

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): May 23, 2024

Vistagen Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

NEVADA
(State or other jurisdiction of
incorporation)

000-54014
(Commission File Number)

20-5093315
(IRS Employer
Identification Number)

343 Allerton Ave.
South San Francisco, California 94080
(Address of principal executive offices)

(650) 577-3600
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

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))

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, par value \$0.001 per share	VTGN	Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR 230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR 240.12b-2)

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 8.01 Other Events.

On May 23, 2024, Vistagen Therapeutics, Inc. (the “Company”) announced that it will present posters highlighting fasedienol, the Company’s investigational pherine candidate in Phase 3 development for the acute treatment of social anxiety disorder, and itruvone, the Company’s investigational pherine candidate in Phase 2 development for the treatment of major depressive disorder, at the American Society of Clinical Psychopharmacology Conference in Miami Beach, Florida, from May 28 to 31, 2024. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.**(d) Exhibits Index**

Exhibit No.	Description
99.1	Press Release issued by Vistagen Therapeutics, Inc., dated May 23, 2024.
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 thereunto duly authorized.

Vistagen Therapeutics, Inc.

Date: May 23, 2024

By: /s/ Shawn K. Singh
Shawn K. Singh
Chief Executive Officer



Vistagen to Present at the 2024 American Society of Clinical Psychopharmacology (ASCP) Conference

SOUTH SAN FRANCISCO, Calif., May 23, 2024 – [Vistagen](#) (Nasdaq: VTGN), a late clinical-stage biopharmaceutical company pioneering neuroscience to deliver groundbreaking therapies for individuals affected by psychiatric and neurological disorders, today announced that it will present posters highlighting fasedienol, its investigational pherine candidate in Phase 3 development for the acute treatment of social anxiety disorder (SAD), and itruvone, its investigational pherine candidate in Phase 2 development for the treatment of major depressive disorder (MDD), at the American Society of Clinical Psychopharmacology Conference in Miami Beach, Florida from May 28 to 31, 2024.

Poster Presentation

Date: Wednesday, May 29, 2024, 11:15 a.m. Eastern Time

Title: Fasedienol (PH94B) Nasal Spray for Acute Treatment of Social Anxiety Disorder (SAD):

Results from the PALISADE-2 Phase 3 Trial

Authors: Michael R. Liebowitz, MD; Ester Salmán, MPH; Rita Hanover, PhD; Brittany Reed, PA; Ross A. Baker, PhD; and Louis Monti, MD, PhD

Poster Number: W96

Poster Presentation

Date: Wednesday, May 29, 2024, 11:15 a.m. Eastern Time

Title: Brain and Peripheral Tissue Distribution of Intranasal Radiolabeled Itruvone (PH10) in Laboratory Rats

Authors: Jo Cato PhD; Ross A. Baker, PhD; and Louis Monti, MD, PhD

Poster Number: W78

The posters will be available on the [Publications page](#) of Vistagen's website on Monday, June 3, 2024.

About Fasedienol Nasal Spray

Vistagen's fasedienol (PH94B) is a first-in-class, synthetic rapid-onset investigational pherine nasal spray in Phase 3 development for the acute treatment of social anxiety disorder (SAD). Fasedienol's novel neurocircuitry-focused proposed mechanism of action (MOA) is differentiated from the SSRIs and SNRI currently approved for the treatment of SAD, as well as all benzodiazepines and other medications prescribed off label for SAD. There is no FDA-approved acute treatment of SAD. When administered intranasally in microgram-level doses, fasedienol activates receptors in peripheral nasal chemosensory neurons that, in turn, activate olfactory system neurocircuitry and limbic amygdala neurocircuits involved in the pathophysiology of SAD, and potentially other acute anxiety and mood disorders. Fasedienol is pharmacologically active without requiring systemic absorption and distribution, or binding to neurons in the brain. Given fasedienol's rapid-onset MOA and patient-tailored as-needed administration, it has the potential to become the first FDA-approved acute treatment for SAD, which is the focus of Vistagen's ongoing registration-directed PALISADE Phase 3 program. The U.S. FDA has granted Fast Track designation for the investigation of fasedienol nasal spray for the acute treatment of SAD.

About Itruvone Nasal Spray

Itruvone (PH10) is a synthetic rapid-onset investigational pherine nasal spray in Phase 2 development for the treatment of moderate to severe major depressive disorder (MDD). Itruvone's proposed mechanism of action (MOA) is fundamentally differentiated from the MOA of all currently approved treatments for MDD. Administered intranasally at microgram-level doses, itruvone's MOA involves the regulation of olfactory-to-amygdala neural circuits believed to increase the activity of the limbic-hypothalamic sympathetic nervous system and increase the release of catecholamines. Unlike all currently approved depression therapies, itruvone does not require systemic absorption and distribution or binding to neurons in the brain to produce antidepressant effects without the side effects and safety concerns that may be associated with current antidepressant therapies. The U.S. FDA has granted Fast Track designation for the development of itruvone as a potential treatment for MDD.



About Vistagen

Vistagen (Nasdaq: VTGN) is a biopharmaceutical company pioneering neuroscience to deliver groundbreaking therapies for individuals affected by psychiatric and neurological disorders. Five of Vistagen's clinical-stage neuroscience pipeline candidates belong to a new class of drugs known as pherines, which are investigational neuroactive nasal sprays with innovative proposed mechanisms of action that activate chemosensory neurons in the nasal passages to impact fundamental neural circuitry in the brain without the need for systemic absorption or binding to receptors in the brain. Vistagen's sixth investigational candidate is an oral prodrug with potential to modulate NMDA receptor activity. At Vistagen, we are passionate about delivering differentiated treatments that set new standards of care for people living with anxiety, depression, and other neurological disorders. Connect at www.Vistagen.com.

Forward-looking Statements

This press release contains certain forward-looking statements within the meaning of the federal securities laws. These forward-looking statements involve known and unknown risks that are difficult to predict and include all matters that are not historical facts. In some cases, you can identify forward-looking statements by the use of words such as "may," "could," "expect," "project," "outlook," "strategy," "intend," "plan," "seek," "anticipate," "believe," "estimate," "predict," "potential," "strive," "goal," "continue," "likely," "will," "would" and variations of these terms and similar expressions, or the negative of these terms or similar expressions. Such forward-looking statements are necessarily based upon estimates and assumptions that, while considered reasonable by Vistagen (the Company) and its management, are inherently uncertain. As with all pharmaceutical products, there are substantial risks and uncertainties in the process of development and commercialization and actual results or developments may differ materially from those projected or implied in these forward-looking statements. Among other things, there can be no guarantee that any of the Company's drug candidates will successfully complete ongoing or future clinical trials, receive regulatory approval or be commercially successful. These risks and others are more fully discussed in the section entitled "Risk Factors" in the Company's most recent Annual Report on Form 10-K for the fiscal year ended March 31, 2023, and in the Company's Quarterly Report on Form 10-Q for the period ended December 31, 2023, as well as discussions of potential risks, uncertainties, and other important factors in our other filings with the U.S. Securities and Exchange Commission (SEC). The Company's SEC filings are available on the SEC's website at www.sec.gov. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this press release and should not be relied upon as representing the Company's views as of any subsequent date. The Company explicitly disclaims any obligation to update any forward-looking statements other than as may be required by law. If the Company does update one or more forward-looking statements, no inference should be made that the Company will make additional updates with respect to those or other forward-looking statements.

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