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 12, 2026

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 May 12, 2026, Vistagen Therapeutics, Inc. (the "*Company*") issued a press release to announce preliminary positive data from the ongoing open-label extension portion of its PALISADE-3 Phase 3 study of fasedienol 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 May 12, 2026
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 12, 2026

By: */s/ Shawn K. Singh*

Shawn K. Singh
President and Chief Executive Officer

EXHIBIT 99.1

Vistagen Announces Preliminary Positive Data in Ongoing Open-Label Extension Portion of PALISADE-3 Phase 3 Study of Fasedienol for the Acute Treatment of Social Anxiety Disorder

Fasedienol nasal spray has been well-tolerated in patients with social anxiety disorder with no new drug-related safety findings after as-needed use in daily life for up to 12 months

Clinically relevant improvement in social anxiety over time was observed on both clinician-administered and patient-reported scales over four months

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)—May 12, 2026-- Vistagen (Nasdaq: VTGN), a late clinical-stage biopharmaceutical company pioneering neuroscience with nose-to-brain neurocircuitry to develop and commercialize a new class of intranasal product candidates called pherines, today announced preliminary positive data from the ongoing open-label extension (OLE) portion of its PALISADE-3 Phase 3 study of fasedienol for the acute treatment of social anxiety disorder.

In a recent analysis of subjects who elected to participate in the OLE portion of PALISADE-3 (safety population: n=341), administration of 3.2 µg of fasedienol - taken as needed, up to six times per day in real-world, anxiety-provoking situations in daily life for up to 12 months - has been well-tolerated, with no new drug-related safety findings or trends identified. Exploratory efficacy data over the first four months of treatment demonstrated a clinically relevant improvement over time on both the clinician-administered Liebowitz Social Anxiety Scale (LSAS) and the Social Phobia Inventory (SPIN).

“Social anxiety disorder surfaces in the everyday moments of people's lives,” said Shawn Singh, President and Chief Executive Officer of Vistagen. “Among our core goals is giving patients the ability to manage their anxiety in the daily life situations that matter most to them. We’re continually encouraged by the improvements observed over time when patients in our open-label studies self-administer fasedienol as they feel it’s needed.”

Preliminary Safety Data

In the OLE portion of PALISADE-3, as of May 8, 2026, fasedienol nasal spray, taken as-needed, up to six times a day, was observed to be well-tolerated in adults with social anxiety disorder.

- The rate of discontinuation due to adverse events was 2.6% (9/341), with no discontinuations attributed to fasedienol.
- Substantially all (>95%) of TEAEs were mild or moderate in severity.
- The only TEAEs occurring in > 5% of subjects were headache (10.9%, 37/341) and upper respiratory infection (11.4%, 39/341).
- There were no Serious Adverse Events related to fasedienol.
- No safety signals of concern were identified related to laboratory values, ECGs, physical examinations, and vital sign assessments following exposure to fasedienol.

Preliminary Exploratory Efficacy Data

Liebowitz Social Anxiety Scale (LSAS)

The OLE portion of PALISADE-3 explored the change from baseline (study entry) on the LSAS, a 24-item clinician-administered scale (range 0-144), which measures fear and avoidance experienced over time due to social anxiety disorder during anxiety-provoking social and performance situations. The recent analysis of a data cut from the initial four-month period in the OLE portion of PALISADE-3 demonstrated a clinically relevant improvement over time on the LSAS for subjects participating in the OLE:

- At study entry, the mean baseline LSAS score (99.2, n=341) indicated very severe social anxiety (≥80).
- At Month 1, mean improvement on the LSAS was 16.3 points (n=305, 38% had a ≥ 20 point-improvement).
- At Month 2, mean improvement on the LSAS was 22.4 points (n=269, 49% had a ≥ 20 point-improvement).
- At Month 3, mean improvement on the LSAS was 24.1 points (n=248, 54% had a ≥ 20 point-improvement).
- At Month 4, mean improvement on the LSAS was 25.4 points (n=228, 56% had ≥ 20 point-improvement).

Improvements were observed on both the fear and avoidance subscales, suggesting that patients engaging in daily life have experienced less fear and avoidance of anxiety-provoking situations. Moreover, subjects who did not respond to fasedienol administered in the simulated single-dose, clinic-based public speaking challenge during the randomized portion of PALISADE-3 showed comparable change at Month 1 and Month 4 compared to the total population in both LSAS mean improvement (Month 1 = 13.4 and Month 4 = 20.8) and LSAS response of ≥20 point improvement (Month 1 = 40% and Month 4 = 50% of subjects).

Social Phobia Inventory (SPIN)

The OLE portion of PALISADE-3 also explores the change from baseline on the SPIN, a 17-item patient-reported scale (range 0-64) which measures fear, avoidance, and physiological components of social phobia over time. The recent analysis of the initial four-month data cut from the OLE portion of PALISADE-3 demonstrated a clinically relevant improvement over time on the SPIN for subjects participating in the OLE:

- At study entry, the mean baseline SPIN score (48.7, n=341) indicated severe social anxiety (≥41).
- At Month 1, mean improvement on the SPIN was 7.9 points (n=305, 35% had a ≥ 10-point improvement).
- At Month 4, mean improvement on the SPIN was 12.4 points (n=228, 55% had a ≥ 10-point improvement).

“The magnitude of improvement on both the LSAS and the SPIN scales through four months of treatment in patients with very severe social anxiety support the potential clinical meaningfulness of these findings,” said Dr. Michael R. Liebowitz, a consultant and clinical advisor to Vistagen, the innovator of the LSAS, former Columbia University psychiatrist, founder and former director of the Anxiety Disorders Clinic at the New York State Psychiatric Institute, and former Managing Director of The Medical Research Network LLC in New York City.

The Company believes that the interim safety and exploratory efficacy results of the OLE are consistent with the safety and efficacy previously reported in the fasedienol Long Term Safety Study (LTSS) data[1] and results of a randomized, double-blind, placebo-controlled Phase 2 crossover study of fasedienol in a real-world setting conducted by Dr. Liebowitz[2]. Results from both prior studies suggest that as-needed self-administration of fasedienol prior to anxiety-provoking real-world situations in daily life was accompanied by a persistent change in the overall severity of social anxiety disorder. Specifically, both studies showed a reduction in fear and anxiety, and less frequent avoidance, as measured by the LSAS over the course of fasedienol usage.

About the OLE Portion of PALISADE-3
The OLE is a voluntary extension of the randomized double-blind, placebo-controlled portion of the PALISADE-3 Phase 3 study of fasedienol for the acute treatment of social anxiety disorder, available to participants who choose to continue in the study per the study protocol. It is designed to evaluate the safety and tolerability of multiple, as-needed intranasal administrations of fasedienol (up to six times daily, maximum daily dose of 19.2 µg fasedienol) in adults with social anxiety disorder over time in daily life. Monthly safety and tolerability assessments include monthly change in adverse events (AEs), laboratory values, 12-lead electrocardiograms (ECGs), physical examinations, and vital sign assessments. The study is also evaluating the change from baseline over time in standard clinical measurements (the LSAS and the SPIN) as participants use fasedienol in real-world social situations in their daily lives. Endpoints of the OLE portion of PALISADE-3 include a monthly evaluation of the change from baseline at study entry on the LSAS and a Month 1 and Month 4 evaluation of change from baseline at study entry on the SPIN patient self-report questionnaire. Both scales provide a validated psychological assessment of the severity of social anxiety disorder, with a focus on fear, avoidance, and physiological discomfort in social and performance situations.

About PALISADE-3
PALISADE-3 is a U.S. multi-center, randomized, double-blind, placebo-controlled Phase 3 public speaking challenge study designed to evaluate the efficacy and safety of fasedienol in reducing anxiety symptoms during a simulated single-dose, clinic-based public speaking challenge using the Subjective Units of Distress Scale (SUDS). PALISADE-3 subjects who chose to continue with the open-label extension of the study can use fasedienol as needed in their daily lives up to six times per day for up to twelve months. In December 2025, Vistagen announced topline results from the randomized portion of PALISADE-3. The single-dose randomized portion of the study did not achieve its primary endpoint, as measured by the least squares (LS) mean change from baseline on the SUDS for fasedienol (13.6 +/-1.54 standard error, SE) compared with placebo (14.0 +/-1.51 SE). There was no treatment difference between fasedienol and placebo for the secondary endpoints. The favorable safety data of fasedienol were consistent with previously completed clinical trials.

About Ongoing PALISADE Program Clinical Trials
The ongoing clinical trials in Vistagen's PALISADE Phase 3 Program for fasedienol for the acute treatment of social anxiety disorder include the open label extension portion of its PALISADE-3 and PALISADE-4 Phase 3 trials and a small exploratory Phase 2 randomized, placebo-controlled trial designed to assess efficacy, safety and tolerability of a repeat dose of fasedienol in adults with social anxiety disorder in a public speaking challenge in a clinical setting (Repeat Dose Study). PALISADE-4 is a multi-center, randomized, double-blind, placebo-controlled Phase 3 trial to evaluate the efficacy, safety, and tolerability of the acute administration of fasedienol to relieve anxiety symptoms in subjects with social anxiety disorder induced by a public speaking challenge conducted in a clinical setting. On May 8, 2026, the Company announced that the last patient completed the last visit in the randomized, double-blind, placebo-controlled portion of PALISADE-4. PALISADE-4 subjects who chose to continue with the open-label extension of the study can use fasedienol as needed in their daily lives up to six times per day for up to twelve months. PALISADE-4 remains on track for topline data in the second quarter of 2026. Topline results for the exploratory Phase 2 Repeat Dose Study are expected in the third quarter of 2026. Vistagen believes that PALISADE-4, if successful, together with the positive results from its PALISADE-2 Phase 3 trial and further evidence Vistagen plans to generate to support the clinical meaningfulness of the duration and magnitude of effect of fasedienol, could provide substantial evidence of fasedienol's effectiveness in support of a potential New Drug Application (NDA) submission to the FDA for the acute treatment of social anxiety disorder.

About Vistagen
Vistagen (Nasdaq: VTGN) is a late clinical-stage biopharmaceutical company leveraging a deep understanding of nose-to-brain neurocircuitry to develop and commercialize a new class of rapid-onset neurocircuitry-focused intranasal product candidates called pherines. Vistagen's pherine product candidates are designed to achieve therapeutic benefits without requiring absorption into the blood or uptake into the brain, giving them the potential to be a safer alternative to other pharmacological options, if successfully developed and approved. Vistagen's pherine pipeline currently consists of five clinical-stage investigational product candidates focused on improving the current standard of care for multiple highly prevalent indications, including social anxiety disorder, major depressive disorder, and vasomotor symptoms (hot flashes) due to menopause. Connect at www.Vistagen.com.

Forward-looking Statements

This press release contains certain forward-looking statements within the meaning of the federal securities laws, including, without limitation, statements regarding indication of improvements observed over time by patients in the OLE portion of PALISADE-3; the ability of preliminary findings from the OLE portion of PALISADE-3 to support the potential clinical meaningfulness; indications of safety data from the OLE portion of the PALISADE-3; the Company's belief that the results of the OLE are consistent with the previously reported LTSS data and a Phase 2 crossover study of fasedienol; Vistagen's other beliefs about the understandings drawn from the preliminary OLE data; statements regarding the expected timing for topline results from the randomized portion of PALISADE-4 and the Repeat Dose Study; and Vistagen's belief that successful results from its PALISADE Phase 3 development program, including PALISADE-4, could provide substantial evidence of fasedienol's effectiveness in support of a potential NDA submission to the FDA. 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. There can be no guarantee that any of Vistagen's product candidates, including fasedienol, will successfully complete ongoing or future clinical trials within estimated timelines or at all, receive regulatory approval or be commercially successful. Other factors that may cause such a difference include, without limitation, risks and uncertainties relating to conducting and/or completing ongoing clinical trials, including those that are a part of Vistagen's fasedienol PALISADE Phase 3 program, as currently expected or at all; Vistagen's ability to ability to successfully employ cash preservation measures and/or secure adequate financing for its operations, including financing or collaborative support for continued clinical development of its product candidates; Vistagen's dependence on third-party collaborators for the development, regulatory approval, and/or commercialization of its product candidates and other aspects of its business, which are outside of Vistagen's full control; the scope and enforceability of Vistagen's patents, including patents related to Vistagen's pherine product candidates; and other technical and unexpected hurdles in the development, manufacture and/or potential commercialization of Vistagen's product candidates. These risks and others are more fully discussed in the section entitled "Risk Factors" in Vistagen's Quarterly Report on Form 10-Q for the period ended December 31, 2025, 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.

References:

1. Lappalainen, J et al. (2023). A Phase 3 Open-label Safety Trial of Fasedienol (PH94B) Nasal Spray in the Treatment of Anxiety in Adults with Social Anxiety Disorder (SAD). American Society of Clinical Psychopharmacology (ASCP) 2023 Annual Meeting.
2. Liebowitz MR, Hanover R, Draine A, Lemming R, Careri J, Monti L (2016). Effect of as-needed use of intranasal PH94B on social and performance anxiety in individuals with social anxiety disorder. Depress Anxiety 33: 1081-1089.

Investor Inquiries:
IR@vistagen.com

Media Inquiries:
media@vistagen.com