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): January 30, 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 3.01 Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing.

On January 31, 2020, VistaGen Therapeutics, Inc. (the "*Company*") received a letter from the Listing Qualifications Staff of The Nasdaq Stock Market, LLC ("*Nasdaq*") indicating that, based upon the closing bid price of the Company's common stock, par value $0.001 per share ("*Common Stock*"), for the last 30 consecutive business days, the Company is not currently in compliance with the requirement to maintain a minimum bid price of $1.00 per share for continued listing on the Nasdaq Capital Market, as set forth in Nasdaq Listing Rule 5550(a)(2) (the "*Notice*").

The Notice has no immediate effect on the continued listing status of the Company's Common Stock on the Nasdaq Capital Market, and, therefore, the Company's listing remains fully effective.

The Company is provided a compliance period of 180 calendar days from the date of the Notice, or until July 29, 2020, to regain compliance with the minimum closing bid requirement, pursuant to Nasdaq Listing Rule 5810(c)(3)(A). If at any time before July 29, 2020, the closing bid price of the Company's Common Stock closes at or above $1.00 per share for 10 consecutive business days, Nasdaq will provide written notification that the Company has achieved compliance with the minimum bid price requirement, and the matter would be resolved. If the Company does not regain compliance during the compliance period ending July 29, 2020, then Nasdaq may grant the Company a second 180 calendar day period to regain compliance, provided the Company (i) meets the continued listing requirement for market value of publicly-held shares and all other initial listing standards for the Nasdaq Capital Market, other than the minimum closing bid price requirement and (ii) notifies Nasdaq of its intent to cure the deficiency.

The Company will continue to monitor the closing bid price of its Common Stock and seek to regain compliance with all applicable Nasdaq requirements within the allotted compliance periods. If the Company does not regain compliance within the allotted compliance periods, including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that the Company's Common Stock will be subject to delisting. The Company would then be entitled to appeal that determination to a Nasdaq hearings panel. There can be no assurance that the Company will regain compliance with the minimum bid price requirement during the 180-day compliance period, secure a second period of 180 days to regain compliance or maintain compliance with the other Nasdaq listing requirements.

Item 8.01. Other Events.

On January 30, 2019, the Company announced that its Investigational New Drug application for AV-101, the Company's oral NMDAR (N-methyl-D-aspartate receptor) glycine site antagonist, as a potential treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy has been cleared by the U.S. Food and Drug Administration. The Company also announced that it has received a notice of allowance from the U.S. Patent and Trademark Office for a new AV-101 U.S. Patent for treatment of dyskinesia induced by the administration of levodopa. 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 January 30, 2019.

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: January 31, 2020

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

Exhibit 99.1

VistaGen Therapeutics Receives FDA Clearance of IND for Phase 2 Clinical Study of AV-101 as a Potential Treatment of Dyskinesia in Parkinson's Disease Patients

Company also Receives a Notice of Allowance from the USPTO for a New AV-101 U.S. Patent for Treatment of Dyskinesia Induced by Levodopa Therapy

SOUTH SAN FRANCISCO, Calif., January 30, 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 that its Investigational New Drug (IND) application for AV-101, the Company's oral NMDAR (N-methyl-D-aspartate receptor) glycine site antagonist, as a potential treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy has been cleared by the U.S. Food and Drug Administration (FDA). The FDA's IND clearance permits VistaGen to proceed with Phase 2 clinical development of AV-101 in this indication. The Company also announced that the U.S. Patent and Trademark Office (USPTO) has issued a Notice of Allowance for U.S. Patent Application 16/003,816 related to therapeutic use of AV-101 for treatment of dyskinesia induced by the administration of levodopa. The patent, once issued, will be in effect until at least 2034.

"Current drug treatment options for levodopa-induced dyskinesia, or LID, may cause serious side effects, including hallucinations and sedation. In all clinical studies to date, AV-101 has not been associated with any psychotomimetic side effects or drug-related serious adverse events. With its exceptional safety profile, recently successful preclinical studies in the leading primate model for LID, and the successful Phase 1b NMDAR target engagement clinical study conducted by Baylor College of Medicine in healthy volunteer U.S. military Veterans, we are excited by AV-101's potential as a novel therapy for LID," said Shawn Singh, Chief Executive Officer of VistaGen. "These are important milestones for our AV-101 program, both a key regulatory advance and expanded commercial protection for AV-101 in the U.S. market."

AV-101 Preclinical Data in LID

In November 2019, at the *7th International Conference on Parkinson's and Movement Disorders in London*, Dr. Thérèse Di Paolo, Professor in the Faculty of Pharmacy at Laval University and among the world's leading researchers focused on Parkinson's disease and LID, presented preclinical data involving AV-101 in the "gold standard" MPTP non-human primate model for reproducing motor complications of Parkinson's disease, including dyskinesia observed in Parkinson's disease patients treated with levodopa. In the MPTP primate model, the antidyskinetic activity of AV-101 compared favorably with prior observations with amantadine in parkinsonian monkeys. However, better than amantadine, with its known side effects (in humans with Parkinson's disease and in parkinsonian monkeys), no adverse effects with AV-101 were observed. In the study, AV-101's efficacy against LID was measured through behavioral scores on a dyskinesia scale, and a parkinsonian disability scale was used to measure levodopa antiparkinsonian efficacy. Importantly, this study demonstrated that AV-101 significantly ($p = 0.01$) reduced LID without affecting the timing, extent, or duration of the therapeutic benefits of levodopa.

About Parkinson's Disease and LID

Parkinson's disease is the second most common neurodegenerative disease worldwide, affecting approximately one million people in the U.S. and ten million people worldwide, according to the Parkinson's Foundation. There is no "one-size-fits-all" description of Parkinson's disease. Rather, it is a complex neurodegenerative disorder that occurs when brain cells that make dopamine, a chemical that coordinates movement, stop working or die, resulting in progressive deterioration of voluntary motor control. Classic motor symptoms of Parkinson's disease include muscular rigidity, resting tremor, and postural and gait impairment. Typically, patients with Parkinson's disease present with a combination of motor and non-motor symptoms. Non-motor symptoms may include cognitive impairment, sleep disorders, pain and fatigue. There is currently no medication to slow, delay, stop or cure Parkinson's disease, and currently available treatments are symptomatic. Treatment of motor symptoms with oral levodopa, introduced about 50 years ago, remains the "gold standard" treatment.

Dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy is a disorder that is characterized by unpredictable, involuntary and purposeless movements after continuous long-term use (often longer than five years). Although clinical manifestations of LID are heterogenous, these motor complications tend to become more severe as a patient's Parkinson's disease progresses and as the duration of levodopa treatment is extended, until the impact of LID may compromise the advantage of treatment with levodopa. Once LID develops, Parkinson's disease patients treated with levodopa may be faced with a choice between immobility due to untreated and uncontrolled Parkinson's disease, or mobility with the associated dyskinesia.

About AV-101
AV-101 (4-Cl-KYN) belongs to a new generation of investigational medicines in neuropsychiatry and neurology known as NMDAR (N-methyl-D-aspartate receptor) modulators. The NMDAR is a pivotal receptor in the brain and abnormal NMDAR function is associated with numerous CNS diseases and disorders. AV-101 is an oral prodrug of 7-chloro-kynurenic acid (7-Cl-KYNA), a potent and selective full antagonist of the glycine site of the NMDAR. With its exceptional side effect and safety profile in all studies to date (no psychological side effects or safety concerns similar to those that may be caused by amantadine and ketamine), AV-101 has potential to be a new oral, at-home, non-sedating treatment for multiple large market CNS indications where current treatments are inadequate to meet high unmet patient needs. The FDA has granted Fast Track designation for development of AV-101 as both a potential adjunctive treatment for MDD and as a non-opioid treatment for neuropathic pain.

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 AV-101 for various therapeutic purposes, including dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, epilepsy, major depressive disorder, neuropathic pain 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 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; (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.

Company Contact
Mark A. McPartland
VistaGen Therapeutics Inc.
Phone: +1 (650) 577-3600
Email: IR@vistagen.com

Investor Contact
Valter Pinto / Allison Soss
KCSA Strategic Communications
Phone: +1 (212) 896-1254/+1 (212) 896-1267
Email: VistaGen@KCSA.com

Media Contact
Caitlin Kasunich / Lisa Lipson
KCSA Strategic Communications
Phone: +1 (212) 896-1241/+1 (508) 843-6428
Email: VistaGen@KCSA.com