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 22, 2026

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 22, 2026, Vistagen Therapeutics, Inc. (the "*Company*") issued a press release to announce that the Company has received a "Study May Proceed" letter from the U.S. Food and Drug Administration ("*FDA*") under its U.S. Investigational New Drug application for refisolone nasal spray, the Company's non-hormonal, non-systemic product candidate in Phase 2 development for treatment of moderate to severe vasomotor symptoms (also known as "hot flashes") due to menopause.

The FDA's Study May Proceed letter enables the Company to pursue further Phase 2 clinical development of refisolone in the U.S., building on successful exploratory Phase 2a clinical studies for the treatment of menopausal hot flashes and premenstrual dysphoric disorder previously conducted in Mexico. 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 22, 2026
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 28, 2026

By: */s/ Shawn K. Singh*

Shawn K. Singh
President and Chief Executive Officer

Exhibit 99.1

Vistagen

Vistagen Receives FDA "Study May Proceed" Letter Under its Refisolone IND Application, Enabling Further Phase 2 Clinical Development for the Treatment of Vasomotor Symptoms (Hot Flashes) due to Menopause

SOUTH SAN FRANCISCO, Calif. – April 22, 2026 – Vistagen (Nasdaq: VTGN), a late clinical-stage biopharmaceutical company pioneering neuroscience with nose-to-brain neurocircuitry to develop and commercialize a new class of intranasal product candidates called pherines, today announced receipt of a "Study May Proceed" letter from the U.S. Food and Drug Administration (FDA) under its U.S. Investigational New Drug (IND) application for refisolone nasal spray, the Company's non-hormonal, non-systemic product candidate in Phase 2 development for treatment of moderate to severe vasomotor symptoms (VMS) (also known as "hot flashes") due to menopause. The FDA's Study May Proceed letter enables the Company to pursue further Phase 2 clinical development of refisolone in the U.S. for a large unmet need in women's health, building on successful exploratory Phase 2a clinical studies for the treatment of menopausal hot flashes and premenstrual dysphoric disorder conducted in Mexico.

"This regulatory milestone marks another important step forward in our women's health program for refisolone. Approximately 75% of all women in America experience hot flashes during their menopausal transition, yet there is a critical need for new treatment options," said Shawn Singh, President and Chief Executive Officer of Vistagen. "As demonstrated in exploratory Phase 2a clinical data, refisolone has the potential to advance women's health and bring a fast-acting, non-hormonal treatment option for millions of women seeking relief from menopausal hot flashes."

In an exploratory randomized (N=36), double-blind, placebo-controlled Phase 2a clinical study in VMS (hot flashes) due to menopause in menopausal women with eight (8) or more daily hot flashes, refisolone was administered intranasally at a 3.2 µg dose as needed up to five (5) times daily for four (4) weeks. Refisolone (n=18) demonstrated statistically significant improvements versus placebo (n=18) in both the frequency and severity of daily menopausal hot flashes, with hot flash frequency reduced by 80% in refisolone-treated patients compared to 36% in the placebo group. The reduction in the frequency of hot flashes was observed as early as one (1) week ($p < .001$) in the refisolone population. Refisolone was well-tolerated in the study, with no serious drug-related adverse events. The exploratory Phase 2a study was conducted in Mexico by Pherin Pharmaceuticals, now a wholly owned subsidiary of Vistagen.

About Refisolone Nasal Spray
Refisolone (PH80) nasal spray is a clinical-stage investigational pherine with a novel proposed mechanism of action and potential to treat multiple women's health disorders. Refisolone is fundamentally differentiated from other investigational product candidates, as well as the FDA-approved treatments, for moderate to severe vasomotor symptoms (hot flashes) due to menopause. It is designed as a potential on-demand, fast-acting, non-hormonal, and non-systemically absorbed treatment, potentially without certain drug-related adverse events or hormone-related safety signals associated with current FDA-approved treatment options. Refisolone is administered intranasally at microgram-level doses to rapidly activate chemosensory neurons in the nasal cavity, which engage olfactory–limbic and olfactory–hypothalamic pathways that modulate anxiety and thermoregulatory neural circuits.

About Vistagen
Vistagen (Nasdaq: VTGN) is a late clinical-stage biopharmaceutical company leveraging a deep understanding of nose-to-brain neurocircuitry to develop and commercialize a new class of rapid-onset neurocircuitry-focused intranasal product candidates called pherines. Vistagen's pherine product candidates are designed to achieve therapeutic benefits without requiring absorption into the blood or uptake into the brain, giving them the potential to be a safer alternative to other pharmacological options, if successfully developed and approved. Vistagen's pherine pipeline currently consists of five clinical-stage investigational product candidates focused on improving the current standard of care for multiple highly prevalent indications, including social anxiety disorder, major depressive disorder, and vasomotor symptoms (hot flashes) due to menopause. Connect at www.Vistagen.com.

Forward Looking Statements

This press release contains certain forward-looking statements within the meaning of the federal securities laws, including, without limitation, statements regarding the potential to pursue and conduct, and the intended outcome of, further Phase 2 clinical studies of refisolone for women's health conditions, including refisolone's potential as a new treatment option for moderate to severe vasomotor symptoms (hot flashes) due to menopause, and the proposed mechanism of action of refisolone and Vistagen's other pherine product candidates. 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 pursuing development and commercialization of development-stage product candidates, and actual results or developments may differ materially from those projected or implied in these forward-looking statements. There can be no guarantee that any of Vistagen's product candidates, including refisolone, will successfully complete ongoing or future clinical trials within estimated timelines or at all, receive regulatory approval or be commercially successful. Other factors that may cause such a difference include, without limitation, risks and uncertainties relating to conducting and/or completing ongoing clinical trials, as currently expected or at all; Vistagen's ability to successfully employ cash preservation measures and secure adequate financing for its operations, including financing or collaborative support for continued clinical development of refisolone and its other product candidates; Vistagen's dependence on third-party collaborators for the development, regulatory approval, and/or commercialization of its product candidates and other aspects of its business, which are outside of Vistagen's full control; risks associated with current and potential future healthcare reforms; the scope and enforceability of Vistagen's pending patent applications and patents, including some patent properties related to various methods of using refisolone to treat migraines and dysmenorrhea and other patent properties related to methods of using Vistagen's other pherine product candidates to treat various disorders; fluctuating costs of materials and other resources and services required to conduct Vistagen'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 Vistagen's product candidates. These risks and others are more fully discussed in the section entitled "Risk Factors" in Vistagen's Quarterly Report on Form 10-Q for the period ended December 31, 2025, 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). Vistagen'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 Vistagen's views as of any subsequent date. Vistagen explicitly disclaims any obligation to update any forward-looking statements other than as may be required by law. If Vistagen does update one or more forward-looking statements, no inference should be made that Vistagen will make additional updates with respect to those or other forward-looking statements.

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References

Monti, L. et. al. (2024) Refisolone PH80 Nasal Spray for Treatment of Vasomotor Symptoms (Hot Flashes) Associated with Menopause: Phase 2 Randomized, Controlled Study. The Menopause Society 2024 Annual Meeting. September 10, 2024