Helius Medical Technologies, Inc. Reports First Quarter 2021 Financial Results

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NEWTOWN, Pa., May 17, 2021 (GLOBE NEWSWIRE) -- Helius Medical Technologies, Inc. (Nasdaq:HSDT) (TSX:HSM) ("Helius" or the "Company"), a neurotech company focused on neurological wellness, today reported financial results for the quarter ended March 31, 2021.

First Quarter Business Updates

- Its wholly owned subsidiary, Helius Medical, Inc., received marketing authorization from the U.S. Food and Drug Administration ("FDA") for the Portable Neuromodulation Stimulator (PoNS™) device.
    - The PoNS device is indicated for use 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.
- The Company closed an underwritten public offering of common stock and warrants for net proceeds of approximately $9.6 million.
- The Company received written notice from The Nasdaq Stock Market LLC in January 2021 that the Company's minimum bid price deficiency has been cured and Helius was in compliance with all applicable listing standards.
- The Centers for Medicare & Medicaid Services ("CMS") announced that it is finalizing a new coverage pathway, Medicare Coverage for Innovative Technology, or "MCIT," for FDA-designated breakthrough medical devices cleared by FDA.
    - The MCIT rule will provide national Medicare coverage as early as the same day as FDA market authorization for breakthrough devices and coverage would last up to four years.
    - On May 14, 2021, CMS delayed the effective date of the final rule until December 15, 2021. The Company is still evaluating the recent announcement and its implications for Helius' reimbursement strategy.
- The Company expanded its Board of Directors with the appointment of Sherrie Perkins, effective March 15, 2021.

First Quarter 2021 Financial Summary

- Revenue of $84 thousand, compared to revenue of $207 thousand in first quarter of 2020.
- Operating loss of $3.5 million, compared to operating loss of $4.0 million in first quarter of 2020.
- Net loss of $3.4 million, compared to net loss of $4.8 million in first quarter of 2020.
- As of March 31, 2021, the Company had cash of $11.4 million, compared to $3.3 million at December 31, 2020. The Company had no debt outstanding as of March 31, 2021.

"We made strong progress on our U.S. regulatory strategy during the first quarter and were ultimately proud to secure U.S. marketing authorization of our PoNS device for MS in March, approximately one year since we first announced our strategic focus on pursuing this indication," said Dane Andreeff, Interim President and Chief Executive Officer of Helius. "Obtaining U.S. marketing authorization is the most important milestone in our Company's history, one that reflects both the safety and efficacy profile of our innovative PoNS technology as well as the capabilities of our regulatory and clinical affairs team. In addition to our regulatory progress, we raised $11 million in net proceeds through our February Public Offering and the exercise of warrants to strengthen our balance sheet and support our operations while continuing to control our discretionary expenses. In Canada, while our commercialization efforts continued to be impacted by the recent spike in COVID-19 cases and its effects on clinics and patients, our commercial team expanded our network of authorized PoNS clinics to a total of 33 locations as of March 31, 2021, leaving us incrementally better positioned to drive adoption once the environment normalizes."

Mr. Andreeff continued: “Looking ahead to the rest of the year, we are intently focused on preparing to commercialize our PoNS Treatment in the U.S., which we expect to begin in the first quarter of 2022. As part of our U.S. pre-commercial activities, we are securing our state distribution licenses, establishing the dedicated team to lead our commercialization efforts and building relationships to target and educate neurorehabilitation centers focused on the treatment of MS patients. While we expect our initial U.S. customers to be cash pay, we remain focused on working with CMS to obtain Medicare coverage as part of our reimbursement strategy. Given our rapid pace of progress in recent months, we remain convinced that we are pursuing the most effective and efficient strategy to facilitate the widespread adoption of our PoNS technology, bring relief to patients in need and create value for our shareholders.”

First Quarter 2021 Financial Results

Total revenue for the first quarter of 2021 was $84 thousand, compared to $207 thousand in the first quarter of 2020. Product sales represented approximately 92% of total revenue in the first quarter of 2021 consistent with the prior year period. Product sales in both periods were generated through sales of the PoNS device pursuant to supply agreements with PoNS Authorized clinic locations in Canada. License and fee revenue represented 8% of sales in the first quarter of 2021, consistent with the prior year period.

Gross profit for the first quarter of 2021 was $69 thousand, compared to gross profit of $106 thousand in the first quarter of 2020. Operating expenses for the first quarter of 2021 decreased $0.5 million, or 13% year-over-year, to $3.6 million, compared to $4.1 million in the first quarter of 2020.

Operating loss for the first quarter of 2021 decreased $0.5 million, or 13% year-over-year, to $3.5 million, compared to $4.0 million in the first quarter of 2020.

Total other income for the first quarter of 2021 was $139 thousand, compared to total other expense of $755 thousand in the first quarter of 2020.

Net loss for the first quarter of 2021 was $3.4 million, or $(1.65) per basic and diluted common share, compared to a net loss of $4.8 million, or $(5.38) per basic and diluted common share, in the first quarter of 2020. Weighted average shares used to compute basic and diluted net loss per common share were 2.0 million and 0.9 million for the first quarter of 2021 and 2020, respectively.

Net cash provided by financing activities during the three months ended March 31, 2021 was $11.0 million.

As of March 31, 2021, the Company had cash of $11.4 million, compared to $3.3 million at December 31, 2020. The Company had no debt outstanding at March 31, 2021.

Full Year 2021 Outlook

The Company is not providing a formal financial outlook for the full year 2021 at this time, given the continued uncertainty related to the duration and impact of the COVID-19 pandemic on its financial and operating results.

Conference Call

Management will host a conference call at 5:00 p.m. Eastern Time on May 17, 2021 to discuss the results of the quarter and business outlook. Those who would like to participate may dial 877-407-2988 (201-389-0923 for international callers) and provide access code 13718676. A live webcast of the call will also be provided on the Events section of the Company's investor relations website at: https://heliusmedical.com/index.php/investor-relations/events/upcoming-events.

For those unable to participate, a replay of the call will be available for two weeks at 877-660-6853 (201-612-7415 for international callers); access code 13718676. The webcast will be archived on the Events section of the Company’s investor relations website.

About Helius Medical Technologies, Inc.

Helius Medical Technologies is a neurotech company focused on neurological wellness. The Company’s purpose is to develop, license and acquire unique and non-invasive platform technologies that amplify the brain’s ability to heal itself. 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 Treatment™

The Portable Neuromodulation Stimulator (PoNS™) is an innovative non-surgical device, inclusive of a controller and mouthpiece, which delivers electrical stimulation to the surface of the tongue to provide treatment of gait deficit. 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. It is authorized for sale in Canada as a class II, non-implantable, medical device intended as a short term treatment (14 weeks) of gait deficit due to mild and moderate symptoms from MS, and chronic balance deficit due to mild-to-moderate traumatic brain injury (“mmTBI”) and is to be used in conjunction with physical therapy. The PoNS™ is an investigational medical device in the European Union (“EU”) and Australia (“AUS”). It is currently under premarket review by the AUS Therapeutic Goods Administration.

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,” “looking ahead,” “will” and similar expressions. Such forward-looking statements include, among others, statements regarding the COVID-19 pandemic, including its impact on the Company, the Company’s future growth and operational progress, including clinical and regulatory development plans for the PoNS device, the Company’s expectations regarding the sufficiency of funds for anticipated future operations, expected time to commercialization, the Company’s ability to obtain four years of Medicare coverage under the MCIT pathway, the Company’s ability to secure state distribution licenses and build relationships with target neurorehabilitation centers, the Company’s ability to facilitate the widespread adoption of the PoNS technology, the success of the Company’s business and commercialization initiatives and objectives.

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, market awareness of the PoNS device, future

clinical trials and the clinical development process, manufacturing and supply chain risks, potential changes to the MCIT program resulting from the 60-day deferral of the program implementation, 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, 2020, its Quarterly Report on Form 10-Q for the quarter ended March 31, 2021 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.

The Toronto Stock Exchange has not reviewed and does not accept responsibility for the adequacy or accuracy of the content of this news release.

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

	March 31, 2021	December 31, 2020
ASSETS		
Current assets		
Cash	$ 11,397	$ 3,331
Accounts receivable, net	49	74
Other receivables	154	156
Inventory, net	484	389
Prepaid expenses	779	735
Total current assets	12,863	4,685
Property and equipment, net	477	486
Other assets		
Goodwill	769	759
Intangible assets, net	479	527
Operating lease right-of-use asset, net	76	90
Total other assets	1,324	1,376
TOTAL ASSETS	**$ 14,664**	**$ 6,547**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 1,093	$ 747
Accrued liabilities	1,096	1,337
Operating lease liability	61	59
Deferred revenue	284	281
Total current liabilities	2,534	2,424
Non-current liabilities		
Operating lease liability	16	32
Deferred revenue	216	220
TOTAL LIABILITIES	**2,766**	**2,676**
STOCKHOLDERS' EQUITY		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding as of March 31, 2021 and December 31, 2020	—	—
Class A Common stock, $0.001 par value; 150,000,000 shares authorized; 2,311,868 and 1,484,362 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	2	1
Additional paid-in capital	135,388	123,872
Accumulated other comprehensive loss	(1,227)	(1,099)
Accumulated deficit	(122,265)	(118,903)
TOTAL STOCKHOLDERS' EQUITY	**11,898**	**3,871**
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 14,664**	**$ 6,547**

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

	Three Months Ended March 31,	
	2021	**2020**
Revenue:		

Product sales	$ 77	$ 191
Fee revenue	—	9
License revenue	7	7
Total operating revenue	**84**	**207**
Cost of sales:		
Cost of product sales	15	101
Gross profit	**69**	**106**
Operating expenses:		
Research and development	1,316	1,120
Selling, general and administrative	2,197	2,862
Amortization expense	57	126
Total operating expenses	**3,570**	**4,108**
Operating loss	**(3,501)**	**(4,002)**
Other income (expense):		
Other income	—	6
Change in fair value of derivative financial instruments	—	4
Foreign exchange gain (loss)	139	(765)
Total other income (expense)	**139**	**(755)**
Net loss	**(3,362)**	**(4,757)**
Other comprehensive loss:		
Foreign currency translation adjustments	(128)	636
Comprehensive loss	**$ (3,490)**	**$ (4,121)**
Net loss per share		
Basic	**$ (1.65)**	**$ (5.38)**
Diluted	**$ (1.65)**	**$ (5.38)**
Weighted average shares outstanding		
Basic	**2,040,839**	**884,915**
Diluted	**2,040,839**	**884,915**

Helius Medical Technologies, Inc.
Unaudited Condensed Consolidated Statements of Cash Flows
(Amounts in thousands)

	March 31, 2021	**2020**
Cash flows from operating activities:		
Net loss	$ (3,362)	$ (4,757)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of derivative financial instruments	—	(4)
Stock-based compensation expense	527	842
Unrealized foreign exchange (gain) loss	(132)	738
Depreciation expense	28	37
Amortization expense	57	126
(Recovery of) provision for doubtful accounts	(11)	139
Amortization of ROU asset	15	35
Intangible asset impairment	—	174
Changes in operating assets and liabilities:		
Accounts receivable	36	(39)
Other receivables	2	240
Inventory	(95)	4
Prepaid expenses	(44)	(77)
Operating lease liability	(15)	(40)
Accounts payable	234	(626)
Accrued liabilities	(160)	(459)
Deferred revenue	(1)	(84)
Net cash used in operating activities	**(2,921)**	**(3,751)**
Cash flows from investing activities:		
Purchase of property and equipment	(19)	(3)
Internally developed software	(2)	(7)

Net cash used in investing activities	**(21)**	**(10)**
Cash flows from financing activities:		
Proceeds from the issuance of common stock and accompanying warrants	11,037	2,992
Share issuance costs	(1,331)	(340)
Proceeds from the exercise of warrants	1,314	—
Net cash provided by financing activities	**11,020**	**2,652**
Effect of foreign exchange rate changes on cash	(12)	10
Net increase (decrease) in cash	8,066	(1,099)
Cash at beginning of year	3,331	5,459
Cash at end of year	**$ 11,397**	**$ 4,360**

CONTACT: Investor Relations Contact:

Westwicke Partners on behalf of Helius Medical Technologies, Inc.
Jack Powell, Vice President
investorrelations@heliusmedical.com