
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): December 6, 2018

VIVEVE MEDICAL, INC.
(Exact name of registrant as specified in its charter)

DELAWARE
(State or other jurisdiction
of incorporation)

1-11388
(Commission
File Number)

04-3153858
(I.R.S. Employer
Identification No.)

345 Inverness Drive South, Building B, Suite 250
Englewood, Colorado
(Address of principal executive offices)

80112
(Zip Code)

Registrant's telephone number, including area code: (720) 696-8100

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01. Other Events.

Stress Urinary Incontinence Feasibility Study Results

On December 6, 2018, Viveve Medical, Inc. (the “**Company**”) issued a press release titled “Viveve Announces Positive 12-Month Data from Stress Urinary Incontinence Feasibility Study.” A copy of this press release is filed herewith as Exhibit 99.1 and is incorporated herein by reference.

Business Update

On December 6, 2018, the Company filed with the Securities and Exchange Commission (the “**SEC**”) a preliminary prospectus supplement in connection with a proposed public offering of shares of the Company’s common stock (the “**Offering**”). The preliminary prospectus supplement contains an updated description of certain aspects of the Company’s business. Accordingly, the Company is filing this information with this Current Report on Form 8-K for the purpose of updating the description of certain aspects of its business from the disclosure contained in the Company’s prior filings with the SEC, including the Company’s most recent Annual Report on Form 10-K for the year ended December 31, 2017, filed with the SEC on March 16, 2018. The updated disclosure is filed herewith as Exhibit 99.2 and is incorporated herein by reference.

Launch of Public Offering of Common Stock

On December 6, 2018, the Company issued a press release announcing the Offering. A copy of this press release is filed herewith as Exhibit 99.3 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Press release “Viveve Announces Positive 12-Month Data from Stress Urinary Incontinence Feasibility Study” issued by Viveve Medical, Inc. on December 6, 2018.</u>
99.2	<u>Updated Business Disclosure by Viveve Medical, Inc.</u>
99.3	<u>Press release issued by Viveve Medical, Inc. on December 6, 2018.</u>

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: December 6, 2018

VIVEVE MEDICAL, INC.

By: /s/ Scott Durbin

Scott Durbin

Chief Executive Officer

Viveve Announces Positive 12-Month Data from Stress Urinary Incontinence Feasibility Study

- 72% of women treated experienced an improvement in the one-hour pad weight with an overall mean improvement of 56%
- Clinically meaningful benefit achieved at one year across all patient-reported outcome measures
- Complete results to be presented during live webcast of SUI symposium with physician key opinion leaders on December 11, 2018

ENGLEWOOD, CO – December 6, 2018 -- Viveve Medical, Inc. (NASDAQ: VIVE) (“Viveve”), a medical technology company focused on women's intimate health, today announced positive 12-month data from an investigator-initiated, single-arm, 12-month feasibility study using its cryogen-cooled, monopolar radiofrequency (CMRF) technology platform for the treatment of mild-to-moderate stress urinary incontinence (SUI) in women. The study was conducted by Bruce Allan, PhD, MD, FRCS(C), founder and medical director of the Allan Centre in Calgary, Alberta.

“These positive results build upon the demonstrated effectiveness and durability of our single-session CMRF treatment for women experiencing SUI symptoms, as previously reported in the six-month interim data from this feasibility study, as well as the 12-month data in the separate SUI pilot study,” said Scott Durbin, chief executive officer and director of Viveve. “We look forward to reporting the full data from this feasibility study at our upcoming SUI physician key opinion leader symposium and are continuing to advance our two SUI clinical registration trials, LIBERATE-International, currently underway, and the planned LIBERATE-U.S. study, pending U.S. Food and Drug Administration approval of an Investigational Device Exemption.”

Summary Results

This single-arm feasibility study initially included 35 subjects with mild-to-moderate SUI, based on the objective 1-hour Pad Weight Test, who underwent treatment with Viveve’s CMRF technology under a proprietary treatment protocol. Twenty-five subjects successfully completed the 12-month study. Clinical results included the objective one-hour pad weight assessment and seven-day bladder voiding diary, as well as composite scores from multiple validated patient-reported outcomes, including: UDI-6 (Urogenital Distress Inventory-Short Form), IIQ-7 (Incontinence Impact Questionnaire) and ICIQ-UI-SF (International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form):

	1-Hr Pad Weight Test	Daily Incontinence Episodes	UDI-6	IIQ-7	ICIQ-UI-SF
MEAN BASELINE SCORES (N=35)	7.3	2.2	47	39	11.3
SCORES AT 12 MONTHS (N=25)	3.2	0.8	29	20	7.8
% REDUCTION FROM BASELINE AT 12 MONTHS (N=25)	56.1%	63.5%	37.4%	48.7%	30.7%
RESPONDER RATE AT 12 MONTHS (IMPROVEMENT FROM BASELINE) (N=25)	72.0%	64.0%	68.0%	72.0%	76.0%

- 72% of patients treated experienced an improvement from baseline in the 1-hour Pad Weight Test at 12 months;
- A greater than 50% reduction in the 1-hour Pad Weight Test was achieved by 52% of patients at 12 months;
- 60% of patients experienced significant benefit as they had \leq one gram of urine leakage in the 1-hour Pad Weight Test at 12 months;
- A clinically meaningful benefit was achieved across all patient-reported outcome measures (SUI symptoms and quality of life) at 12 months (n=25); and
- No device-related safety issues were reported for any of the patients.

Live Webcast of SUI Physician Key Opinion Leader Symposium and Feasibility Study Results

Viveve will host a live webcast of its Key Opinion Leader Symposium focused on SUI on December 11, 2018 beginning at 10:00 am ET. The symposium will address the use of Viveve's proprietary, cryogen-cooled monopolar radiofrequency technology to treat the prevalent condition of SUI in women and will include presentation of the 12-month data from the SUI feasibility study conducted by Dr. Bruce Allan.

The live webcast of this event can be accessed through Viveve's investor relations website at <http://ir.viveve.com>. A webcast replay of the presentation will be posted on the Viveve website approximately two hours after the event and will be available for 90 days.

About Viveve

Viveve Medical, Inc. is a women's intimate health company committed to advancing new solutions to improve women's overall well-being and quality of life. The internationally patented Viveve® System, that delivers the Viveve treatment, 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. In the second quarter of 2018, Viveve initiated VIVEVE II, a multicenter, randomized, double-blind, sham-controlled clinical trial to assess improvement of sexual function in women following vaginal childbirth after receiving approval of an Investigational Device Exemption (IDE) application from the U.S. Food and Drug Administration (FDA) in March of 2018. If successful, this trial 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.

Viveve has initiated LIBERATE-International, one of two planned independent, multicenter, randomized registration trials for the improvement of SUI in women and plans to re-submit an IDE to the FDA for LIBERATE-U.S., after conducting certain safety testing in the third quarter of 2019. The results of these two trials, if successful, could support marketing applications in the U.S. and additional countries around the world for this new commercial indication.

For more information visit Viveve's website at 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, 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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All references in this Exhibit 99.2 to “the Company,” “Viveve,” “we,” “us,” or “our” mean Viveve Medical, Inc., unless we state otherwise or the context otherwise requires.

FORWARD-LOOKING STATEMENTS

This Exhibit 99.2 contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended.

Forward-looking statements in this Exhibit 99.2 reflect our current expectations or forecasts of future events. You can identify these statements by the fact that they do not relate strictly to historical or current facts. You can find many (but not all) of these statements by looking for words such as “approximates,” “believes,” “hopes,” “expects,” “anticipates,” “estimates,” “projects,” “intends,” “plans,” “would,” “should,” “could,” “may” or other similar expressions in this Exhibit 99.2. In particular, forward-looking statements include statements relating to future actions, prospective products, applications, customers and technologies and future performance or future financial results. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from our historical experience and our present expectations or projections. Factors that could cause actual results to differ from those discussed in the forward-looking statements include, but are not limited to:

- our limited cash and our history of losses;
- our ability to achieve profitability;
- our limited operating history;
- emerging competition and rapidly advancing technology;
- whether we are successful in having our medical device approved or cleared for sale by the U.S. Food and Drug Administration (the “FDA”) for all indications sought;
- whether demand develops for our medical device;
- the impact of competitive or alternative products, technologies and pricing;
- the adequacy of protection afforded to us by the patents that we own and the cost to us of maintaining, enforcing and defending those patents;
- our ability to obtain, expand and maintain patent protection in the future, and to protect our non-patented intellectual property;
- our exposure to, and ability to defend against, third-party claims and challenges to our patents and other intellectual property rights;
- our ability to obtain adequate financing in the future, as and when we need it;
- our ability to successfully execute a new sales and marketing strategy in the United States commencing in the first quarter of 2019;
- our ability to continue as a going concern;
- our success at managing the risks involved in the foregoing items; and
- other factors discussed in this Exhibit 99.2.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. The forward-looking statements are based upon management’s beliefs and assumptions and are made as of the date of this Exhibit 99.2. We undertake no obligation to publicly update or revise any forward-looking statements included in this Exhibit 99.2 to conform such statements to actual results or changes in our expectations. You should not place undue reliance on these forward-looking statements.

Business Overview

Our Company

Viveve designs, develops, manufactures and markets a platform medical technology, which we refer to as Cryogen-cooled Monopolar RadioFrequency (“CMRF”). Our proprietary CMRF technology is delivered through three main components: a radiofrequency generator housed in a table-top console, a reusable handpiece and a single-use treatment tip that, collectively, constitute the Viveve System. Depending on the relevant country specific clearance or approval, the Viveve System is currently being marketed internationally outside of the United States for the non-invasive treatment of various post-partum conditions including for the treatment of vaginal laxity, for improved sexual function and for vaginal rejuvenation.

At this time, in the United States, the FDA has cleared the Viveve System for use in general surgical procedures for electrocoagulation and hemostasis, but the device has not been cleared or approved for the treatment of vaginal laxity, for improved sexual function or for vaginal rejuvenation. Accordingly, the Company is prohibited under current U.S. regulations from promoting the Viveve System to physicians or consumers for these unapproved uses.

The Viveve System also consists of single-use accessories (e.g. RF return pad, coupling fluid etc.), a cryogen canister that can be used for approximately four to five procedures and a foot pedal. Practitioners attach the single-use treatment tip to the handpiece which is attached to the console. The generator then authenticates the treatment tip and programs the system for the desired treatment without further physician intervention. The treatment is performed in a physician’s office and does not require the use of anesthesia. The tissue remodeling effect resulting from the treatment has been demonstrated by our pre-clinical and clinical research.

We believe the Viveve System provides a number of benefits for physicians and patients, including:

- a safe, minimally-invasive, non-ablative treatment;
- it typically requires only a single treatment;
- compelling physician economics; and
- ease of use.

Currently, the Viveve System is cleared for marketing in 62 countries throughout the world, under the following indications for use:

Indication for Use:	No. of Countries:
General surgical procedures for electrocoagulation and hemostasis	4
	(including the U.S.)
General surgical procedures for electrocoagulation and hemostasis and for the treatment of vaginal laxity	34
For treatment of vaginal laxity	5
For treatment of vaginal laxity, after vaginal childbirth, to improve sexual function	17
For vaginal rejuvenation	1
For treatment of vaginal laxity, urinary incontinence and sexual function	1

Further, our current global commercial footprint for the Viveve System spans 60 countries, which consists of two countries in North America, 17 countries in Europe, 15 countries in Latin America, 14 countries in the Asia Pacific region and 12 countries in the Middle East.

Vaginal laxity and tissue architecture have often been overlooked as contributing etiological factors to female sexual dysfunction. Vaginal laxity can lead to diminished physical sensation during intercourse. This reduction in sensation is often coupled with a reduction in sexual satisfaction, all of which can also impact a woman’s sense of sexual self-esteem and her relationship with her sexual partner. Currently, few clinically proven medical treatments are available to treat vaginal laxity. Based on our research and data analyses conducted in 2017, we believe that vaginal laxity affects between 12 to 14 million women worldwide, representing a near-term, estimated global consumable market of \$6 to \$8 billion.

On January 31, 2018, we announced the expansion of our CMRF technology platform to address the mild-to-moderate stress urinary incontinence (“SUI”) market. Based on our research and data analyses conducted in 2017, we believe that SUI affects an estimated 25 to 30 million women worldwide, representing a near-term, estimated global market of \$10 to \$12 billion. SUI is a major challenge for women, particularly those who have experienced vaginal childbirth. We believe that upwards of 55% of all women with a previous vaginal delivery may exhibit mild-to-moderate symptoms of SUI. Women often use an external pad to absorb urine leakage associated with SUI that occurs under normal activities such as coughing or laughing, which we believe is often an unsatisfactory, inconvenient and embarrassing outcome that negatively impacts a woman’s quality of life. Currently, treatment options for mild-to-moderate SUI are very limited.

In the United States, the Viveve System is cleared by the FDA for use in general surgical procedures for electrocoagulation and hemostasis and we market and sell through a direct sales force and through commercial partnerships in the United States. Outside the United States, we market and sell primarily through distribution partners. We have distribution partners covering 58 countries and a direct salesforce in Canada in addition to the United States.

As of September 30, 2018, we have sold an aggregate of 646 Viveve Systems, consisting of 323 systems sold in North America (comprised of the United States and Canada) and 323 systems sold internationally outside of North America, and approximately 28,700 single-use treatment tips worldwide.

Our goal is to become the leading provider of non-invasive solutions to treat certain women's intimate health conditions by:

- *Expanding the conditions we treat by conducting robust clinical trials and regulatory label expansion.* In addition to pursuing clearance or approval in the United States for the improvement of sexual function, we are in the process of conducting several clinical trials and, if successful, we intend to submit applications for regulatory clearance or approval in the United States and internationally for mild-to-moderate SUI and, potentially, vulvovaginal atrophy;
- *Increasing the Number of Viveve Systems.* In our existing markets, we plan to (i) increase the number of Viveve Systems by leveraging our current and future clinical trials and through innovative marketing programs directed at both physicians and patients, where permissible by law, and (ii) expand our efforts and obtain regulatory approvals in additional markets, although there are no assurances that we will ever receive such approvals;
- *Driving Increased Treatment Tip Usage.* We work collaboratively with our physician customer base to increase treatment tip usage by enhancing customer awareness and facilitating the marketing efforts of our physician customers to their patients, where permitted by law. We intend to launch innovative marketing programs with physician customers. In addition, we plan to incorporate practice development managers into our sales organization to support our physician customers;
- *Broadening Our Physician Customer Base in the United States.* While our initial focus has been on marketing and selling our Viveve System to a variety of physician specialties, we intend to extend our marketing and our sales efforts in the near future to certain specialists, including gynecologists, urogynecologists and urologists;
- *Developing New Treatment Tips and System Enhancements.* We intend to continue to expand our line of treatment tips to allow for even shorter procedure times to benefit both physicians and patients. We also plan to pursue potential system modifications and next generation enhancements that will further increase the ease-of-use of the Viveve System; and
- *Investing in Intellectual Property and Patent Protection.* We will continue to defend and invest in expanding our intellectual property portfolio, and we intend to file for additional patents to strengthen our intellectual property rights.

During the fourth quarter of 2018, we expect to:

- Announce 12-month data for the SUI feasibility study;
- Obtain FDA clearance to continue VIVEVE II (FSFI) study enrollment; and
- Complete LIBERATE-INT (SUI) study enrollment.

During 2019, we expect to:

- Complete VIVEVE II study enrollment by June 30, 2019;
- Announce the final 6-month data for the LIBERATE-INT (SUI) study by June 30, 2019;
- Obtain Investigational Device Exemption application ("IDE") approval from the FDA for LIBERATE US (SUI) study and initiate the clinical trial by September 30, 2019; and
- Complete enrollment in the LIBERATE-US (SUI) study by December 31, 2019.

Recent Developments

LIBERATE-US Trial Update

On September 17, 2018, we submitted our IDE to the FDA to conduct the LIBERATE-US SUI trial. On October 17, 2018, we received the first response letter from the FDA which requested additional safety data and provided us with certain study design considerations and suggestions. On October 30, 2018, we resubmitted our IDE to the FDA to address the items included in the FDA's first response letter and also included final study reports from various preclinical safety studies we had conducted.

On November 30, 2018, we received a second response letter from the FDA which requested additional preclinical safety testing and provided us with further additional study design considerations. We intend to address the second letter by submitting a pre-submission meeting request to the FDA by December 31, 2018 which will propose an in-vivo animal study to demonstrate the safety of our SUI protocol. Following our pre-submission meeting and receipt of feedback from the FDA, we expect to be able to complete our in vivo animal safety testing in the third quarter of 2019 and, if the results of this testing are positive, we intend to resubmit our IDE immediately thereafter. If acceptable to the FDA, we expect to begin our LIBERATE-US trial by September 30, 2019.

Feasibility Study Results (SUI)

Our single-arm SUI feasibility study included 35 subjects at baseline with mild-to-moderate SUI (based on the one-hour pad weight test) who underwent treatment with Viveve's CMRF technology under a treatment protocol. Twenty-five subjects successfully completed the twelve-month study. Our twelve-month data shows:

- 72% of patients treated experienced an improvement from baseline in the 1-hour Pad Weight Test at 12 months;
- A greater than 50% reduction in the 1-hour Pad Weight Test was achieved by 52% of patients at 12 months;
- 60% of patients experienced significant benefit as they had \leq one gram of urine leakage in the 1-hour Pad Weight Test at 12 months;
- A clinically meaningful benefit was achieved across all patient-reported outcome measures (SUI symptoms and quality of life) at 12 months (n=25); and
- No device-related safety issues were reported for any of the patients.

This study was conducted by Dr. Bruce Allan who is the medical director of the Allan Centre in Alberta, Canada.

Amended Term Loan with CRG

On November 29, 2018, we entered into Amendment No. 2 ("Amendment No. 2") to the Term Loan Agreement, which was initially entered into on May 22, 2017 and subsequently amended and modified (the "Loan Agreement"), among us, CRG Servicing LLC, as administrative agent and collateral agent, the lenders from time to time party thereto and certain other parties. Amendment No. 2, among other things, amends our minimum revenue covenant for sales of the Viveve System under the Loan Agreement for fiscal year 2018 from at least \$20,000,000 to at least \$17,000,000.

New Sales and Marketing Strategy in the United States

Currently, our sales and marketing organization is structured so that we would rely on a direct sales force to sell the Viveve System in the United States. Beginning in the first quarter of 2019, we anticipate reorganizing our U.S. sales and marketing organization such that we now expect to utilize (i) our existing partnership with Aesthetic Management Partners (AMP), which is a network of independent partnership sales representatives, and regional distribution partners for the sales and marketing of our products to aesthetic practices, and (ii) a direct sales force for sales and marketing to other medical practitioners including specialists such as gynecologists, urologists and urogynecologists. We plan to continue to incorporate practice development managers into our sales organization to support such medical practitioners. We believe our reorganization will help reduce our operating expenses through 2019 and 2020 while allowing us to focus on our market development efforts. We do not currently anticipate making any changes to our international distribution network. The reorganization may not have the desired effect of reducing our operating expenses and may result in a disruption to our business, adversely affect our sales and marketing organization and make it more difficult to retain qualified personnel.

Risk Factor

We currently have limited sales and marketing resources or experience; and the failure to build and manage a sales force, or to market and distribute the Viveve System effectively, could have a material adverse effect on our business.

Currently, our sales and marketing organization is structured so that we would rely on a direct sales force to sell the Viveve System in the United States. Beginning in the first quarter of 2019, we anticipate reorganizing our U.S. sales and marketing organization such that we now expect to utilize (i) our existing partnership with Aesthetic Management Partners (AMP), which is a network of independent partnership sales representatives, and regional distribution partners for the sales and marketing of our products to aesthetic practices, and (ii) a direct sales force for sales and marketing to other medical practitioners including specialists such as gynecologists, urologists and urogynecologists. We plan to continue to incorporate practice development managers into our sales organization to support such medical practitioners. We believe our reorganization will help reduce our operating expenses through 2019 and 2020 while allowing us to focus on our market development efforts. We do not currently anticipate making any changes to our international distribution network.

Our reorganization may not have the desired effect of reducing our operating expenses and may result in a disruption to our business, adversely affect our sales and marketing organization and make it more difficult to retain qualified personnel. In addition, our management may divert a disproportionate amount of time away from its day-to-day activities to devoting a substantial amount of time to managing the reorganization which may increase our expenses. Our future financial performance and ability to compete effectively will depend, in part, on our ability to effectively manage the reorganization and future growth. To that end, we must be able to:

- hire qualified individuals as needed;
- provide adequate training for the effective sale of our device; and
- retain and motivate sales employees.

We may not be able to accomplish these tasks and successfully execute the reorganization which could harm our financial results and have a material adverse effect on our business.

Viveve Announces Proposed Public Offering of Shares of Common Stock

ENGLEWOOD, CO--(Marketwired – December 6, 2018) - Viveve Medical, Inc. (“Viveve”) (NASDAQ: VIVE), a medical technology company focused on women’s intimate health, today announced that it has commenced an underwritten public offering of shares of its common stock. All shares of common stock will be offered by Viveve. Viveve expects to grant the underwriters a 30-day option to purchase up to an additional 15% of the shares of common stock in connection with the public offering. Viveve intends to use the net proceeds from this offering to support the continued commercialization of its products in North America and internationally, to obtain additional regulatory clearances and to conduct the VIVEVE II Sexual Function and LIBERATE – International and LIBERATE – U.S. stress urinary incontinence (SUI) clinical trials, and for general corporate and working capital purposes.

Cowen is acting as sole book-running manager of the offering. The offering is subject to market and other conditions, and there can be no assurance as to whether or when the offering may be completed, or as to the actual size or terms of the offering.

This announcement shall not constitute an offer to sell or a solicitation of an offer to buy these securities nor shall there be any offer or sale of these securities in any state or jurisdiction in which such an offer, solicitation or sale would be unlawful. The securities described above are being offered by Viveve pursuant to Viveve’s registration statements on Form S-3 (File Nos. 333-221432 and 333-213682) previously filed and declared effective by the U.S. Securities and Exchange Commission (the “SEC”).

The offering will be made only by means of a prospectus supplement and accompanying prospectuses. A preliminary prospectus supplement and accompanying prospectuses relating to and describing the terms of this offering will be filed with the SEC. When available, copies of the preliminary prospectus supplement and accompanying prospectuses can be obtained from Cowen and Company, LLC, c/o Broadridge Financial Solutions, 1155 Long Island Avenue, Edgewood, New York 11717, Attn: Prospectus Department, or by email at PostSaleManualRequests@broadridge.com, or by accessing the SEC’s website, www.sec.gov.

About Viveve

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International regulatory approvals and clearances have been received for vaginal laxity and/or improvement in sexual function indications in over 50 countries. In the second quarter of 2018, Viveve initiated VIVEVE II, a multicenter, randomized, double-blind, sham-controlled clinical trial to assess improvement of sexual function in women following vaginal childbirth after receiving approval of an Investigational Device Exemption (IDE) application from the U.S. Food and Drug Administration (FDA) in March of 2018. If successful, this trial 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.

Viveve has initiated LIBERATE-International, one of two planned independent, multicenter, randomized registration trials for the improvement of SUI in women and plans to re-submit an IDE to the FDA for LIBERATE-U.S., after conducting certain safety testing in the third quarter of 2019. The results of these two trials, if successful, could support marketing applications in the U.S. and additional countries around the world for this new commercial indication.

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, our anticipated public offering, future expectations, plans and prospects for us, and the timing of these events, along with those risks set forth in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, our Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, and the prospectus supplement related to the public offering, as well as discussions of potential risks, uncertainties and other important factors in our subsequent filings with the SEC, which are or will be 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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