

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 21, 2022

VistaGen Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Nevada
(State or other jurisdiction of
incorporation)

000-54014
(Commission File Number)

20-5093315
(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 21, 2022, VistaGen Therapeutics, Inc. (the “*Company*”) issued a press release to announce the presentation of preclinical data supporting the differentiated mechanism of action for the Company’s lead product candidate, PH94B, at two upcoming major scientific congresses - the Annual Meeting of the Society of Biological Psychiatry and the Annual Meeting of the American Society of Clinical Psychopharmacology. 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 April 21, 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 21, 2022

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



VistaGen to Present Preclinical Data on Lead Candidate PH94B at Upcoming Scientific Congresses

Research presented at the Annual Meeting of the Society of Biological Psychiatry and of the American Society of Clinical Psychopharmacology highlight fundamentally differentiated mechanism of action for PH94B

These preclinical data demonstrate that intranasal radiolabelled-PH94B is largely confined to the nasal passages where it stimulates chemosensory neurons located in the nasal epithelium. The localized effect within the nasal epithelium may explain why PH94B's anxiolytic properties in humans do not require systemic uptake or transport into the brain.

SOUTH SAN FRANCISCO, Calif., April 21, 2022 —VistaGen Therapeutics, Inc. (Nasdaq: VTGN) (VistaGen) 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 that researchers will present preclinical data supporting the differentiated mechanism of action (MOA) for VistaGen's lead product candidate, PH94B, at two upcoming major scientific congresses. VistaGen is currently evaluating PH94B in multiple Phase 3 trials for the acute treatment of anxiety in adults with social anxiety disorder (SAD).

Louis Monti, M.D., Ph.D., VistaGen's Vice President of Translational Medicine, will present the data based on the study, *Brain and Peripheral Distribution of Intranasal Radiolabeled PH94B in Laboratory Rats* as follows:

- As a late-breaking poster presentation on April 30 from 3:00 p.m. to 5:00 p.m. Pacific Time at the Annual Meeting of the Society of Biological Psychiatry (SOBP), occurring on April 28 – April 30, 2022, in New Orleans, Louisiana; and
- As a poster at the Annual Meeting of the American Society of Clinical Psychopharmacology (ASCP), occurring May 31 – June 03, 2022, in Scottsdale, Arizona.

Late last year, VistaGen released preclinical data that further support that the proposed MOA of PH94B involves binding to receptors of peripheral neurons in the nasal passages, rather than neuronal receptors in the CNS. These data suggest that anxiolytic activity can be achieved without systemic exposure or transport into the brain, resulting in a lower risk for side effects.

"VistaGen is committed to transforming the existing standards of treatments for anxiety and depression disorders," said Shawn Singh, Chief Executive Officer of VistaGen. "As these preclinical data demonstrate, the proposed mechanism of action of our Phase 3 clinical candidate, PH94B, is fundamentally unique from all currently available anti-anxiety therapies. In the pandemic years alone, mental health crisis incidents have tripled, making it clear that patients need options that are faster, safer, and more tolerable than the current products on the market. Our ongoing PALISADE Phase 3 Program for SAD is designed to assess PH94B's potential to address that need."

About PH94B

VistaGen's PH94B is a first-in-class, rapid-onset (approximately 15 minutes) pherine nasal spray being evaluated for the acute 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 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 neurons in the nasal passages, with very limited systemic exposure. Taken together, these 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 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. The FDA has granted Fast Track designation for the development of PH94B as a potential treatment for SAD.

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 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 limbic amygdala 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; 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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