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): January 10, 2025

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 January 10, 2025, Vistagen Therapeutics, Inc. (the "*Company*") issued a press release to announce that it has enrolled the first subject in an exploratory repeat dose study of fasedienol, its investigational neuroactive pherine nasal spray, as part of its fasedienol U.S. Phase 3 development program 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 January 10, 2025
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: January 13, 2025

By: */s/ Shawn K. Singh*

Shawn K. Singh
Chief Executive Officer

EXHIBIT 99.1

Vistagen Initiates Fasedienol Repeat Dose Study for the Acute Treatment of Social Anxiety Disorder

All planned clinical studies in fasedienol U.S. registration-directed Phase 3 program for the acute treatment of social anxiety disorder are underway

SOUTH SAN FRANCISCO, Calif, January 10, 2025 - Vistagen (Nasdaq: VTGN), a late clinical-stage company dedicated to pioneering neuroscience based on nose-to-brain neurocircuitry, today announced enrollment of the first subject in a repeat dose study of fasedienol, its investigational neuroactive pherine nasal spray in Phase 3 development for the acute treatment of social anxiety disorder (SAD).

The repeat dose study is a small exploratory Phase 2 U.S. multi-center, randomized, double-blind, placebo-controlled, three-arm clinical trial designed to assess the efficacy, safety, and tolerability of a repeat dose of fasedienol (3.2 micrograms) in adults with SAD during a public speaking challenge conducted in a clinical setting. The three dosing arms will be fasedienol followed by fasedienol (total 6.4 micrograms), fasedienol followed by placebo (total 3.2 micrograms), and placebo followed by placebo, with the second dose in each arm administered ten minutes after the initial dose. Other than the repeat dose and the additional study arm, the study is similar in design to the ongoing PALISADE Phase 3 studies for the acute treatment of adults with SAD, including an open-label extension.

"The initiation of this fasedienol repeat dose study marks another significant milestone in our U.S. Phase 3 program for the acute treatment of social anxiety disorder," said Shawn Singh, President and Chief Executive Officer of Vistagen. "With the increasing prevalence of social anxiety disorder over decades, millions of individuals in the U.S. live with debilitating acute fear and anxiety in everyday social situations without any U.S. FDA-approved acute treatment option. Our mission and PALISADE Phase 3 program for fasedienol are focused on changing that."

About Vistagen's U.S. Registration-directed PALISADE Phase 3 Program for Fasedienol for the Acute Treatment of Social Anxiety Disorder
Complementing its statistically significant PALISADE-2 U.S. Phase 3 trial of fasedienol for the acute treatment of adults with SAD reported in 2023, Vistagen's U.S. registration-directed PALISADE Phase 3 program for fasedienol for the acute treatment of SAD includes its ongoing PALISADE-3 and PALISADE-4 U.S. Phase 3 trials and a small U.S. Phase 2 repeat dose study. PALISADE-3 and PALISADE-4 are each a multi-center randomized, double-blind, placebo-controlled Phase 3 trial designed similarly to PALISADE-2 to evaluate the efficacy, safety, and tolerability of the acute administration of fasedienol to relieve anxiety symptoms in subjects with SAD induced by a public speaking challenge conducted in a clinical setting. Vistagen believes either PALISADE-3 or PALISADE-4, if successful, together with PALISADE-2, may establish

substantial evidence of the effectiveness of fasedienol in support of a potential fasedienol New Drug Application (NDA) submission to the U.S. FDA for the acute treatment of SAD.

About Fasedienol Nasal Spray for the Acute Treatment of Social Anxiety Disorder
Fasedienol is a potential first-in-class, investigational neurocircuitry-focused pherine nasal spray designed to have rapid onset with a novel mechanism of action (MOA) that is differentiated from all currently approved anxiety medications. Fasedienol is designed to regulate the olfactory-amygdala neural circuits of fear and anxiety and attenuate the tone of the sympathetic autonomic nervous system without systemic absorption, potentiation of GABA-A receptors, or binding to neurons in the brain. Vistagen's U.S. registration-directed PALISADE Phase 3 program for fasedienol is focused on the acute treatment of SAD. There is no U.S. FDA-approved acute treatment for SAD, and the U.S. FDA has granted Fast Track designation for the development of fasedienol for the acute treatment of SAD.

About Vistagen
Headquartered in South San Francisco, CA, Vistagen (Nasdaq: VTGN) is a late clinical-stage company leveraging its pioneering neuroscience and deep understanding of nose-to-brain neurocircuitry to develop and commercialize a broad and diverse pipeline of a new class of intranasal product candidates called pherines. Each pherine product candidate in Vistagen's neuroscience pipeline is designed to rapidly activate brain neurocircuitry through the olfactory system to achieve desired therapeutic benefits. Pherines do not require systemic absorption or binding to neurons in the brain, which may contribute to a favorable safety profile. Vistagen's neuroscience pipeline also includes an oral prodrug, AV-101, with potential to impact certain neurological conditions involving the NMDA receptor. Vistagen is passionate about developing transformative treatment options to improve the lives of individuals underserved by the current standard of care for multiple highly prevalent disorders, including social anxiety disorder, major depressive disorder, and vasomotor symptoms (hot flashes) associated with menopause. Connect at www.Vistagen.com.

Forward-looking Statements
This press release contains certain forward-looking statements within the meaning of the U.S. 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 timelines, 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 Vistagen's product candidates will successfully complete ongoing or future clinical trials within the timeframe estimated by Vistagen or at all, receive regulatory approval or be commercially successful, or that Vistagen will be able to successfully replicate the result of past studies of its product candidate fasedienol or its other product 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 trials that are a part of Vistagen's PALISADE Phase 3 development program for fasedienol; Vistagen's submission of a NDA to the U.S. FDA for any product candidate, including fasedienol; the ability of any clinical trial information submitted by Vistagen to the U.S. FDA to support a

NDA; the availability as well as the scope and enforceability of Vistagen's patents in the U.S. and elsewhere, including patents related to Vistagen's pherine product candidates and AV-101; fluctuating costs of materials and other resources and services required to conduct Vistagen'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 Vistagen's product candidates. These risks are more fully discussed in the section entitled "Risk Factors" in Vistagen's most recent Annual Report on Form 10-K for the fiscal year ended March 31, 2024, and Quarterly Report on Form 10-Q for the period ended September 30, 2024, 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). Vistagen'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 Vistagen's views as of any subsequent date. Vistagen explicitly disclaims any obligation to update any forward-looking statements other than as may be required by law. If Vistagen does update one or more forward-looking statements, no inference should be made that Vistagen will make additional updates with respect to those or other forward-looking statements.

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