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): November 9, 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 November 9, 2026, Vistagen Therapeutics, Inc. (the "*Company*") announced a regulatory update from its recent, productive Type C meeting with the U.S. Food and Drug Administration ("*FDA*") to discuss potential registrational paths forward for the development of its lead product candidate, fasedienol, in social anxiety disorder ("*SAD*"). A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1.

Forward-looking Statements

This Current Report on Form 8-K and Exhibit 99.1 hereto contain certain forward-looking statements within the meaning of the federal securities laws including, without limitation, statements regarding the Company's interpretation of FDA feedback concerning future development plans for fasedienol, its proposed clinical development and regulatory pathway of fasedienol for the treatment of SAD, the design, timing and potential outcomes of future clinical trials of fasedienol, including the Company's proposed study using the Liebowitz Social Anxiety Scale ("*LSAS*") as a primary endpoint in a future Phase 3 study, the potential sufficiency of existing clinical data and the outcome of future Phase 3 studies to support a future New Drug Application, fasedienol's potential to benefit a broad population of patients with SAD, and the Company's ability to secure sufficient financing to advance its development plans. These forward-looking statements involve known and unknown risks and uncertainties and are based on assumptions that, while considered reasonable by the Company, are inherently uncertain. Actual results may differ materially from those expressed or implied. There can be no assurance that FDA feedback will result in a successful registrational pathway, that future clinical trials will demonstrate the safety and efficacy of fasedienol for either the overall or acute treatment of SAD, that existing clinical evidence and future study outcomes will be sufficient to support regulatory approval, or that the Company will obtain the financing necessary to advance its development plans. The FDA may require additional studies or information, and there can be no guarantee that fasedienol or any other of the Company's product candidates will receive regulatory approval or be commercially successful. These risks and other important factors are discussed in the Company's Annual Report on Form 10-K for the fiscal year ended March 31, 2026, Quarterly Report on Form 10-Q for the quarter ended June 30, 2026, and other filings with the U.S. Securities and Exchange Commission ("*SEC*"), available at www.sec.gov. Readers should not place undue reliance on these forward-looking statements, which speak only as of the date of this release. The Company undertakes no obligation to update them except as required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits Index

Exhibit No.	Description
99.1	Press Release issued by Vistagen Therapeutics, Inc., dated November 9, 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: November 9, 2026

By: */s/ Shawn K. Singh*

Shawn K. Singh
President and Chief Executive Officer

EXHIBIT 99.1

Vistagen

Vistagen Provides Regulatory Update Following Productive Type C Meeting with U.S. FDA on Phase 3 Development of Fasedienol for Social Anxiety Disorder

Constructive feedback from FDA clarifies potential Phase 3 development path forward

SOUTH SAN FRANCISCO, Calif. (NEWSWIRE) November 9, 2026, Vistagen (Nasdaq: VTGN), a late clinical-stage biopharmaceutical company pioneering neuroscience with nose-to-brain neurocircuitry, today announced a regulatory update from its recent, productive Type C meeting with the U.S. Food and Drug Administration (FDA) to discuss potential registrational paths forward for the development of its lead product candidate, fasedienol, in social anxiety disorder (SAD).

The FDA shared constructive feedback regarding the Company's proposed use of the Liebowitz Social Anxiety Scale (LSAS) as the primary endpoint in a future Phase 3 study in adults with social anxiety disorder, including recommendations regarding interim assessments to assess whether acute effects of fasedienol could lead to longer-term overall functional improvement in patients over time, consistent with the unique proposed mechanism of action and treatment hypothesis for fasedienol. Vistagen plans to incorporate interim assessments of fasedienol's effect using eDiaries and qualitative patient surveys in the future Phase 3 study design, and to submit a revised protocol to the FDA.

"Receiving the FDA's feedback is an important milestone for our continued Phase 3 development of fasedienol," said Shawn Singh, President and Chief Executive Officer of Vistagen. "The feedback provides important direction as we refine our registration-directed study design and development plan."

The FDA's feedback from the meeting also included its recognition of fasedienol's reported safety profile and potential to benefit a broad population of patients with SAD. Based on the FDA's feedback, Vistagen plans to focus future development on the general SAD population, and to pursue the development of fasedienol for the overall (not simply acute) treatment of SAD.

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 social anxiety disorder, itruvone for major depressive disorder, and refisolone for 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 Vistagen's interpretation of FDA feedback concerning future development plans for fasedienol, its proposed clinical development and regulatory pathway of fasedienol for the treatment of SAD, the design, timing and potential outcomes of future clinical trials of fasedienol, including Vistagen's proposed study using the LSAS as a primary endpoint in a future Phase 3 study, the potential sufficiency of existing clinical data and the outcome of future Phase 3 studies to support a future New Drug Application, fasedienol's potential to benefit a broad population of patients with SAD, and the Company's ability to secure sufficient financing to advance its development plans.

These forward-looking statements involve known and unknown risks and uncertainties and are based on assumptions that, while considered reasonable by Vistagen, are inherently uncertain. Actual results may differ materially from those expressed or implied. There can be no assurance that FDA feedback will result in a successful registrational pathway, that future clinical trials will demonstrate the safety and efficacy of fasedienol for either the overall or acute treatment of SAD, that existing clinical evidence and future study outcomes will be sufficient to support regulatory approval, or that Vistagen will obtain the financing necessary to advance its development plans. The FDA may require additional studies or information, and there can be no guarantee that fasedienol or any other Vistagen product candidate will receive regulatory approval or be commercially successful.

These risks and other important factors are discussed in Vistagen's Annual Report on Form 10-K for the fiscal year ended March 31, 2026, Quarterly Report on Form 10-Q for the quarter ended June 30, 2026, and other filings with the U.S. Securities and Exchange Commission (SEC), available at www.sec.gov. Readers should not place undue reliance on these forward-looking statements, which speak only as of the date of this release. Vistagen undertakes no obligation to update them except as required by law.

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