July 22, 2019

Viveve Announces Top-line Results of LIBERATE-International Trial for SUI, Q2 Transition to New U.S. Commercial Model, and Pursuit of Financial and Strategic Alternatives

ENGLEWOOD, CO / ACCESSWIRE / July 22, 2019 /Viveve Medical, Inc. (NASDAQ: VIVE), a medical technology company focused on women's intimate health, today provided an update on the company's clinical development programs and transition to a new U.S. business model, and also announced that it is conducting a review of financial and strategic alternatives.

LIBERATE-International Clinical Trial

The company today announced that the LIBERATE-International trial, a multicenter, randomized, double-blinded, sham-controlled trial to evaluate the safety and efficacy of its proprietary, cryogen-cooled monopolar radiofrequency (CMRF) technology for the improvement of stress urinary incontinence (SUI) in women, did not demonstrate greater improvement in SUI in treated patients as compared with the control group, and therefore did not achieve statistical significance in the intent-to-treat-population on the primary endpoint of change from baseline to six months post-treatment in the 1-hour pad weight test. The median change from baseline at six months post-treatment was -8.0g in the active group of 66 subjects (baseline median 12.8g) and -8.0g in the sham-control group of 33 subjects (baseline median 12.9g).

"We are very disappointed that the LIBERATE-International trial did not achieve its primary endpoint," said Scott Durbin, chief executive officer and director of Viveve. "We have conducted a full review of the primary efficacy data and expect to receive the complete data results including all secondary end-points in early August. We thank the patients, physicians, study coordinators and our internal clinical team for their support of this trial. Following a review of the complete data set we will make a determination related to opportunities for a path forward for our SUI development program."

The Company also has an ongoing study using its CMRF technology for the improvement of sexual function in women. VIVEVE II is a randomized, double-blinded, sham-controlled trial that has completed enrollment of 250 subjects at 19 clinical sites in the United States and Canada. The topline 12-month data readout of the VIVEVE II trial is expected in April 2020.

U.S. Commercial Transition to Recurring Revenue Model

Viveve also today announced the transition of its U.S. business model to renting systems versus selling under a capital equipment model. In June 2019, U.S. sales of the Viveve®

System transitioned from a capital sales model to a recurring revenue rental model intended to lower up-front costs for customers and thus lower hurdles to adoption, increase placement rates, and improve profitability by significantly reducing selling time per unit. The new model has successfully increased physician adoption rates. In June 2019, Viveve placed 27 systems with new North American customers under this new program, a higher monthly productivity rate per rep than any prior month in the company's history.

"The transition to a recurring revenue model provides the opportunity to increase the rate of placements to U.S. clinics, improve profitability by lowering selling costs, and grow revenue faster in future years," said Mr. Durbin.

Sale of Viveve products outside of the U.S. will continue to be supported by the company's current distributors without significant change to the international business model.

Due primarily to the change to the recurring revenue model in the U.S. and the associated accounting impact of recognizing revenue over time, and due to lower sales in Q2 to certain distribution partners, Viveve recorded substantially lower revenue in Q2 than previously anticipated. As a result of the change in the U.S. business model, the Company is withdrawing current revenue guidance for 2019 and will reset revenue guidance in the future.

Review of Strategic Alternatives

The Viveve Board of Directors has initiated a strategic analysis of the company's business to preserve cash and to explore financing and strategic alternatives to maximize value.

Viveve will proceed in an orderly manner to identify and evaluate possible financial and strategic alternatives for the Company and their implications. There can be no assurance either that the Company will be able to obtain financing to continue funding independent operations or that the strategic review will result in any transaction or other outcome. The Company does not currently intend to publicly discuss or disclose further developments related to the strategic review unless and until its Board of Directors has approved a transaction or otherwise determined that further disclosure is appropriate.

About Viveve

Viveve Medical, Inc. is a medical technology company focused on women's intimate health. Viveve is committed to advancing new solutions to improve women's overall well-being and quality of life. The internationally patented Viveve® System incorporates cryogen-cooled monopolar radiofrequency (CMRF) technology to uniformly deliver volumetric heating while gently cooling surface tissue to generate neocollagenesis in a single in-office session.

International regulatory approvals and clearances have been received for vaginal laxity and/or improvement in sexual function indications in over 50 countries. Viveve is conducting VIVEVE II, a multicenter, randomized, double-blind, sham-controlled clinical trial to assess improvement of sexual function in women following vaginal childbirth. Completion of full 250 subject enrollment was announced in early March 2019. If successful, VIVEVE II results could support a marketing application for a new U.S. commercial indication. Currently, in the United States, the Viveve® System is cleared by the FDA for use in general surgical procedures for electrocoagulation and hemostasis.

For more information visit Viveve's website atwww.viveve.com.

Safe Harbor Statement

All statements in this press release that are not based on historical fact are "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. While management has based any forward-looking statements included in this press release on its current expectations, the information on which such expectations were based may change. These forward-looking statements rely on a number of assumptions concerning future events and are subject to a number of risks, uncertainties and other factors, many of which are outside of our control, which could cause actual results to materially differ from such statements. Such risks, uncertainties and other factors include, but are not limited to, the fluctuation of global economic conditions, the performance of management and our employees, our ability to obtain financing or pursue strategic alternatives, our ability to obtain approval or clearance for sale of our medical device for all indications sought, competition, general economic conditions and other factors that are detailed in our periodic and current reports available for review at www.sec.gov. Furthermore, we operate in a highly competitive and rapidly changing environment where new and unanticipated risks may arise. Accordingly, investors should not place any reliance on forward-looking statements as a prediction of actual results. We disclaim any intention to, and undertake no obligation to, update or revise forward-looking statements to reflect events or circumstances that subsequently occur or of which we hereafter become aware, unless required by law.

Viveve is a registered trademark of Viveve, Inc.

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Financial-and-Strategic-Alternatives