
**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

August 15, 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:

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 August 15, 2022, Helius Medical Technologies, Inc. (the “Registrant”) issued a press release announcing its financial results for the quarter ended June 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 August 15, 2022.
104	Cover Page Interactive Data File (embedded within Inline XBRL document)



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

-- Net proceeds from August 2022 financing and cash on hand expected to fund operations through 2023 --

-- Company to host call at 4:30pm today --

NEWTOWN, Pa., Aug. 15, 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 June 30, 2022.

Second Quarter and Recent Business Updates

- Fulfilled first U.S. prescriptions of PoNS Therapy for use in multiple sclerosis (“MS”) patients experiencing gait deficit.
- Made PoNS Therapy training available online and on-demand in July, eliminating a major bottleneck to patient access.
- Launched Patient Therapy Access Program in June to provide qualifying patients access to on-label PoNS Therapy at a significantly reduced price.
- Added Shepherd Center in Atlanta, Georgia to the Company-sponsored Therapeutic Experience Program (“TEP”), an open label observational interventional trial designed to evaluate the impact of subjects’ adherence on PoNS Therapy outcomes in patients with MS.
- Q2 2022 revenue increased by 68% to \$119 thousand compared to \$71 thousand in Q2 2021.
- Closed a \$18 million public offering on August 9th, raising net proceeds of approximately \$16.4 million.

“The second quarter saw the start of PoNS commercial sales in the United States, and we have already received several hundred inquiries. Though revenue during the quarter increased on a year-over-year basis, we did not have the sequential growth we’d expected. As a result, we’ve implemented several programs to eliminate the impediments to prescription fulfillment. First, we introduced an online training module so physical therapists can be trained in three hours or less, at the therapist’s own pace, instead of through an in-person, multi-day course. This module, which became available in mid-July, is already proving effective in onboarding physical therapists and clinics speedily and more efficiently, without added cost, allowing patients and physicians to spend less time waiting for a qualified and available therapist,” said Dane Andreeff, President and Chief Executive Officer of Helius. “On June 1st, we also announced the launch of the Patient Therapy Access Program, which provides patients suffering from MS access to on-label PoNS Therapy at a greatly reduced price and, later this year, we will roll out our online pharmacy initiative. Through a network of fully licensed providers with e-prescribing capabilities, our upcoming direct-to-consumer e-platform will streamline access to PoNS Therapy, and further reduce the time it takes for a patient to get the treatment they need.”

“We are excited to build on this momentum going into the second half of the year, and our recently announced public offering gives us the runway to focus on getting PoNS Therapy to as many patients as possible,” concluded Mr. Andreeff.

Second Quarter 2022 Financial Results

Total revenue for the second quarter of 2022 was \$119 thousand, an increase of 67.6% compared to \$71 thousand in the second quarter of 2021 and was comprised primarily of product sales in both periods.

For the three months ended June 30, 2022, cost of sales was \$88 thousand as compared to \$67 thousand for the three months ended June 30, 2021. The increase was primarily attributable to higher product sales in the current period. Gross profit for the second quarter of 2022 was \$31 thousand, compared to gross profit of \$4 thousand in the second quarter of 2021.

Operating expenses for the second quarter of 2022 decreased to \$3.5 million, compared to \$6.2 million in the second quarter of 2021. The decrease was primarily due a decrease in stock-based compensation expense as well as lower product development and clinical trial costs.

Operating loss for the second quarter of 2022 decreased \$2.7 million to a loss of \$3.4 million, compared to an operating loss of \$6.2 million in the second quarter of 2021.

Net loss was \$3.8 million for the second quarter of 2022, compared to a net loss of \$6.0 million, in the corresponding prior year period. The basic and diluted net loss per share for the second quarter 2022 was \$0.97, compared to net loss per share of \$2.58 in the second quarter 2021.

As of June 30, 2022, the Company had cash of \$3.3 million, compared to \$11.0 million at December 31, 2021. Including the estimated net proceeds of \$16.4 million from our August 9, 2022 financing, our proforma cash balance at June 30, 2022 is \$19.7 million. The Company had no debt outstanding at June 30, 2022.

Third Quarter and Near-Term Guidance

The Company currently expects third quarter revenue to be modestly above the second quarter levels, factoring in the timing required to pair patients with trained physical therapists and potential delays for some portion of U.S. patients to pursue insurance coverage prior to filling their prescriptions. 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 the year and through 2023 as the U.S. commercialization of PoNS develops.

Conference Call

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

Date:	Monday, August 15, 2022
Time:	4:30 PM ET
Register* (Audio Only):	Click Here
Webcast:	https://edge.media-server.com/mmc/p/uaji4a8t

The webcast will be archived under the Newsroom section of the Company's investor relations website.

* Beginning this quarter, conference call participants should register to obtain their dial-in and passcode details. The new, streamlined process improves security and eliminates wait times when joining the call. Please be sure to register using a valid email address.

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. Heliuss 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 (“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, 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.

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Unaudited Condensed Consolidated Statements of Operations

(Amounts in thousands except shares and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenue:				
Product sales, net	\$ 119	\$ 63	\$ 302	\$ 140
Other revenue	—	8	7	15
Total operating revenue	119	71	309	155
Cost of sales:				
Cost of product sales	88	67	212	83
Gross profit	31	4	97	72
Operating expenses:				
Research and development	953	1,377	2,717	2,694
Selling, general and administrative	2,461	4,744	5,280	6,939
Amortization expense	47	49	94	106
Total operating expenses	3,461	6,170	8,091	9,739
Operating loss	(3,430)	(6,166)	(7,994)	(9,667)
Other income (expense):				
Other income	—	—	1	—
Foreign exchange (loss) gain	(380)	185	(163)	324
Net other income (expense)	(380)	185	(162)	324
Loss before provision for income taxes	(3,810)	(5,981)	(8,156)	(9,343)
Provision for income taxes	—	—	—	—
Net loss	\$ (3,810)	\$ (5,981)	\$ (8,156)	\$ (9,343)
Net loss per share				
Basic	\$ (0.97)	\$ (2.58)	\$ (2.11)	\$ (4.29)
Diluted	\$ (0.97)	\$ (2.58)	\$ (2.11)	\$ (4.29)
Weighted average shares outstanding				
Basic	3,928,704	2,317,389	3,858,676	2,179,878
Diluted	3,928,704	2,317,389	3,858,676	2,179,878

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

	<u>June 30, 2022</u>	<u>December 31, 2021</u>
ASSETS		
Current assets		
Cash	\$ 3,273	\$ 11,005
Accounts receivable, net	9	66
Other receivables	187	185
Inventory, net	577	476
Prepaid expenses	996	862
Other current assets	22	—
Total current assets	<u>5,064</u>	<u>12,594</u>
Property and equipment, net	365	409
Other assets		
Goodwill	753	763
Intangible assets, net	236	333
Operating lease right-of-use asset, net	128	3
Total other assets	<u>1,117</u>	<u>1,099</u>
TOTAL ASSETS	<u>\$ 6,546</u>	<u>\$ 14,102</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 1,043	\$ 1,069
Accrued liabilities	654	1,433
Operating lease liability	52	3
Deferred revenue	28	148
Total current liabilities	<u>1,777</u>	<u>2,653</u>
Non-current liabilities		
Operating lease liability	83	—
Deferred revenue	184	193
TOTAL LIABILITIES	<u>2,044</u>	<u>2,846</u>
STOCKHOLDERS' EQUITY		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding as of June 30, 2022 and December 31, 2021	—	—
Class A common stock, \$0.001 par value; 150,000,000 shares authorized; 4,195,113 and 3,780,674 shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively	4	4
Additional paid-in capital	150,665	149,412
Accumulated deficit	(145,191)	(137,035)
Accumulated other comprehensive loss	(976)	(1,125)
TOTAL STOCKHOLDERS' EQUITY	<u>4,502</u>	<u>11,256</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 6,546</u>	<u>\$ 14,102</u>