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 5, 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 5, 2021, VistaGen Therapeutics, Inc. announced new mechanism of action data from a preclinical tissue distribution study in laboratory rats demonstrating that a single intranasal administration of radiolabeled carbon-14 PH94B was largely confined to the nasal passages and minimal or undetectable in most other tissues, including the CNS. No appreciable activity was observed in the brain. 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 5, 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 5, 2021

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

EXHIBIT 99.1

VistaGen Therapeutics Reports New Preclinical Mechanism of Action Data Supporting PH94B's Potential Anti-Anxiety Activity via Peripheral Nasal Neurons without Entry into the Brain

Preclinical study of intranasal radiolabeled PH94B in laboratory rats further differentiates PH94B's mechanism of action from benzodiazepines

SOUTH SAN FRANCISCO, Calif., October 5, 2021– VistaGen Therapeutics (NASDAQ: VTGN), a biopharmaceutical company developing a new generation of medicines with potential to go beyond the current standard of care for anxiety, depression and other central nervous system (CNS) disorders, today announced new mechanism of action data from a preclinical tissue distribution study in laboratory rats demonstrating that a single intranasal administration of radiolabeled carbon-14 PH94B ([^{14}C]PH94B) was largely confined to the nasal passages and minimal or undetectable in most other tissues, including the CNS. No appreciable activity was observed in the brain.

These data further support the proposed mechanism of action of PH94B involving binding to receptors of peripheral neurons in the nasal passages, not to neuronal receptors in the CNS, and thereby limiting transport of molecules to the circulatory system and minimizing potential systemic exposure.

"We are very excited about these new study results, which further highlight how the mechanism of action of PH94B is fundamentally differentiated from all current anti-anxiety therapies," stated Shawn K. Singh, Chief Executive Officer of VistaGen. "When combined with previously announced preclinical electrophysiology data demonstrating that the mechanism of action of PH94B does not involve direct activation of GABA-A receptors, which is in distinct contrast to the mechanism of action of benzodiazepines, we see a growing body of evidence suggesting that PH94B has potential to achieve anti-anxiety effects without requiring systemic uptake or causing benzodiazepine-like side effects and safety concerns. At a time when the current drug treatment paradigm for Social Anxiety Disorder, or SAD, is falling far short of delivering necessary relief without worrisome potential consequences, an innovative treatment alternative is imperative. If successfully developed in our ongoing PALISADE Phase 3 Program, PH94B has the potential to fill that void as the first fast-acting, on demand acute treatment of anxiety for more than 23 million Americans who suffer from SAD."

“In this study, the absence of radiolabeled PH94B in the rodent brain is an encouraging sign that PH94B may have limited circulatory systemic exposure when administered intranasally,” stated Mark Smith, MD, PhD, Chief Medical Officer of VistaGen. “Furthermore, the tissue distribution of radiolabeled carbon-14 PH94B was minimal in the tested lab animals, with the highest concentration primarily in the nasal turbinates. These findings strongly support a local disposition of PH94B in the olfactory receptor neurons and an absence of binding of PH94B in the central nervous system. We believe that this is another positive indication supporting the clinical development of PH94B.”

About PH94B
PH94B is an investigational, first-in-class, odorless, rapid-onset (approximately 15 minutes) CNS pherine nasal spray with the potential to be the first FDA-approved, fast-acting, on-demand acute treatment of anxiety for millions of Americans who suffer from Social Anxiety Disorder (SAD), with therapeutic potential in multiple additional anxiety disorders. Administered intranasally at microgram doses, PH94B activates peripheral nasal chemosensory neurons that trigger neural circuits in the brain that suppress fear and anxiety. Following successful Phase 2 development, VistaGen has initiated two ongoing Phase 3 clinical trials of PH94B in its PALISADE Phase 3 Program, PALISADE-1 and PALISADE-2, for potential 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 PH94B’s unique mechanism of action.

About VistaGen Therapeutics
VistaGen Therapeutics is a biopharmaceutical company committed to developing and commercializing innovative medicines with 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 observed to be 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: preclinical study results in laboratory rats and/or other laboratory animals may not be indicative of potential results in human clinical trials, including clinical studies in the Company's PALISADE Phase 3 Program for PH94B in SAD; success in preclinical 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 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; completion of clinical studies in the Company's PALISADE Phase 3 Program, including, but not limited to 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 may decide that the results of PALISADE-1 and PALISADE-2 and other studies in the Company's PALISADE Phase 3 Program for PH94B are not sufficient to support 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; development of PH94B may not be successful in any indication. 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.

VistaGen Company Contacts
Media:
Mark McPartland
Vice President, Corporate Development
Phone: (650) 577-3606
Email: markmcp@vistagen.com

Investors:
Mark Flather
Vice President, Investor Relations
Phone: (650) 577-3617
Email: mflather@vistagen.com