



Vistagen Announces Completion of Last Patient Visit in PALISADE-4 Phase 3 Public Speaking Challenge Study of Fasedienol for Acute Treatment of Social Anxiety Disorder

May 8, 2026

Topline results for the randomized portion of PALISADE-4 are expected in the second quarter of 2026

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--May 8, 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 that the last patient has completed the last visit in the randomized, double-blind, placebo-controlled portion of PALISADE-4, the Company's Phase 3 clinical trial evaluating fasedienol nasal spray for the acute treatment of social anxiety disorder. The open label extension (OLE) portion of the PALISADE-4 study remains ongoing.

"The completion of the randomized portion of PALISADE-4 is another important step for our fasedienol Phase 3 program in social anxiety disorder, and we expect to announce topline results this quarter," said Shawn Singh, President and Chief Executive Officer. "We extend our sincere thanks to the participants, clinical investigators, site staff, and contract research organization whose hard work, collaboration, and commitment brought this portion of the study to completion."

PALISADE-4 is a U.S. multi-center, randomized, double-blind, placebo-controlled Phase 3 clinical study designed to evaluate the efficacy, safety, and tolerability of a single dose of fasedienol in reducing anxiety symptoms in adults with social anxiety disorder during a simulated anxiety-provoking public speaking challenge conducted in a clinical setting using the Subjective Units of Distress Scale (SUDS) as the primary endpoint. Participants in the randomized portion of PALISADE-4 who chose to continue with the OLE portion of the study can use fasedienol in their daily lives up to six times per day for up to twelve months.

As previously announced, Vistagen continues to analyze datasets from the randomized portions of the PALISADE-1, PALISADE-2, and PALISADE-3 Phase 3 studies for fasedienol for the acute treatment of social anxiety disorder, including with the assistance of collaborators and proprietary artificial intelligence and machine learning methodologies. Based on these analyses, Vistagen refined the statistical analysis plan (SAP) for PALISADE-4 to incorporate each participant's distress level immediately prior to dosing, as measured by the SUDS (pre-IP SUDS), into the primary efficacy analysis. While there is no guarantee the Company's refinements to the PALISADE-4 SAP will result in a positive outcome for the study, Vistagen believes the refined SAP reflects established statistical principles supporting the use of baseline covariates in randomized clinical trials consistent with U.S. Food and Drug Administration (FDA) guidance regarding adjustments for covariates (Adjusting for Covariates in Randomized Clinical Trials for Drugs and Biological Products, May 2023). The FDA has informed the Company that it has no comments on the refinements to the PALISADE-4 SAP. No changes were made to the PALISADE-4 clinical study protocol as a result of the ongoing dataset analyses or refinement of the PALISADE-4 SAP.

The FDA has granted Fast Track designation for the development of fasedienol for the acute treatment of social anxiety disorder. Vistagen believes that PALISADE-4, if successful, together with the positive results from its PALISADE-2 Phase 3 trial and further evidence Vistagen plans to generate to support the clinical meaningfulness of the duration and magnitude of effect of fasedienol, could provide substantial evidence of fasedienol's effectiveness in support of a potential New Drug Application (NDA) submission to the FDA for the acute treatment of social anxiety disorder.

About Social Anxiety Disorder

Social anxiety disorder is a highly prevalent, serious, and sometimes life-threatening psychiatric mental health disorder affecting over 30 million adults in the U.S. While often experienced on a long-term basis, social anxiety disorder can manifest acutely when triggered by anxiety-provoking social and performance situations in daily life, causing anxiety, distress, and the fear of embarrassment, judgment, and humiliation. Social anxiety disorder can also significantly disrupt social life and hinder occupational functioning, as well as increase the risk of depression and substance use disorders, suicidal ideation, and suicide.

About Fasedienol Nasal Spray for Acute Treatment of Social Anxiety Disorder

Fasedienol is Vistagen's lead neurocircuitry-focused pherine product candidate in U.S. Phase 3 clinical development for the acute treatment of anxiety in adults with social anxiety disorder. Fasedienol's proposed mechanism of action (MOA) is fundamentally differentiated from all FDA-approved anti-anxiety medications. When administered intranasally in microgram-level doses, neurocircuitry-focused fasedienol modulates the nasal-limbic amygdala fear and anxiety neurocircuits involved in the pathophysiology of social anxiety disorder. Fasedienol is pharmacologically active without requiring apparent systemic absorption or uptake into the brain to achieve its rapid-onset anxiolytic effects. Fasedienol also has no observed binding on certain cellular receptors isolated from the brain that are associated with known drug abuse liability potential (for example, dopamine and opiate receptors) when activated by certain other pharmaceutical compounds for neuropsychiatric and neurological disorders. Unlike benzodiazepines, fasedienol has no observed potentiation of GABA-A receptors. Because of its innovative non-systemic neurocircuitry-focused proposed MOA, Vistagen believes fasedienol has the potential to achieve rapid-onset anxiolytic effects for individuals with social anxiety disorder on an acute, as-needed basis, with a significantly reduced risk of unwanted side effects and safety concerns, such as potential drug-drug interactions, abuse, misuse, and addiction, associated with certain current oral and other systemically absorbed neuropsychiatric pharmaceuticals that act directly on neurons in the brain and are sometimes prescribed off-label for the acute treatment of social anxiety disorder.

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 expected timing for topline results from the randomized portion of PALISADE-4; the design of the PALISADE-4 clinical trial and its ability to evaluate the efficacy and safety of fasedienol to reduce anxiety symptoms in patients with social anxiety disorder; continued analysis of datasets from the PALISADE-1, PALISADE-2 and PALISADE-3 Phase 3 studies; the refinements to the PALISADE-4 SAP, and the ability of the refined PALISADE-4 SAP to result in a positive outcome for PALISADE-4; Vistagen's belief that the refined SAP reflects established statistical principles supporting the use of baseline covariates in randomized clinical trials and is consistent with publicly available FDA guidance; Vistagen's belief that successful results from its PALISADE Phase 3 development program, including PALISADE-4, could provide substantial evidence of fasedienol's effectiveness in support of a potential NDA submission to the FDA; fasedienol's potential to achieve rapid-onset anxiolytic effects for individuals with social anxiety disorder on an acute, as-needed basis. 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 product candidates, there are substantial risks and uncertainties in the process of development and potential commercialization, 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 pherine product candidates, including fasedienol, 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, including those that are a part of Vistagen's Phase 3 development of fasedienol in the PALISADE program, as currently expected or at all; submission of a NDA to the FDA for any of Vistagen's product candidates, including fasedienol; the ability of any clinical trial information submitted by Vistagen to the FDA to successfully support an NDA; 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 patents, including patents related to Vistagen's fasedienol and other pherine product candidates; 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 are more fully discussed in the section entitled "Risk Factors" in Vistagen's Annual Report on Form 10-K for the fiscal year ended March 31, 2025, and 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 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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