



Helius Medical Technologies, Inc. Reports Second Quarter 2024 Financial Results

August 12, 2024 8:05 PM EDT

Company to host call at 4:30pm today

NEWTOWN, Pa., Aug. 12, 2024 (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 ended June 30, 2024.

Second Quarter and Recent Business Updates

- Secured the first third-party reimbursement for the Portable Neuromodulation Stimulator ("PoNS®") device from a major insurance carrier at \$23,900, representing a significant milestone toward increasing PoNS accessibility.
- Received preliminary Centers for Medicare & Medicaid Services ("CMS") payment determination for reimbursement of PoNS, paving the way to final price determination on October 1, 2024.
- Completed site participation enrollment for the U.S. registrational program in stroke; on track for a submission in the first half of 2025 to the U.S. Food and Drug Administration ("FDA").
- Secured Federal Supply Schedule contract pricing with the U.S. Department of Veterans Affairs ("VA") at \$23,843.72 and \$7,344.97 for the PoNS device and mouthpiece, respectively, through its partnership with Lovell® Government Services.
- Secured DAPA contract pricing with the U.S. Department of Defense ("DoD") at \$23,724.50 and \$7,308.25 for the PoNS device and mouthpiece, respectively, through its partnership with Lovell Government Services.
- Commenced building out nationwide sales representation at VA sites in June 2024, establishing coverage in thirteen states plus Puerto Rico to date.
- Q2 2024 revenue up \$47 thousand or 35% compared to Q1 2024, reflecting increased product sales in both the U.S. and Canada.
- Q2 2024 revenue of \$182 thousand, compared to \$256 thousand in Q2 2023, reflecting the expiration of the Patient Therapy Access Program ("PTAP") on June 30, 2023.
- Closed on \$6.4 million public offering, raising net proceeds of approximately \$5.5 million.

"Our team has been working tirelessly to get PoNS into the hands of MS patients who suffer from gait and balance impairment. These efforts are starting to pay off and during the quarter we made several important advancements toward removing barriers to our innovative technology. We were pleased to announce the first third-party reimbursement for PoNS from a major insurance carrier at \$23,900 and are now just a few weeks away from CMS publishing its final reimbursement rates to be effective on October 1, which we believe will be a significant catalyst for growing revenue as well as negotiating reimbursement with other third-party payers," stated Helius' President and Chief Executive Officer, Dane Andreeff.

He continued, "In June, we completed site participation enrollment for our registrational program in stroke. This groundbreaking program is being conducted at several of the top neurorehabilitation centers in the U.S., and the results will be crucial to seeking regulatory approval in 2025. To bolster our FDA submission and support national reimbursement efforts in Canada, we've begun a Canadian study with the goal of enrolling at least 40 subjects at three centers of excellence for stroke rehabilitation."

"The third quarter of 2024 will be pivotal for Helius and will help frame our future. We expect to have a first read of the primary endpoint's results of our PoNSTEP study, further expand our VA sales rep organization and penetrate VA sites, and receive final reimbursement determination by CMS. I'm proud of what we've accomplished to get to this point and excited about the outlook for Helius as these key milestones play out," concluded Andreeff.

Second Quarter 2024 Financial Results

Total revenue for the second quarter of 2024 was \$182 thousand, a decrease of \$74 thousand compared to \$256 thousand in the second quarter of 2023, resulting from the termination of PTAP on June 30, 2023, and the termination of temporary cash pay pricing in May 2024. Revenue for the quarter increased by \$47 thousand or 35% compared to the first quarter of 2024, as a result of increased sales in both the U.S. and Canada.

Cost of revenue decreased to \$118 thousand for the three months ended June 30, 2024, compared to \$184 thousand for the comparable period in

2023, primarily attributable to lower sales compared to the same period in the prior year.

Selling, general and administrative expenses for the second quarter of 2024 were \$2.5 million, comparable to the \$2.6 million reported in the second quarter of 2023.

Research and development expenses for the second quarter of 2024 increased slightly to \$0.9 million, compared to \$0.7 million in the second quarter of 2023, driven primarily by an increase in clinical trial activities for stroke and risk of fall programs.

Total operating expenses for the second quarter of 2024 were \$3.3 million, flat compared to the \$3.3 million reported in the second quarter of 2023.

Operating loss for the second quarter of 2024 was \$3.3 million, compared to an operating loss of \$3.2 million for the prior year period.

Net loss was \$1.6 million for the second quarter of 2024, flat compared to a net loss of \$1.6 million in the corresponding prior year period. The basic and diluted net loss per share for the second quarter was \$0.64 per share, compared to a net loss of \$2.92 per share for the second quarter of 2023.

Cash and Liquidity

Cash used in operating activities was flat at \$5.9 million for the six months ended June 30, 2024 and June 30, 2023.

As of June 30, 2024, the Company had cash of \$6.4 million and no debt outstanding with a projected cash runway into 2025.

Conference Call

Date: Monday, August 12, 2024
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 an orally applied technology platform that amplifies the brain's ability to engage physiologic compensatory mechanisms and promote neuroplasticity, improving the lives of people dealing with neurologic diseases. The Company's first commercial product is the Portable Neuromodulation Stimulator. For more information about the PoNS® or Helius Medical Technologies, visit www.heliusmedical.com.

About the PoNS Device and PoNS Therapy

The Portable Neuromodulation Stimulator (PoNS) is an innovative, non-implantable, orally applied therapy that delivers neurostimulation through a mouthpiece connected to a controller and it's used, primarily at home, with physical rehabilitation exercise, to improve balance and gait. The PoNS device, which delivers mild electrical impulses to the tongue, 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 has shown effectiveness in treating gait or balance and a significant reduction in the risk of falling in stroke patients in Canada, where it received authorization for sale in three indications: (i) for use as a short-term treatment (14 weeks) of gait deficit due to mild and moderate symptoms from stroke and is to be used in conjunction with physical therapy; (ii) 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 (iii) 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.

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 sufficiency of the Company's future cash position, the development, commercialization and success of the Company's PoNS and PoNS Treatment, the progress of the Company's clinical programs, future decisions and approvals from applicable regulatory entities in the U.S. and Canada, reimbursement status with third party payers, the Company's strategic operating plans, and the uses and effectiveness of PoNS and PoNS Therapy.

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 Company's ability to find additional sources of funding, manufacturing, labor shortage and supply chain risks, including risks related to manufacturing delays, the Company's ability to obtain national Medicare insurance coverage and to obtain a reimbursement code, the Company's ability to continue to build internal commercial infrastructure, secure state distribution licenses, market awareness of the PoNS device, future clinical trials and the clinical development process, the product development process and the 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, 2024, 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.

Helius Medical Technologies, Inc.
Unaudited Condensed Consolidated Statements of Operations
(in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenue				
Product sales, net	\$ 171	\$ 244	\$ 295	\$ 350
Other revenue	11	12	22	17
Total revenue	182	256	317	367
Cost of revenue	118	184	241	306
Gross profit	64	72	76	61
Operating expenses				
Selling, general and administrative expenses	2,457	2,569	5,090	5,443
Research and development expenses	870	684	1,658	1,570
Amortization expense	7	38	14	77
Total operating expenses	3,334	3,291	6,762	7,090
Loss from operations	(3,270)	(3,219)	(6,686)	(7,029)
Nonoperating income (expense)				
Interest income (expense), net	(5)	89	(13)	189
Change in fair value of derivative liability	1,733	1,223	2,875	2,444
Foreign exchange gain (loss)	(141)	259	(429)	254
Other income, net	71	—	125	—
Nonoperating income, net	1,658	1,571	2,558	2,887
Loss before provision for income taxes	(1,612)	(1,648)	(4,128)	(4,142)
Provision for income taxes	—	—	—	—
Net loss	\$ (1,612)	\$ (1,648)	\$ (4,128)	\$ (4,142)
Loss per share				
Basic	\$ (0.64)	\$ (2.92)	\$ (2.48)	\$ (7.34)
Diluted	\$ (0.64)	\$ (2.92)	\$ (2.48)	\$ (7.34)
Weighted average number of common shares outstanding				
Basic	2,518,071	564,423	1,667,699	564,279
Diluted	2,518,071	564,423	1,667,699	564,279

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

	June 30, 2024	December 31, 2023
ASSETS		
Current assets		
Cash and cash equivalents	\$ 6,387	\$ 5,182
Accounts receivable, net	121	117
Other receivables	538	520
Inventory, net	821	457
Prepaid expenses and other current assets	774	1,162
Total current assets	8,641	7,438
Property and equipment, net	165	178
Intangible assets, net	9	24
Operating lease right-of-use asset, net	31	52
Total assets	\$ 8,846	\$ 7,692
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 1,287	\$ 531
Accrued and other current liabilities	694	1,260
Current portion of operating lease liabilities	35	45
Current portion of deferred revenue	41	43

Total current liabilities	2,057	1,879
Operating lease liabilities, net of current portion	—	12
Deferred revenue, net of current portion	103	128
Derivative liability	347	3,323
Total liabilities	<u>2,507</u>	<u>5,342</u>
STOCKHOLDERS' EQUITY		
Class A common stock, \$0.001 par value; 150,000,000 shares authorized; 3,198,196 and 714,590 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	3	1
Additional paid-in capital	170,666	162,979
Accumulated deficit	(164,085)	(159,957)
Accumulated other comprehensive loss	(245)	(673)
Total stockholders' equity	<u>6,339</u>	<u>2,350</u>
Total liabilities and stockholders' equity	<u>\$ 8,846</u>	<u>\$ 7,692</u>