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): June 15, 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 5.02 Departure of Directors and Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On and effective June 15, 2022, VistaGen Therapeutics, Inc. (the "*Company*") terminated the employment of H. Ralph Snodgrass, Ph.D., who served as the Company's President and Chief Scientific Officer.

Item 8.01 Other Events.

On June 22, 2022, the Company issued a press release to announce that the last patient has completed the study protocol in the Company's PALISADE-1 Phase 3 clinical trial of PH94B 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 Index

Exhibit No.	Description
99.1	Press Release issued by VistaGen Therapeutics, Inc., dated June 22, 2022

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: June 22, 2022

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

VistaGen Announces Completion of PALISADE-1 Phase 3 Clinical Study of PH94B for the Acute Treatment of Social Anxiety Disorder

PALISADE Phase 3 Program focused on PH94B's potential as a rapid-onset, acute treatment of anxiety in adults with social anxiety disorder

FDA Fast Track designation granted

Topline results anticipated mid-2022

SOUTH SAN FRANCISCO, Calif., June 22, 2022 – VistaGen Therapeutics, Inc. (Nasdaq: VTGN), a late clinical-stage central nervous system (CNS)-focused biopharmaceutical company aiming to transform the treatment landscape for individuals living with anxiety, depression, and other CNS disorders, today announced that the last patient has completed the study protocol in its PALISADE-1 Phase 3 clinical trial of PH94B for the acute treatment of anxiety in adults with social anxiety disorder (SAD).

VistaGen's PALISADE-1 Phase 3 clinical trial is a U.S. multi-center, randomized, double-blind, placebo-controlled, parallel design, clinical study in adults diagnosed with SAD. The study is designed to evaluate the efficacy, safety, and tolerability of the acute administration of PH94B to relieve symptoms of anxiety in adult patients living with SAD during a simulated public speaking challenge conducted in a clinical setting, measured using the Subjective Units of Distress Scale (SUDS). Topline results from VistaGen's PALISADE-1 Phase 3 clinical study are anticipated in mid-2022, consistent with the Company's prior guidance.

"We would like to thank the many individuals currently living with social anxiety disorder who participated in PALISADE-1, as well as Dr. Michael Liebowitz, the Principal Investigator in the study and a leading expert in SAD, the clinical site investigators and their teams, and our CRO. Together with our internal team, all are an integral part of our PALISADE Phase 3 Program for PH94B. Social anxiety disorder affects an estimated 25 million individuals in the United States, and this milestone further reflects our Company's continuing commitment to develop novel treatment options with potential to go beyond the current standard of care for widespread mental health disorders," said **Shawn Singh, Chief Executive Officer of VistaGen**.

VistaGen is also evaluating PH94B for SAD in a second Phase 3 clinical trial, PALISADE-2, a U.S. multi-center, randomized, double-blind, placebo-controlled Phase 3 clinical trial designed as a replicate of PALISADE-1 to evaluate the efficacy, safety, and tolerability of PH94B for the acute treatment of anxiety in adults with SAD. Topline results from PALISADE-2 are anticipated in late-2022.

PALISADE Phase 3 Program for PH94B in Social Anxiety Disorder
VistaGen's PALISADE Phase 3 Program in social anxiety disorder (SAD) is designed to further demonstrate the potential of PH94B as a fast-acting, acute treatment of anxiety in adults with SAD. The Company's PALISADE-1 and PALISADE-2 Phase 3 clinical trials are replicate U.S. multi-center, randomized, double-blind, placebo-controlled Phase 3 clinical trials designed to evaluate the efficacy, safety, and tolerability of PH94B for the acute treatment of anxiety in adults with SAD. If the Company's PALISADE Phase 3 Program is successful, then VistaGen plans to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) to approve the use of PH94B for the acute treatment of anxiety in adults with SAD. The FDA has granted Fast Track designation for the development of PH94B for SAD.

About Social Anxiety Disorder
Social anxiety disorder (SAD) affects an estimated 25 million Americans. A person with SAD feels intense, persistent symptoms of anxiety or fear in certain social situations, such as meeting new people, making comments in a business meeting, 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 embarrassed, evaluated, humiliated, 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 is likely to involve interpersonal interaction. It can lead to avoidance and opportunity costs that can significantly impact a person's employment and social activities and be very disruptive to their overall quality of life. SAD is commonly treated long-term with certain FDA-approved antidepressants, which have a slow onset of effect (several weeks) and provide limited therapeutic benefits, and benzodiazepines, which are not FDA-approved for the treatment of SAD. Both antidepressants and benzodiazepines have known side effects and significant safety concerns that may make them unattractive to individuals affected by SAD.

About PH94B
VistaGen's PH94B is a first-in-class, odorless, tasteless, rapid-onset (approximately 15 minutes) investigational pherine nasal spray with a novel mechanism of action (MOA) that regulates the olfactory-amygdala neural circuits of fear and anxiety and attenuates the tone of the sympathetic autonomic nervous system. Based on positive Phase 2 data in social anxiety disorder (SAD) patients, VistaGen is currently evaluating PH94B in two Phase 3 clinical studies in the U.S., PALISADE-1 and PALISADE-2, for the acute treatment of anxiety in adults with SAD. Designed for intranasal administration in low microgram doses, the proposed novel MOA of PH94B is fundamentally differentiated from all currently approved anti-anxiety medications, including benzodiazepines.

VistaGen's proposed MOA for PH94B 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 receptors in peripheral chemosensory neurons in the nasal passages to regulate the olfactory-amygdala fear and anxiety neural circuits. Both clinical and preclinical data suggest that PH94B has the potential to achieve rapid-onset anti-anxiety effects without systemic uptake or transport into the brain, reducing the risk of benzodiazepine-like side effects and other safety concerns. VistaGen is conducting a Phase 2A clinical trial to evaluate the potential use of PH94B to treat adjustment disorder with anxiety and is considering the evaluation of PH94B for potential use in the treatment of other anxiety-related disorders, including procedural anxiety, post-traumatic stress disorder (PTSD), postpartum anxiety, and panic disorder.

About VistaGen

VistaGen (Nasdaq: VTGN) is a late clinical-stage, central nervous system (CNS)-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 clinical-stage candidates are targeting multiple forms of anxiety and depression. PH94B and PH10 belong to a new class of drugs known as pherines, which are odorless, tasteless, neuroactive steroids designed to bind to distinct receptors on chemosensory neurons in the nasal passages and can impact the limbic amygdala with rapid-onset and without systemic uptake or direct activity on CNS neurons in the brain. VistaGen's lead candidate, PH94B, is a nasally-administered spray currently in multiple Phase 3 trials in the U.S., with topline 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. 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. 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 the completion and results of the Company's PALISADE-1 and PALISADE-2 Phase 3 clinical trials; the Company's ability to submit a NDA to the FDA following the completion of PALISADE-1 and/or PALISADE-2 Phase 3 clinical trials; 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; adverse healthcare reforms and changes of 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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