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 25, 2024

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 94080
(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 25, 2024, Vistagen Therapeutics, Inc. (the "*Company*") issued a press release to announce positive results from a previously unreported randomized, double-blind, placebo-controlled, crossover Phase 2A pilot study of PH15, the Company's investigational pherine nasal spray, for improvement of psychomotor impairment caused by mental fatigue. PH15 demonstrated a statistically significant improvement in reaction time compared to placebo and caffeine in sleep-deprived study participants. 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 25, 2024.
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 25, 2024

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

Vistagen

Vistagen Announces Positive Results from Phase 2A Pilot Study of PH15 for Improvement of Psychomotor Impairment Caused by Mental Fatigue

PH15 nasal spray demonstrates statistically significant efficacy versus placebo and caffeine in a placebo-controlled Phase 2A pilot study in sleep-deprived participants

PH15 was safe and well-tolerated with an adverse event profile similar to placebo

SOUTH SAN FRANCISCO, Calif., April 25, 2024 – Vistagen (Nasdaq: VTGN), a biopharmaceutical company pioneering neuroscience to deliver groundbreaking therapies for individuals affected by psychiatric and neurological disorders, today announced positive results from a Phase 2A pilot study of PH15, an investigational pherine nasal spray, for improvement of psychomotor impairment caused by mental fatigue. PH15 demonstrated a statistically significant improvement in reaction time compared to placebo and caffeine in sleep-deprived study participants.

The previously unreported randomized, double-blind, placebo-controlled, crossover Phase 2A pilot study of PH15 was designed to explore the efficacy, safety, and tolerability of intranasal administration of PH15 on psychomotor performance as measured by reaction time in sleep-deprived participants. Ten participants were randomly administered PH15 (multiple 1.6 µg doses, total dose of 9.6 µg), placebo (nasal spray and oral), or caffeine (single 400 mg oral dose administered 1 hour before the session) in sequential sleep deprivation study sessions spaced one week apart. During each sleep deprivation session, participants received blinded treatments before the start of each of four testing periods, at 6:00 p.m., 9:00 p.m., midnight, and 3:00 a.m. The participants' reaction times to both isochronous (regular interval) and stochastic (random interval) "flash" light stimuli were computer-measured during each testing period as participants responded to the luminous stimuli.

Statistically Significant Efficacy
During both isochronous and stochastic reaction time tests, administration of 1.6 µg PH15 nasal spray induced a significantly faster mean reaction time compared to placebo nasal spray across all time points ($p<0.001$). PH15 also demonstrated a statistically significant improvement in reaction time compared to oral caffeine ($p<0.001$) for both reaction time tests during the testing periods at midnight and 3:00 a.m. when subjects were most fatigued.

Well-tolerated Therapy
PH15 was well-tolerated with no serious adverse events reported. The adverse event profiles of PH15 and placebo were comparable, with brief nasal itching in one PH15-dosed participant and three placebo-dosed subjects. Participants on oral caffeine, however, experienced palpitations, euphoria, dry mouth, stomachache, and polyuria.

"In this Phase 2A pilot study, PH15 nasal spray demonstrated significant improvement in reaction time when compared to both oral caffeine and placebo in sleep-deprived participants. These pilot findings contribute to our confidence in PH15's potential as an innovative treatment for enhancing psychomotor performance and potentially cognitive impairment, particularly in addressing the challenges of mental fatigue," said Shawn Singh, Chief Executive Officer of Vistagen. "Numerous disorders, such as shift work disorder, sleep apnea, and narcolepsy, can lead to debilitating sleep deprivation and mental fatigue. Individuals affected by these disorders require improved treatment options with a differentiated safety profile, one without the potential for abuse liability or negative and treatment-limiting side effects and safety concerns. We anticipate exploring PH15's potential to emerge as a new and transformative solution for these underserved individuals."

Vistagen

This previously unreported Phase 2A pilot study of PH15 was sponsored by Pherin Pharmaceuticals (Pherin), now a wholly owned subsidiary of Vistagen, and conducted at the National Institute of Psychiatry, Sleep Disorders Clinic in Mexico City, Mexico in 2011. Vistagen gained access to the results of this study in connection with its acquisition of Pherin in February 2023. The late Jose Maria Calvo, MD, formerly Associate Professor, National Institute of Psychiatry in Mexico City, served as the Principal Investigator of the study.

About Pherines

Pherines are novel neurocircuitry-focused drug candidates delivered intranasally for treatment of psychiatric and neurological disorders. The proposed mechanisms of action (MOAs) of pherines are fundamentally differentiated from the MOAs of all approved drugs, offering a new standard of care for multiple central nervous system (CNS) disorders. Their effect on the CNS is through the activation of nasal chemosensory receptors, which send signals through neural circuitry to specific brain regions. The novel nose-to-brain MOAs of pherines offer the potential to deliver meaningful, rapid-onset efficacy and a differentiated safety profile, without systemic absorption or CNS uptake. All of the five pherines in Vistagen's clinical-stage neuroscience pipeline have demonstrated a favorable safety profile in clinical trials completed to date.

About PH15

PH15 is an odorless, tasteless synthetic investigational pherine with a novel, rapid-onset proposed mechanism of action (MOA) that is fundamentally differentiated from the MOA of all currently approved treatments to improve psychomotor or cognitive impairment caused by mental fatigue. PH15's proposed MOA targets nasal receptors that activate olfactory-amygdala and olfactory hippocampus neural circuits in the limbic system that are known to be associated with psychomotor activity and cognition, without requiring systemic absorption or direct action on neurons in the brain. PH15 has demonstrated an excellent safety profile in all clinical trials completed to date. Vistagen is currently evaluating the potential Phase 2 development path forward for PH15 and a nonclinical program required to support a U.S. Investigational New Drug application to facilitate further Phase 2 development of PH15 in the U.S.

About Vistagen

Vistagen (Nasdaq: VTGN) is a biopharmaceutical company pioneering neuroscience to deliver groundbreaking therapies for individuals affected by psychiatric and neurological disorders. Five of Vistagen's clinical-stage neuroscience pipeline candidates belong to a new class of drugs known as pherines, which are investigational neuroactive nasal sprays with innovative proposed mechanisms of action that activate chemosensory neurons in the nasal passages to impact fundamental neural circuitry in the brain without the need for systemic absorption or binding to receptors in the brain. Vistagen's sixth investigational candidate is an oral prodrug with potential to modulate NMDA receptor activity. At Vistagen, we are passionate about delivering differentiated treatments that set new standards of care for people living with anxiety, depression, and other neurological disorders. Connect at www.Vistagen.com.

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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, or that the Company will be able to successfully replicate the result of past studies of any of its product candidates, including PH15. Other factors that may cause such a difference include, without limitation, risks and uncertainties related to delays in launching, conducting and/or completing nonclinical programs for any of the Company's drug candidates, including PH15; launching, conducting and/or completing ongoing and future clinical trials for any of the Company's drug candidates; the scope and enforceability of the Company's patents; the Company's ability to secure adequate financing for clinical development of certain of its drug candidates; fluctuating costs of materials and other resources and services required to conduct the Company's ongoing and/or future clinical and nonclinical 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 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, 2023, and in the Company's most recent Quarterly Report on Form 10-Q for the quarter ended December 31, 2023, 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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