Helius Medical Technologies, Inc. Reports Fourth Quarter and Full Year 2019 Financial Results; Introduces Full Year 2020 Outlook

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NEWTOWN, Pa., March 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 and full year ended December 31, 2019.

Full Year 2019 Financial Summary

- Revenue of $1.5 million, compared to revenue of $0.5 million in 2018.
  - Total revenue comprised of:
    - Product sales of $1.454 million, compared to no product sales in 2018
    - Fee and license revenue of $42 thousand, compared to fee and license revenue of $478 thousand in 2018.
- Operating loss of $24.0 million, compared to operating loss of $26.7 million in 2018.
- Net loss of $9.8 million, compared to net loss of $28.6 million in 2018.

Fourth Quarter 2019 Financial Summary

- Revenue of $0.2 million, compared to revenue of $0.5 million in fourth quarter of 2018.
  - Total revenue comprised of:
    - Product sales of $159 thousand, compared to no product sales in fourth quarter of 2018.
    - Fee and license revenue of $(7) thousand, compared to fee and license revenue of $478 thousand in fourth quarter of 2018.
- Operating loss of $5.6 million, compared to operating loss of $5.3 million in fourth quarter of 2018.
- Net loss of $5.3 million, compared to net loss of $5.1 million in fourth quarter of 2018.

Fourth Quarter and Recent Business Updates

- On October 24, 2019, the Company provided an update outlining the Company's U.S. regulatory strategy following its pre-submission meeting with the U.S. Food and Drug Administration ("FDA").
- On November 19, 2019, the Company reported that P3 Health, a leading healthcare facility located in downtown Toronto, was the seventh clinic to be authorized as a PoNS Treatment Center in Canada.
- On November 22, 2019, the Company announced the pricing of its previously announced underwritten public offering of 4,815,010 shares of its Class A common stock at a price to the public of $0.35 per share. Gross proceeds from the offering were $1.7 million.
- On December 19, 2019, the Company announced that the results from independent research conducted at the University of Wisconsin-Madison on translingual neurostimulation for the treatment of chronic symptoms due to mild-to moderate traumatic brain injury ("mmTBI") have been published in the December 2019 issue of the *Archives of Rehabilitation Research and Clinical Translation*.
- 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's 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. Helius has now expanded access for patients seeking PoNS Treatment to fourteen clinic locations in Canada, with eight in Ontario, the most populous province.

"2019 was a year of important progress for Helius," said Philippe Deschamps, Chief Executive Officer of Helius. "We began the initial commercialization of our PoNS Treatment in Canada, developing our network of authorized clinics to include seven clinics and generating $1.5 million in revenue from the sale of our PoNS devices in 2019. As we progressed through our initial commercialization, we made important changes to our commercial strategy, which included acquiring the Heuro Canada operating entity and establishing an internal team to lead our commercial efforts. Under the leadership of our new internal team, in 2020 we have implemented a new targeting and pricing strategy to enhance clinic engagement and patient adoption and expanded our authorized clinic network to include a total of fourteen clinic locations."

Mr. Deschamps continued: "From a regulatory standpoint, in 2019 we engaged with Health Canada to pursue a new clinical indication for the treatment of gait deficit caused by Multiple Sclerosis ("MS"), with the goal of expanding our addressable patient population to include the approximately 93,000 individuals living with MS in Canada. We were pleased to complete our application for this indication on February 27, 2020. Importantly, as we announced in our strategic update press release on March 2nd, we are also prioritizing an MS indication as the pathway to pursue for our first US clearance of the PoNS device. This important business decision was made based on the quality of the data included in our Health Canada application and the large number of U.S. patients suffering from MS that stand to benefit from PoNS Treatment. We believe that we have made considerable progress in 2019 and recent months in developing our pathway to pursuing our new request for de novo classification and clearance of the PoNS device for the treatment of chronic balance deficit due to mmTBI. After incorporating specific recommendations received from the FDA in January 2020, we have finalized the design for a new trial, called TBI-002, which will be used to support our submission for the mmTBI indication."

"As a result of our efforts in 2019 and recent months, we believe we are well-positioned in 2020 to build on our initial commercial traction and regulatory progress. We have begun this year with a clear commercial and marketing strategy in Canada and the potential to expand our addressable market opportunity further with a new indication for MS. In the U.S., we are prioritizing an MS indication as the pathway to pursue for our first US clearance of the PoNS device, which will expand our global addressable market opportunity further. Lastly, we expect to begin enrollment for TBI-002 in April 2020 and target submission to the FDA in the second quarter of 2021. With these opportunities in view, we look forward to executing efficiently this year in order to expand access to our innovative PoNS technology for the benefit of our patients and shareholders."

Fourth Quarter 2019 Financial Results

Total revenue for the fourth quarter of 2019 was $0.2 million, compared to $0.5 million in the fourth quarter of 2018. Product sales represented approximately 100% of total revenue in the fourth quarter of 2019 compared to 0% of total revenue in the fourth quarter of 2018. Product sales in the fourth quarter of 2019 was generated through sales of the PoNS device pursuant to supply agreements with seven neuroplasticity clinics in Canada. License and fee revenue represented 0% of sales in the fourth quarter of 2019, compared to 100% of sales in the fourth quarter of 2018.

Gross loss for the fourth quarter of 2019 was $0.2 million, compared to gross profit of $0.5 million in the fourth quarter of 2018. Operating expenses for the fourth quarter of 2019 decreased 5% year-over-year, to $5.5 million, compared to $5.7 million in the fourth quarter of 2018.

Operating loss for the fourth quarter of 2019 increased $0.3 million, or 7%, to $5.6 million, compared to $5.3 million in the fourth quarter of 2018.

Total other income for the fourth quarter of 2019 was $0.3 million, compared to $0.1 million in the fourth quarter of 2018.

Net loss for the fourth quarter of 2019 was $5.3 million, or $(0.19) per basic and diluted common share, compared to a net loss of $5.1 million, or $(0.21) per basic common share and $(0.22) per diluted common share, in the fourth quarter of 2018. Weighted average shares used to compute basic net loss per common share were 27.8 million and 24.5 million for the fourth quarters of 2019 and 2018, respectively. Weighted average shares used to compute diluted net loss per common share were 27.8 million and 24.8 million for the fourth quarters of 2019 and 2018, respectively.

Full Year 2019 Financial Results

Total revenue for full year 2019 was $1.5 million, compared to total revenue of $0.5 million for full year 2018. Product sales represented approximately 97% of total revenue for full year 2019, compared to 0% of total revenue for full year 2018. Product sales for full year 2019 was generated through sales of the PoNS device pursuant to supply agreements with seven neuroplasticity clinics in Canada. License and fee revenue represented 3% of sales for full year 2019, compared to 100% of sales for full year 2018.

Gross profit for full year 2019 was $0.7 million, compared to $0.5 million for full year 2018. Operating expenses for full year 2019 decreased $2.6 million, or 9% year-over-year, to $24.6 million, compared to $27.2 million for full year 2018.

Operating loss for full year 2019 decreased $2.7 million, or 10% year-over-year, to $24.0 million, compared to operating loss of $26.7 million for full year 2018.

Total other income for full year 2019 was $14.2 million, compared to total other expense of $1.9 million for full year 2018.

Net loss for full year 2019 was $9.8 million, or $(0.37) per basic and diluted common share, compared to net loss of $28.6 million, or $(1.26) per basic and diluted common share, for full year 2018. Weighted average shares used to compute basic and diluted net loss per share were 26.4 million and 22.8 million for full year 2019 and full year 2018, respectively.

As of December 31, 2019, the Company had cash of $5.5 million, compared to $25.6 million at December 31, 2018. The Company had no debt outstanding at December 31, 2019.

Full Year 2020 Outlook

For the twelve months ending December 31, 2020, the Company expects total revenue of approximately $2.0 million.

Conference Call

Management will host a conference call at 5:00 p.m. Eastern Time on March 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 13698861. 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 (201-389-0923 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, visit www.heliusmedical.com.

About the PoNS Device and PoNS Treatment

The Portable Neuromodulation Stimulator (PoNS) is an active, therapeutic, class II medical device authorized for sale in Canada 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 therapeutic activities. The PoNS is an investigational medical device in the United States, the European Union ("EU"), and Australia ("AUS"), and it 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 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, 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)

	December 31, 2019	December 31, 2018
ASSETS		
Current assets		

Cash	$ 5,459	$ 25,583
Accounts receivable, net	210	177
Other receivables	364	98
Inventory, net of reserve	598	392
Prepaid expenses	610	447
Other current assets	—	264
Total current assets	7,241	26,961
Property and equipment, net	712	554
Other assets		
Goodwill	1,242	—
Intangible assets, net	582	—
Operating lease right-of-use asset, net	552	—
Non-current receivables	—	294
Other assets	18	18
Total other assets	2,394	312
TOTAL ASSETS	**$ 10,347**	**$ 27,827**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 1,676	$ 2,392
Accrued liabilities	1,519	1,812
Operating lease liability	172	—
Derivative financial instruments	5	13,769
Deferred revenue	430	—
Total current liabilities	3,802	17,973
Non-current liabilities		
Operating lease liability	465	—
Deferred revenue	245	—
TOTAL LIABILITIES	**4,512**	**17,973**
STOCKHOLDERS' EQUITY		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding as of December 31, 2019 and December 31, 2018	—	—
Class A common stock, $0.001 par value; 150,000,000 shares authorized; 30,718,554 and 25,827,860 shares issued and outstanding as of December 31, 2019 and December 31, 2018, respectively	31	26
Additional paid-in capital	111,479	105,411
Accumulated other comprehensive loss	(902)	(591)
Accumulated deficit	(104,773)	(94,992)
TOTAL STOCKHOLDERS' EQUITY	**5,835**	**9,854**
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 10,347**	**$ 27,827**

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

	Three Months Ended December 31,		Year Ended December 31,	
	2019	**2018**	**2019**	**2018**
Revenue:				
Product sales, net	$ 159	$ —	$ 1,454	$ —
Fee revenue	(12)	—	37	—
License revenue	5	478	5	478
Total operating revenue	**152**	**478**	**1,496**	**478**
Cost of sales:				
Cost of product sales	308	—	846	—
Gross profit	**(156)**	**478**	**650**	**478**
Operating expenses:				
Research and development	1,599	2,159	8,061	9,939
Selling, general and administrative	3,806	3,582	16,521	17,214
Amortization expense	64	—	64	—
Total operating expenses	**5,469**	**5,741**	**24,646**	**27,153**
Operating loss	**(5,625)**	**(5,263)**	**(23,996)**	**(26,675)**

Other income (expense):				
Other income	60	—	95	63
Change in fair value of derivative financial instruments	80	(221)	14,113	(3,577)
Foreign exchange gain	154	368	7	1,566
Total other income (expense)	**294**	**147**	**14,215**	**(1,948)**
Net loss	**(5,331)**	**(5,116)**	**(9,781)**	**(28,623)**
Other comprehensive loss:				
Foreign currency translation adjustments	(143)	292	(311)	(638)
Comprehensive loss	**$ (5,474)**	**$ (4,824)**	**$ (10,092)**	**$ (29,261)**
Net loss per share				
Basic	**$ (0.19)**	**$ (0.21)**	**$ (0.37)**	**$ (1.26)**
Diluted	**$ (0.19)**	**$ (0.22)**	**$ (0.37)**	**$ (1.26)**
Weighted average shares outstanding				
Basic	**27,787,678**	**24,461,357**	**26,352,642**	**22,786,192**
Diluted	**27,787,678**	**24,826,566**	**26,352,642**	**22,786,192**

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

	Year Ended December 31,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (9,781)	$ (28,623)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of derivative financial instruments	(14,113)	3,577
Stock-based compensation expense	4,691	8,095
Unrealized foreign exchange loss (gain)	70	(1,711)
Depreciation expense	127	59
Amortization expense	64	—
Provision for doubtful accounts	220	—
Changes in operating assets and liabilities:		
Accounts receivable	(438)	(259)
Other receivables	(278)	394
Inventory	(206)	(392)
Prepaid expenses	(163)	(95)
Other current assets	264	(264)
Operating lease liability	(13)	—
Accounts payable	(1,116)	(1,087)
Accrued liabilities	(327)	685
Net cash used in operating activities	**(20,999)**	**(19,621)**
Cash flows from investing activities:		
Purchase of property and equipment	(278)	(440)
Business acquisitions, net of cash acquired	(416)	—
Internally developed software	(75)	—
Net cash used in investing activities	**(769)**	**(440)**
Cash flows from financing activities:		
Proceeds from the issuance of common stock and accompanying warrants	1,685	38,526
Share issuance costs	(247)	(3,161)
Proceeds from the exercise of stock options and warrants	215	4,663
Net cash provided by financing activities	**1,653**	**40,028**
Effect of foreign exchange rate changes on cash	(9)	54
Net (decrease) increase in cash	(20,124)	20,021
Cash at beginning of period	25,583	5,562
Cash at end of period	**$ 5,459**	**$ 25,583**

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