

March 14, 2019



Viveve Reports Fourth Quarter and Full Year 2018 Financial Results

ENGLEWOOD, CO / ACCESSWIRE / March 14, 2019 Viveve Medical Inc. (NASDAQ: VIVE), a medical technology company focused on women's intimate health, today reported financial results for the three months and full year ended December 31, 2018.

"2018 was a year of solid progress even as we worked to address some considerable challenges. We grew revenue despite facing significant market headwinds in the second half of the year that affected the entire women's intimate health industry. We also continued our paths forward in our clinical programs as we advanced our U.S. sexual function trial and launched our programs in stress urinary incontinence (SUI) with Viveve's cryogen-cooled, monopolar radiofrequency (CMRF) technology," said Scott Durbin, Viveve's chief executive officer. "In January, we also realigned our organization to reduce expenses and focus on our core initiatives of expanding system placements, increasing treatment tip utilization, reducing cost of goods and completing our clinical development programs in female sexual function and SUI."

2018 and Recent Business Highlights

- **Achieved continued growth in global revenue:** Reported 2018 total revenue of approximately \$18.5 million from the sale of 259 Viveve Systems and over 18,000 disposable treatment tips, representing a 21% year-over-year revenue increase.
- **Advanced and fully enrolled U.S. clinical trial for the improvement of sexual function in women:** Following U.S. Food and Drug Administration (FDA) approval of the Investigational Device Exemption (IDE) and successful review of patient safety data submitted to the Agency, Viveve received approval to proceed to full patient enrollment in late December 2018. In March 2019 Viveve completed enrollment of 250 patients in VIVEVE II, our U.S. multi-center randomized, double-blind, sham-controlled trial for improved sexual function in women.
- **Advanced clinical programs in stress urinary incontinence (SUI):** Reported positive 12-month results from a pilot study and separate feasibility study using the Viveve System for the treatment of SUI. Viveve initiated and completed patient enrollment in the LIBERATE-International trial with results expected in the third quarter of 2019. The company also worked closely with FDA throughout 2018 to define the data needed in 2019 to support starting a U.S. registration study for SUI.
- **Introduced an enhanced technology platform:** Successfully executed the initial launch of Viveve 2.0., the company's next generation system, with the potential to deliver improved gross margins in 2019.
- **Expanded awareness of Viveve's CMRF technology:** Data was reported in more than 20 clinical publications and presented by gynecology, urology, women's intimate health and aesthetic physician opinion leaders at 15 leading global medical conferences and meetings.
- **Successfully protected Viveve's IP estate:** Announced a favorable settlement of the

company's patent infringement litigation, further protecting Viveve's intellectual property portfolio.

- **Expanded Board:** Appointed two new, independent, and seasoned commercial executives to Viveve's Board of Directors; Steven Basta and Karen Zaderej.

Mr. Durbin continued, "With the sale of 259 Viveve Systems in 2018, we now have a commercial installed base of over 700 systems worldwide. We anticipate reporting continued momentum in system sales and consumable treatment tip utilization in 2019 as we advance our global commercial, regulatory, and market development strategies."

Fourth Quarter 2018 Financial Results

Revenue for the fourth quarter of 2018 totaled approximately \$4.5 million from the sale of 57 Viveve Systems and approximately 4,600 treatment tips, compared to revenue of approximately \$5.1 million for the same period in 2017, representing a 12% decrease over the fourth quarter of 2017.

Gross profit for the fourth quarter of 2018 was approximately \$1.7 million, or 37% of revenue, compared to gross profit of approximately \$2.8 million, or 54% of revenue in the fourth quarter of 2017.

Total operating expenses for the fourth quarter of 2018 was \$13.9 million compared to total operating expenses of \$12.2 million in the same period in 2017. The increase was primarily the result of increased efforts to support the commercialization of Viveve's products in the U.S. and clinical studies in SU1 and sexual function.

Spending on research and development during the fourth quarter of 2018 was \$2.8 million compared to \$3.1 million in the fourth quarter of 2017.

Selling, general and administrative expenses for the fourth quarter of 2018 were \$11.1 million compared to \$9.2 million in the fourth quarter of 2017.

Net loss for the fourth quarter of 2018 was \$13.5 million, or a net loss of \$0.38 per share based on 35,484,596 weighted average shares outstanding during the period.

Cash and cash equivalents were approximately \$29.5 million as of December 31, 2018.

Full Year 2018 Financial Results

Revenue for 2018 totaled approximately \$18.5 million from the sale of 259 Viveve Systems and approximately 18,450 treatment tips, compared to revenue of approximately \$15.3 million for the full year of 2017, an increase of 21% year-over-year.

Gross profit for 2018 was approximately \$7.3 million, or 40% of revenue, compared to gross profit of approximately \$7.4 million, or 49% of revenue for the full year of 2017.

Total operating expenses for 2018 was approximately \$52.3 million compared to \$41.2 million for the full year of 2017.

Spending on research and development for 2018 was approximately \$13.7 million compared to approximately \$12.3 million in 2017 and increased due to costs associated with

engineering and development work with the company's contract manufacturer related to product line improvement and expansion efforts.

Selling, general and administrative (SG&A) expenses during 2018 were approximately \$38.6 million compared to \$28.8 million in 2017. The increase in SG&A spending was primarily the result of increased costs associated with Viveve's expansion of the commercial sales organization, marketing efforts to build brand and market awareness, expenses associated with being a public company and financing efforts.

Net loss for 2018 was approximately \$50.0 million, or a net loss of \$1.61 per share based on 31,059,483 weighted average shares outstanding during the period, compared with a net loss of \$37.0 million, or a net loss of \$2.11 per share for 2017.

Conference Call Information

The company will host a live conference call at 5:00 p.m. ET 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/vive190314.html>. Participants may also pre-register for the conference call at <http://dpreregister.com/10128440>.

A recording of the webcast will be posted on the company's investor relations website following the call at 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.

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.

Viveve has fully enrolled LIBERATE-International, one of two planned independent, multicenter, randomized registration trials for the improvement of stress urinary incontinence in women and plans to re-submit an IDE to the FDA for LIBERATE-U.S. after conducting certain safety testing. The results of these two trials, if successful, could support marketing applications in the U.S. and in over 35 countries around the world for this new commercial indication.

For more information visit Viveve's website at www.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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VIVEVE MEDICAL, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)
(unaudited)

	<u>December 31,</u> <u>2018</u>	<u>December 31,</u> <u>2017</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 29,523	\$ 20,730
Accounts receivable, net of allowance for doubtful accounts	5,704	6,213
Inventory	4,119	2,390
Prepaid expenses and other current assets	2,558	2,741
Total current assets	<u>41,904</u>	<u>32,074</u>
Property and equipment, net	2,916	1,303
Investment in limited liability company	1,843	2,500
Other assets	171	202
Total assets	<u>\$ 46,834</u>	<u>\$ 36,079</u>
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	\$ 3,994	\$ 4,799
Accrued liabilities	6,766	4,605
Total current liabilities	<u>10,760</u>	<u>9,404</u>
Note payable, noncurrent portion	30,528	28,948
Other noncurrent liabilities	634	327
Total liabilities	<u>41,922</u>	<u>38,679</u>
Stockholders' equity (deficit):		
Common stock and additional paid-in capital	160,297	102,981
Accumulated deficit	(155,385)	(105,581)
Total stockholders' equity (deficit)	<u>4,912</u>	<u>(2,600)</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 46,834</u>	<u>\$ 36,079</u>

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

	<u>Three Months Ended</u> <u>December 31,</u>		<u>Year Ended</u> <u>December 31,</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
Revenue	\$ 4,472	\$ 5,101	\$ 18,517	\$ 15,288
Cost of revenue	2,807	2,329	11,197	7,844
Gross profit	<u>1,665</u>	<u>2,772</u>	<u>7,320</u>	<u>7,444</u>
Operating expenses:				
Research and development	2,846	3,051	13,716	12,343
Selling, general and administrative	11,087	9,150	38,569	28,831
Total operating expenses	<u>13,933</u>	<u>12,201</u>	<u>52,285</u>	<u>41,174</u>
Loss from operations	(12,268)	(9,429)	(44,965)	(33,730)
Interest expense, net	(1,133)	(784)	(4,372)	(3,169)
Other income (expense), net	27	(11)	13	(60)
Net loss from consolidated companies	(13,374)	(10,224)	(49,324)	(36,959)
Loss from minority interest in limited liability company	(118)	-	(657)	-
Comprehensive and net loss	<u>\$ (13,492)</u>	<u>\$ (10,224)</u>	<u>\$ (49,981)</u>	<u>\$ (36,959)</u>
Net loss per share:				
Basic and diluted	<u>\$ (0.38)</u>	<u>\$ (0.53)</u>	<u>\$ (1.61)</u>	<u>\$ (2.11)</u>
Weighted average shares used in computing net loss per common share:				
Basic and diluted	<u>35,484,596</u>	<u>19,435,347</u>	<u>31,059,483</u>	<u>17,496,942</u>

SOURCE: Viveve Medical Inc.

