**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 14, 2025**

# 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 January 14, 2025, Vistagen Therapeutics, Inc. (the "*Company*") issued a press release to announce positive results from an exploratory Phase 2A study of its investigational pherine nasal spray, PH284, in cancer cachexia. In the study, PH284 demonstrated higher mean subjective feeling of hunger as compared to placebo and appeared safe and well-tolerated with an adverse event profile similar to placebo in a population compromised by terminal cancer. 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 January 14, 2025 |
| 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: January 14, 2025

By: */s/ Shawn K. Singh*

Shawn K. Singh
President and Chief Executive Officer

**EXHIBIT 99.1**

Vistagen

# Vistagen Announces Positive Results from Exploratory Phase 2A Study of PH284 in Cancer Cachexia

*PH284 nasal spray demonstrated improvements to subjective feelings of hunger in cancer patients*

*PH284 is the fifth pherine product candidate in Vistagen's neuroscience pipeline with a positive efficacy signal*

**SOUTH SAN FRANCISCO, Calif, January 14, 2025** - Vistagen (Nasdaq: VTGN), a late clinical-stage company dedicated to pioneering neuroscience based on nose-to-brain neurocircuitry, today announced positive results from an exploratory Phase 2A study of PH284 in cancer cachexia. PH284 is an investigational pherine nasal spray differentiated from all current treatments for the loss of appetite associated with chronic disorders, such as cancer. In the study, PH284 demonstrated higher mean subjective feeling of hunger as compared to placebo and appeared safe and well-tolerated with an adverse event profile similar to placebo in a population compromised by terminal cancer.

"We are highly encouraged by the potential of PH284 to improve the quality of life for those challenged by the debilitating impacts of cancer cachexia," stated Shawn Singh, President and Chief Executive Officer of Vistagen. "Loss of appetite from cancer and other illnesses not only negatively impacts overall health and quality of life, but can also reduce the effectiveness of critical therapies, such as chemotherapy in cancer patients. PH284 is our fifth novel investigational pherine, each supported by positive Phase 2 or later clinical data and placebo-like tolerability, underscoring the breadth, diversity and potential of our neuroscience pipeline to address multiple significant unmet needs."

The previously unreported double-blind, placebo-controlled exploratory Phase 2A study was designed to evaluate the efficacy, safety, and tolerability of intranasal administration of PH284 in female patients diagnosed with cachexia (induced by chronic loss of appetite) due to terminal cancer (n=40). PH284 nasal spray (0.4 µg/50 µL) was administered intranasally, one spray in each nostril (total daily dose = 3.2µg), four times daily before meals (breakfast, mid-morning snack, lunch, and dinner). From Day 1 through Day 4, all subjects were administered placebo 30 minutes prior to each meal. Beginning on Day 5 through Day 11 subjects were randomized in a 1:1 fashion to receive either PH284 or placebo.

*Efficacy*
Patients measured Subjective Feeling of Hunger (SFH) ten minutes before each meal. PH284, as compared to placebo, induced a cumulative effect on mean SFH scores, with scores increasing from breakfast to lunch and lunch to dinner throughout the treatment period. Specifically, prior to dinner on Day 7 of treatment, PH284 subjects reported a 71% improvement in SFH versus baseline, while placebo subjects reported a less than 1% improvement.

*Safety and Tolerability*
No unusual changes in body weight were observed in either the PH284 or placebo groups, though on average, there was a small gain in body weight for PH284 versus a small loss in placebo. PH284 demonstrated no serious adverse events, and adverse events reported for the PH284 group were similar to those reported in the placebo-treated group. All the adverse events reported were attributed to the

underlying medical condition (cancer) and were not deemed to be related to the administration of PH284 or placebo.

**About Cachexia**

Cachexia, also known as wasting syndrome, is a complex metabolic syndrome that causes a gradual loss of muscle and body weight. Cachexia is associated with chronic diseases like cancer, AIDS, heart failure, chronic obstructive pulmonary disease (COPD), anorexia nervosa, multiple sclerosis, tuberculosis, and anemias. The current definition of cancer cachexia is a loss of 5% or more of body weight over the preceding six months, accompanied by any of a handful of other symptoms, including fatigue and reduced strength. According to the National Cancer Institute, cachexia is estimated to occur in up to 80% of people with advanced cancer, depending on the type of cancer and how well they respond to cancer treatment. Cachexia is thought to directly cause up to 30% of cancer deaths, often because of heart or respiratory failure related to muscle loss. Maintaining nutritional support and alleviating cachexia has the potential to improve the underlying condition of cancer. Currently, there are no effective medical interventions or approved drugs proven to alleviate cachexia.

This previously unreported Phase 2A exploratory study of PH284 was sponsored by Pherin Pharmaceuticals (Pherin), now a wholly owned subsidiary of Vistagen, and conducted at the National Institute of Oncology (INCAN) and National Institute of Nutrition (INNSZ) in Mexico City, Mexico, in 2005. Vistagen gained access to the results of this study in connection with its acquisition of Pherin in February 2023. Hector Burges, MD, former Director, Institute of Nutrition; Marcos Cano Guardiana, MD, Associate Professor, National Institute of Oncology, Mexico City; and Ricardo Plancarte Sanchez, MD, Head of the Pain Clinic, Institute of Oncology, Mexico City, served as the Principal Investigators of the study.

**About PH284**

PH284 is an investigational neuroactive pherine nasal spray with a novel, rapid-onset potential mechanism of action (MOA) that is fundamentally differentiated from the MOA of all current treatments for the loss of appetite associated with chronic disorders, such as cancer or heart disease. PH284 is thought to act by regulating olfactory to mediobasal-hypothalamus neural circuits involved in appetite control. PH284 has demonstrated an excellent safety profile in all clinical trials completed to date. Vistagen is currently evaluating the potential path forward for PH284, including an assessment of completed studies and studies we believe are necessary to support a U.S. Investigational New Drug application for potential further Phase 2 clinical development of PH284 for the treatment of cachexia.

**About Vistagen**

Headquartered in South San Francisco, CA, Vistagen (Nasdaq: VTGN) is a late clinical-stage company leveraging its pioneering neuroscience and deep understanding of nose-to-brain neurocircuitry to develop and commercialize a broad and diverse pipeline of intranasal product candidates called pherines. Each pherine product candidate in Vistagen's neuroscience pipeline is designed to rapidly activate olfactory system and brain neurocircuitry to achieve desired therapeutic benefits and differentiated safety without requiring systemic absorption or binding to neurons in the brain. Vistagen's neuroscience pipeline also includes an oral prodrug, AV-101, with potential to impact certain neurological conditions involving the NMDA receptor. Vistagen is passionate about developing transformative treatment options to improve the lives of individuals underserved by the current standard of care for multiple highly prevalent disorders, including social anxiety disorder, major depressive disorder, and vasomotor symptoms (hot flashes) associated with 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. 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 timelines, results or development may differ materially from those projected or implied in these forward-looking statements. There can be no guarantee that PH284, or any of Vistagen's product candidates, will successfully replicate past clinical trials, complete ongoing or future clinical trials within the timeframe estimated by Vistagen 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 delays in launching, conducting and/or completing ongoing and planned clinical trials; the availability and scope of applicable patents; fluctuating costs of materials and other resources and services required to conduct Vistagen's ongoing and/or planned 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 Vistagen's product candidates. These risks are more fully discussed in the section entitled "Risk Factors" in Vistagen's most recent Annual Report on Form 10-K for the fiscal year ended March 31, 2024 and Quarterly Report on Form 10-Q for the period ended September 30, 2024, 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. 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 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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