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): April 6, 2023

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 April 6, 2023, Vistagen Therapeutics, Inc. (the "*Company*") issued a press release to announce that the European Patent Office has granted the Company a patent for AV-101, its oral NMDAR (N-methyl-D-aspartate receptor) glycine site antagonist. The patent relates to the synthesis of AV-101 and certain chemical intermediaries, which synthesis yields AV-101 in commercial quantities and has the scalability for commercial manufacture. The new European patent is a counterpart to previously granted U.S. patent 11,427,530 and will be in effect until at least 2039. 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 April 6, 2023.
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: April 6, 2023

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

Vistagen

Vistagen Receives New European Patent for AV-101

SOUTH SAN FRANCISCO, Calif. – **April 6, 2023** – 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 that the European Patent Office (EPO) has granted the Company a patent for AV-101, its oral NMDAR (N-methyl-D-aspartate receptor) glycine site antagonist. The patent relates to the synthesis of AV-101 and certain chemical intermediaries, which synthesis yields AV-101 in commercial quantities and has the scalability for commercial manufacture. The new European patent is a counterpart to previously granted U.S. patent 11,427,530 and will be in effect until at least 2039. Based on observations and findings from preclinical animal models translatable to human conditions targeting the NMDAR, AV-101 has the potential to become a new oral treatment alternative for multiple CNS disorders involving the NMDAR, such as dyskinesia associated with levodopa therapy for Parkinson's disease, major depressive disorder and neuropathic pain.

"Expanding our patent portfolio for all of our product candidates is an ongoing priority to support our global development and commercialization strategies across our pipeline," said Shawn Singh, Chief Executive Officer of Vistagen. "AV-101's potential to inhibit the function of the NMDAR, without fully blocking it like other NMDAR antagonists such as ketamine, anchors our interest in developing it as an innovative therapy for millions of patients affected by CNS disorders involving the NMDAR. This new patent covering our improved and streamlined manufacturing process may result in advantages for getting AV-101 to patients, on our own or potentially with a partner."

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 N-methyl-D-aspartate 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. Preclinical studies demonstrate that AV-101 activity appears to be specific to the GlycineB site, with virtually no off-target activity in a panel of more than 50 receptor targets, including dopamine and opioid receptors, making AV-101 a potentially safer option for patients than current treatments for numerous CNS disorders involving the NMDAR. Based on observations and findings from preclinical animal models translatable to human conditions targeting the NMDAR, including dyskinesia associated with levodopa therapy for Parkinson's disease, major depressive disorder and neuropathic pain, Vistagen believes that AV-101 has the potential to become a new oral treatment alternative for one or more of such CNS disorders involving the NMDAR. At doses administered in multiple clinical studies completed to date, AV-101 has been observed to be well tolerated and has not exhibited dissociative or hallucinogenic psychological side effects. Vistagen's ongoing Phase 1B drug-drug interaction clinical study of AV-101 in combination with probenecid is intended to facilitate potential future Phase 2A clinical development, alone or in combination with probenecid, in one or more CNS disorders involving the NMDAR. The FDA has granted Fast Track designation for development of AV-101 as a potential adjunctive treatment for major depressive disorder and as a stand-alone non-opioid treatment for neuropathic pain.

Vistagen

About Vistagen
Vistagen (Nasdaq: VTGN) is a late clinical-stage 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 for treatment of anxiety, depression and multiple CNS disorders. Vistagen's pipeline includes multiple product candidates, including fasedienol and itruvone, belonging to a new class of drugs known as pherines, in addition to an oral NMDAR antagonist. Pherines, which are administered as nasal sprays, are designed with a novel rapid-onset mechanism of action that activates chemosensory neurons in the nasal passages and can beneficially impact key neural circuits in the brain 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, depression and several other CNS disorders. 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 development 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 the Company's ability to secure adequate financing for its operations, including financing or collaborative support for continued clinical development of AV-101 and/or its other product candidates; the scope and enforceability of the Company's patents; the completion and results of the Company's ongoing clinical studies of AV-101 and itruvone (PH10); other risks and uncertainties related to delays in launching, conducting and/or completing ongoing and planned clinical trials; fluctuating costs of materials and other resources and services 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 December 31, 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. Additionally, you should not place undue reliance on these forward-looking statements in the future, because they 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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