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): March 8, 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 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 8.01 Other Events.

On March 8, 2023, Vistagen Therapeutics, Inc. (the "*Company*") announced that the last participant in the Company's U.S. Phase 1 clinical trial of itruvone (PH10), the Company's investigational pherine nasal spray in development for the stand-alone treatment of major depressive disorder ("*MDD*") has completed the study protocol.

The primary objective of this U.S. single-center, randomized, double-blind, placebo-controlled Phase 1 study is to investigate the safety and tolerability of itruvone in healthy adult subjects. The study is intended to confirm the favorable safety profile of itruvone established in three previous clinical studies conducted in Mexico, including a published Phase 2A study for the stand-alone treatment of MDD, as well as facilitate the Company's plans for Phase 2B development of itruvone as a stand-alone treatment for MDD. 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 March 8, 2023.
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: March 8, 2023

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

Vistagen

Vistagen Announces Completion of Last Patient, Last Visit in Phase 1 Clinical Trial of Itruvone (PH10), an Investigational Pherine Nasal Spray for Major Depressive Disorder

U.S. Phase 1 study with newly optimized formulation intended to facilitate Phase 2B development of itruvone as a stand-alone treatment of major depressive disorder

Top line results anticipated in Q2 2023

SOUTH SAN FRANCISCO, Calif. – **March 08, 2023** – Vistagen (NASDAQ: VTGN) 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 that the last participant has completed the study protocol in its U.S. Phase 1 clinical trial of itruvone (PH10), the Company's investigational pherine nasal spray for the treatment of major depressive disorder (MDD).

The primary objective of this U.S. single-center, randomized, double-blind, placebo-controlled Phase 1 study is to investigate the safety and tolerability of itruvone in healthy adult subjects. The study is intended to confirm the favorable safety profile of itruvone established in three previous clinical studies conducted in Mexico, including a published Phase 2A study of itruvone as a stand-alone treatment of MDD, as well as facilitate Phase 2B development of itruvone as a stand-alone treatment for MDD. Vistagen anticipates top line results in Q2 2023.

"With the treatment protocol for our final enrolled participant complete, we look forward to reviewing the data and advancing Phase 2B development plans for itruvone as an innovative treatment for major depressive disorder," said Shawn Singh, Chief Executive Officer of Vistagen. "Major depressive disorder continues to disrupt the lives of millions of individuals and there is clear need for safer, more effective treatments, especially treatments with potential for rapid-onset and sustained benefits without causing sexual side effects or weight gain. We anticipate this U.S. Phase 1 trial will build on itruvone's exceptional safety and tolerability profile as demonstrated in all prior clinical studies to date."

About Itruvone (PH10)
Itruvone (PH10) is an investigational pherine nasal spray designed with a potential rapid-onset mechanism of action (MOA) that is fundamentally differentiated from the MOA of all currently approved treatments for depression disorders. Itruvone, which is administered at microgram-level doses, is designed to engage and activate chemosensory neurons in the nasal passages connected to neural circuits in the brain that produce antidepressant effects. Specifically, itruvone's proposed MOA involves binding to receptors of chemosensory neurons in the nasal passages that regulate the olfactory-amygdala neural circuits believed to increase the activity of the limbic-hypothalamic sympathetic nervous system and increase the release of catecholamines. Importantly, unlike all currently approved oral antidepressants and rapid-onset ketamine-based therapy (KBT), including both intravenous ketamine and intranasal ketamine, we believe itruvone does not require systemic uptake or brain penetration to produce rapid-onset of antidepressant effects, avoiding side effects and safety concerns potentially associated with rapid-onset KBT and longer acting oral antidepressants.

Vistagen

About Vistagen

Vistagen (Nasdaq: VTGN) is a late clinical-stage 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 for treatment of anxiety and depression disorders. Several of Vistagen's product candidates belong to a new class of drugs known as pherines, which are designed with a novel rapid-onset mechanism of action that activates chemosensory neurons in the nasal passages and can impact key 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 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. Among other things, there can be no guarantee that any of Vistagen's drug candidates, including itruvone (PH10), will successfully complete ongoing or future clinical trials, receive regulatory approval or be commercially successful. Other factors that may cause such a difference include, without limitation, risks and uncertainties relating to the Company's ongoing clinical studies of fasedienol (PH94B), itruvone and AV-101; delays in launching, conducting and/or completing ongoing and/or planned clinical trials; fluctuating costs of materials and other resources required to conduct the Company's ongoing and/or planned clinical and non-clinical trials; the scope of protection provided by the U.S. patents issued for any of the Company's drug candidates will be sufficient to deter competition; 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. Certain of these risks and others are more 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 December 31, 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.

Investors
Mark Flather
Vice President, Investor Relations
(650) 577-3617
mflather@vistagen.com

Media
Nate Hitchings
SKDK
nhitchings@skdknick.com