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): April 1, 2024

Vistagen Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

NEVADA	**000-54014**	**20-5093315**
(State or other jurisdiction of incorporation)	*(Commission File Number)*	*(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 April 1, 2024, Vistagen Therapeutics, Inc. (the "*Company*") issued a press release to announce that it has enrolled the first patient in its PALISADE-3 Phase 3 trial of fasedienol, an investigational pherine candidate in development for the acute treatment of social anxiety disorder. 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 April 1, 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: April 1, 2024

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

Exhibit 99.1

Vistagen Initiates PALISADE-3 Phase 3 Study of Fasedienol for the Acute Treatment of Social Anxiety Disorder following Positive Results of PALISADE-2

Key study underway in registration-directed PALISADE Phase 3 program for fasedienol in social anxiety disorder

Social anxiety disorder affects over 25 million Americans

SOUTH SAN FRANCISCO, Calif., April 1, 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 has enrolled the first patient in its PALISADE-3 Phase 3 trial of fasedienol, an investigational pherine candidate in development for the acute treatment of social anxiety disorder (SAD).

"Initiating PALISADE-3 is another major milestone in our plan to develop and commercialize fasedienol as the first treatment of its kind for social anxiety disorder," said Shawn Singh, Chief Executive Officer. "We look forward to initiating PALISADE-4 in the second half of this year and advancing our innovative pherine pipeline to deliver pioneering neuroscience to patients affected by mental health disorders and unsatisfied with current treatments."

PALISADE-3, similar to PALISADE-2, is a randomized, double-blind, placebo-controlled Phase 3 study designed to evaluate the efficacy, safety, and tolerability of the acute administration of fasedienol to relieve anxiety symptoms in patients with SAD induced by a public speaking challenge conducted in a clinical setting. The primary outcome measure is the patient self-rated Subjective Units of Distress Scale (SUDS). The U.S. multi-center study is planned to randomize approximately 236 adults ages 18 through 65. Patients will be randomized in a 1:1 ratio to fasedienol or placebo. Patients who complete PALISADE-3 will have an option to enroll in an open-label extension. Vistagen plans to initiate PALISADE-4, which will be a replicate of PALISADE-3, during the second half of 2024.

About Fasedienol Nasal Spray
Vistagen's fasedienol (PH94B) is a first-in-class, rapid-onset investigational pherine nasal spray with a novel proposed mechanism of action (MOA) that is differentiated from all currently approved anxiety medications, including the SSRIs and SNRI currently approved for the treatment of social anxiety disorder (SAD), as well as benzodiazepines prescribed off-label. Fasedienol's proposed MOA regulates the olfactory-amygdala neural circuits of fear and anxiety and attenuates the tone of the sympathetic autonomic nervous system, without systemic distribution, potentiation of GABA-A receptors, or direct activity on neurons in the brain. Vistagen's registration-directed PALISADE Phase 3 program for fasedienol is focused on the acute treatment of SAD. Fasedienol has not demonstrated any signals of abuse potential or physical dependence in any clinical trial conducted to date.

The U.S. FDA has granted Fast Track designation for the investigation of fasedienol for the acute treatment of SAD.

About Social Anxiety Disorder
Social anxiety disorder (SAD) affects over 25 million Americans. A person with SAD feels intense, persistent symptoms of anxiety or fear in certain social situations, such as meeting new people, making comments in a business meeting, dating, being on a job interview, answering a question in class, or talking to a cashier in a store. Doing common, everyday things in front of people causes profound anxiety or fear of being embarrassed, evaluated, humiliated, judged, or rejected. SAD can get in the way of going to work, attending school, or doing a wide variety of things in a situation that is likely to involve interpersonal interaction. It can lead to avoidance and opportunity costs that can significantly impact a person's employment and social activities and can be very disruptive to their overall quality of life. There is no FDA-approved acute, as-needed treatment for SAD. Current FDA-approved treatments for SAD include only antidepressants, which have a slow onset of effect (several weeks), provide limited therapeutic benefits, and have known side effects that may make them unattractive to individuals affected by SAD.

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 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, or that the Company will be able to successfully replicate the result of past studies of its product candidates, including fasedienol, itruvone, PH80 or its other drug candidates. Other factors that may cause such a difference include, without limitation, risks and uncertainties relating to conducting and/or completing ongoing clinical trials, including PALISADE-3; launching planned clinical trials for any of our product candidates, including fasedienol; the Company's submission of an U.S. NDA to the FDA for any product candidate, including fasedienol; the ability of any clinical trial information submitted by the Company to the FDA to support an U.S. NDA; the scope and enforceability of the Company's patents, including patents related to the Company's pherine drug candidates and AV-101; fluctuating costs of materials and other resources and services required to conduct the Company's ongoing and/or planned clinical and non-clinical trials; market conditions; the impact of general economic, industry or political conditions in the United States or internationally; and other technical and unexpected hurdles in the development, manufacture and commercialization of the Company's product candidates. These risks 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.

Investors:
Mark McPartland
(650) 577-3606
markmcp@vistagen.com

Media:

Caren Scannell
(650) 577-3601
cscannell@vistagen.com