# Vistagen Announces Topline Results from PALISADE-3 Phase 3 Public Speaking Challenge Study of Fasedienol for the Acute Treatment of Social Anxiety Disorder

December 17, 2025

*Study did not demonstrate statistically significant improvement on primary endpoint of reduction in anxiety as measured by SUDS scores compared to placebo*

*Favorable safety and tolerability data were consistent with previous studies*

*Company's cash preservation measures expected to provide runway into 2027*

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Dec. 17, 2025-- 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 PALISADE-3 Phase 3 study of intranasal fasedienol for the acute treatment of social anxiety disorder did not demonstrate a statistically significant improvement on the primary endpoint of change on the Subjective Units of Distress Scale (SUDS). The trial did not achieve its primary endpoint, as measured by the least squares (LS) mean change from baseline on the Subjective Units of Distress Scale (SUDS) score for fasedienol (13.6 +/-1.54 standard error, SE) compared with placebo (14.0 +/-1.51 SE), a LS mean difference of 0.4 (p = not significant). There was no treatment difference between fasedienol and placebo for the secondary endpoints. The favorable safety data of fasedienol were consistent with previous clinical trials.

"We are disappointed by the unexpected results of this public speaking challenge trial, which are inconsistent with positive outcomes observed in Phase 2 and our PALISADE-2 Phase 3 study," said Shawn Singh, President and Chief Executive Officer of Vistagen. "We are thoroughly reviewing the results of the study, evaluating the potential impact of the results on our ongoing studies and plan to seek feedback from the FDA. In parallel, we are implementing company-wide cash preservation measures in an effort to enhance operational efficiency, provide cash runway into 2027, and maintain strategic optionality across our pherine pipeline. I'd like to thank the patients, coordinators, and investigators, as well as the development team at Vistagen, for their time and efforts in conducting this trial."

**About PALISADE-3**

PALISADE-3 is a U.S. multi-center, randomized, double-blind, placebo-controlled Phase 3 public speaking challenge study designed to evaluate the efficacy and safety of a single dose of fasedienol in reducing anxiety symptoms during a simulated public speaking challenge using the Subjective Units of Distress Scale (SUDS). PALISADE-3 subjects who choose to continue with the open label extension of the study can use fasedienol for up to twelve months in their daily lives.

**About Fasedienol**

Fasedienol is a modulator of the olfactory-limbic amygdala fear/anxiety neurocircuits. It specifically and selectively binds as an agonist on peripheral receptors on human nasal chemosensory neurons and is designed to rapidly trigger olfactory bulb-to-brain neurocircuits believed to regulate brain areas involved in behavior and autonomic nervous system activity. Fasedienol is designed to achieve therapeutic benefits without requiring absorption into the blood or uptake into the brain, giving it the potential to be a safer alternative to other pharmacological options if successfully developed and approved. Neurocircuit modulation occurs without binding to neurotransmitter receptors in the brain, giving it a differentiated tolerability profile coupled with no positive signal of abuse potential based on nonclinical data. The U.S. Food and Drug Administration (FDA) has granted Fast Track designation for the development of fasedienol 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 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 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 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 Vistagen's plans to review the results of the PALISADE-3 clinical trial and evaluate the potential impact of the results of*

*PALISADE-3 on ongoing clinical studies, Vistagen's plans to seek feedback from the FDA, the therapeutic potential of fasedienol as an acute treatment for social anxiety disorder, and Vistagen's expectation that its cash preservation measures and efforts to enhance operational efficiency will be sufficient to provide cash runway into 2027 and will maintain strategic optionality across its pherine pipeline. 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 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 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 fasedienol PALISADE Phase 3 program, as currently expected or at all; submission of a New Drug Application (NDA) to the FDA for any of Vistagen's product candidates, including fasedienol; and the ability of any clinical trial information submitted by Vistagen to the FDA to successfully support an NDA. 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 September 30, 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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