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 16, 2022

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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

See Item 8.01 below.

Item 8.01 Other Events.

On November 17, 2022, Vistagen Therapeutics, Inc. (the "*Company*") issued a press release announcing the publication of positive results from a preclinical study of the effects of AV-101, its oral NMDA receptor glycine site antagonist, in a widely used MPTP non-human primate model for reproducing motor complications of Parkinson's disease ("*PD*"), including dyskinesia (sudden uncontrolled movements) observed in PD patients treated with levodopa ("*L-Dopa*"). Findings from the preclinical study were published in the international, peer-reviewed journal, *Cells*. In the preclinical study, AV-101 reduced L-Dopa-induced dyskinesias by about 25% while maintaining the antiparkinsonian response to L-Dopa. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1.

On November 16, 2022, Dr. Mark A. Smith notified the Company of his intention to depart from the Company as Chief Medical Officer, effective December 1, 2022. Following his departure, Dr. Smith will serve as a member of the Company's Clinical and Regulatory Advisory Board and provide consulting services to the Company regarding the development of its product candidates, including, but not limited to, PH94B, PH10 and AV-101.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits Index

Exhibit No.	Description
99.1	Press Release issued by Vistagen Therapeutics, Inc., dated November 17, 2022.
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: November 21, 2022

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

Vistagen

Vistagen Announces Publication in *Cells* Demonstrating AV-101's Potential for Treating Levodopa-Induced Dyskinesia in Patients with Parkinson's Disease

Preclinical data in "gold standard" MPTP non-human primate model of Parkinson's disease show significant reduction of levodopa-induced dyskinesia by AV-101, while maintaining antiparkinsonian activity of levodopa

SOUTH SAN FRANCISCO, Calif. – November 17, 2022 –Vistagen (NASDAQ: VTGN) a late clinical-stage biopharmaceutical company aiming to transform the treatment landscape for individuals living with anxiety, depression and other central nervous system (CNS) disorders, today announced the publication of positive results from a preclinical study of the effects of AV-101, its oral NMDA receptor glycine site antagonist, in a widely used MPTP non-human primate model for reproducing motor complications of Parkinson's disease (PD), including dyskinesia (sudden uncontrolled movements) observed in PD patients treated with levodopa (L-Dopa). Findings from the preclinical study were published in the international, peer-reviewed journal, *Cells*. In the preclinical study, AV-101 reduced L-Dopa-induced dyskinesias (LID) by about 25% while maintaining the antiparkinsonian response to L-Dopa.

"While L-Dopa remains the most effective pharmacotherapy for Parkinson's disease, the occurrence of LID is difficult to manage and drastically interferes with Parkinson's patients' quality of life. This preclinical study showed that AV-101 reduced LID with no adverse effects of treatment," stated Shawn Singh, Chief Executive Officer of Vistagen. "Dr. Di Paolo has been at the forefront of research in neuropharmacology and treatments for Parkinson's disease for decades. Her preclinical data from this study are compelling and highlight AV-101's potential to improve the treatment paradigm for LID associated with Parkinson's therapy by reducing LID while still maintaining the antiparkinsonian activity of L-Dopa."

The MPTP primate model used in this study is the "gold standard" for animal modeling of PD and has been used extensively to study both antiparkinsonian therapies and LID. MPTP is a neurotoxin that kills dopaminergic neurons in the striatum, producing motor symptoms similar to those of PD. In this 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. 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. No adverse events attributable to the drug were observed during the study. This preclinical study was conducted by Dr. Thérèse Di Paolo, Emeritus Professor in the Faculty of Pharmacy at Laval University and among the world's leading researchers focused on Parkinson's disease and LID, pursuant to Vistagen's research agreement with CHU de Québec – Université Laval Research Center in Québec, Canada.

The article is entitled "*AV-101, a Pro-Drug Antagonist at the NMDA Receptor Glycine Site, Reduces L-Dopa Induced Dyskinesias in MPTP Monkeys*," and is available online at: https://doi.org/10.3390/cells11223530

The U.S. Patent and Trademark Office (USPTO) has issued US Patent No. 10,632,091 related to therapeutic use of AV-101 for treatment of dyskinesia induced by the administration of L-Dopa. The patent will be in effect until at least 2034.

About AV-101

AV-101 (4-chlorokynurenine) is an oral prodrug of 7-chloro-kynurenic acid (7-Cl-KYNA), which is a potent and selective full antagonist of the glycine co-agonist site of the NMDA receptor (NMDAR) that inhibits certain functions of the NMDAR. Unlike ketamine and many other NMDAR antagonists, 7-Cl-KYNA is not an ion channel blocker. At doses administered in studies completed to date, AV-101 has been observed to be well tolerated and has not exhibited dissociative or hallucinogenic psychological side effects or safety concerns, unlike other modulators of the NMDAR. Based on observations and findings from preclinical studies, Vistagen believes that AV-101, alone or in combination with FDA-approved oral probenecid, has the potential to become a new oral treatment alternative for certain CNS disorders involving the NMDAR. Vistagen is presently conducting an exploratory Phase 1B drug-drug interaction clinical study of AV-101 in combination with probenecid. The FDA has granted Fast Track designation for development of AV-101 as a potential adjunctive treatment for MDD and as a non-opioid treatment for neuropathic pain.

About Vistagen

Vistagen (Nasdaq: VTGN) is a late clinical-stage CNS-focused biopharmaceutical company aiming to transform the treatment landscape for individuals living with anxiety, depression and other CNS disorders. The Company is advancing therapeutics with the potential to be faster-acting, and with fewer side effects and safety concerns, than those that are currently available. Vistagen's clinical-stage candidates are targeting multiple forms of anxiety and depression. PH94B and PH10 belong to a new class of drugs known as pherines, which are odorless and tasteless investigational neuroactive steroids designed with a novel rapid-onset mechanism of action that activates chemosensory neurons in the nasal passages and can impact the olfactory-amygdala neural circuits without systemic uptake or direct activity on CNS neurons in the brain. Vistagen is passionate about transforming mental health care and redefining what is possible in the treatment of anxiety and depression. Connect at www.Vistagen.com.

Forward Looking Statements

This press release contains certain forward-looking statements within the meaning of the federal securities laws. These forward-looking statements involve known and unknown risks that are difficult to predict and include all matters that are not historical facts. In some cases, you can identify forward-looking statements by the use of words such as "may," "could," "expect," "project," "outlook," "strategy," "intend," "plan," "seek," "anticipate," "believe," "estimate," "predict," "potential," "strive," "goal," "continue," "likely," "will," "would" and variations of these terms and similar expressions, or the negative of these terms or similar expressions. Such forward-looking statements are necessarily based upon estimates and assumptions that, while considered reasonable by Vistagen and its management, are inherently uncertain. As with all pharmaceutical products, there are substantial risks and uncertainties in the process of development and commercialization and actual results or developments may differ materially from those projected or implied in these forward-looking statements. Among other things, there can be no guarantee that any of the Company's drug candidates will successfully complete ongoing or future clinical trials, receive regulatory approval or be commercially successful. Other factors that may cause such a difference include, without limitation, risks and uncertainties relating to development of AV-101 and the Company's other product candidates, PH94B and PH10; delays in launching, conducting and/or completing other ongoing and planned clinical trials; fluctuating costs of materials and other resources required to conduct the Company's ongoing and/or planned clinical and non-clinical trials; market conditions; the impact of general economic, industry or political conditions in the United States or internationally; and other technical and unexpected hurdles in the development, manufacture and commercialization of the Company's CNS drug candidates. These risks are more fully discussed in the section entitled "Risk Factors" in the Company's most recent Annual Report on Form 10-K for the fiscal year ended March 31, 2022 and in the Company's most recent Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, as well as discussions of potential risks, uncertainties, and other important factors in our other filings with the U.S. Securities and Exchange Commission (SEC). The Company's SEC filings are available on the SEC's website at www.sec.gov. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this press release and should not be relied upon as representing the Company's views as of any subsequent date. The Company explicitly disclaims any obligation to update any forward-looking statements, other than as may be required by law. If the Company does update one or more forward-looking statements, no inference should be made that the Company will make additional updates with respect to those or other forward-looking statements.

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