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): September 8, 2022

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 94090
(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.

On September 8, 2022, Vistagen Therapeutics, Inc. (the "*Company*") issued a press release announcing the completion of the interim analysis of PALISADE-2, the Company's second Phase 3 clinical trial assessing drug candidate PH94B as an acute treatment of anxiety in adults with Social Anxiety Disorder ("*SAD*"), which concluded that PALISADE-2 should continue as planned.

The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "*Exchange Act*") or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the "*Securities Act*") or the Exchange Act, except as may be expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On September 8, 2022, the Company announced that, based on the recommendation of the independent biostatisticians who conducted the interim analysis of PALISADE-2 to proceed with the Phase 3 clinical trial of PH94B an acute treatment of anxiety in adults with SAD, the Company will continue PALISADE-2 as planned to the full enrollment of 208 subjects, without any adjustment to the size of the study. The Company expects topline results from the PALISADE-2 trial in the first half of 2023. Independent biostatisticians reviewed unblinded data from the 140 subjects who completed PALISADE-2 before the Company paused enrollment in the study in July 2022, following announcement of topline results from PALISADE-1, its first Phase 3 clinical trial of PH94B in SAD. The Company does not itself have access to unblinded data from PALISADE-2.

Forward- Looking Statements

This Current Report on Form 8-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act, including those relating to the development of PH94B, the Company's clinical trials, clinical and regulatory timelines, possible or assumed future results of operations, business strategies, potential growth opportunities and other statement that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which the Company operates and management's current beliefs and assumptions.

These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential," "predict," "project," "should," "would" and similar expressions and the negatives of those terms. These statements relate to future events or our financial performance and involve known and unknown risks, uncertainties, and other factors which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in the Company's filings with the Securities and Exchange Commission ("*SEC*"). Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this press release. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits Index

Exhibit No.	Description
99.1	Press Release issued by Vistagen Therapeutics, Inc., dated September 8, 2022.
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: September 8, 2022

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

Exhibit 99.1

Vistagen to Proceed with PALISADE-2 Phase 3 Clinical Trial of PH94B in Social Anxiety Disorder following Interim Analysis

Independent biostatisticians recommend continuing PALISADE-2 without any changes after conducting interim analysis of 140 completed subjects

Topline data for PALISADE-2 trial expected in the first half of 2023

SOUTH SAN FRANCISCO, Calif. (BUSINESS WIRE) September 8, 2022—Vistagen Therapeutics, Inc. (Nasdaq: VTGN) (Vistagen, the Company), a late clinical-stage biopharmaceutical company aiming to transform the treatment landscape for individuals living with anxiety, depression and other central nervous system (CNS) disorders, today announced the completion of an interim analysis of PALISADE-2, the Company's second Phase 3 clinical trial assessing drug candidate PH94B as an acute treatment of anxiety in adults with Social Anxiety Disorder (SAD), which concluded that PALISADE-2 should continue as planned.

Independent biostatisticians reviewed unblinded data from the 140 subjects who completed PALISADE-2 before the Company paused enrollment in the study in July 2022, following announcement of topline results from PALISADE-1, its first Phase 3 clinical trial of PH94B in SAD. Although the Company does not itself have access to unblinded data from PALISADE-2, based on the outcome of the interim analysis and the recommendation of the independent biostatisticians, Vistagen will continue PALISADE-2 as planned to the full enrollment of 208 subjects, without any adjustment to the size of the study. Vistagen expects topline results from PALISADE-2 in the first half of 2023.

"We are encouraged by the recommendation to continue PALISADE-2 to full enrollment as originally planned," said Shawn Singh, Chief Executive Officer of Vistagen. "Following the results of PALISADE-1, we had independent biostatisticians conduct the interim analysis to gain insight on the best course of action for PALISADE-2, including possibly expanding the number of subjects in the study, significantly amending the study protocol or halting the study altogether. We believe that the recommendation resulting from the interim analysis to resume PALISADE-2 is the best course of action. While we further evaluate the results of PALISADE-1, building on both the continuation of PALISADE-2 and preliminary data from our open label safety study of PH94B, we are also preparing to meet with the FDA later this year to discuss our plans for further Phase 3 development of PH94B in Social Anxiety Disorder."

PH94B is an innovative, fast-acting, odorless pherine administered intranasally at microgram doses. It is currently in clinical trials to treat multiple anxiety disorders without the side effects and safety concerns associated with currently prescribed and off-label medications. PH94B demonstrated tolerability in PALISADE-1 that was consistent with reported results from previous clinical trials. No severe or serious adverse events were reported for PH94B in PALISADE-1 or PALISADE-2 or in other clinical trials.

About Vistagen

Vistagen (Nasdaq: VTGN) is a late clinical-stage, CNS-focused biopharmaceutical company aiming to transform the treatment landscape for individuals living with anxiety, depression and other CNS disorders. The Company is advancing therapeutics with the potential to be faster-acting, and with fewer side effects and safety concerns, than those that are currently available. PH94B and PH10 belong to a new class of drugs known as pherines, which are odorless and tasteless investigational neuroactive steroid nasal sprays designed with a novel rapid-onset mechanism of action that activates chemosensory neurons in the nasal passages and can impact the olfactory-amygdala neural circuits without systemic uptake or direct activity on CNS neurons in the brain. VistaGen is passionate about transforming mental health care and redefining what is possible in the treatment of anxiety and depression. Connect at www.Vistagen.com.

Forward Looking Statements
This press release contains certain forward-looking statements within the meaning of the 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 any pharmaceutical product, 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. Among other things, there can be no guarantee that the Company’s PALISADE-2 Phase 3 clinical trial will be successful or that PH94B or any of the Company’s other drug candidates will receive regulatory approval or be commercially successful. Other factors that may cause such a difference include, without limitation, risks and uncertainties relating to resuming and completing the Company’s PALISADE-2 Phase 3 clinical trial; the effect, if any, of the previously announced topline results of the Company’s PALISADE-1 Phase 3 clinical trial; the completion and results of the Company’s ongoing clinical studies of PH94B, including the Company’s Phase 2A clinical trial of PH94B in adults experiencing adjustment disorder with anxiety; delays in launching, conducting and/or completing other ongoing and planned clinical trials, including delays due to the impact of the ongoing COVID-19 pandemic; fluctuating costs of materials and other resources required to conduct the Company’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 the Company’s CNS drug candidates. These risks are fully discussed in the section entitled "Risk Factors" in the Company’s most recent Annual Report on Form 10-K for the fiscal year ended March 31, 2022 and in the Company’s most recent Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, 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). The Company’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.

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