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): April 12, 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 8.01 Other Events.

On April 12, 2022, VistaGen Therapeutics, Inc. ("*VistaGen*") and AffaMed Therapeutics ("*AffaMed*") issued a press release to announce that they have completed regulatory preparations to initiate PALISADE Global, a Phase 3 clinical trial to evaluate the efficacy, safety, and tolerability of VistaGen's PH94B (referred to by AffaMed as AM005) for the acute treatment of anxiety in adults with social anxiety disorder. Enrollment of patients in PALISADE Global is anticipated to begin in the second half of 2022 in the U.S. and China, with plans to subsequently include additional clinical sites in Canada, Mexico, and South Korea thereafter, subject to completion of regulatory preparations in those territories. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1, and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits Index

Exhibit No.	Description
99.1	Press Release issued by VistaGen Therapeutics, Inc., dated April 12, 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: April 13, 2022

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

VistaGen and AffaMed Complete Key Regulatory Submissions for PALISADE Global Phase 3 Clinical Trial for PH94B

Companies plan to initiate the global study of PH94B for the acute treatment of social anxiety disorder (SAD) in the second half of 2022

Trial designed to support commercialization of PH94B in China and other markets outside the U.S.

SOUTH SAN FRANCISCO, Calif., and SHANGHAI, China, April 12, 2022 - VistaGen Therapeutics, Inc. (Nasdaq: VTGN) (VistaGen) and AffaMed Therapeutics (AffaMed) today announced they have completed regulatory preparations to initiate PALISADE Global, a Phase 3 clinical trial to evaluate the efficacy, safety, and tolerability of VistaGen's PH94B (referred to by AffaMed as AM005) for the acute treatment of anxiety in adults with social anxiety disorder (SAD), in the U.S. and China. The primary purpose of PALISADE Global, the design of which is based on VistaGen's ongoing PALISADE-1 and PALISADE-2 Phase 3 clinical studies of PH94B in the U.S., is to support potential commercialization of PH94B in China and other markets outside of the U.S.

VistaGen's recent submission of the PALISADE Global study protocol to the U.S. Food and Drug Administration (FDA) under its existing PH94B Investigational New Drug (IND) application in SAD and AffaMed's recent receipt of regulatory clearance of its Clinical Trial Application (CTA) from the National Medical Products Administration (NMPA) in China have cleared the way for initiation of PALISADE Global in the U.S. and China during the second half of 2022. The companies also anticipate initiating this Phase 3 study in Canada, Mexico, and South Korea. PH94B is an odorless, fast-acting neuroactive pherine nasal spray with a unique potential mechanism of action (MOA) for the acute treatment of anxiety in adults with SAD. PH94B works differently than all therapies currently approved for the treatment of SAD by either the FDA or the NMPA.

"We are very pleased with the substantial progress that our teams have made toward initiating PALISADE Global in two of the world's largest pharmaceutical markets," said Shawn Singh, Chief Executive Officer of VistaGen. "AffaMed's clearance from the NMPA affirms our belief that AffaMed is the right partner for PH94B in China, and we remain confident in our collaboration as we advance this important late-stage clinical program for PH94B for the acute treatment of anxiety in adults with SAD. VistaGen remains committed to transforming the treatment of anxiety disorders for the millions of individuals worldwide who need better, safer, and faster-acting therapeutics in their journey toward mental health wellness."

"NMPA's clearance to begin the PALISADE Global Phase 3 trial is a tremendous milestone in advancing our product portfolio targeting neurological and psychiatric indications. I'm very proud of the dedication of our teams to bring forward a new treatment option for the rapidly growing number of individuals in China, South Korea, and Southeast Asia living with SAD," said Dr. Dayao Zhao, Chief Executive Officer of AffaMed. "We appreciate VistaGen's essential work in the U.S. under its PH94B IND application with the FDA. We thank the NMPA for recognizing the importance of this Phase 3 study and rapidly expediting the approval of our CTA. We look forward to dosing participants later this year."

In June 2020, VistaGen Therapeutics entered into a strategic licensing and collaboration agreement with AffaMed Therapeutics for the clinical development and commercialization of PH94B in China, South Korea, and Southeast Asia.

To date, health authorities in the U.S. and China have not approved any medications for acute (as-needed) treatment of anxiety in adults with SAD. SAD is commonly treated in the U.S. with certain antidepressants approved by the FDA, which have a slow onset (several weeks) and limited therapeutic benefits. Benzodiazepines, which are not FDA-approved for the treatment of SAD, are prescribed for off-label use. Both antidepressants and benzodiazepines have known side effects and safety concerns that may make them unattractive to many individuals affected by SAD.

About PALISADE Global

PALISADE Global is a randomized, multi-regional, multi-center, double-blind, placebo-controlled Phase 3 clinical trial that replicates VistaGen's clinical trial design for its PALISADE-1 and PALISADE-2 Phase 3 studies of PH94B currently underway in the U.S. PALISADE Global will encompass clinical sites in the U.S., China, Canada, Mexico, and South Korea with a target enrollment totaling approximately 208 randomized adult subjects. Michael Liebowitz, M.D., a Columbia University psychiatrist, former director and founder of the Anxiety Disorders Clinic at the New York State Psychiatric Institute, director of the Medical Research Network in New York City, and creator of the Liebowitz Social Anxiety Scale (LSAS), is serving as the clinical trial's principal investigator.

The design of the PALISADE-1, PALISADE-2 and PALISADE Global Phase 3 studies is substantially similar to the public speaking component of a peer-reviewed published Phase 2 study of PH94B for the acute treatment of anxiety in adults with SAD. In that Phase 2 study, PH94B was observed to rapidly reduce anxiety (within 15 minutes) in response to a public speaking challenge ($p=0.002$). VistaGen and AffaMed plan to begin enrolling participants in PALISADE Global during the second half of 2022, with topline results anticipated in mid-2024. PALISADE Global is a study separate from PALISADE-1 and PALISADE-2, which are currently underway and designed to support VistaGen's PH94B New Drug Application (NDA) submission to the FDA, should the studies be successful. The PALISADE Global trial, if successful, is primarily intended to support regulatory submissions for potential approval in China and certain other markets outside of the U.S.

About PH94B (AffaMed AM005)

VistaGen's PH94B is a first-in-class, rapid-onset (approximately 15 minutes) pherine nasal spray being evaluated for the treatment of SAD in adults. Pherines are odorless, synthetic neuroactive steroids that bind to distinct receptors on chemosensory cells in the nasal passages and can impact the limbic amygdala without systemic uptake. Designed to be administered intranasally at microgram doses, the unique potential mechanism of action (MOA) of PH94B is fundamentally differentiated from all current anti-anxiety medications, including benzodiazepines. PH94B's proposed MOA does not involve either direct activation of GABA-A receptors or binding to neuronal receptors in the central nervous system (CNS). Rather, PH94B's proposed MOA involves binding to peripheral neurons in the nasal passages, thereby limiting the transport of molecules to the circulatory system and minimizing systemic exposure, suggesting that PH94B has the potential to achieve rapid-onset anti-anxiety effects without requiring systemic uptake or causing benzodiazepine-like side effects and safety concerns. Currently, PH94B is not approved by the FDA, the NMPA, or any other regulatory agency for use in patients outside clinical studies. Separate from PALISADE Global, VistaGen is currently evaluating PH94B in Phase 3 clinical studies and a long-term safety study that, if successful, will support VistaGen's PH94B NDA submission to the FDA. The FDA has granted Fast Track designation for the development of PH94B as a potential treatment for SAD.

About Social Anxiety Disorder (SAD)

Social anxiety disorder affects as many as 23.7 million Americans and 188 million worldwide, including at least 11.3 million in China.[1,2,3] According to the National Institutes of Health, SAD is the third most common psychiatric condition after depression and substance use in the United States. SAD can interfere with going to work, attending school, and a wide variety of common, everyday social and performance situations. Currently, there are no rapid-onset medications approved by the FDA or NMPA for the acute treatment of SAD.

About VistaGen

VistaGen (Nasdaq: VTGN) is a late clinical-stage, neuro-focused biopharmaceutical company striving 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. VistaGen's lead candidates are targeting multiple forms of anxiety and depression. They belong to a new class of drugs known as pherines, which are odorless, neuroactive steroids that bind to distinct receptors on chemosensory neurons in the nasal passages and can impact the limbic amygdala without systemic uptake or direct activity on CNS neurons in the brain. VistaGen's lead asset, PH94B, is a nasally administered spray currently in multiple Phase 3 trials in the U.S., with results anticipated in 2022. Should ongoing Phase 3 studies be successful, PH94B has the potential to be the first FDA-approved, fast-acting, acute treatment of anxiety for adults with social anxiety disorder. With an experienced leadership team and a steady flow of near- and long-term potential milestones, 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.

About AffaMed

AffaMed Therapeutics is a clinical stage biopharmaceutical company focused on developing and commercializing transformative pharmaceutical, digital and surgical products that address critical unmet medical needs in ophthalmological, neurological and psychiatric disorders for patients in Greater China and around the world. The leadership team at AffaMed Therapeutics has gained deep industry expertise and an extensive track record in high-quality discovery, clinical development, regulatory affairs, business development, manufacturing, and commercial operations at leading multi-national biopharmaceutical companies in China and globally. To conform with product portfolio naming convention, AffaMed refers to PH94B as AM005 in its materials.

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1. Kantar Health. September 2020. National Health and Wellness Survey (NHWS), 2020. [US]. Malvern, PA.
2. Stein, D.J., Lim, C.C.W., Roest, A.M. et al. The cross-national epidemiology of social anxiety disorder: Data from the World Mental Health Survey Initiative. BMC Med 15, 143 (2017).
3. Frost & Sullivan. January 2022. Global Market Study of CNS and Opthalmic Treatment Market, 2022. Shanghai, China.

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, its management and VistaGen's partners, are inherently uncertain. The Company's actual results or developments may differ materially from those projected or implied in these forward-looking statements. Factors that may cause such a difference include, without limitation, risks and uncertainties relating to delays in launching, conducting and/or completing ongoing and planned clinical trials, both in the U.S. and internationally, 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 U.S. or internationally; adverse healthcare reforms and changes of any applicable laws and regulations; manufacturing and marketing risks, which may include, but are not limited to, unavailability of or delays in delivery of raw materials for manufacture of the Company's CNS drug candidates due to the ongoing COVID-19 pandemic or otherwise; inadequate and/or untimely supply of one or more of the Company's CNS drug candidates to meet demand; entry of competitive products; and other technical and unexpected hurdles in the development, manufacture and commercialization of the Company's CNS drug candidates; and the risks 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, 2021 and in the Company's most recent Quarterly Report on Form 10-Q for the quarter ended December 31, 2021, 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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