Helius Medical Technologies, Inc. Reports First Quarter of Full Year 2020 Financial Results; Updates Full Year 2020 Outlook

May 7, 2020 12:00 PM EDT

NEWTOWN, Pa., May 07, 2020 (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, 2020.

First Quarter 2020 Financial Summary

- Revenue of $0.2 million, compared to revenue of $0.7 million in first quarter of 2019.
  - Total revenue comprised of:
    - Product sales of $191 thousand, compared to product sales of $677 thousand in first quarter of 2019.
    - Fee and license revenue of $16 thousand, compared to no fee and license revenue in first quarter of 2019.
- Operating loss of $4.0 million, compared to operating loss of $6.8 million in first quarter of 2019.
- Net loss of $4.8 million, compared to net income of $1.3 million in first quarter of 2019.
- As of March 31, 2020, the Company had cash of $4.4 million, compared to $5.5 million at December 31, 2019. The Company had no debt outstanding at March 31, 2020.
- Net cash provided by financing activities during the three months ended March 31, 2020 was $2.7 million, which consisted of proceeds from the issuance of common stock in connection with the Company's At The Market Offering Agreement ("ATM") during the first quarter of 2020, and proceeds from the issuance of common stock and unregistered warrants in connection with Helius' registered direct offering and concurrent private placement on March 20, 2020.

First Quarter and Recent Business Updates

- On January 10, 2020, the Company announced that it received the Pioneer Technology Development Award for its development of the PoNS™ device.
- On January 16, 2020, the Company announced that its fully owned subsidiary, Helius Medical Inc, entered into an agreement with the University Health Network to perform a clinical experience program to enable it, and three independent neurorehabilitation clinics in Canada, to evaluate Helius' PoNS device, in conjunction with physical therapy, on patients with chronic balance deficit due to mmTBI in Canada.
- On February 7, 2020, the Company announced the authorization of Clinic Medical Centre in Nanaimo, British Columbia, the eighth clinic to be authorized as a PoNS Treatment center in Canada.
- On February 24, 2020, the Company announced that Helius CEO, Philippe Deschamps, had been invited to brief the U.S. Congress on the latest technologies, innovations and policies in clinical neuroscience at the 9th Annual Brain Mapping Foundation Congressional briefing at the U.S. Congress on February 25, 2020.
- On March 2, 2020, the Company reported preliminary unaudited financial results for the fourth quarter and full year ended December 31, 2019, provided an update on its commercial and regulatory activities and announced it has submitted a Canadian Class II license amendment application for the treatment of gait deficit in patients with mild and moderate Multiple

Sclerosis.

- On March 9, 2020, the Company provided details on five additional PoNS Treatment clinics that were recently authorized in the Greater Toronto Area and Southwestern Ontario.
- On March 18, 2020, the Company entered into definitive agreements with healthcare focused institutional investors that provide for the purchase and sale of an aggregate of approximately 6.3 million shares of its Class A Common Stock and warrants, resulting in total gross proceeds of approximately $2.2 million.
- On March 24, 2020, the Company announced that its Canadian Class II license amendment application for the treatment of gait deficit in patients with mild and moderate symptoms from multiple sclerosis ("MS") was successful and that Health Canada granted marketing authorization to the PoNS for the new MS indication.
- On April 22, 2020, the Company announced the appointment of Jeffrey S. Mathiesen, CPA, to its Board of Directors, effective as of June 9, 2020. Upon his appointment, Mr. Mathiesen will serve as Chair of the Company's Audit Committee.
- On April 30, 2020, the Company announced that its registrational clinical trial, TBI-001, was published on April 29, 2020 in *Neuromodulation: Technology at the Neural Interface*. The TBI-001 trial found that PoNS Treatment™ provided significant improvement in balance in patients with a chronic balance deficit following a mild-to-moderate traumatic brain injury ("mmTBI").

"We continued to make progress on our U.S. regulatory strategy during the first quarter of 2020, and while our pursuit of regulatory clearance for Multiple Sclerosis ("MS") continued relatively unaffected by the COVID-19 pandemic, our regulatory activity may be adversely affected by Covid-19 going forward." said Philippe Deschamps, Chief Executive Officer of Helius. "Based on the quality of the data included in our Health Canada application for an MS indication – including a statistically significant, peer-reviewed clinical trial and real-world treatment data from Canada – and the fact that more than 1 million patients suffer from MS in the U.S., we made the strategic decision to prioritize the MS indication as the pathway to pursue our first U.S. regulatory clearance. We are pleased with our pace of progress in pursuing our MS indication in the U.S., and continue to anticipate submitting a request for de novo classification for this indication in the second half of 2020. During the first quarter, we obtained marketing authorization from Health Canada in March for a new clinical indication to treat gait deficit in patients with mild and moderate symptoms from MS, significantly expanding our addressable patient population. Lastly, we finalized the design of new trial, TBI-002, to support our U.S. submission for an indication to treat chronic balance deficit due to mmTBI. COVID-19 has temporarily halted clinical trial activity across the U.S. and Canada, we have thus put this project on hold for the foreseeable future until the clinical trial environment and financial conditions allow us to reengage this project.

Mr. Deschamps continued: "During the first quarter, we also made important progress with respect our commercial strategy in Canada. We expanded our network of authorized clinics to a total of fourteen clinic locations and generated revenue of $0.2 million from sales of our PoNS device. While our performance during the first two months of 2020 was consistent with expectations, our business trends slowed materially in the last two weeks of March as a result of the disruption caused by the COVID-19 pandemic. Specifically, our authorized clinics in Canada suspended in-patient treatments and announced temporary closures in order to adhere to enacted mandates from the government in an effort to slow the spread of the virus. In response to COVID-19, we quickly implemented health and safety measures to protect our employees and enable them to operate remotely. We are closely monitoring the activities of the PoNS authorized clinics in Canada and continue to support their staff and patients during this difficult time."

Mr. Deschamps continued: "Given the uncertainty surrounding the duration and impact of the COVID-19 pandemic on our financial and operating performance, we are withdrawing our full year 2020 outlook at this time. However, our team is executing efficiently to help mitigate the impact of this pandemic on our business and to continue pursuing the commercial and regulatory priorities we have outlined for this year. We are engaging virtually with new clinics, key opinion leaders and industry associations to raise awareness of our PoNS Treatment and our new clinical indication in MS. Most importantly, we remain confident in the potential of our PoNS technology and committed to expanding its access as effectively and efficiently as possible for the benefit of our patients and shareholders."

First Quarter 2020 Financial Results

Total revenue for the first quarter of 2020 was $0.2 million, compared to $0.7 million in the first quarter of 2019. Product sales represented 92% of total revenue in the first quarter of 2020 compared to 100% of total revenue in the first quarter of 2019. Product sales in the first quarter of 2020 was generated through sales of the PoNS device pursuant to supply agreements with 14 neuroplasticity clinics in Canada. License and fee revenue represented 8% of total revenue in the first quarter of 2020, compared to 0% of total revenue in the first quarter of 2019.

Gross profit for the first quarter of 2020 was $0.1 million, compared to gross profit of $0.4 million in the first quarter of 2019. Operating expenses for the first quarter of 2020 decreased $3.2 million, or 43% year-over-year, to $4.1 million, compared to $7.3 million in the first quarter of 2019.

Operating loss for the first quarter of 2020 decreased $2.8 million, or 41%, to $4.0 million, compared to $6.8 million in the first quarter of 2019.

Total other expense for the first quarter of 2020 was $0.8 million, compared to $8.1 million of other income in the first quarter of 2019.

Net loss for the first quarter of 2020 was $4.8 million, or $(0.15) per basic and diluted common share, compared to net income of $1.3 million, or $0.05 per basic common share and $(0.06) per diluted common share, in the first quarter of 2019. Weighted average shares used to compute basic net loss per common share were 31.0 million and 25.8 million for the first quarters of 2020 and 2019, respectively. Weighted average shares used to compute diluted net loss per common share were 31.0 million and 26.8 million for the first quarters of 2020 and 2019, respectively.

Full Year 2020 Outlook

The Company is currently unable to estimate the duration and impact of the COVID-19 pandemic on its financial and operating results for the full year

2020. As a result, the Company is withdrawing its previously announced full year 2020 outlook, which was introduced on March 12, 2020.

Conference Call

Management will host a conference call at 5:00 p.m. Eastern Time on May 7, 2020 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 13701495. 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 13698861. 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 product in development is the Portable Neuromodulation Stimulator (PoNS™). For more information, visitwww.heliusmedical.com.

About the PoNS Device and PoNS Treatment

The Portable Neuromodulation Stimulator (PoNS) is an authorized class II, non-implantable medical device authorized for sale in Canada. PoNS is intended as a short term treatment (14 weeks) of chronic balance deficit due to mild-to-moderate traumatic brain injury and is to be used in conjunction with physical therapy and is indicated 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. The PoNS is an investigational medical device in the United States, the European Union, and Australia, and is currently under review for clearance by the AUS Therapeutic Goods Administration. PoNS Treatment is currently not commercially available in the United States, the European Union or Australia.

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," "look forward," "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 clinical and regulatory development plans for the PoNS, the success of the Company's planned study, business and commercialization initiatives and objectives, the potential receipt of regulatory clearance of the PoNS device in the United States and the Company's revenue guidance.

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 the uncertainties associated with clinical trial enrollments and the results of the planned study, uncertainties associated with the clinical development process and FDA regulatory submission and approval process, including the Company's capital requirements to achieve its business objectives and other risks detailed from time to time in the filings made by the Company with securities regulators, and including the risks and uncertainties about the Company's business described in the "Risk Factors" sections of the Company's Annual Report on Form 10-K for the years ended December 31, 2019 and December 31, 2018, its Quarterly Report on Form 10-Q for the quarter ended March 31, 2020 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, 2020	December 31, 2019
ASSETS		
Current assets		
Cash	$ 4,360	$ 5,459
Accounts receivable, net	110	210
Other receivables	124	364
Inventory, net of reserve	594	598
Prepaid expenses	687	610
Total current assets	5,875	7,241
Property and equipment, net	678	712
Other assets		
Goodwill	686	1,242
Intangible assets, net	687	582
Operating lease right-of-use asset, net	517	552
Other assets	18	18
Total other assets	1,908	2,394
TOTAL ASSETS	**$ 8,461**	**$ 10,347**

LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 1,111	$ 1,676
Accrued liabilities	1,005	1,519
Operating lease liability	180	172
Derivative financial instruments	—	5
Deferred revenue	321	430
Total current liabilities	2,617	3,802
Non-current liabilities		
Operating lease liability	417	465
Deferred revenue	218	245
TOTAL LIABILITIES	**3,252**	**4,512**
Commitments and contingencies (Note 6)		
STOCKHOLDERS' EQUITY		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding as of March 31, 2020 and December 31, 2019	—	—
Class A common stock, $0.001 par value; 150,000,000 shares authorized; 38,041,666 and 30,718,554 shares issued and outstanding as of March 31, 2020 and December 31, 2019, respectively	38	31
Additional paid-in capital	114,967	111,479
Accumulated other comprehensive loss	(266)	(902)
Accumulated deficit	(109,530)	(104,773)
TOTAL STOCKHOLDERS' EQUITY	**5,209**	**5,835**
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 8,461**	**$ 10,347**

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

	Three Months Ended March 31,	
	2020	**2019**
Revenue:		
Product sales, net	$ 191	$ 677
Fee revenue	9	—
License revenue	7	—
Total operating revenue	**207**	**677**
Cost of sales:		
Cost of product sales	101	236
Gross profit	**106**	**441**
Operating expenses:		
Research and development	1,120	2,681
Selling, general and administrative	2,862	4,581
Amortization expense	126	—
Total operating expenses	**4,108**	**7,262**
Operating loss	**(4,002)**	**(6,821)**
Other income (expense):		
Other (expense) income	6	11
Change in fair value of derivative financial instruments	4	8,289
Foreign exchange gain (loss)	(765)	(155)
Total other (expense) income	**(755)**	**8,145**
Net (loss) income	**(4,757)**	**1,324**
Other comprehensive (loss) income:		
Foreign currency translation adjustments	636	(112)
Comprehensive (loss) income	**$ (4,121)**	**$ 1,212**
Net (loss) income per share		
Basic	**$ (0.15)**	**$ 0.05**
Diluted	**$ (0.15)**	**$ (0.06)**
Weighted average shares outstanding		
Basic	**30,972,064**	**25,832,190**
Diluted	**30,972,064**	**26,785,708**

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

	March 31, 2020	2019
Cash flows from operating activities:		
Net (loss) income	$ (4,757)	$ 1,324
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of derivative financial instruments	(4)	(8,289)
Stock-based compensation expense	842	835
Unrealized foreign exchange (gain) loss	738	176
Depreciation expense	37	22
Amortization expense	126	—
Provision for doubtful accounts	139	—
Intangible asset impairment	174	—
Changes in operating assets and liabilities:		
Accounts receivable	(39)	(740)
Other receivables	240	(84)
Inventory	4	(339)
Prepaid expenses	(77)	95
Other current assets	—	264
Operating lease liability	(5)	(3)
Accounts payable	(626)	83
Accrued liabilities	(459)	(144)
Deferred revenue	(84)	—
Net cash used in operating activities	**(3,751)**	**(6,800)**
Cash flows from investing activities:		
Purchase of property and equipment	(3)	(161)
Internally developed software	(7)	—
Net cash used in investing activities	**(10)**	**(161)**
Cash flows from financing activities:		
Proceeds from the issuances of common stock and warrants	2,992	—
Share issuance costs	(340)	(52)
Proceeds from the exercise of stock options and warrants	—	92
Net cash provided by financing activities	**2,652**	**40**
Effect of foreign exchange rate changes on cash	10	(6)
Net (decrease) increase in cash	(1,099)	(6,927)
Cash at beginning of period	5,459	25,583
Cash at end of period	**$ 4,360**	**$ 18,656**

CONTACT: Investor Relations Contact:

Westwicke Partners on behalf of Helius Medical Technologies, Inc.
Mike Piccinino, CFA
investorrelations@heliusmedical.com