

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): December 1, 2020

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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 December 1, 2020, VistaGen Therapeutics, Inc. (the “*Company*”) issued a press release to announce that Louis Monti, M.D., Ph.D., a pioneer in the research and development of neuroactive steroids known as “pherines,” including the Company’s intranasal drug candidates PH94B for anxiety disorders and PH10 for depression disorders, has joined the Company as Vice President, Translational Medicine. 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 December 1, 2020

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: December 1, 2020

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



VistaGen Therapeutics Expands R&D Team with Appointment of Louis Monti, M.D., Ph.D., Pioneer in the Development of Neuroactive Steroids known as Pherines as Potential Treatments for Anxiety and Depression Disorders, as Vice President, Translational Medicine

Dr. Monti developed the innovative scientific platform that enabled the early research and development of VistaGen's PH94B and PH10, intranasal neuroactive steroid drug candidates (pherines) with potential for the rapid-onset treatment of anxiety and depression disorders, respectively

SOUTH SAN FRANCISCO, Calif., December 1, 2020 – VistaGen Therapeutics (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 that Louis Monti, M.D., Ph.D., a pioneer in the research and development of neuroactive steroids known as “pherines,” including VistaGen’s intranasal drug candidates PH94B for anxiety disorders and PH10 for depression disorders, has joined the Company as Vice President, Translational Medicine.

“We have had the pleasure of working closely with Dr. Monti in a consultative capacity since 2018 to complement our efforts to develop PH94B and PH10 to improve the lives of millions of people worldwide who suffer from anxiety and depression disorders every day,” stated Shawn K. Singh, Chief Executive Officer of VistaGen. “As we approach several potentially significant milestones for these differentiated neuropsychiatric drug candidates in 2021 and beyond, Dr. Monti’s unique knowledge, expertise, and insight about their potential, as well as potential opportunities for further expansion of our CNS pipeline, will be valuable. We are excited that he has now joined us as a full-time member of our R&D team.”

Dr. Monti commented, “Driving research of neuroactive pherines to develop innovative medicines with the potential to lift the burdens of anxiety and depression has been a passion throughout my career. I am truly pleased to join a team that shares that sense of commitment and purpose. I am excited that my new role at VistaGen will allow me both to continue to assist with the late-stage clinical development of PH94B and PH10 and apply my R&D experience working with neuroactive steroids to explore potential pipeline expansion opportunities.”

Dr. Monti has served as President and CEO of Pherin Pharmaceuticals since July 2018. He previously served as its Executive Vice President between 2002 and 2018 and as its Vice President of Research from its founding in 1991 to 2002. Prior to joining Pherin, Dr. Monti held various academic positions at the University of Utah and the University of the Republic, Uruguay. He earned an M.D. from the University of the Republic, Uruguay School of Medicine, and a Ph.D. in Physiology and Pharmacology from the University of Utah. Dr. Monti holds memberships in the New York Academy of Sciences, the American Society of Clinical Psychopharmacology, and the International Brain Organization.

About PH94B

PH94B is an innovative odorless investigational synthetic neuroactive steroid nasal spray with therapeutic potential in multiple mental health disorders involving anxiety or phobia and is designed to have rapid onset. Self-administered in microgram-level doses, in Phase 2 studies for the treatment of social anxiety disorder (SAD), PH94B produced rapid-onset (within approximately 15 minutes) anti-anxiety effects without sedation or systemic uptake and distribution.

VistaGen is currently preparing PH94B for Phase 3 development as a potential acute treatment of anxiety in adults with SAD. The FDA has granted Fast Track designation for the development of PH94B for this indication.

With rapid-onset pharmacology and favorable safety results seen in all clinical studies to date, we believe PH94B has the potential to provide an innovative treatment alternative to benzodiazepines and other pharmacological alternatives in the acute drug treatment paradigm for SAD, as well as others anxiety disorders.

About PH10

PH10 is an innovative odorless investigational synthetic neuroactive nasal spray designed to have rapid onset and therapeutic potential in several neuropsychiatric indications involving depression and suicidal ideation. Following successfully completed exploratory Phase 2A clinical development, VistaGen is preparing for Phase 2B clinical development of PH10 as a potential stand-alone, rapid-onset treatment for major depressive disorder (MDD).

About VistaGen

VistaGen Therapeutics, Inc. is a clinical-stage 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 three 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 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 clinical development and commercialization of PH94B for anxiety disorders and PH10 for depression disorders. 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: development and approval of PH94B and PH10 may not be achieved in any market; the FDA may decide that the results of the Company's PH94B and PH10 clinical programs are not sufficient for regulatory approval for acute treatment of anxiety in adult patients with SAD or MDD, respectively, or any other anxiety- or depression-related disorder; development of PH94B and PH10 may not be successful in any indication; success in nonclinical studies or in earlier-stage clinical trials may not be repeated or observed in future studies, which may not support further development or be sufficient to gain regulatory approval to market PH94B or PH10; 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, including risks related to the COVID-19 pandemic, which may include, but are not limited to, unavailability of or delays in delivery of raw materials for manufacture of PH94B or PH10; inadequate and/or untimely supply of PH94B or PH10 to meet demand; entry of competitive products; and other technical and unexpected hurdles in the development, manufacture and commercialization of PH94B and PH10, as well as those risks more fully discussed in the section entitled "Risk Factors" in VistaGen's Annual Report on Form 10-K for the year ended March 31, 2020, and in its most recent Quarterly Report on Form 10-Q for the quarter and six months ended September 30, 2020, as well as discussions of potential risks, uncertainties, and other important factors in the Company's 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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