Helius Medical Technologies, Inc. Reports Second Quarter of Fiscal Year 2020 Financial Results

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NEWTOWN, Pa., Aug. 12, 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 June 30, 2020.

Second Quarter and Recent Business Updates

- 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").
- On May 12, 2020, the Company announced that it has received Breakthrough Designation for its PoNS™ device as a potential treatment for gait deficit due to symptoms of Multiple Sclerosis ("MS"), to be used as an adjunct to a supervised therapeutic exercise program.
- On July 14, 2020, the Company announced the dismissal of a putative shareholder class action lawsuit in the Southern District of New York.
- On August 6, 2020, the Company announced that it has submitted a request to the U.S. Food and Drug Administration ("FDA") for de novo classification and clearance of the Portable Neuromodulation Stimulator (PoNS™) device and reported preliminary financial results for the second quarter and six months ended June 30, 2020.

Second Quarter 2020 Financial Summary

- Revenue of $0.1 million, compared to revenue of $0.5 million in second quarter of 2019.
- Operating loss of $3.7 million, compared to operating loss of $5.8 million in second quarter of 2019.
- Net loss of $3.4 million, compared to net loss of $0.2 million in second quarter of 2019.
- As of June 30, 2020, the Company had cash of $5.3 million, compared to $5.5 million at December 31, 2019. The Company had no debt outstanding at June 30, 2020.
- Net cash provided by financing activities during the three months ended June 30, 2020 was $4.1 million.

"Helius is excited by the considerable progress we have made on our U.S. regulatory strategy, following our strategic decision in the first quarter to prioritize an Multiple Sclerosis ("MS") indication as the regulatory pathway to pursue our first U.S. regulatory clearance," said Philippe Deschamps, Chief Executive Officer of Helius. "After obtaining Breakthrough Device Designation in May, our clinical and regulatory team continued to work diligently during the second quarter, with the goal of submitting a request for de novo classification and clearance for an MS indication in the second half of 2020. The submission of our request for de novo classification and clearance – which we announced on August 6th – is the culmination of their collective effort and success, as well as an important step forward on the path to making our PoNS Treatment available to the estimated 1 million MS patients in the U.S."

Mr. Deschamps continued: "From a commercial standpoint, during the second quarter we, like many companies in the medical device industry, continued to be impacted by the unprecedented level of disruption created by the COVID-19 pandemic. Most notably, PoNS authorized clinics in Canada continued to suspend in-clinic patient treatments and remained effectively closed in April to comply with government restrictions enacted to slow the spread of the virus. We have been pleased to see clinics reopen in late-May and June, albeit under federal and provincial requirements limiting their capacity to 50% of normal services. As a result of these COVID-related mandates, along with clinic policies designed to ensure appropriate social distancing, clinics in Canada continue to operate at significantly reduced productivity. As such, we believe we remain in the very early stages of recovery, and are unlikely to see material improvements in business trends until these federal and provincial requirements are lifted. Despite the challenging operating environment, our Canadian commercial team has remained focused on supporting our existing clinic customers, and has made important progress in expanding our network of authorized clinics in recent months."

Mr. Deschamps concluded: "In spite of the ongoing challenges presented by COVID-19, I'm incredibly proud of the commitment and focus that our team has shown with regard to executing against our regulatory and commercial objectives. Most importantly, we remain convinced that our PoNS Treatment represents a truly novel technology, with the potential to improve the lives of patients suffering from the effects of MS, TBI, and other chronic

conditions. Looking ahead, we remain committed to pursuing our regulatory and commercial strategies efficiently and effectively to bring our novel PoNS technology into the hands of as many patients as possible."

Second Quarter 2020 Financial Results

Total revenue for the second quarter of 2020 was $0.1 million, compared to $0.5 million in the second quarter of 2019. Product sales represented approximately 95% of total revenue in the second quarter of 2020 compared to 91% of total revenue in the second quarter of 2019. Product sales both periods were generated through sales of the PoNS device pursuant to supply agreements with nineteen PoNS Authorized clinic locations in Canada. License and fee revenue represented 5% of sales in the second quarter of 2020, compared to 9% of sales in the second quarter of 2019.

Gross profit for the second quarter of 2020 was $0.1 million, compared to gross profit of $0.3 million in the second quarter of 2019. Operating expenses for the second quarter of 2020 decreased $2.3 million, or 38% year-over-year, to $3.8 million, compared to $6.1 million in the second quarter of 2019.

Operating loss for the second quarter of 2020 decreased $2.1 million, or 36% year-over-year, to $3.7 million, compared to $5.8 million in the second quarter of 2019.

Total other income for the second quarter of 2020 was $0.4 million, compared to $5.6 million in the second quarter of 2019.

Net loss for the second quarter of 2020 was $3.4 million, or $(0.08) per basic and diluted common share, compared to a net loss of $0.2 million, or $(0.01) per basic and diluted common share, in the second quarter of 2019. Weighted average shares used to compute basic and diluted net loss per common share were 40.6 million and 25.9 million for the second quarters of 2020 and 2019, respectively.

Six Months Ended June 30, 2020 Financial Results

Total revenue for the six months ended June 30, 2020 was $0.3 million, compared to $1.2 million in the prior year period. Product sales represented 94% of total revenue for the six months ended June 30, 2020, compared to 96% of total revenue in the prior year period. Product sales in both periods were generated through sales of the PoNS device pursuant to supply agreements with nineteen PoNS Authorized clinic locations in Canada. License and fee revenue represented 6% of total revenue for the six months ended June 30, 2020, compared to 4% of total revenue in the prior year period.

Gross profit for the six months June 30, 2020 was $0.2 million, compared to gross profit of $0.7 million in the prior year period. Operating expenses for the six months ended June 30, 2020 decreased $5.5 million, or 41% year-over-year, to $7.9 million, compared to $13.4 million in the prior year period.

Operating loss the six months ended June 30, 2020 decreased $4.9 million, or 39% year-over-year, to $7.7 million, compared to operating loss of $12.6 million in the prior year period.

Total other expense for the six months ended June 30, 2020 was $0.4 million, compared to $13.8 million of other income in the prior year period.

Net loss for the six months ended June 30, 2020 was $8.1 million, or $(0.22) per basic and diluted common share, compared to net income of $1.1 million, or $0.04 per basic and diluted common share, in the prior year period. Weighted average shares used to compute basic net income (loss) per share were 36.2 million and 25.9 million for the six months ended June 30, 2020 and 2019, respectively. Weighted average shares used to compute diluted net income (loss) per share were 36.2 million and 26.0 million for the six months ended June 30, 2020 and 2019, respectively.

Net cash provided by financing activities during the six months ended June 30, 2020 was $6.7 million, of which $4.8 million consisted of net proceeds from the issuance of 8,138,808 shares of the Company's common stock at an average price of $0.62 per share in connection with the Company's At The Market Agreement ("ATM").

As of June 30, 2020, the Company had cash of $5.3 million, compared to $5.5 million at December 31, 2019.

Full Year 2020 Outlook

On May 7, 2020, the Company withdrew its previously announced 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.

Conference Call

Management will host a conference call at 5:00 p.m. Eastern Time on August 12, 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 13705949. 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 13705949. 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, 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 gait deficit due to mild and moderate symptoms from MS and is to be used in conjunction with physical therapy and is indicated 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. 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 June 30, 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)

	June 30, 2020	December 31, 2019
ASSETS		
Current assets		
Cash	$ 5,264	$ 5,459
Accounts receivable, net	56	210
Other receivables	138	364
Inventory, net of reserve	570	598
Prepaid expenses	715	610
Total current assets	6,743	7,241
Property and equipment, net	478	712
Other assets		
Goodwill	710	1,242
Intangible assets, net	638	582
Operating lease right-of-use asset, net	117	552
Other assets	18	18
Total other assets	1,483	2,394
TOTAL ASSETS	**$ 8,704**	**$ 10,347**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 456	$ 1,676
Accrued liabilities	1,084	1,519
Operating lease liability	154	172
Derivative financial instruments	1	5
Deferred revenue	332	430
Total current liabilities	2,027	3,802
Non-current liabilities		
Operating lease liability	62	465
Deferred revenue	219	245
TOTAL LIABILITIES	**2,308**	**4,512**
STOCKHOLDERS’ EQUITY		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding as of June 30, 2020 and December 31, 2019	—	—
Class A common stock, $0.001 par value; 150,000,000 shares authorized; 45,114,506 and 30,718,554 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively	45	31
Additional paid-in capital	119,763	111,479
Accumulated other comprehensive loss	(521)	(902)
Accumulated deficit	(112,891)	(104,773)
TOTAL STOCKHOLDERS’ EQUITY	**6,396**	**5,835**
TOTAL LIABILITIES AND STOCKHOLDERS’ EQUITY	**$ 8,704**	**$ 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 June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Revenue:				
Product sales, net	$ 126	$ 469	$ 317	$ 1,146
Fee revenue	—	49	9	49
License revenue	7	—	13	—
Total operating revenue	**133**	**518**	**339**	**1,195**
Cost of sales:				
Cost of product sales	64	212	165	448
Gross profit	**69**	**306**	**174**	**747**
Operating expenses:				
Research and development	1,308	2,275	2,428	4,956
Selling, general and administrative	2,394	3,845	5,255	8,426
Amortization expense	89	—	215	—
Total operating expenses	**3,791**	**6,120**	**7,898**	**13,382**
Operating loss	**(3,722)**	**(5,814)**	**(7,724)**	**(12,635)**
Other income (expense):				
Other income	56	13	63	24
Change in fair value of derivative financial instruments	(1)	5,548	3	13,837
Foreign exchange gain (loss)	306	67	(460)	(88)
Total other income (expense)	**361**	**5,628**	**(394)**	**13,773**
Net (loss) income	**(3,361)**	**(186)**	**(8,118)**	**1,138**
Other comprehensive (loss) income:				
Foreign currency translation adjustments	(255)	(124)	381	(236)
Comprehensive (loss) income	**$ (3,616)**	**$ (310)**	**$ (7,737)**	**$ 902**
Net (loss) income per share				
Basic	**$ (0.08)**	**$ (0.01)**	**$ (0.22)**	**$ 0.04**
Diluted	**$ (0.08)**	**$ (0.01)**	**$ (0.22)**	**$ 0.04**
Weighted average shares outstanding				
Basic	**40,623,343**	**25,870,600**	**36,179,362**	**25,851,501**
Diluted	**40,623,343**	**25,870,600**	**36,179,362**	**25,953,654**

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

	Six Months Ended June 30,	
	2020	**2019**
Cash flows from operating activities:		
Net (loss) income	$ (8,118)	$ 1,138
Adjustments to reconcile net (loss) income to net cash used in operating activities:		
Change in fair value of derivative financial instruments	(3)	(13,837)
Stock-based compensation expense	1,571	1,776
Unrealized foreign exchange loss	433	153
Depreciation expense	67	47
Amortization expense	215	—
Provision for doubtful accounts	153	—
Intangible asset impairment	181	—
Loss from disposal of property and equipment	110	—
Gain from lease modification	(56)	—
Changes in operating assets and liabilities:		
Accounts receivable	1	(546)
Other receivables	226	(207)

Inventory	28	(510)
Prepaid expenses	(105)	145
Other current assets	—	264
Operating lease liability	70	(7)
Accounts payable	(1,288)	655
Accrued liabilities	(381)	(285)
Deferred revenue	(83)	—
Net cash used in operating activities	**(6,979)**	**(11,214)**
Cash flows from investing activities:		
Purchase of property and equipment	(3)	(204)
Proceeds from sale of property and equipment	61	—
Internally developed software	(7)	—
Net cash provided by (used in) investing activities	**51**	**(204)**
Cash flows from financing activities:		
Proceeds from the issuance of common stock and accompanying warrants	7,233	—
Share issuance costs	(506)	(52)
Proceeds from the exercise of stock options and warrants	—	215
Proceeds from Paycheck Protection Program Loan	323	—
Repayment of Paycheck Protection Program Loan	(323)	—
Net cash provided by financing activities	**6,727**	**163**
Effect of foreign exchange rate changes on cash	6	(17)
Net decrease in cash	(195)	(11,272)
Cash at beginning of period	5,459	25,583
Cash at end of period	**$ 5,264**	**$ 14,311**

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