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 5, 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 May 5, 2022, VistaGen Therapeutics, Inc. (the "*Company*") issued a press release to announce a key regulatory update from the U.S. Food and Drug Administration ("*FDA*") on its PALISADE Phase 3 Program for PH94B for the acute treatment of anxiety in adults with social anxiety disorder ("*SAD*").

The FDA indicated the following regarding the Company's late-stage development of PH94B for acute treatment of SAD: (i) nonclinical and clinical data in studies completed to date provide no signal of abuse potential; (ii) receptor binding data do not show that PH94B has affinity for abuse-related sites, such as dopamine, opiate or GABA; (iii) intravenous administration of PH94B to animals provides no overt behavioral responses; (iv) no additional nonclinical studies are needed to evaluate the abuse potential of PH94B; and (v) while the need for a human abuse potential ("*HAP*") study with PH94B may be revisited by the FDA upon completion of the Company's current and planned clinical trials, because nonclinical and clinical studies completed to date provide no signal of abuse potential, at this time, conducting a HAP study of PH94B is not necessary. 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 May 5, 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: May 5, 2022

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

VistaGen Announces Key Regulatory Update on PH94B for the Acute Treatment of Social Anxiety Disorder

The FDA agreed that data from nonclinical and clinical studies of PH94B completed to date provide no signal of abuse potential

The FDA also agreed that additional nonclinical studies are not necessary to evaluate the abuse potential of PH94B and, at this time, based on studies completed to date, a human abuse potential (HAP) study with PH94B is not required

SOUTH SAN FRANCISCO, Calif., May 5, 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, announced today a key regulatory update on its PALISADE Phase 3 Program for PH94B for the acute treatment of anxiety in adults with social anxiety disorder (SAD).

The U.S. Food and Drug Administration (FDA) recently indicated the following regarding VistaGen's late-stage development of PH94B for the acute treatment of SAD:

- *Nonclinical and clinical data in studies completed to date provide no signal of abuse potential;*
- *Receptor binding data do not show that PH94B has affinity for abuse-related sites, such as dopamine, opiate or GABA;*
- *Intravenous administration of PH94B to animals provides no overt behavioral responses;*
- *No additional nonclinical studies are needed to evaluate the abuse potential of PH94B; and*
- *While the need for a human abuse potential (HAP) study with PH94B may be revisited by the FDA upon completion of current and planned clinical trials, because studies completed to date provide no signal of abuse potential, at this time, conducting a HAP study of PH94B is not necessary.*

"There are more than 25 million people in the United States suffering from social anxiety disorder, or SAD, and many of them do not have adequate treatment options available," said Shawn Singh, Chief Executive Officer of VistaGen. "As PH94B continues to progress through our Phase 3 development program in SAD, we are encouraged by our consensus view with the FDA on the important dimension of abuse liability. This clear and timely feedback from the FDA further emboldens our team and our steadfast efforts to advance PH94B on behalf of the millions of people struggling with SAD."

About PH94B
VistaGen's PH94B is a first-in-class, odorless, tasteless rapid-onset (10-15 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, and a long-term safety study, for the acute treatment of anxiety in adults with SAD. Designed for intranasal administration in low microgram doses, the innovative 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 CNS. Rather, PH94B's proposed MOA involves binding to peripheral chemosensory neurons in the nasal passages to modulate 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. In addition to SAD, for which the FDA has granted Fast Track designation, PH94B has potential in adjustment disorder with anxiety, procedural anxiety, PTSD, postpartum anxiety and panic disorder.

About VistaGen
VistaGen (Nasdaq: VTGN) is a late clinical-stage, CNS-focused biopharmaceutical company striving to transform the treatment landscape for individuals living with anxiety, depression and other CNS disorders. The Company is advancing first-in-class 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. 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 olfactory to limbic amygdala circuit 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 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.

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 delays in launching, conducting and/or completing 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; future regulatory and clinical development matters, including potential clinical or non-clinical occurrences that may cause regulators such as the FDA to require HAP studies of PH94B or the Company's other CNS drug candidates in the future; 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; market conditions; the impact of general economic, industry or political conditions in the United States or internationally; 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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