



Helius Medical Technologies Reports Preliminary Unaudited Fourth Quarter and Full Year Unaudited 2019 Financial Results, Provides Commercial and Regulatory Update and Announces Submission to Health Canada for Multiple Sclerosis (MS) Label Expansion and New US Regulatory Prioritization for MS

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NEWTOWN, Pa., March 02, 2020 (GLOBE NEWSWIRE) -- Helius Medical Technologies, Inc. (NASDAQ:HSDT) (TSX:HSM) ("Helius" or the "Company"), a neurotech company focused on neurological wellness, today 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 ("MS").

"We are pleased to provide an update today on our recent financial and operational progress in advance of our earnings call on March 12th," said Philippe Deschamps, Chief Executive Officer of Helius. "In 2019, our first year as a commercial stage company in Canada, preliminary total revenue was approximately \$1.5 million, within our guidance range of \$1.5 million to \$1.6 million. Overall, 2019 was a year marked by important progress in advancing and refining our commercial strategy in Canada and regulatory strategy in the U.S."

Mr. Deschamps continued: "In Canada, we developed and expanded our authorized clinic network to include six clinics and one satellite clinic by the end of the year, exceeding our goal for 2019. Beginning in the third quarter of 2019, we also made important changes to our commercial strategy in Canada, acquiring the Heuro Canada operating entity and establishing an internal team to lead our commercial efforts going forward. During the fourth quarter of 2019, and in recent months, we enhanced our targeting criteria for the clinics with which we engage and authorize to provide PoNS Treatment, prioritizing clinics that have established commercial operations, strong referral networks with local neurological hospitals and reimbursement and an exclusive focus on neurorehabilitation. We have authorized 7 new clinics with 9 locations in the first two months of 2020 for a total of 16 clinics to provide PoNS Treatment across Canada."

Preliminary Fourth Quarter 2019 Financial Results (Unaudited)

Preliminary revenue for the fourth quarter of 2019 was approximately \$0.1 million. The Company's revenue was generated exclusively through sales of the PoNS device pursuant to supply agreements with five neuroplasticity clinics in Canada.

Gross loss for the fourth quarter of 2019 is expected to be approximately \$0.2 million. Operating expenses for the fourth quarter of 2019 are expected to be approximately \$5.4 million, compared to \$5.7 million in the fourth quarter of 2018. The year-over-year decrease in operating expenses in the fourth quarter was primarily driven by an expected decrease of approximately \$0.6 million, or 26%, in research and development expenses. The decrease in research and development expenses was primarily due to a reduction in product development costs.

Full Year 2019 Financial Results (Unaudited)

Preliminary revenue for the twelve months ended December 31, 2019 was approximately \$1.5 million. The Company's revenue was generated almost exclusively through sales of the PoNS device pursuant to supply agreements with seven neuroplasticity clinics in Canada. In addition, the Company generated approximately \$37,000 in fee revenue from franchise agreements its wholly owned subsidiary, Heuro Canada, Inc., or Heuro, executed with neuroplasticity clinics that have been engaged to provide the PoNS Treatment.

Gross profit for the twelve months ended December 31, 2019 is expected to be approximately \$0.6 million. Operating expenses for the twelve months ended December 31, 2019 are expected to be approximately \$24.6 million, compared to \$27.2 million in the twelve months ended December 31, 2018.

The Company has not completed the preparation of its financial statements for the fourth quarter and the full year 2019 and additional details with respect to the fourth quarter and full year 2019 results of operations are not yet available. The Company plans to release fourth quarter and full year 2019 actual results after the completion of its annual audit.

Cash Position

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.

Regulatory Update

On February 27, 2020, the Company submitted a Canadian Class II license amendment application for the treatment of gait deficit in patients with mild and moderate Multiple Sclerosis ("MS"). This is an important new clinical indication for the PoNS device, given the approximately 100,000 individuals living with MS in Canada. The Company believes this label expansion will significantly expand its addressable market opportunity in Canada to include a patient population that is motivated to pursue treatment options which may resolve or delay the progression of MS symptoms.

Based on the quality of the data included in its MS submission package to Health Canada, the Company is prioritizing the MS indication as the pathway to pursue for its first US clearance of the PoNS device. The Company believes the existing published data and clinical experience with use of the PoNS for the treatment of gait disorder in patients with mild and moderate MS are sufficient to demonstrate a favorable risk/benefit profile, as required for de novo clearance. The Company plans to submit to the FDA for this high unmet medical need in the second half of 2020.

The Company will continue to pursue its TBI indication with a new trial, called TBI-002, which will be used to support its new request for de novo classification and clearance of the PoNS device for the treatment of chronic balance deficit due to mild to moderate traumatic brain injury ("mTBI"). The design of TBI-002 incorporates specific recommendations that the Company received from the FDA in January 2020. The Company expects the trial to cost \$6 million and to begin enrollment in April 2020 and the Company is targeting submission to the FDA in the second quarter of 2021.

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 authorized class II, non-implantable, medical device in Canada intended 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. 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 from the AUS Therapeutic Goods Administration. PoNS™ is currently not commercially available in the United States, the European Union or Australia.

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Cautionary Disclaimer Statement:

The 2019 financial results contained in this news release are subject to finalization in connection with the preparation of the Company's Annual Report on Form 10-K for the year ended December 31, 2019. 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, such as the Company's preliminary 2019 financial information contained in this press release. 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 device and the potential regulatory clearance of the PoNS device.

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 the regulation of commercially available medical devices in Canada, including Health Canada's ongoing assessment of post-market data, the clinical development, regulatory submission and approval process in the United States, the European Union and Australia, as well as the Company's capital requirements needed 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 year ended December 31, 2018, its Quarterly Report on Form 10-Q for the quarter ended September 30, 2019 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.