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): November 14, 2019

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 7.01. Regulation FD Disclosure.

On November 14, 2019, VistaGen Therapeutics, Inc. (the "*Company*") announced topline results from the ELEVATE study, a Phase 2 study of AV-101, the Company's NMDA (N-methyl-D-aspartate) receptor glycine site antagonist, as an adjunctive treatment of major depressive disorder. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1.

The information in Item 7.01 of this Current Report on Form 8-K, including the information set forth in Exhibit 99.1, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "*Exchange Act*"), nor shall Exhibit 99.1 filed herewith be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Exhibits.

See Exhibit Index.

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: November 14, 2019

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release issued by VistaGen Therapeutics, Inc., dated November 14, 2019.

VistaGen Reports Topline Phase 2 Results for AV-101 as an Adjunctive Treatment of Major Depressive Disorder

SOUTH SAN FRANCISCO, Calif., November 14, 2019 – VistaGen Therapeutics (NASDAQ: VTGN), a clinical-stage biopharmaceutical company developing new generation medicines for central nervous system (CNS) diseases and disorders with high unmet need, today announced topline results from the ELEVATE study, a Phase 2 study of AV-101, its NMDA (N-methyl-D-aspartate) receptor glycine site antagonist, as an adjunctive treatment of major depressive disorder (MDD). In this study, the AV-101 treatment arm did not differentiate from placebo on the primary endpoint (change in the Montgomery-Åsberg Depression Rating Scale (MADRS-10) total score compared to baseline). As in prior clinical studies, AV-101 was well tolerated, with no psychotomimetic side effects or serious adverse events.

"While we are disappointed with the topline results of the study, it is possible that efficacy may have been compromised by either insufficient transport of AV-101 across the blood brain barrier or subsequent inadequate concentrations of its active metabolite, 7-Cl-KYNA, in the brain. We will continue to examine the full dataset from this study to evaluate effects on other endpoints and pharmacokinetics, as well as consider both the upcoming results from a target engagement study and the potential impact of compelling new evidence from recent preclinical studies demonstrating substantial concentration increases of AV-101 (approximately a 7-fold increase) and 7-Cl-KYNA (approximately a 35-fold increase) in the brain in rodent studies when AV-101 is administered in combination with probenecid, an FDA-approved anion transport inhibitor used adjunctively with numerous well-established medications to enhance efficacy," said Shawn Singh, Chief Executive Officer of VistaGen.

"The rigorous conduct of the study makes us confident that AV-101, at the concentrations used, was not effective, but will also allow us to interrogate the database without the confound of excessive placebo responses. There is a clear need for new and safe agents that can be used for augmentation among depressed patients with inadequate response to antidepressant therapies," said Dr. Maurizio Fava, Psychiatrist-in-Chief of Massachusetts General Hospital.

"We remain excited by and focused on continued execution of our Phase 3 program for PH94B in social anxiety disorder and our Phase 2 program for PH10 in major depressive disorder," added Mr. Singh. "Each of these first-in-class compounds is further along in development than AV-101, as they have already demonstrated clinical proof of concept in Phase 2 studies, and, thus, in 2020, we will be proceeding into Phase 3 and Phase 2b studies, respectively. During 2020, we also will review the total body of preclinical and clinical work on AV-101, across all indications (depression, epilepsy, levodopa-induced dyskinesia, neuropathic pain and suicidal ideation), as well as additional preclinical studies involving AV-101 and probenecid, and then determine the most appropriate path forward for potential clinical development of AV-101. We deeply appreciate the patients, their caregivers, and the investigators who supported the ELEVATE study, including Dr. Fava as principal investigator. Our determination to develop safe, life-changing new generation medications for mental health disorders and neurological conditions with high unmet need remains firm and unchanged."

Study Overview

The ELEVATE study was a Phase 2, double-blind, placebo-controlled, multi-center, sequential parallel comparison design (SPCD) study that evaluated the safety, tolerability, and efficacy of AV-101 as an adjunctive treatment in patients with MDD who had an inadequate response to a stable dose of standard antidepressant therapy (either a selective serotonin reuptake inhibitor (SSRI) or a serotonin norepinephrine reuptake inhibitor (SNRI)). The study randomized 199 patients across 25 clinical research centers in the United States. Consistent with the SPCD, the study was conducted in two, two-week sequential stages. Eligible subjects continued receiving their SSRI or SNRI antidepressant at a stable dose for the duration of the study. Patients were randomly assigned (1:3) to AV-101 1440 mg/day or placebo in Stage 1. Placebo non-responders (defined as a < 50% reduction from baseline in MADRS-10 total score at the end of Stage 1) were re-randomized (1:1) in Stage 2 to receive AV-101 1440 mg/day or placebo for 2 weeks. The primary efficacy endpoint was the absolute change from baseline to end of treatment in the MADRS-10 score of AV-101 compared to placebo, both in combination with ongoing therapy with an SSRI or SNRI. Treatment differences from Stage 1 and Stage 2 were combined as weighted averages.

About VistaGen

VistaGen Therapeutics is a 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 in all clinical studies to date, 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.

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 three drug candidates: (i) AV-101 for MDD, neuropathic pain, epilepsy, dyskinesia associated with levodopa therapy for Parkinson's disease and suicidal ideation; (ii) PH94B for social anxiety disorder and other anxiety disorders; and (iii) PH10 for MDD. In addition, statements concerning the Company's future expectations may include statements regarding intellectual property and commercial protection 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 trials 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 AV-101, PH94B, and/or PH10; (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 preclinical 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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