

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): September 23, 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 7.01. Regulation FD Disclosure.**

On September 23, 2021, the Company issued a press release entitled “Viveve Announces Issuance of New Method Patent for Stress Urinary Incontinence in Australia”. A copy of the Company’s press release is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

The information in Item 7.01 of this Current Report on Form 8-K, including Exhibits 99.1 attached hereto, is being furnished and shall not be deemed “filed” for the 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 subject to the requirements of amended Item 10 of Regulation S-K, nor shall it be deemed incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing. The furnishing of this information hereby shall not be deemed an admission as to the materiality of any such information.

---

**Item 9.01. Financial Statements and Exhibits.**

*(d) Exhibits*

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press Release issued by the Company on September 23, 2021, furnished herewith.</a>
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: September 23, 2021

Viveve Medical, Inc.

By: /s/ Scott Durbin

Scott Durbin

Chief Executive Officer

**Viveve Announces Issuance of New Method Patent for Stress Urinary Incontinence in Australia**

Patent strengthens and expands Viveve's intellectual property portfolio for the treatment of stress urinary incontinence

**ENGLEWOOD, CO – September 23, 2021** - Viveve Medical, Inc. (NASDAQ: VIVE), a medical technology company focused on women's intimate health, today announced that the Australian Patent Office has issued Patent No. 2016324168 covering Viveve's unique method of treatment to address stress urinary incontinence (SUI) in women. The newly granted patent strengthens the Company's intellectual property portfolio as subject enrollment advances in its U.S. pivotal PURSUIT clinical trial for SUI in women.

Viveve's dual-energy technology has demonstrated its ability to activate fibroblasts and initiate collagen formation in underlying vaginal tissue in a non-invasive, painless and comfortable procedure. When applied in the area of the urethra and tissue surrounding the bladder neck, the technology's unique mechanism of action may strengthen and improve the function of connective tissues, improve vaginal structural integrity and reduce urethral hypermobility, a leading cause of SUI in women.

"We are pleased with the issuance of the SUI patent in Australia. The addition of this new patent strengthens the Company's already robust intellectual property portfolio, recently expanded by a U.S. and two Asia Pacific patents and a U.S. SUI patent issued in the fall of 2020. As we continue to advance our pivotal PURSUIT trial, our strong IP position supports Viveve's focus to develop and commercialize a new method for the treatment of SUI pending regulatory approval," said Scott Durbin, Viveve's chief executive officer.

"Currently, there is an enormous unmet need in the market for a non-invasive, safe, efficacious, and durable SUI treatment. We look forward to completing enrollment in our PURSUIT clinical trial early in the fourth quarter of this year. Positive results from this trial may support a new U.S. indication for the treatment of moderate SUI in women," concluded Mr. Durbin.

**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. Previously reported FDA approved changes to the U.S. pivotal PURSUIT trial protocol are intended to strengthen the overall study and its potential to achieve its primary efficacy endpoint. Study changes including an increase in the trial's size and more strict patient selection criteria were a result of guidance from Viveve's Clinical Advisory Board upon review of positive results from the Company's SUI feasibility and preclinical studies. Viveve received FDA approval of its 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 on January 21, 2021 and subject enrollment is underway. If positive, results from the PURSUIT trial may support a new SUI indication in the U.S.

For more information visit [www.viveve.com](http://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](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.*

**Investor Relations contacts:**

Amato and Partners, LLC  
Investor Relations Counsel  
[admin@amatoandpartners.com](mailto:admin@amatoandpartners.com)

**Media contact:**

Bill Berry  
Berry & Company Public Relations  
(212) 253-8881  
[bberry@berrypr.com](mailto:bberry@berrypr.com)