

## Viveve Reports Full Year 2019 Financial Results

- **Company completes successful U.S. commercial transition from traditional capital sales model to recurring revenue rental model**
- **Landmark pivotal sexual function trial (VIVEVE II) completed with data readout scheduled for April**
- **SUI clinical development program with short-term feasibility study continues to advance**
- **Company to host conference call at 5:00 PM ET today**

**ENGLEWOOD, CO / ACCESSWIRE / March 19, 2020** Viveve Medical Inc. (NASDAQ:VIVE), a medical technology company focused on women's intimate health, today reported financial results for the year ended December 31, 2019. The Company will provide a corporate update on its scheduled conference call at 5:00 PM ET today.

"2019 was a transformational year for Viveve where we achieved several significant milestones in our commercial operations and clinical development programs. Our U.S. commercial team successfully transitioned to a new recurring revenue rental model, resulting in an increase in the number of Viveve® Systems placed at a lower acquisition cost per customer," said Scott Durbin, Viveve's chief executive officer.

"We are also pleased to report significant advancement in our clinical development programs in sexual function and stress urinary incontinence (SUI) in 2019 and early 2020," continued Mr. Durbin. "We completed enrollment and patient monitoring in Viveve II, our landmark pivotal clinical trial evaluating participants for improved sexual function following treatment with Viveve's Cryogen-cooled Monopolar Radiofrequency (CMRF) technology. We remain on track to report topline data from this trial next month. If the results are positive, we intend to submit a marketing application for our CMRF technology to the U.S. Food and Drug Administration (FDA) in 2020 for the improvement of sexual function in women following vaginal childbirth."

"Also, following the inconclusive results of our LIBERATE-International SUI trial reported in August 2019, we were pleased that the Canadian Ministry of Health approved the Investigational Testing Application (ITA) for our important short-term SUI feasibility study in mid-December 2019. We quickly initiated the SUI feasibility study and completed enrollment in early March 2020. The trial data readout expected in the third quarter of this year will chart our course for potential global product label expansion for SUI, a condition that affects an estimated 25-30 million women worldwide."

### 2019 and Recent Business Highlights

#### Implemented New U.S. Commercial Sales Model and Realigned Organization

- **Transitioned U.S. Commercial Sales to Recurring Revenue Rental Model:** In June 2019, U.S. sales of the Viveve System transitioned from a capital equipment sales model to a recurring revenue rental model. The new U.S. commercial sales model reduced up-front costs for customers and thus lowered hurdles to adoption, leading to increased placement rates, improved profit margins and a significant reduction in average selling time per unit. In December 2019, Viveve System placements with new customers represented a higher monthly productivity rate per sales representative and lower cost per sales representative per system placed than any prior month in the Company's history.
- **Implemented a Strategic Organizational Realignment Plan:** In January 2019, the Company undertook a strategic organizational realignment to reduce operating expenses and prepare for the potential of expanded indications for its CMRF technology platform. International commercial distribution remains unchanged through Viveve's global network of distributor partners. The restructuring contributed to a reduction in total operating expenses in the first quarter of 2019 as projected, and additional operating cost savings occurred through the remainder of 2019.

#### Advanced Sexual Function Clinical Development Program

- **Completed VIVEVE II Pivotal FDA Clinical Trial for Improvement of Sexual Function:** In March 2019, Viveve completed enrollment of 250 patients in VIVEVE II, our U.S. Investigational Device Exemption (IDE)-approved multicenter, randomized, double-blind, sham-controlled trial evaluating our CMRF technology for improvement of sexual function in women. In March 2020, the final 12-month patient visits were completed and announced. We remain on schedule to present a topline data readout from the trial in April 2020. If positive, the results could support a marketing application for a new U.S. commercial indication for our CMRF technology.

## Advanced Stress Urinary Incontinence (SUI) Clinical Development Program

- **Initiated ITA Approved Three-Arm Feasibility Study in SUI:** In December 2019, the Company received approval of an ITA from the Canadian Ministry of Health and in January 2020 our team initiated a three-arm, three-month feasibility study comparing Viveve's CMRF treatment and a cryogen-only sham to an inert sham treatment for the improvement of SUI in women. The results of the short-term feasibility trial may provide a strategic path forward in our pursuit of global product label expansion in SUI. The feasibility study data readout is expected in the third quarter of 2020.
- **Reported Clinical Results from LIBERATE-International SUI Trial:** In July 2019, we reported topline results from the LIBERATE-International study in SUI conducted under an ITA approved by the Canadian Ministry of Health. In August 2019, Viveve also reported additional clinical outcomes data from the study. While the study did not achieve statistical significance on the primary endpoint of mean change from baseline on the 1-hour Pad Weight Test at six months post-treatment compared to the control group, the full clinical data demonstrated a consistency of benefit at six months post-treatment across all endpoints in the majority of patients within both groups. Across all endpoints, the efficacy of both the active (RF and cryogen) and sham (cryogen-only) treatments were highly clinically relevant. Analysis of the results of the trial led Viveve to conduct the short-term SUI feasibility trial that is currently underway.

## Launched Next Generation 2.0 Platform in Key Global Markets

- **South Korea:** In December 2019, Viveve received registration clearance from the Korean Ministry of Food and Drug Safety for its next generation Viveve 2.0 CMRF System for use in general surgical procedures for electrocoagulation and hemostasis as well as for the treatment of vaginal laxity.
- **China:** In December 2019, Viveve reported the launch of its next generation 2.0 System and consumable treatment tips in mainland China, Hong Kong, and Macau with Paragon Meditech, the Company's exclusive distribution partner in the region. Paragon hosted a launch event that included more than 70 key opinion leader customers in Dalian, China, which was enthusiastically received by participating women's health and aesthetic practitioners from Mainland China and other Asian markets across Paragon's territories.
- **United States:** In June 2019, the Company received 510(k) clearance from the FDA for its next generation Viveve 2.0 System and consumable treatment tips for use in general surgical procedures for electrocoagulation and hemostasis. The FDA clearance is believed to represent another important confirmation of the safety profile of Viveve's CMRF technology platform.
- **European Union:** In April 2019, the Company received CE Mark clearance for its next generation Viveve 2.0 CMRF System and treatment tips in the European Union and European Economic Area countries. As part of our ongoing regulatory strategy to expand the commercial launch of our Viveve 2.0 CMRF System globally, the Company's next generation system and its consumable treatment tips are now available in more than 30 countries in Europe.

"As of the end of 2019 Viveve had a global installed base of 840 systems and had sold more than 41,000 consumable treatment tips. Our international business continues to show strength and with the demonstrated success of the U.S. recurring revenue rental model, greater long-term revenue per customer, lower selling costs per unit placed, and improved revenue from consumables sales, we believe we will realize more predictable quarterly and annual sales growth. Combined with continuing advances in our clinical development programs and upcoming trial readouts, we believe that Viveve is positioned to significantly advance the science and practice of women's intimate health in the months and years ahead," concluded Mr. Durbin.

## Full Year 2019 Financial Results

Revenue for 2019 totaled approximately \$6.6 million compared to revenue of approximately \$18.5 million for 2018, a decrease of \$12.0 million, or approximately 65%. The decrease in revenue was primarily due to our shift in our U.S. commercial sales model to a recurring revenue rental model versus selling systems under a capital equipment sales model. Sales in 2019 included 137 Viveve Systems and approximately 7,850 disposable treatment tips. Under the U.S. recurring revenue rental model, which was launched in June 2019, the Company placed 82 Viveve Systems. Rental revenue on these leases is recognized on a straight-line basis over the term of the lease.

Gross profit for 2019 was approximately \$1.0 million, or 15% of revenue, compared to gross profit of approximately \$7.3 million, or 40% of revenue for 2018, a decrease of \$6.3 million or approximately 86%. The decrease in gross profit was primarily due to the lower sales volume of Viveve Systems sold as the Company transitioned its U.S. business model to a recurring revenue rental model versus selling systems under a capital equipment sales model.

Total operating expenses for 2019 were approximately \$31.7 million compared to \$52.3 million for 2018. The decrease is mainly the result of lower sales costs associated with the U.S. shift to the recurring revenue rental

model in June 2019 as well as certain cost savings in connection with the Company's strategic organizational realignment in early 2019.

Spending on research and development for 2019 was approximately \$8.6 million compared to approximately \$13.6 million in 2018. The decrease was primarily due to higher costs in 2018 associated with engineering and development work with the Company's contract manufacturer related to product line improvements and expansion efforts of the next generation Viveve 2.0 System and disposable treatment tips.

Selling, general and administrative (SG&A) expenses during 2019 were approximately \$22.4 million compared to approximately \$38.7 million in 2018, a decrease of \$16.3 million, or approximately 42%. The decrease in SG&A spending in 2019 was primarily due to certain cost savings in connection with the Company's strategic organizational realignment, which occurred in the first quarter of 2019. The restructuring included a reduction in headcount of approximately 40 full-time employees. Reduced professional and legal fees associated with strategies to protect our intellectual property also contributed to the reduction in SG&A expenses in 2019.

Net loss attributable to common stockholders for 2019 was approximately \$42.9 million, or a net loss of \$34.39 per share of common stock based on 1,247,768 weighted average shares outstanding during the period, compared with a net loss of approximately \$50.0 million, or a net loss of \$160.92 per share of common stock for 2018 based on 310,589 weighted average shares outstanding during the period (adjusted for the Company's 1-for-100 reverse stock split in September 2019).

### **Conference Call Information (updated)**

The Company will host a live conference call at 5:00 p.m. E.T. today. The conference call may be accessed by dialing 1-833-255-2833 (domestic) or 1-412-902-6728 (international) or via live webcast at <https://services.choruscall.com/links/vive200319.html>. Participants may also pre-register for the conference call at <http://dpreregister.com/10138365>.

A recording of the webcast will be posted on the Company's investor relations website following the call at [ir.viveve.com](http://ir.viveve.com) and will be available online for 90 days.

### **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.

In the United States the Viveve System is cleared by the Food and Drug Administration (FDA) for use in 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 more than 50 countries.

For more information, visit Viveve's website at [viveve.com](http://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 impact of the novel coronavirus on our clinical development and on the manufacturing, placements and patient utilization of our Viveve Systems, 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](http://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.

**VIVEVE MEDICAL, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
(in thousands)  
(unaudited)

	<b>December 31, 2019</b>	<b>December 31, 2018</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 13,308	\$ 29,523
Accounts receivable, net	1,573	5,704
Inventory	4,861	4,119
Prepaid expenses and other current assets	2,447	2,558
Total current assets	22,189	41,904
Property and equipment, net	3,046	2,916
Investment in limited liability company	1,216	1,843
Other assets	526	171
Total assets	\$ 26,977	\$ 46,834
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,608	\$ 3,994
Accrued liabilities	4,698	6,766
Total current liabilities	6,306	10,760
Note payable, noncurrent portion	3,983	30,528
Other noncurrent liabilities	167	634
Total liabilities	10,456	41,922
Stockholders' equity:		
Capital stock and additional paid-in capital	214,432	160,297
Accumulated deficit	(197,911)	(155,385)
Total stockholders' equity	16,521	4,912
Total liabilities and stockholders' equity	\$ 26,977	\$ 46,834

**VIVEVE MEDICAL, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
(in thousands, except share and per share data)  
(unaudited)

	<b>Year Ended December 31,</b>	
	<b>2019</b>	<b>2018</b>
Revenue	\$ 6,567	\$ 18,517
Cost of revenue	5,551	11,197
Gross profit	1,016	7,320
Operating expenses:		
Research and development	8,590	13,616
Selling, general and administrative	22,363	38,669
Restructuring costs	742	-
Total operating expenses	31,695	52,285
Loss from operations	(30,679)	(44,965)

Loss on debt restructuring	(6,705)	-
Interest expense, net	(4,354)	(4,372)
Other income (expense), net	(161)	13
Net loss from consolidated companies	(41,899)	(49,324)
Loss from minority interest in limited liability company	(627)	(657)
Comprehensive and net loss	(42,526)	(49,981)
Series B convertible preferred stock dividends	(380)	-
Net loss attributable to common stockholders	<u>\$ (42,906)</u>	<u>\$ (49,981)</u>
Net loss per share of common stock:		
Basic and diluted	<u>\$ (34.39)</u>	<u>\$ (160.92)</u>
Weighted average shares used in computing net loss per common share:		
Basic and diluted	<u>1,247,768</u>	<u>310,589</u>

Note: All share and per share data has been adjusted to reflect the 1-for-100 reverse stock split which became effective after the Nasdaq Capital Market trading closed on September 18, 2019.

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