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): February 20, 2020

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 February 20, 2020, VistaGen Therapeutics, Inc. (the "*Company*") announced positive results from a newly published exploratory Phase 2a clinical study of PH10, the Company's investigational first-in-class, rapid-onset synthetic neurosteroid nasal spray, for treatment of major depressive disorder. Results of the double-blind, randomized, placebo-controlled Phase 2a study have been published in the peer-reviewed British Journal of Pharmaceutical and Medical Research. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1.

Item 9.01. Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release issued by VistaGen Therapeutics, Inc., dated February 20, 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: February 20, 2020

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

Exhibit 99.1

VistaGen Announces Positive Results of Newly Published Exploratory Phase 2a Study of PH10 for Rapid-Onset Treatment of Major Depressive Disorder

PH10, a Neurosteroid Nasal Spray, Demonstrated Significant Rapid-Onset Antidepressive Benefit versus Placebo, without Psychological Side Effects or Safety Concerns Often Associated with Ketamine-based Therapy

SOUTH SAN FRANCISCO, Calif., February 20, 2020 – VistaGen Therapeutics (NASDAQ: VTGN), a clinical-stage biopharmaceutical company developing new generation medicines for central nervous system (CNS) diseases and disorders with high unmet medical need, today announced positive results from a newly published exploratory Phase 2a clinical study of PH10, its investigational first-in-class, rapid-onset synthetic neurosteroid nasal spray, for treatment of major depressive disorder (MDD). Results of the double-blind, randomized, placebo-controlled Phase 2a study have been published in the peer-reviewed *British Journal of Pharmaceutical and Medical Research*.

In the single-site exploratory Phase 2a study (n=30), randomized participants received placebo or either a 3.2 µg or a 6.4 µg dose of PH10 neuroactive nasal spray twice daily for eight weeks. Change in total score on the 17-item Hamilton Depression Rating Scale (HAM-D-17), a multiple-item questionnaire used to provide an indication of depression as a guide to evaluate recovery, was measured at the end of each week of treatment. A rapid antidepressant benefit from the PH10 6.4 µg dose was evidenced by changes in HAM-D-17 scores at the end of the first week of treatment. After one week of treatment, the mean reduction of HAM-D-17 scores for the PH10 6.4 µg group was 10.1 points, which was statistically greater ($p = 0.03$) than the mean reduction in the placebo group of 4.2 points from baseline. Also, at the end of the last week of treatment (Week 8), the PH10 6.4 µg group showed a mean HAM-D-17 score reduction of 17.8, which was statistically greater than the mean reduction in the placebo group of 10.9 points from baseline ($p = 0.02$). Thus, in the PH10 6.4 µg treatment group, the HAM-D-17 score improved significantly from the baseline within one week and this effect was sustained until the Week 8 study endpoint. Notably, both the PH10 3.2 µg and 6.4 µg treatment groups showed strong effect sizes after one week of treatment (0.72 for the 3.2µg dose and 1.01 for the 6.4 µg dose) and at the Week 8 study endpoint (0.74 for the 3.2µg dose and 0.95 for the 6.4 µg dose).

There were no reports of serious adverse events. At the end of treatment, all subjects reported to have tolerated twice daily self-administration. The results of this peer-reviewed published study suggest PH10's potential as a non-systemic, rapid-onset, new generation antidepressant for the millions of people suffering from depression around the world. VistaGen is currently preparing for Phase 2b clinical development of PH10 in the U.S. for treatment of MDD.

"The results of this exploratory Phase 2a clinical study demonstrate PH10's exciting potential to treat patients with MDD with a first-in-class, non-systemic, rapid-onset antidepressant without the serious psychological side effects and safety concerns of ketamine-based therapy. The large separation from placebo seen at one week, the first time point measured, and sustained through eight-week completion is very encouraging. The significant reduction in HAM-D-17 with the 6.4 µg dose at the end of the first week of treatment suggests that the antidepressant effect of PH10 may have started even earlier than 1 week. Our plan for Phase 2b development of PH10 in MDD includes a next-step study of four weeks in duration, with an earlier initial measurement of antidepressant effect, likely within the first 24 to 48 hours of initial dose administration," stated Mark Smith, M.D., Ph.D., Chief Medical Officer of VistaGen.

"Depression remains a highly prevalent and difficult to treat mental illness, but we believe these data suggest a new path forward in providing treatment for the millions of individuals with MDD. The significant reduction in HAM-D-17 scores for the PH10 6.4 µg group versus the placebo group not only offers evidence of PH10's potential to be a fast-acting, easily administered MDD treatment alternative, but also supports the nasal chemosensory system as a novel way of delivering CNS active medications, which is also relevant for VistaGen's other neuroactive nasal spray, PH94B for social anxiety disorder entering Phase 3 development later this year," added Dr. Smith.

About VistaGen
VistaGen Therapeutics is a multi-asset, clinical-stage biopharmaceutical company developing new generation medicines for CNS diseases and disorders where current treatments are inadequate, resulting in high unmet need. VistaGen's pipeline is focused on clinical-stage CNS drug candidates with a differentiated mechanism of action, an exceptional safety profile, and therapeutic potential in multiple large and growing CNS markets. For more information, please visit www.vistagen.com and connect with VistaGen on Twitter, LinkedIn and Facebook.

About PH10
PH10 is an investigational first-in-class, odorless, fast-acting synthetic neurosteroid with therapeutic potential in a wide range of neuropsychiatric indications involving depression and suicidal ideation. VistaGen is initially developing PH10 as a potential fast-acting, non-sedating, non-addictive new generation treatment of MDD that can be conveniently self-administered at home. Upon self-administration, a non-systemic microgram-level dose of PH10 sprayed into the nose binds to nasal chemosensory receptors that, in turn, activate neural circuits in the brain that lead to rapid-onset antidepressant effects, without side effects, systemic exposure or safety concerns that may be caused by FDA-approved drug treatments for MDD, including oral antidepressants and esketamine. Following successfully completed Phase 2a development for MDD,VistaGen is now preparing for planned Phase 2b clinical development of PH10 for MDD.

Forward-Looking Statements
This release contains various statements concerning VistaGen's future expectations, plans and prospects, including without limitation, our expectations regarding development and commercialization of our drug candidate PH10 for MDD and multiple additional depression-related disorders and suicidal ideation. In addition, statements concerning the Company's future expectations may include statements regarding intellectual property and commercial protection of each of our drug candidates. Each of these statements constitute forward-looking statements for the purposes of the safe harbor provisions under the Private Securities Litigation Reform Act of 1995. These forward-looking statements are neither promises nor guarantees of future performance and are subject to a variety of risks and uncertainties, many of which are beyond our control, and may cause actual results to differ materially from those contemplated in these forward-looking statements. Those risks include the following: (i) we may encounter unexpected adverse events in patients during our clinical development of any product candidate that cause us to discontinue further development; (ii) we may not be able to successfully demonstrate the safety and efficacy of our product candidates at each stage of clinical development; (iii) success in preclinical studies or in early-stage clinical studies may not be repeated or observed future studies, and ongoing or future preclinical and clinical results may not support further development of, or be sufficient to gain regulatory approval to market any of our product candidates; (iv) decisions or actions of regulatory agencies may negatively affect the progress of, and our ability to proceed with, further clinical studies or to obtain marketing approval for our drug candidates; (v) we may not be able to obtain or maintain adequate intellectual property protection and other forms of marketing and data exclusivity for our product candidates; (vi) we may not have access to or be able to secure substantial additional capital to support our operations, including our ongoing nonclinical and clinical development activities; and (vii) we may encounter technical and other unexpected hurdles in the manufacturing and development of any of our product candidates. Certain other risks are more fully discussed in the section entitled "Risk Factors" in our most recent annual report on Form 10-K, and subsequent quarterly reports on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in our other filings with the Securities and Exchange Commission (SEC). Our SEC filings are available on the SEC's website at www.sec.gov. In addition, any forward-looking statements represent our views only as of the issuance of this release and should not be relied upon as representing our views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.

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