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): August 6, 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 7.01 Regulation FD Disclosure

On August 6, 2026, Vistagen Therapeutics, Inc. (the "*Company*") issued a press release announcing topline results of its exploratory Phase 2 repeat dose study evaluating fasedienol nasal spray in adult subjects with social anxiety disorder. A copy of the press release is furnished as Exhibit 99.1 hereto.

The information furnished pursuant to this Item 7.01, including Exhibit 99.1, shall not be deemed to be "filed" for 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 to be incorporated by reference into any of the Company's filings with the U.S. Securities and Exchange Commission ("*SEC*") under the Exchange Act or the Securities Act of 1933, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such a filing, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events

On August 6, 2026, the Company announced the topline results of its three-arm, multicenter, randomized, double-blind, placebo controlled exploratory Phase 2 clinical trial (N=61) designed to assess the efficacy, safety, and tolerability of two 3.2 µg doses of fasedienol administered ten minutes apart compared with a single 3.2 µg dose and placebo, for the acute treatment of anxiety induced by a public speaking challenge. The study was not designed to demonstrate statistically significant differences between treatment groups.

The exploratory study met its safety objective, demonstrating that a second dose administered within ten minutes of the first dose produced safety and tolerability data comparable to single-dose administration, with no new safety findings and overall safety findings consistent with previous clinical studies.

In addition, both active treatment arms in the primary endpoint analysis, change in Subjective Units of Distress ("*SUDS*") score from Visit 2 (baseline speech, V2) to Visit 3 (randomized speech, V3), showed numerical separation from placebo, although the differences between treatment groups and placebo were not statistically significant.

In the prespecified analysis of patients with very severe social anxiety disorder as defined by a baseline Liebowitz Social Anxiety Scale ("*LSAS*") score of 95 or greater, fasedienol showed nominally statistically significant responses for the single dose arm compared with placebo and as pooled. The treatment effect for repeat dose fasedienol was numerically larger, although the smaller sample size and variability resulted in a higher p-value. The findings in the very severe group of patients defined by LSAS ≥95 are consistent with results previously observed in the randomized portion of the Company's PALISADE-4 Phase 3 trial for the acute treatment of social anxiety disorder, where in a post-hoc analysis of patients with very severe social anxiety defined by LSAS ≥95, fasedienol also demonstrated a nominally statistically significant improvement compared with placebo.

Responder rates for the Clinician Global Impression of Improvement ("*CGI-I*") and the Patient Global Impression of Change ("*PGI-C*") secondary endpoints were directionally higher for fasedienol than placebo, providing consistency across primary and secondary endpoints for the total population in the study. In addition, the fasedienol responder rates in the repeat dose arm were more than twice those observed with placebo. Responder rates were also directionally higher for fasedienol compared with placebo for the very severe social anxiety disorder subpopulation, with repeat dose rates at four times or more than those observed with placebo.

A prespecified exploratory analysis in V2 to V3 change of anticipatory anxiety prior to the beginning of the public speaking challenge showed a larger decrease in mean SUDS score for fasedienol compared with placebo, with the repeat dose and pooled fasedienol showing nominal statistical significance (where anticipatory anxiety is the average of SUDS measures taken 3 minutes and 4 minutes prior to the start of the speech).

Forward-Looking Statements

This Current Report on Form 8-K and the exhibit furnished herewith contain forward-looking statements within the meaning of the federal securities laws, including, without limitation, without limitation, statements regarding topline efficacy signals observed in the repeat dose study across prespecified analyses, which remain subject to change upon completion of a full analysis and audit of the complete data set from the study, the significance of such signals to the overall body of clinical evidence supporting fasedienol's therapeutic potential, and the Company's plans for upcoming discussions with the U.S. Food and Drug Administration ("*FDA*") regarding the potential registrational pathway for fasedienol. 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 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. There can be no guarantee that any of the Company's product candidates, including fasedienol, will successfully complete any future clinical trials, receive regulatory approval or be commercially successful. Because the repeat dose study was not powered to demonstrate statistical significance, there can be no assurance that the numerical trends and nominally significant findings described in the exhibit furnished herewith will be replicated in future, adequately powered clinical trials, or that the FDA will view such findings as supportive of a registrational pathway for fasedienol. Other factors that may cause such a difference include, without limitation, risks and uncertainties relating to the Company's 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; submission of a New Drug Application ("*NDA*") to the FDA for any of the Company's product candidates, including fasedienol; and the ability of any clinical trial information submitted by the Company to the FDA to successfully support an NDA. These risks and others are more fully discussed in the section entitled "Risk Factors" in the Company's Annual Report on Form 10-K for the period ended March 31, 2026, as well as discussions of potential risks, uncertainties, and other important factors in our other filings with the 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 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.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits Index

Exhibit No.	Description
99.1	Press Release issued by Vistagen Therapeutics, Inc., dated August 6, 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: August 6, 2026

By: */s/ Shawn K. Singh*

Shawn K. Singh
President and Chief Executive Officer

EXHIBIT 99.1

Vistagen

Vistagen Announces Topline Results for Repeat Dose Study of Fasedienol for Acute Treatment of Social Anxiety Disorder

Repeat dose of fasedienol demonstrated favorable safety and tolerability similar to single dose

Efficacy signals were observed across primary and secondary endpoints in repeat dose and single dose

Prespecified analysis of patients with very severe social anxiety disorder demonstrated nominally statistically significant improvement

Efficacy signals and responder analyses provide additional supportive evidence for discussion with the FDA regarding fasedienol registrational pathway

SOUTH SAN FRANCISCO, Calif.--(GLOBE NEWSWIRE)-- August 6, 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 the topline results of its exploratory Phase 2 repeat dose study evaluating fasedienol nasal spray in adult subjects with social anxiety disorder. The three-arm, multicenter, randomized, double-blind, placebo controlled clinical study (N=61), which included an open label extension, was designed to assess the efficacy, safety, and tolerability of two 3.2 µg doses of fasedienol administered ten minutes apart compared with a single 3.2 µg dose and placebo, for the acute treatment of anxiety induced by a public speaking challenge. The study was not designed to demonstrate statistically significant differences between treatment groups.

The exploratory study met its safety objective, demonstrating that a second dose administered within ten minutes of the first dose produced safety and tolerability data comparable to single-dose administration, with no new safety findings and overall safety findings consistent with previous clinical studies. In addition, both active treatment arms in the primary endpoint analysis, LS mean change in subjective units of distress (SUDS) score from Visit 2 (baseline speech, V2) to Visit 3 (randomized speech, V3), showed numerical separation from placebo, although the differences between treatment groups and placebo were not statistically significant (p=0.2)[1].

Primary Endpoint

The primary efficacy results showed numerical separation from placebo in mean SUDS change from V2 to V3:

- Pooled fasedienol (N=40**):** -15.0, p=0.10(Cohen's d effect size=0.46)
- Repeat dose fasedienol (N=19**):** -15.4, p=0.17(Cohen's d=0.44)
- Single dose fasedienol (N=21**):** -14.7, p=0.14, (Cohen's d=0.47)
- Placebo (N=21): -6.8.

In the prespecified analysis of patients with very severe social anxiety disorder as defined by a baseline Liebowitz Social Anxiety Scale (LSAS) score of ≥ 95, fasedienol showed nominally[2] statistically significant responses for the single dose arm compared with placebo and as pooled:

- Pooled fasedienol (N=24**):** -16.2, p=0.04 (Cohen's d=0.78)
- Repeat dose fasedienol (N=10): -17.5, p=0.08 (Cohen's d=0.74)
- Single dose fasedienol (N=14**):** -15.3, p=0.05 (Cohen's d=0.80)
- Placebo (N=13): -1.6

The treatment effect for repeat dose fasedienol was numerically larger, although the smaller sample size and variability resulted in a higher p-value. The findings in the very severe group of patients defined by LSAS ≥95 are consistent with results previously observed in the randomized portion of the Company's PALISADE-4 Phase 3 trial for the acute treatment of social anxiety disorder, where in a post-hoc analysis of patients with very severe social anxiety defined by LSAS ≥95, fasedienol also demonstrated a nominally statistically significant improvement compared with placebo (p=0.036).

Secondary Endpoints

Responder rates for the Clinician Global Impression of Improvement (CGI-I) and the Patient Global Impression of Change (PGI-C) secondary endpoints were directionally higher for fasedienol than placebo, providing consistency across primary and secondary endpoints for the total population in the study. In addition, the fasedienol responder rates in the repeat dose arm were more than twice those observed with placebo.

- CGI-I responder rates**:** 40% for pooled fasedienol (n=40), 47% for repeat dose fasedienol (n=19),33% for single dose fasedienol (n=21), and 19% for placebo (n=21)
- PGI-C responder rates: 33% for pooled fasedienol (n=40), 42% for repeat dose fasedienol (n=19), 29% for single dose fasedienol (n=21), and 19% for placebo (n=21)

Responder rates were also directionally higher for fasedienol compared with placebo for the very severe social anxiety disorder subpopulation, with repeat dose rates at four times or more than those observed with placebo.

- CGI-I responder rates: 40% for pooled fasedienol (n=24), 60% for repeat dose fasedienol (n=10), 29% for single dose fasedienol (n=14), and 15% for placebo (n=13)
- PGIC responder rates: 33% for pooled fasedienol (n=24), 50% for repeat dose fasedienol (n=10), 29% for single dose fasedienol (n=14), and 8% for placebo (n=13)

Exploratory Endpoint

A prespecified exploratory analysis in V2 to V3 change of anticipatory anxiety prior to the beginning of the public speaking challenge showed a larger decrease in mean SUDS score for fasedienol compared with placebo, with the repeat dose and pooled fasedienol showing nominal statistical significance (where anticipatory anxiety is the average of SUDS measures taken 3 minutes and 4 minutes prior to the start of the speech):

- Pooled fasedienol (N=40): -13.8, p=0.03 (Cohen's d=0.61)
- Repeat dose fasedienol (N=19): -19.3, p=0.01 (Cohen's d=0.83)
- Single dose fasedienol (N=21): -8.7, p=0.2 (Cohen's d=0.40) Placebo (N=21): -0.9

"We are encouraged by the directionally favorable efficacy signals observed in this FDA-informed study," said Dr. Angel Angelov, Chief Medical Officer of Vistagen. "Although not designed to show statistical significance, the study showed consistent findings across multiple efficacy measures and contributes to our growing understanding of how patients may benefit from fasedienol, including its repeat dose use. As observed in the post-hoc analyses from our PALISADE-4 Phase 3 trial, the pronounced separation from placebo within the very severe social anxiety disorder subpopulation reflects an enhanced fasedienol signal and minimized placebo change in very severe social anxiety disorder patients. Together with the broad body of clinical evidence from Phase 2 and Phase 3 studies, these results will help inform our discussions with the FDA regarding a potential registrational pathway for fasedienol."

About Social Anxiety Disorder
Social anxiety disorder is a highly prevalent, serious, and sometimes life-threatening psychiatric mental health disorder affecting over 30 million adults in the U.S. While often experienced on a long-term basis, social anxiety disorder can manifest acutely when triggered by anxiety-provoking social and performance situations in daily life, causing anxiety, distress, and the fear of embarrassment, judgment, and humiliation. Social anxiety disorder can also significantly disrupt social life and hinder occupational functioning, as well as increase the risk of depression and substance use disorders, suicidal ideation, and suicide.

About Fasedienol
Fasedienol, Vistagen's most advanced neurocircuitry-focused investigational pherine product candidate, is in U.S. Phase 3 clinical development for social anxiety disorder. Fasedienol's proposed mechanism of action (MOA) is fundamentally differentiated from all FDA-approved anti-anxiety medications. When administered intranasally in microgram-level doses, neurocircuitry-focused fasedienol modulates the nasal-limbic amygdala fear and anxiety neurocircuits involved in the pathophysiology of social anxiety disorder. Fasedienol is pharmacologically active without requiring apparent systemic absorption or uptake into the brain to achieve its rapid-onset anxiolytic effects. Fasedienol also has no observed binding on certain cellular receptors isolated from the brain that are associated with known drug abuse liability potential (for example, dopamine and opiate receptors) when activated by certain other pharmaceutical compounds for psychiatric disorders. Unlike benzodiazepines, fasedienol has no observed potentiation of GABA-A receptors. Because of its innovative no-systemic neurocircuitry-focused proposed MOA, Vistagen believes fasedienol has the potential to achieve rapid-onset anxiolytic effects for individuals with social anxiety disorder with a significantly reduced risk of unwanted side effects and safety concerns, such as potential drug-drug interactions, abuse, misuse, and addiction, associated with certain current oral and other systemically absorbed neuropsychiatric pharmaceuticals that act directly on neurons in the brain and are sometimes prescribed off-label for the 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 most advanced intranasal pherine product candidates are fasedienol for the acute treatment of social anxiety disorder, itruvone for treatment of major depressive disorder, and refisolone for treatment of 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 topline efficacy signals observed in the repeat dose study across prespecified analyses, which remain subject to change upon completion of a full analysis and audit of the complete data set from the study, the significance of such signals to the overall body of clinical evidence supporting fasedienol's therapeutic potential, and Vistagen's plans for upcoming discussions with the FDA regarding the potential registrational pathway for fasedienol. 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 any future clinical trials, receive regulatory approval or be commercially successful. Because the repeat dose study was not powered to demonstrate statistical significance, there can be no assurance that the numerical trends and nominally significant findings described in this press release will be replicated in future, adequately powered clinical trials, or that the FDA will view such findings as supportive of a registrational pathway for fasedienol. Other

factors that may cause such a difference include, without limitation, risks and uncertainties relating to Vistagen's 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; submission of a NDA to the FDA for any of Vistagen's product candidates, including fasedienol; and the ability of any clinical trial information submitted by Vistagen to the FDA to successfully support an NDA. These risks and others are more fully discussed in the section entitled "Risk Factors" in Vistagen's Annual Report on Form 10-K for the period ended March 31, 2026, 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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Footnotes

1. Based on the prespecified ANCOVA model from the statistical analysis plan. All other p-values were calculated using two-sided t-tests.
2. The study did not achieve statistical significance on the planned primary endpoint, therefore all subsequent analyses showing significance are classified as nominally statistically significant.