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): October 14, 2021

VistaGen Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

NV	**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 October 14, 2021, VistaGen Therapeutics, Inc. issued a press release to announce the initiation of a Phase 2A clinical trial to evaluate the efficacy, safety and tolerability of PH94B as a potential treatment of anxiety in adults with Adjustment Disorder with Anxiety. 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 October 14, 2021
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: October 14, 2021

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

EXHIBIT 99.1

VistaGen Therapeutics Expands Clinical Development of PH94B with Initiation of Phase 2A Trial in Adjustment Disorder

Study Launches Phase 2A Clinical Program Designed to Explore PH94B's Potential in Multiple Additional Anxiety Disorders

Phase 2A Study in Adjustment Disorder to Run in Parallel with Ongoing Phase 3 Studies in Acute Treatment of Social Anxiety Disorder

SOUTH SAN FRANCISCO, Calif., – October 14, 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 a Phase 2A clinical trial to evaluate the efficacy, safety and tolerability of PH94B as a potential treatment of anxiety in adults with Adjustment Disorder with Anxiety (AjDA). In parallel with advancing its ongoing PALISADE Phase 3 clinical program for PH94B in the acute treatment of anxiety in adults with Social Anxiety Disorder (SAD), the Company plans to explore PH94B's potential in additional anxiety disorders through a series of small Phase 2A trials, the first of which is in AjDA. PH94B is an investigational pherine nasal spray with a unique potential mechanism of action designed to achieve rapid-onset anti-anxiety effects without requiring systemic uptake or causing benzodiazepine-like side effects and safety concerns.

The exploratory Phase 2A clinical trial of PH94B in AjDA is a randomized, double-blind, placebo-controlled study with an enrollment target of approximately 40 adults at clinical sites in the Boston and New York City metro areas. Dr. Michael Liebowitz, a Columbia University psychiatrist, former director and founder of the Anxiety Disorders Clinic at the New York State Psychiatric Institute, and director of the Medical Research Network in New York City is serving as Principal Investigator of the trial. The study's primary outcome measure is the change from baseline in anxiety level as measured by the Hamilton Anxiety Rating Scale (HAM-A). Additional details about the clinical trial can be found at www.clinicaltrials.gov, identifier NCT04404192.

"As we continue to advance ongoing Phase 3 clinical development of PH94B in our PALISADE Phase 3 Program in Social Anxiety Disorder, we are excited to launch our Phase 2A clinical program to explore PH94B's potential in multiple additional anxiety disorders with unmet need," said Shawn Singh, Chief Executive Officer of VistaGen. "There has been a significant shift in mental health since early last year. Emotional stress and impaired functioning as a result of anxiety-provoking stressors brought on by sudden changes in health, safety, economic and social circumstances, including the diverse impacts of the COVID-19 pandemic, have directly or indirectly affected hundreds of millions of individuals around the world and may have led to a considerable increase in the prevalence of Adjustment Disorder with Anxiety. We believe the impact of the pandemic on mental health will be long-term and varied across a wide range of anxiety disorders, and we are committed to becoming part of the solution for people who need to find help. Expanding on our ongoing efforts to address the alarming prevalence of Social Anxiety Disorder, the initiation of this exploratory Phase 2A study in Adjustment Disorder with Anxiety is an exciting next step toward our goal."

About Adjustment Disorder with Anxiety
Almost everyone experiences significant life events, changes, or stressors from time to time, and while some individuals adjust to such changes within a few months, others cannot and may experience adjustment disorder. Adjustment Disorder with Anxiety (AjDA) is the development of emotional or behavioral symptoms considered excessive or disproportionate in response to a sudden change, stressful event or circumstance, or other identifiable anxiety-provoking stressor, such as loss of work, divorce or a health setback, significantly impairing a person's social, occupational and/or other important area(s) of functioning.

About PH94B
PH94B is a first-in-class, odorless, rapid-onset (approximately 15 minutes) pherine nasal spray with the potential to be the first FDA-approved, fast-acting, on-demand acute treatment for millions of Americans who suffer from Social Anxiety Disorder (SAD), with additional therapeutic potential in Adjustment Disorder with Anxiety (AjDA), Postpartum Anxiety, Procedural Anxiety, Post-traumatic Stress Disorder, Panic Disorder and Generalized Anxiety Disorder. Designed to be administered intranasally at microgram doses, the proposed mechanism of action (MOA) of PH94B is fundamentally differentiated from that of 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 CNS. Rather, PH94B's proposed MOA involves binding to peripheral neurons in the nasal passages, thereby limiting transport of molecules to the circulatory system and minimizing potential 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.

Following successful Phase 2 development, VistaGen has recently initiated two ongoing Phase 3 clinical trials of PH94B, PALISADE-1 and PALISADE-2, to assess the efficacy, safety and tolerability of PH94B for the acute treatment of anxiety in adults with SAD. In addition, VistaGen's exploratory Phase 2A clinical program for PH94B in additional anxiety disorders is now underway with the recent initiation of its Phase 2A clinical trial in AjDA. The FDA has granted Fast Track designation for the development of PH94B as a treatment for SAD. View more background on 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 our website at www.VistaGen.com and connect with VistaGen on social media - Twitter, LinkedIn, Instagram 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 exploratory Phase 2A development of PH94B in AjDA and 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: completion of the Phase 2A study in AjDA, PALISADE-1 and/or PALISADE-2 may be delayed due to a variety of factors, including factors related to the ongoing COVID-19 pandemic; development and approval of PH94B may not be achieved in any market; the FDA or the Company may decide that the results of the Phase 2A study of PH94B in AjDA, or in PALISADE-1 and/or PALISADE-2 and other studies in the Company's PALISADE Phase 3 Program for PH94B in SAD are not sufficient to support further development in AjDA in the case of the Phase 2A study, or, with respect to the PALISADE Phase 3 Program in SAD, a U.S. New Drug Application, or for regulatory approval for the acute treatment of anxiety in adults with SAD or any other anxiety-related disorder, including AjDA; 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 Phase 2A development in AjDA or in the PALISADE Phase 3 Program, including during PALISADE-1 and/or PALISADE-2, 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 the 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, 2021, and in its most recent Quarterly Report on Form 10-Q for the quarter ended June 30, 2021 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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