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): October 2, 2023

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 October 2, 2023, Vistagen Therapeutics, Inc. (the "*Company*") provided details regarding the Company's development plans for fasedienol, the Company's lead product candidate in development for the acute treatment of anxiety for adults with social anxiety disorder ("*SAD*"). The Company believes that utilizing a public speaking challenge clinical trial design similar to PALISADE-2 provides the most efficient path forward to advance the clinical development of fasedienol as a potential acute treatment of anxiety for adults with SAD.

To complement the positive topline results from PALISADE-2, the Company plans to launch two similar Phase 3 clinical trials in 2024, PALISADE-3 in the first half of 2024 and PALISADE-4 in the second half of 2024. Like PALISADE-2, both PALISADE-3 and PALISADE-4 will be multi-center, randomized, double-blind, placebo-controlled, Phase 3 clinical trials designed to evaluate the efficacy, safety, and tolerability of the acute administration of fasedienol to relieve anxiety symptoms in adult patients with SAD after a single dose of fasedienol during a simulated, anxiety-provoking public speaking challenge in a clinical setting, as measured using the patient-reported Subjective Units of Distress Scale ("*SUDS*") as the primary efficacy endpoint. Also, like PALISADE-2, both PALISADE-3 and PALISADE-4 will have an open-label extension for a period of up to 12-months. If successful, the Company believes either PALISADE-3 or PALISADE-4, together with PALISADE-2, may establish substantial evidence of effectiveness of fasedienol in support potential submission of a potential fasedienol U.S. New Drug Application for the acute treatment of anxiety in adults with SAD with the U.S. Food and Drug Administration ("*FDA*") in the first half of 2026.

The Company is also planning to initiate a PALISADE Phase 2 re-dosing clinical trial ("*PALISADE Re-Dosing Trial*") in the second half of 2024. The PALISADE Re-Dosing Trial will be a multi-center, randomized, double-blind, placebo-controlled, clinical trial designed to evaluate repeated dosing of fasedienol in adult patients with SAD during a single simulated, anxiety-provoking public speaking challenge in a clinical setting. The PALISADE Re-Dosing Trial will consist of three different dosing arms, with an open-label extension for a period of up to 12-months.

As a potential future expansion of the Company's PALISADE Phase 3 program for fasedienol in SAD, the Company may conduct additional clinical trials of fasedienol in adult and/or pediatric populations in a real-world setting over a multiple week period, with the Liebowitz Social Anxiety Scale ("*LSAS*") for adult subjects or the LSAS-CA, which is the version of the LSAS the Company believes is suitable for use with subjects who are children or adolescents, as the primary efficacy endpoint. If conducted, these clinical trials will be part of the Company's potential FEARLESS program for fasedienol and will be designed to build on results from a previous randomized, double-blind, placebo-controlled, Phase 2 real-world crossover clinical trial of fasedienol in SAD and exploratory efficacy observations measured by the LSAS in a large cohort of subjects in the Company's PALISADE open label safety study. Initiation of all planned clinical trials of fasedienol remains subject to FDA feedback of the Company's proposed study designs.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits Index

Exhibit No.	Description
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: October 2, 2023

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