Helius Medical Technologies, Inc. Submits Request for FDA Clearance for PoNS™ Device; Reports Preliminary Financial Results for the Second Quarter and Six Months Ended June 30, 2020

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NEWTOWN, Pa., Aug. 06, 2020 (GLOBE NEWSWIRE) -- Helius Medical Technologies, Inc. (NASDAQ:HSDT) (TSX:HSM) ("Helius" or the "Company"), a neurotech company focused on neurological wellness, today 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. The PoNS device was granted Breakthrough Designation by FDA on May 7, 2020.

"Helius is excited to announce the submission of our request for de novo classification and clearance of the PoNS device for the treatment of gait deficit due to symptoms from Multiple Sclerosis ("MS"), to be used as an adjunct to a supervised therapeutic exercise program in patients over 18 years of age," said Philippe Deschamps, Helius' President, CEO and Chairman. "The achievement of this important milestone reflects our strong pace of progress since the first quarter of this year, when we made the strategic decision to prioritize an MS indication as the regulatory pathway to pursue our first U.S. breakthrough designation and regulatory clearance. Most importantly, our submission brings us a step closer to making our novel PoNS Treatment available for the 1 million U.S. patients estimated to be living with MS, a disease with a significant unmet medical need, particularly in addressing associated gait dysfunction. We look forward to the FDA's review of our submission, as we strive to provide patients with gait deficit due to MS symptoms a non-drug, non-implantable treatment that has the potential to significantly improve their ability to walk."

Mr. Deschamps continued: "As anticipated, our second quarter financial performance was impacted by the disruption caused by the COVID-19 pandemic – with our clinics in Canada affected by government mandates enacted to slow the spread of the virus. However, we were pleased by the efforts and progress made by our team, who worked diligently during the quarter to help mitigate the impact of this pandemic on our business and continue pursuing our commercial and regulatory priorities. We remain focused on expanding access to our novel PoNS technology in Canada as efficiently and effectively as possible for the benefit of our patients and shareholders and look forward to discussing our recent progress in more detail on our second quarter earnings call."

Second Quarter 2020 Preliminary Financial Results

Preliminary revenue for the second quarter of 2020 is expected to be approximately $0.1 million, compared to $0.5 million in the second quarter of 2019. The Company's revenue was generated almost exclusively through sales of the PoNS device pursuant to supply agreements with neuroplasticity clinics in Canada.

Gross profit for the second quarter of 2020 is expected to be approximately $0.1 million. Operating expenses for the second quarter of 2020 are expected to be approximately $3.7 million, compared to $6.1 million in the second quarter of 2019. The year-over-year decrease in operating expenses was primarily driven by an expected decrease of approximately $1.5 million, or 39%, in selling, general and administrative expenses. The decrease in selling, general and administrative expenses was primarily due to a reduction in commercial operations expense coupled with a reduction in wages and salaries.

Operating loss for the second quarter of 2020 is expected to be $3.7 million, compared to $5.8 million in the second quarter of 2019.

Six Months Ended June 30, 2020 Preliminary Financial Results

Preliminary revenue for the six months ended June 30, 2020 is expected to be approximately $0.3 million, compared to $1.2 million in the prior year period. The Company's revenue was generated almost exclusively through sales of the PoNS device pursuant to supply agreements with neuroplasticity clinics in Canada.

Gross profit for the six months ended June 30, 2020 is expected to be approximately $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 are expected to be approximately $7.8 million, compared to $13.4 million in the six months ended June 30, 2019.

Operating loss for the six months ended June 30, 2020 is expected to be $7.6 million, compared to operating loss of $12.6 million in the prior year period.

The Company has not completed the preparation of its financial statements for the quarter ended June 30, 2020 and additional details with respect to the quarter ended June 30, 2020 results of operations are not yet available. The Company plans to release quarter ended June 30, 2020 actual results after the completion of its quarterly review.

Cash Position

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.

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 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 multiple sclerosis (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 United States, the European Union ("EU"), and Australia ("AUS"). The device is currently under review for clearance by the FDA. It is also under premarket review by 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:

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 device and the potential regulatory clearance of the PoNS device, 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, the European Union and Australia 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 clinical trials, 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 year ended December 31, 2019, and Form 10-Q for the quarter ended March 31, 2020 filed on May 11, 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.