



Helius Medical Technologies, Inc. Reports Third Quarter 2023 Financial Results

November 9, 2023 9:06 PM EST

-- Cash runway extended into Q2 2024 --
-- Company to host call at 4:30pm today --

NEWTOWN, Pa., Nov. 09, 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 ended September 30, 2023.

Third Quarter and Recent Business Updates

- Q3 2023 revenue of \$143 thousand, compared to \$196 thousand in Q3 2022, the decrease due to the expiration of the Patient Therapy Access Program ("PTAP") on June 30, 2023.
- Operating cash burn of \$2.5 million in Q3 2023, a decrease of \$1.4 million compared to Q3 2022, reflecting continued focus on cash management.
- Ended the quarter with \$7.0 million of cash, cash equivalents, and proceeds receivable from warrant exercises, extending the Company's cash runway into Q2 2024.
- Received universal product code ("UPC") numbers from Wolters Kluwer Health – Medi-Span® ("Medi-Span") for the Portable Neuromodulation Stimulator ("PoNS®") system and mouthpiece. Together with the previously announced Durable Medical Equipment, Prosthetics, Orthotics and Supplies ("DMEPOS") accreditation, the UPC numbers allow for dual paths of reimbursement.
- Received a letter of intent ("LOI") from the Québec Ministry of Health and Social Services ("MSSS") for the purchase of up to 30 PoNS systems across multiple sites to be used to evaluate the benefit of PoNS Therapy™ and determine reimbursement opportunities for stroke patients.
- Received an order for 10 PoNS Systems from the School of Rehabilitation at the Université de Montréal ("UdeM") to be used to evaluate the benefit and health economic value of PoNS Therapy in the treatment of stroke patients.
- Added sixth Center of Excellence to the PoNS Therapeutic Experience Program ("PoNSTEP"), a multi-center, company-sponsored, open label observational interventional trial designed to evaluate the impact of adherence to PoNS Therapy in patients with multiple sclerosis ("MS").
- Announced the release of a white paper published by Pacific Blue Cross ("PBC") and HealthTech Connex ("HTC") demonstrating that PoNS Therapy™ can drastically decrease disability and improve the likelihood of returning to work for patients suffering from traumatic brain injury ("TBI").

"We are pleased with the tremendous progress we made in the third quarter and recent weeks," said Dane Andreeff, President and Chief Executive Officer of Helius. "We began the third quarter with the successful conclusion of our Patient Therapy Access Program, which expired on June 30. Through PTAP, we sold PoNS to qualifying patients at a significant discount, thereby reducing a major barrier to access while allowing us to add to our ongoing MS patient registry. The registry collects important health economic evidence to establish the value of PoNS on key clinical and therapeutic outcomes, which is critical for third party reimbursement. In September, we opened a second path toward reimbursement in the U.S. by receiving UPC numbers for both the PoNS system and mouthpiece and having the codes listed in the Medi-Span database, as we also continue to pursue HCPCS codes for reimbursement under our DMEPOS accreditation. As a result, we are now in the position to begin negotiating with payers using the UPC codes specific to the PoNS systems and mouthpieces with the listed prices of \$25,700 and \$7,900, respectively.

We also developed relationships with two important Canadian Healthcare providers, receiving an order for ten PoNS systems from the School of Rehabilitation at the Université de Montréal as well as a letter of intent from the Québec Ministry of Health and Social Services to purchase thirty PoNS systems to treat gait and/or balance deficit in stroke patients. We believe that evidence from the treatment outcome will support the health economic benefit and cost effectiveness of incorporating PoNS Therapy as a first line treatment for stroke patients. Furthermore, this evidence should provide a valuable benchmark for other Canadian healthcare providers and private payers as they evaluate reimbursement of PoNS Therapy. The data from these clinical application trials will also provide supporting evidence of PoNS Therapy's therapeutic benefit that can strengthen the registrational program for stroke currently ongoing in the U.S."

Andreeff continued, "Finally, we were thrilled by the study results from the white paper recently published by Pacific Blue Cross and HealthTech Connex demonstrating that PoNS Therapy can drastically decrease disability in 89% of patients suffering from long-term disability due to chronic TBI and promote a sustainable return to work outcome for approximately 50% of these patients. We believe that these findings will significantly strengthen our reimbursement efforts with Canadian insurance companies and healthcare providers while highlighting the health economic benefit and cost effectiveness of PoNS Therapy as we negotiate coverage with U.S. payers."

"With what we've set in motion during 2023, and a cash runway that will take us into the second quarter of next year, we are excited about the road ahead, and the chance to help more people with MS, TBI, and stroke who suffer from balance and gait impairment," concluded Andreeff.

Third Quarter 2023 Financial Results

Total revenue for the third quarter of 2023 was \$143 thousand, a decrease of \$53 thousand compared to \$196 thousand in the third quarter of 2022, primarily attributable to decreased unit sales of PoNS systems in the U.S. following the termination of the PTAP on June 30, 2023, partially offset by increased net product sales in Canada.

Cost of revenue increased to \$187 thousand for the three months ended September 30, 2023, compared to \$101 thousand for the comparable period in 2022, due to fixed overhead costs, which are primarily comprised of salaries and benefits of employees involved in management of the supply chain and certain production costs.

Selling, general and administrative expenses for the third quarter of 2023 were \$2.2 million, a decrease of \$1.2 million compared to \$3.4 million in the third quarter of 2022, primarily the result of a decrease in performance-based stock-based compensation.

Research and development expenses for the third quarter of 2023 decreased slightly to \$722 thousand, compared to \$751 thousand in the third quarter of 2022.

Total operating expenses for the third quarter of 2023 decreased to \$3.1 million, compared to \$4.9 million in the third quarter of 2022.

Operating loss for the third quarter of 2023 decreased \$1.7 million to a loss of \$3.2 million, compared to an operating loss of \$4.9 million in the third quarter of 2022.

Net loss was \$3.7 million for the third quarter of 2023, compared to a net loss of \$1.0 million in the corresponding prior year period. The basic and diluted net loss per share for the third quarter was \$5.49 per share, compared to a net loss of \$2.90 per share for the third quarter of 2022.

Cash and Liquidity

Cash used in operating activities for the three months ended September 30, 2023 was \$2.5 million, a decrease of \$1.4 million compared to the third quarter of 2022, reflecting the results of our continued focus on managing cash burn.

As of September 30, 2023, the Company had cash of \$6.6 million, compared to \$14.5 million as of December 31, 2022. The Company also had \$0.4 million in proceeds receivable from warrant exercises as of September 30, 2023, and now estimates its cash runway extends into the second quarter of 2024.

The Company had no debt outstanding as of September 30, 2023.

Conference Call

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

Date: Thursday, November 9, 2023

Time: 4:30 p.m. Eastern Time

Toll free: 800-225-9448

International: 203-518-9708

Conference ID: HSDTQ323

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 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 Company's expected results from business and financial performance in 2023, the sufficiency of the Company's future cash position, the development, commercialization and success of the Company's PoNS device and related treatment, future decisions and approvals from applicable regulatory entities in the U.S. and Canada, and the Company's strategic operating plans.

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, disruptions in the banking system and financial markets, lingering impacts of the COVID-19 pandemic, the effect of macroeconomic conditions and the Company's ability to access capital markets, 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, availability of funds, manufacturing, labor shortage and supply chain risks, disruptions in the manufacturing process of the PoNS device due to the transition to a new manufacturer, the Company's ability to maintain and enforce our intellectual property rights, clinical trials and the clinical development process, the product development process, the regulatory submission review and approval process, the Company's operating costs and use of cash, and our ability to achieve significant revenues, 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 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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Helius Medical Technologies, Inc.

Unaudited Condensed Consolidated Statements of Operations

(in thousands, except share and per share data)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2023	2022	2023	2022
Revenue				
Product sales, net	\$ 132	\$ 195	\$ 482	\$ 497
Other revenue	11	1	28	8
Total revenue	143	196	510	505
Cost of revenue	187	101	493	313
Gross profit (loss)	(44)	95	17	192
Operating expenses				
Selling, general and administrative expenses	2,196	3,393	7,639	8,673
Research and development expenses	722	751	2,292	3,468
Amortization expense	32	47	109	141
Goodwill and fixed asset impairment	159	757	159	757
Total operating expenses	3,109	4,948	10,199	13,039
Loss from operations	(3,153)	(4,853)	(10,182)	(12,847)
Nonoperating income (expense)				
Interest income (expense), net	68	(919)	257	(919)
Change in fair value of derivative liability	(393)	5,489	2,051	5,489
Foreign exchange (loss) gain	(192)	(747)	62	(910)

Other income (expense), net	7	—	7	1
Nonoperating income (expense), net	(510)	3,823	2,377	3,661
Loss before provision for income taxes	(3,663)	(1,030)	(7,805)	(9,186)
Provision for income taxes	—	—	—	—
Net loss	<u>\$ (3,663)</u>	<u>\$ (1,030)</u>	<u>\$ (7,805)</u>	<u>\$ (9,186)</u>
Loss per share				
Basic	<u>\$ (5.49)</u>	<u>\$ (2.90)</u>	<u>\$ (13.60)</u>	<u>\$ (53.77)</u>
Diluted	<u>\$ (5.49)</u>	<u>\$ (2.90)</u>	<u>\$ (13.60)</u>	<u>\$ (53.77)</u>
Weighted average number of common shares outstanding				
Basic	<u>667,809</u>	<u>355,754</u>	<u>573,950</u>	<u>170,823</u>
Diluted	<u>667,809</u>	<u>355,754</u>	<u>573,950</u>	<u>170,823</u>

Helius Medical Technologies, Inc.

Unaudited Condensed Consolidated Balance Sheets

(in thousands, except share and per share data)

	<u>September 30, 2023</u>	<u>December 31, 2022</u>
ASSETS		
Current assets		
Cash and cash equivalents	\$ 6,596	\$ 14,549
Accounts receivable, net	94	71
Other receivables	472	272
Inventory, net	521	589
Prepaid expenses and other current assets	893	1,216
Total current assets	<u>8,576</u>	<u>16,697</u>
Property and equipment, net	182	347
Intangible assets, net	31	140
Operating lease right-of-use asset, net	65	103
Total assets	<u>\$ 8,854</u>	<u>\$ 17,287</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 497	\$ 627
Accrued and other current liabilities	849	1,280
Current portion of operating lease liabilities	47	54
Current portion of deferred revenue	42	27
Total current liabilities	<u>1,435</u>	<u>1,988</u>
Operating lease liabilities, net of current portion	23	56
Deferred revenue, net of current portion	136	175
Derivative liability	4,239	6,917
Total liabilities	<u>5,833</u>	<u>9,136</u>
STOCKHOLDERS' EQUITY		
Class A common stock, \$0.001 par value; 150,000,000 shares authorized; 687,799 and 563,974 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	1	1
Additional paid-in capital	162,391	159,645
Accumulated deficit	(158,912)	(151,107)
Accumulated other comprehensive loss	(459)	(388)
Total stockholders' equity	<u>3,021</u>	<u>8,151</u>
Total liabilities and stockholders' equity	<u>\$ 8,854</u>	<u>\$ 17,287</u>