

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): November 12, 2021

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 November 11, 2021, Viveve Medical, Inc. (the “Company”) issued a press release announcing its results for the quarter ended September 30, 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 November 11, 2021, announcing results for the quarter ended September 30, 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: November 12, 2021

Viveve Medical, Inc.

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

Viveve Reports Third Quarter 2021 Financial Results and Provides Corporate Update*Total revenue of \$1.6M reported for Q3**Pivotal SUI PURSUIT trial enrollment nears completion – randomizations on-track for completion in Q4*

ENGLEWOOD, CO – November 11, 2021 – Viveve Medical, Inc. (NASDAQ: VIVE), a medical technology company focused on women's intimate health, today reported financial results for the quarter ended September 30, 2021, and will provide a corporate update on its scheduled conference call at 5:00 PM ET today. The Company's 10-Q documents will be filed on Friday, November 12, 2021, when the U.S. Securities and Exchange Commission reopens following the Veterans Day holiday.

"During the third quarter of 2021, we continued to make great progress in advancing our stress urinary incontinence (SUI) clinical development program. Patient enrollment in our pivotal U.S. PURSUIT trial is close to complete and we expect to fully randomize the trial in the weeks that follow," said Scott Durbin, Viveve's chief executive officer. "We look forward to reaching the PURSUIT trial milestone in the fourth quarter as we move towards a potential future SUI indication in the U.S. if its results are positive. Further, throughout this year we have continued to successfully drive Viveve® System adoption and utilization through core medical specialists in U.S. and Asia Pacific markets."

Third Quarter and Recent Business Highlights

- Reported \$1.6 million total revenue for the third quarter of 2021, including sales of 16 Viveve Systems and approximately 2,300 consumable treatment tips;
- Advanced enrollment in the pivotal U.S. PURSUIT clinical trial for SUI to near completion with full patient randomization expected in the fourth quarter;
- Expanded the Company's robust intellectual property portfolio with issuance of an SUI methods patent in Australia and an additional methods patent granted in the U.S.;
- Established a potential long-term reimbursement pathway with announcement of a Category III CPT® code for Viveve's SUI procedure from the American Medical Association and with the support of key medical societies; and
- Continued to maintain high-quality service and support to U.S. and Asia Pacific customers to drive procedures and consumable treatment tip volumes.

Q3 2021 Financial Results

Revenue for the quarter ended September 30, 2021 totaled \$1.6 million from sales of 16 Viveve Systems and approximately 2,300 consumable treatment tips, compared to revenue of \$1.5 million for the same period in 2020. As of September 30, 2021, the Company had an installed base of 870 Viveve Systems worldwide, 455 in the U.S. and 415 internationally.

Total operating expenses for the third quarter of 2021 were \$5.6 million, compared to \$3.6 million for the same period in 2020. The increase is mainly a result of the Company's efforts to conduct and advance enrollment in our pivotal U.S. PURSUIT clinical trial.

Net loss attributable to common stockholders for the third quarter of 2021 was \$7.0 million, or (\$0.67) per share based on 10,591,834 weighted average shares outstanding during the period, compared to a net loss of \$4.8 million, or (\$2.65) per share, for the same period in 2020 based on 1,807,931 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 \$22.7 million as of September 30, 2021, compared to \$25.4 million as of June 30, 2021.

Conference Call Information

The Company will host a conference call and webcast at 5:00 PM 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/mediaframe/webcast.html?webcastid=DIIOEEg1>. Participants may also register for the conference call at <https://dpregrister.com/sreg/10160082/ed1ef0147c>.

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 U.S., 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 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 as reported on December 10, 2020. Initiation of the trial was reported in January 2021. If PURSUIT trial results are positive, the results may support a future SUI marketing indication in the U.S.

For more information visit 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 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)
(unaudited)

	September 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 22,665	\$ 6,523
Accounts receivable, net	514	770
Inventory	2,150	3,254
Prepaid expenses and other current assets	2,083	2,296
Total current assets	27,412	12,843
Property and equipment, net	1,678	2,759
Investment in limited liability company	645	833
Other assets	649	195
Total assets	<u>\$ 30,384</u>	<u>\$ 16,630</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,292	\$ 881
Accrued liabilities	2,557	2,416
Note payable, current portion	-	918
Total current liabilities	3,849	4,215
Note payable, noncurrent portion	4,964	4,943
Other noncurrent liabilities	1,206	498
Total liabilities	10,019	9,656
Stockholders' equity:		
Capital stock and additional paid-in capital	255,890	226,800
Accumulated deficit	(235,525)	(219,826)
Total stockholders' equity	20,365	6,974
Total liabilities and stockholders' equity	<u>\$ 30,384</u>	<u>\$ 16,630</u>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue	\$ 1,616	\$ 1,524	\$ 4,720	\$ 3,532
Cost of revenue	1,502	1,283	4,059	3,483
Gross profit	<u>114</u>	<u>241</u>	<u>661</u>	<u>49</u>
Operating expenses:				
Research and development	2,695	884	6,804	3,745
Selling, general and administrative	2,911	2,761	9,423	10,476
Total operating expenses	<u>5,606</u>	<u>3,645</u>	<u>16,227</u>	<u>14,221</u>
Loss from operations	(5,492)	(3,404)	(15,566)	(14,172)
Gain on forgiveness of Paycheck Protection Program loan	-	-	1,358	-
Modification of warrants	-	-	(373)	(1,838)
Interest expense, net	(255)	(235)	(734)	(668)
Other expense, net	(78)	(41)	(196)	(159)
Net loss from consolidated companies	(5,825)	(3,680)	(15,511)	(16,837)
Loss from minority interest in limited liability company	(33)	(55)	(188)	(323)
Comprehensive and net loss	(5,858)	(3,735)	(15,699)	(17,160)
Series B convertible preferred stock dividends	(1,190)	(1,053)	(3,463)	(3,064)
Net loss attributable to common stockholders	<u>\$ (7,048)</u>	<u>\$ (4,788)</u>	<u>\$ (19,162)</u>	<u>\$ (20,224)</u>
Net loss per share of common stock:				
Basic and diluted	<u>\$ (0.67)</u>	<u>\$ (2.65)</u>	<u>\$ (1.93)</u>	<u>\$ (14.71)</u>
Weighted average shares used in computing net loss per common share:				
Basic and diluted	<u>10,591,834</u>	<u>1,807,931</u>	<u>9,916,834</u>	<u>1,374,800</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.