year 2022 Financial Results

- Full year 2022 revenue of \$0.8 million, an increase of 51% over 2021 --
- Year-end cash balance of \$14.5 million --
- Company to host call at 4:30pm today --

NEWTOWN, Pa., March 9, 2023 (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 results for the quarter and full year ended December 31, 2022.

### Fourth Quarter and Recent Business Updates

- Q4 2022 revenue increased 9% to \$282 thousand compared to Q4 2021, and increased 44% compared to Q3 2022
- Full year 2022 revenue increased 51% to \$787 thousand compared to 2021
- Introduced UpScript Telehealth e-commerce site, allowing Americans with balance and gait deficits to access online health evaluations, fulfill Portable Neuromodulation Stimulator (PoNS®) Therapy prescriptions through a network of licensed providers, and order home delivery of PoNS devices
- Shipped first e-commerce orders in January 2023
- Extended Patient Therapy Access Program (PTAP) through June 30, 2023, giving more qualifying patients access to PoNS Therapy at a significantly reduced price
- Added three Centers of Excellence in Company’s Therapeutic Experience Program (PoNSTEP), a multi-center, company-sponsored, open label observational interventional trial to evaluate the impact of subjects’ adherence to PoNS Therapy
- Authorization from Health Canada to market PoNS for the treatment of gait deficit due to mild and moderate symptoms from stroke

“We finished our launch year strong, with 44% sequential quarterly revenue growth and the introduction of several programs to increase access to PoNS Therapy for patients suffering from balance and gait impairment. Earlier in the year, we implemented an online training module to standardize the training process and enable faster onboarding of physical therapists. More recently, we launched the ponstherapy.com e-commerce site and also expanded our PTAP program, which provides qualifying MS patients access to PoNS Therapy at a nearly 85% discount to list price. These efforts are already beginning to pay off, and it’s gratifying to see patients who are suffering from MS more quickly receive the relief that they need,” said Dane Andreeff, President and Chief Executive Officer of Helius.

“We are also thrilled to add gait deficit due to mild and moderate symptoms from stroke as another indication for which PoNS has received market authorization in Canada, as announced earlier today. PoNS is a breakthrough technology, and we are excited about the tremendous opportunity to help patients suffering from balance and gait impairment. With the positive reception to PoNS in the North American

marketplace and our strong balance sheet and reduced cash burn, we are well-positioned to build on our momentum in 2023,” Andreeff concluded.

#### **Fourth Quarter 2022 Financial Results**

Total revenue for the fourth quarter of 2022 was \$282 thousand, an increase of 9% compared to \$258 thousand in the fourth quarter of 2021 and was comprised primarily of product sales in both periods.

Cost of revenues was \$150 thousand for the three months ended December 31, 2022, compared to \$129 thousand for the comparable period in 2021, primarily due to increased revenues.

Gross profit for the fourth quarter of 2022 was \$132 thousand, compared to gross profit of \$129 thousand in the fourth quarter of 2021.

Operating expenses for the fourth quarter of 2022 decreased to \$2.8 million, compared to \$4.2 million in the fourth quarter of 2021. The decrease was primarily the result of lower product development and clinical trial activities following the U.S. commercial launch of PoNS.

Operating loss for the fourth quarter of 2022 decreased \$1.4 million to a loss of \$2.7 million, compared to an operating loss of \$4.1 million in the fourth quarter of 2021.

Net loss was \$4.9 million for the fourth quarter of 2022, compared to a net loss of \$4.1 million in the corresponding prior year period. The basic and diluted net loss per share for the fourth quarter 2022 was \$0.17, compared to net loss per share of \$1.31 in the fourth quarter 2021.

#### **Full Year 2022 Financial Results**

Total revenue for the full year 2022 was \$787 thousand, compared to \$522 thousand for the full year 2021, reflecting the U.S. commercial launch of PoNS for MS in April 2022, partially offset by a decrease in product sales in Canada, mostly attributable to lower Canadian to U.S. dollar translation rates during 2022.

Cost of revenue for the full year 2022 increased \$165 thousand to \$463 thousand, compared to cost of revenue of \$298 thousand for the full year 2021, primarily attributable to overhead costs, including salaries and benefits of employees involved in management of the supply chain, and inventory-related cost of sales due to higher sales volume.

Gross profit for the full year 2022 was \$324 thousand, compared to gross profit of \$224 thousand for the full year 2021.

Operating expenses for the full year 2022 decreased \$2.5 million to \$15.8 million, compared to \$18.4 million for the full year 2021, due primarily to a \$2.0 million decrease in stock-based compensation expense and a decrease in product development and clinical trial expenses as we transitioned from product development and clinical trials to U.S. commercialization activities, partially offset by increased compensation expenses related to personnel additions in late 2021 and early in 2022 to support the U.S. commercial launch.

Operating loss for the full year 2022 decreased \$2.6 million to \$15.5 million, compared to \$18.1 million for the full year 2021.

Net loss for the full year 2022 was \$14.1 million, compared to \$18.1 million for the full year 2021. The basic and diluted net loss per share for the full year 2022 was \$1.04 per share, compared to \$7.38 per share, for the full year 2021.

## Cash and Liquidity

Cash used in operating activities for the three months ended December 31, 2022 was \$2.1 million, a significant decrease from the average quarterly run rate of approximately \$4.1 million over the previous three quarters of 2022, reflecting the results of our focus on reducing cash burn and extending our cash runway beyond 2023. Cash used in operations for the twelve months ended December 31, 2022 was \$14.3 million compared to \$13.4 million in the prior year.

As of December 31, 2022, the Company had cash of \$14.5 million, compared to \$11.0 million at December 31, 2021.

The Company had no debt outstanding at December 31, 2022.

## 2023 Guidance

The Company currently expects 2023 revenues to exceed prior year levels and increase throughout the year, though we may experience quarterly fluctuations as we make refinements to our U.S. commercial roll-out of PoNS. We also believe broad third-party payer reimbursement will be needed to achieve our full revenue potential.

## Conference Call

Date: Thursday, March 9, 2023

Time: 4:30 p.m. Eastern Time

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

Webcast: [Click here](#)

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 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](http://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.

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. For more information visit [www.ponstherapy.com](http://www.ponstherapy.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 the Company’s expected business and financial results for the Company’s business and financial performance in 2023.

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, 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, 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](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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**Helius Medical Technologies, Inc.**  
**Consolidated Statements of Operations**  
(in thousands, except share and per share amounts)  
(unaudited)

	Three Months Ended December 31,		Years Ended December 31,	
	2022	2021	2022	2021
<b>Revenue</b>				
Product sales, net	\$ 281	\$ 251	\$ 778	\$ 493
Other revenue	1	7	9	29
Total revenue	282	258	787	522
Cost of revenue	150	129	463	298
Gross profit	132	129	324	224
<b>Operating expenses</b>				
Selling, general and administrative	1,967	2,376	10,640	12,176
Research and development	794	1,808	4,262	5,990
Amortization expense	40	47	181	200
Goodwill impairment	—	—	757	—
Total operating expenses	2,801	4,231	15,840	18,366
Loss from operations	(2,669)	(4,102)	(15,516)	(18,142)
<b>Nonoperating income (expense)</b>				
Interest income (expense), net	85	—	(834)	—
Change in fair value of derivative liability	(2,462)	—	3,027	—
Foreign exchange (loss) gain	154	—	(756)	10
Other income, net	6	—	7	—
Nonoperating income (expense), net	(2,217)	—	1,444	10
Loss before provision for income taxes	(4,886)	(4,102)	(14,072)	(18,132)
Provision for income taxes	—	—	—	—
Net loss	\$ (4,886)	\$ (4,102)	\$ (14,072)	\$ (18,132)
<b>Net loss per share</b>				
Basic	\$ (0.17)	\$ (1.31)	\$ (1.04)	\$ (7.38)
Diluted	\$ (0.17)	\$ (1.31)	\$ (1.04)	\$ (7.38)
<b>Weighted average number of common shares outstanding</b>				
Basic	28,197,189	3,131,448	13,497,159	2,456,782
Diluted	28,197,189	3,131,448	13,497,159	2,456,782



**Heliuss Medical Technologies, Inc.**  
**Consolidated Balance Sheets**  
(in thousands, except share and per share amounts)  
(unaudited)

	<u>December 31, 2022</u>	<u>December 31, 2021</u>
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 14,549	\$ 11,005
Accounts receivable, net	71	66
Other receivables	272	185
Inventory, net	589	476
Prepaid expenses and other current assets	1,216	862
Total current assets	16,697	12,594
Property and equipment, net	347	409
Goodwill	—	763
Intangible assets, net	140	333
Operating lease right-of-use asset, net	103	3
Total assets	<u>\$ 17,287</u>	<u>\$ 14,102</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities</b>		
Accounts payable	\$ 627	\$ 1,069
Accrued liabilities	1,280	1,433
Operating lease liabilities	54	3
Deferred revenue	27	148
Total current liabilities	1,988	2,653
Operating lease liabilities	56	—
Deferred revenue	175	193
Derivative liability	6,917	—
Total liabilities	9,136	2,846
<b>STOCKHOLDERS' EQUITY</b>		
Class A common stock, \$0.001 par value; 150,000,000 shares authorized; 28,207,330 and 3,780,674 shares issued and outstanding as of December 31, 2022 and December 31, 2021, respectively		
	28	4
Additional paid-in capital	159,618	149,412
Accumulated deficit	(151,107)	(137,035)
Accumulated other comprehensive loss	(388)	(1,125)
Total stockholders' equity	8,151	11,256
Total liabilities and stockholders' equity	<u>\$ 17,287</u>	<u>\$ 14,102</u>