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): May 26, 2021

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 May 26, 2021, VistaGen Therapeutics, Inc. (the *Company*) issued a press release to announce the initiation of its PALISADE Phase 3 clinical program with the PALISADE-1 Phase 3 clinical trial, a randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of PH94B, the Company's investigational pherine nasal spray, for the acute treatment of anxiety in adults with Social Anxiety Disorder. 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.

Exhibit No.	Description
99.1	Press Release issued by VistaGen Therapeutics, Inc., dated May 26, 2021

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: May 27, 2021

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release issued by VistaGen Therapeutics, Inc., dated May 26, 2021

Exhibit 99.1

VistaGen Therapeutics Initiates PALISADE Phase 3 Trial of PH94B in Social Anxiety Disorder

PALISADE Phase 3 Program focused on acute treatment of anxiety in adults with Social Anxiety Disorder

FDA Fast Track designation granted

Topline results anticipated in mid-2022

SOUTH SAN FRANCISCO, Calif., – May 26, 2021 – VistaGen Therapeutics Inc. (NASDAQ: VTGN), a biopharmaceutical company committed to developing a new generation of medicines with the potential to go beyond the current standard of care for anxiety, depression and other central nervous system (CNS) disorders, today announced the initiation of its PALISADE Phase 3 clinical program with the PALISADE-1 Phase 3 trial, a randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of PH94B for the acute treatment of anxiety in adults with Social Anxiety Disorder (SAD). PH94B is an odorless, rapid-onset, investigational pherine nasal spray with a unique mechanism of action, working differently than all existing therapies for SAD. There is currently no U.S. Food and Drug Administration (FDA) approved acute treatment of anxiety for adults with SAD.

PALISADE-1 is being conducted across approximately 18 sites in the U.S., with a target of approximately 200 randomized subjects. Dr. Michael Liebowitz, 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 Principal Investigator of the trial. Topline results from PALISADE-1 are anticipated in mid-2022.

“Initiation of PALISADE-1 is a major milestone for our PALISADE Phase 3 clinical program for PH94B, a program aimed at supporting a potential New Drug Application to the FDA. The trial is an essential next step in our efforts to confirm the positive efficacy and safety results we have seen in all PH94B Phase 2 trials to date,” stated Shawn Singh, Chief Executive Officer of VistaGen. “PH94B has the potential to be a life-changing acute, as-needed treatment of anxiety for adults with SAD, similar to how a rescue inhaler is used to prevent an asthma attack. At a time of continuing increase in the number of Americans suffering from SAD and other anxiety disorders, and a current treatment paradigm that falls short of delivering necessary relief, a new fast-acting treatment alternative is imperative. Initiation of our PALISADE-1 trial further reflects our commitment to go beyond the current standard of care for SAD. If successfully developed, PH94B has the potential to be the first fast-acting, non-systemic, non-sedating acute treatment of anxiety for more than 23 million Americans who suffer from SAD.”

“Social Anxiety Disorder is the third most common mental health disorder among Americans, and it can turn everyday social interactions into debilitating, fearful experiences for people who continue to suffer from this growing mental health condition,” said Dr. Liebowitz. “Existing treatments, such as approved antidepressants, have not been effective acute treatment solutions for this large patient population. In addition, the negative side effects and safety concerns associated with benzodiazepines prescribed off-label are a significant cause for concern, as demonstrated by the FDA’s Drug Safety Communication detailing the risks of benzodiazepines issued last Fall. The start of this Phase 3 trial is a major step forward in the clinical development of PH94B, an investigational drug with the potential to displace antidepressants and benzodiazepines in the treatment paradigm for SAD, as well as several other anxiety disorders.”

PH94B Phase 2 Study Results – Public Speaking Challenge

The PALISADE-1 Phase 3 trial design is substantially based upon the design of the laboratory-simulated public speaking challenge in the Phase 2 multi-center, randomized, double-blind, placebo-controlled trial of PH94B for the acute treatment of anxiety in adults with SAD. In that Phase 2 study, PH94B rapidly reduced (within 15 minutes) anxiety in response to both the public speaking challenge ($p=0.002$) and a social interaction challenge ($p=0.009$).

About Social Anxiety Disorder (SAD)
Social Anxiety Disorder affects as many as 23.7 million Americans and, according to the National Institutes of Health, is the third most common psychiatric condition after depression and substance use. A person with SAD feels intense, persistent symptoms of anxiety or fear in certain social situations, such as meeting new people, dating, being on a job interview, answering a question in class, or talking to a cashier in a store. Doing common, everyday things in front of people causes profound anxiety or fear of being humiliated, evaluated, judged, or rejected. SAD can get in the way of going to work, attending school, or doing a wide variety of things in a situation that has the potential for interpersonal interaction. It can lead to avoidance and opportunity cost that can significantly impact a person's employment and social activities and be very disruptive to overall quality of life. SAD is commonly treated chronically with certain FDA-approved antidepressants, which have a slow onset of effect (several weeks) and limited therapeutic benefits, and benzodiazepines, which are not FDA-approved for treatment of SAD but are prescribed for off-label use. Both antidepressants and benzodiazepines have known side effects and safety concerns that may make them unattractive to individuals affected by SAD.

About PH94B
PH94B is a first-in-class, odorless, rapid-onset (approximately 10 to 15 minutes) CNS pherine nasal spray with the potential to be the first FDA-approved, fast-acting, on-demand treatment for millions of Americans who suffer from SAD, with additional potential in adjustment disorder, postpartum anxiety, pre-procedural anxiety, post-traumatic stress disorder, panic disorder and generalized anxiety disorder. Administered at microgram doses, PH94B activates nasal chemosensory neurons that trigger neural circuits in the brain that suppress fear and anxiety. Following successful Phase 2 development, VistaGen has recently initiated its PALISADE-1 Phase 3 clinical trial of PH94B for acute treatment of anxiety in adults with SAD. The FDA has granted Fast Track designation for the development of PH94B as a treatment for SAD. View more background on SAD and PH94B's unique mechanism of action.

About VistaGen Therapeutics
VistaGen Therapeutics is a biopharmaceutical company committed to developing and commercializing innovative medicines with the potential to go beyond the current standard of care for anxiety, depression and other CNS disorders. Each of VistaGen's drug candidates has a differentiated potential mechanism of action, has been well-tolerated in all clinical studies to date and has therapeutic potential in multiple CNS markets. For more information, please visit www.VistaGen.com and connect with VistaGen on Twitter, LinkedIn and Facebook.

Forward Looking Statements
Various statements in this release are "forward-looking statements" concerning VistaGen's future expectations, plans and prospects, including the potential for successful Phase 3 development of PH94B for the acute treatment of anxiety in adults with SAD. These forward-looking statements are neither promises nor guarantees of future performance, and are subject to a variety of risks and uncertainties which could cause actual results to differ materially from those contemplated in these forward-looking statements, including the risks that: development and approval of PH94B may not be achieved in any market; the FDA may decide that the results of the PALISADE-1 trial and the Company's PALISADE PH94B Phase 3 clinical program are not sufficient to support a New Drug Application, or for regulatory approval for the acute treatment of anxiety in adults with SAD or any other anxiety-related disorder; development of PH94B may not be successful in any indication; success in nonclinical studies or in earlier-stage clinical trials may not be repeated or observed at any time during the PALISADE Phase 3 program, including during PALISADE-1, or future trials, which trials may not support further development or be sufficient to gain regulatory approval to market PH94B; adverse events may be encountered at any stage of development that negatively impact further development. Other risks and uncertainties include, but are not limited to, issues related to: adverse healthcare reforms and changes of laws and regulations; general industry and market conditions; manufacturing and marketing risks, which may include, but are not limited to, unavailability of or delays in delivery of raw materials for manufacture of PH94B; inadequate and/or untimely supply of PH94B to meet demand; entry of competitive products; and other technical and unexpected hurdles in the development, manufacture and commercialization of PH94B, as well as those risks more fully discussed in the section entitled "Risk Factors" in the Company’s most recent Annual Report on Form 10-K for the year ended March 31, 2020, and in its most recent Quarterly Report on Form 10-Q for the quarter ended December 31, 2020 as well as discussions of potential risks, uncertainties, and other important factors in its other filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent the Company's views only as of today and should not be relied upon as representing its views as of any subsequent date. The Company explicitly disclaims any obligation to update any forward-looking statements.

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