Company Overview

Viveve, Inc., the wholly owned subsidiary of Viveve Medical, Inc., is a women's intimate health company based in Englewood, Colorado. The company is focused on the commercialization of a revolutionary, non-surgical, non-ablative medical device that remodels collagen and restores vaginal tissue. The internationally patented Viveve® System incorporates clinically-proven, cryogen-cooled, monopolar radiofrequency (CMRF) energy to uniformly deliver deep-penetrating volumetric heat while gently cooling surface tissue to generate robust neocollagenesis in a single in-office session.

In the United States, the Viveve System is cleared by the Food and Drug Administration (FDA) for general surgical procedures for electrocoagulation and hemostasis. 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. The top-line 12-month data read-out of the VIVEVE II trial is expected in April 2020. If successful, VIVEVE II results could support a marketing application for a new U.S. commercial indication.

Viveve continues to advance its clinical development program in stress urinary incontinence (SUI) and plans to initiate a short-term feasibility study upon approval by the Canadian Ministry of Health of the investigational testing application submitted in August 2019. Following the positive yet inconclusive results of the LIBERATE-International trial, the proposed feasibility study will be a single-blind, three-arm, three-month study to compare Viveve's CMRF treatment to cryogen-only treatment and to inert sham treatment in order to capture short-term safety and effectiveness data on use of the Viveve System for the improvement of SUI in women. Results of the planned three-month feasibility study are targeted for read-out in April 2020. If positive, the results could be used to support Viveve's re-submission of its Investigational Device Exemption to the FDA for approval to conduct the LIBERATE-U.S. trial designed to evaluate the safety and effectiveness of the Viveve System for improvement of SUI in women. The results of these trials, if successful, could support marketing applications in the U.S. and over 30 countries around the world for this new commercial indication.

Viveve Announces Clearance of Next Generation 2.0 System in Taiwan

Mar 26 2020, 8:28 AM EDT

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Disclaimer

Except for the historical information contained here in, the matters discussed in this document are forward-looking statements that involve risks and uncertainties, including but not limited to business conditions and the amount of growth in our industry and general economy, competitive factors, and other risks detailed from time to time in the Company’s SEC reports, including but not limited to its annual reports on form 10-K and it's quarterly reports on Form 10-Q. The company does not undertake any obligation to update forward-looking statements. All trademarks and brand name are the property of their respective companies.