

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): March 17, 2022

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock	VIVE	Nasdaq Capital Market

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 2.02. Results of Operations and Financial Conditions.

On March 17, 2022, Viveve Medical, Inc. (the “Company”) issued a press release announcing its results for the fiscal year ended December 31, 2021. A copy of the Company’s press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, regardless of any general incorporation language in such a filing, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued by the Company on March 17, 2022, announcing results for the fiscal year ended December 31, 2021.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: March 17, 2022

Viveve Medical, Inc.

By: /s/ Scott Durbin
Scott Durbin
Chief Executive Officer

Viveve Reports Full Year 2021 Financial Results and Provides Corporate Update

Reported total revenue for year end 2021 of \$6.4 million representing 17% year-over-year growth

Enrollment completed in U.S. pivotal PURSUIT trial for stress urinary incontinence and 12-month post treatment follow-up visits underway

PURSUIT top-line results anticipated at end of 2022

Conference call to be hosted by Company at 5:00 PM ET today

Englewood, CO – March 17, 2022 – 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, 2021. The Company will provide a corporate update on its scheduled conference call at 5:00 PM ET today.

"I am extremely pleased with the milestones achieved throughout 2021 as the entire Viveve team focused on advancing our stress urinary incontinence (SUI) program and growing our core market for SUI. In the midst of the continuing COVID-19 pandemic, we initiated our U.S. pivotal PURSUIT trial in January 2021 and quickly onboarded 30 investigational sites in the following months. Trial enrollment accelerated mid-year as we increased promotional efforts with our clinical sites and successfully reached full 390 patient enrollment in mid-December," said Scott Durbin, Viveve's chief executive officer. "Concurrently, we have continued to support existing Viveve customers and drive System adoption and utilization through core medical specialists in U.S. and Asia Pacific markets. We look forward to the PURSUIT trial readout expected at the end of 2022 while continuing operational efficiencies and efforts to maintain a low cash burn rate."

Mr. Durbin added, "We believe our innovative, single treatment, dual-energy technology may benefit an estimated 25-30 million women in the U.S. who suffer from SUI, which we believe represents a multi-billion-dollar commercial opportunity for Viveve."

2021 and Recent Business Highlights

- Initiated and completed enrollment in U.S. pivotal PURSUIT trial: Advanced our SUI clinical program in pursuit of a new U.S. indication. Patient 12-month follow-up visits underway with top-line results anticipated at the end of 2022.
 - Established potential future reimbursement pathway for Company's SUI procedure. New Category III CPT® code awarded by American Medical Association for Viveve's dual-energy endovaginal procedure for SUI.
 - Reported total revenue for year end 2021 of \$6.4 million: Achieved sales of 46 Viveve Systems and 24 System placements in the U.S. under the Company's subscription program. Maintained high-quality support to existing customers in U.S. and Asia Pacific markets to drive procedures and consumable tip volumes resulting in approximately 10,750 consumable treatment tips globally.
 - Completed equity financing and reduced operational cash burn rate: Successfully closed upsized \$27.6 million offering in early 2021 to support the Company's operations while continuing efforts to maximize operational efficiencies and maintain a reduced cash burn rate through early 2023.
 - Expanded intellectual property portfolio: Strengthened the Company's patent estate with issuances in South Korea, Taiwan, Canada, and two patents in the U.S.
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Full Year 2021 Financial Results

Revenue for 2021 totaled approximately \$6.4 million compared to total revenue of approximately \$5.5 million in 2020. Sales in 2021 included 46 Viveve Systems and approximately 10,750 disposable treatment tips compared to 31 Viveve Systems and approximately 8,900 disposable treatment tips in 2020. Under the Company's subscription program, we placed 24 Viveve Systems in the U.S. market in 2021.

Gross profit for 2021 was approximately \$0.6 million, or 10% of revenue, compared to gross profit of approximately \$0.3 million, or 5% of revenue for 2020. The increase in gross profit was primarily due to the higher volume of Systems and disposable treatment tips sold in 2021.

Total operating expenses for 2021 were approximately \$22.2 million compared to \$18.8 million for 2020. The increase is the result of the Company's efforts to advance our SUI development program and increase enrollment in our PURSUIT clinical trial.

Spending on research and development for 2021 was approximately \$9.7 million compared to approximately \$5.1 million in 2020. The increase in R&D spending was primarily due to costs associated with engineering and development work related to product line improvements and efforts to advance our SUI clinical development program.

Selling, general and administrative expenses during 2021 were approximately \$12.5 million compared to approximately \$13.7 million in 2020. The decrease in SG&A spending in 2021 was primarily due to reduced spending as a result of the cost reduction efforts to increase operational and commercial efficiency and lower cash burn rate.

Net loss attributable to common stockholders for 2021 was approximately \$26.7 million, or a net loss of \$2.65 per share of common stock based on 10,089,722 weighted average shares outstanding during the period, compared with a net loss of approximately \$26.1 million, or a net loss of \$16.56 per share of common stock for 2020 based on 1,573,528 weighted average shares outstanding during the period (adjusted for the Company's 1-for-10 reverse stock split in December 2020).

Cash and cash equivalents were \$19.2 million as of December 31, 2021, compared to \$6.5 million as of December 31, 2020.

Conference Call Information

Viveve will host a conference call today, Thursday, March 17, at 5:00 PM ET. 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/mediaframe/webcast.html?webcastid=NZykfofx>. Participants may also pre-register for the conference call at <https://dpregrister.com/sreg/10163026/f0afd880e8>.

A recording of the webcast will be posted on the Company's investor relations website following the call at ir.viveve.com and 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 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 50 countries.

Viveve continues to advance its clinical development program in stress urinary incontinence (SUI). Viveve received FDA approval of its Investigational Device Exemption (IDE) application to conduct the multicenter, randomized, double-blinded, sham-controlled PURSUIT trial for improvement of SUI in women in July 2020 and FDA approval of its requested amendments to the IDE protocol in December 2020. Initiation of the trial was reported in January 2021 and completion of subject enrollment was announced on December 14, 2021. Topline results are anticipated at the end of 2022. If positive, results from the PURSUIT trial may support a new SUI indication in the U.S.

For more information visit Viveve's website at <https://us.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, including, without limitation, implied and express statements regarding Viveve Medical, Inc.'s plans, timelines or presumptions of results for the PURSUIT trial, the anticipated future impact of the new Category III CPT® code, including any potential reimbursement for Viveve's dual-energy endovaginal procedure for SUI, and our anticipated cash runway. 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 timing, progress and results of our clinical trials, the fluctuation of global economic conditions, the impact of the novel coronavirus termed COVID-19 on our clinical development and regulatory review and clearances 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 evaluation of 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.
CPT is a registered trademark of the American Medical Association.*

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

	December 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 19,162	\$ 6,523
Accounts receivable, net	549	770
Inventory	1,472	3,254
Prepaid expenses and other current assets	1,055	1,031
Total current assets	22,238	11,578
Property and equipment, net	1,554	2,759
Investment in limited liability company	577	833
Other assets	1,544	1,460
Total assets	<u>\$ 25,913</u>	<u>\$ 16,630</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,480	\$ 881
Accrued liabilities	3,053	2,416
Note payable, current portion	-	918
Total current liabilities	4,533	4,215
Note payable, noncurrent portion	5,124	4,943
Other noncurrent liabilities	1,190	498
Total liabilities	10,847	9,656
Stockholders' equity:		
Capital stock and additional paid-in capital	256,919	226,800
Accumulated deficit	(241,853)	(219,826)
Total stockholders' equity	15,066	6,974
Total liabilities and stockholders' equity	<u>\$ 25,913</u>	<u>\$ 16,630</u>

Note: All share and per share data has been adjusted to reflect the 1-for-10 reverse stock split which became effective after market close on December 1, 2020.

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

	Year Ended December 31,	
	2021	2020
Revenue	\$ 6,426	\$ 5,479
Cost of revenue	5,806	5,183
Gross profit	620	296
Operating expenses:		
Research and development	9,665	5,125
Selling, general and administrative	12,508	13,666
Total operating expenses	22,173	18,791
Loss from operations	(21,553)	(18,495)
Gain on forgiveness of PPP loan	1,358	-
Modification of common warrants	(373)	(1,838)
Interest expense, net	(1,000)	(910)
Other expense, net	(203)	(289)
Net loss from consolidated companies	(21,771)	(21,532)
Loss from minority interest in limited liability company	(256)	(383)
Comprehensive and net loss	(22,027)	(21,915)
Series B convertible preferred stock dividends	(4,691)	(4,149)
Net loss attributable to common stockholders	\$ (26,718)	\$ (26,064)
Net loss per share of common stock:		
Basic and diluted	\$ (2.65)	\$ (16.56)
Weighted average shares used in computing net loss per common share:		
Basic and diluted	10,089,722	1,573,528

Note: All share and per share data has been adjusted to reflect the 1-for-10 reverse stock split which became effective after market close on December 1, 2020.