Vistagen Reports Fiscal Year 2025 Financial Results and Provides Corporate Update

June 17, 2025

Topline results of PALISADE-3 Phase 3 Trial of fasedienol for acute treatment of social anxiety disorder expected in the fourth quarter of this year

PALISADE-4 Phase 3 Trial topline results expected in the first half of 2026

Company showcases promising clinical-stage pipeline of five novel intranasal pherine candidates targeting six highly prevalent and underserved disorders

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jun. 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 reported financial results for its fiscal year ended March 31, 2025, and provided a corporate update.

"This was a defining year for Vistagen, marked by significant progress in our registration-directed PALISADE program for fasedienol in social anxiety disorder. With over 30 million U.S. adults affected by this serious and life-threatening disorder and no FDA-approved acute treatment, the need is urgent," said Shawn Singh, President and Chief Executive Officer of Vistagen. "The enthusiasm from both patients and physicians continues to motivate us as we advance toward our next significant milestone of topline data from our PALISADE-3 trial later this year. We are also continuing to advance the development of our other lead programs, itruvone for major depressive disorder and PH80 for menopausal hot flashes and additional women's health indications. With five novel pherine product candidates in our neuroscience pipeline targeting at least six high-need indications, we are energized by the road ahead and confident in our strategic position and potential to deliver meaningful value to patients and our shareholders."

Clinical-stage Neuroscience Product Candidates

Vistagen is developing a broad and diverse pipeline of five clinical-stage intranasal pherine product candidates.

Lead Program Highlights

Fasedienol for the Acute Treatment of Social Anxiety Disorder (SAD)

- The U.S. registration-directed PALISADE Program evaluating intranasal fasedienol for the acute treatment of SAD continues to progress. The PALISADE-3 Phase 3 trial remains on track for expected topline data in the fourth quarter of this year. Topline results for the PALISADE-4 Phase 3 trial are expected in the first half of 2026.
- Vistagen believes either PALISADE-3 or PALISADE-4, if successful, together with the positive results from PALISADE-2 reported in the second half of 2023, may establish substantial evidence of the effectiveness of fasedienol in support of a potential fasedienol New Drug Application (NDA) submission to the U.S. FDA for the acute treatment of SAD.
- Vistagen also continues to advance its US-registration-directed nonclinical, CMC, and human factors programs for fasedienol.
- New research presented by Vistagen at the 2025 Anxiety and Depression Association of America Conference shows that SAD, a serious and potentially life-threatening mental health disorder often associated with co-morbidities such as major depressive disorder and suicidal ideation, now affects more than 30 million U.S. adults, with rising prevalence, especially among those aged 18-22. Yet, diagnosis rates have remained stagnant, and treatment rates have decreased.

Itruvone for Major Depressive Disorder (MDD)

- Building on the positive results from a placebo-controlled exploratory Phase 2A clinical study of itruvone in MDD, Vistagen is currently planning for further Phase 2 development of itruvone under its now open U.S. Investigational New Drug Application (IND). Itruvone has the potential to be a novel, non-systemic, stand-alone treatment for MDD without the weight gain, sexual side effects, and safety concerns associated with currently available depression therapies.

PH80 for Menopausal Hot Flashes and other Women's Health Indications

- Building on the positive results from placebo-controlled exploratory Phase 2A clinical studies of PH80 in vasomotor symptoms (hot flashes) due to menopause and premenstrual dysphoric disorder (PMDD), Vistagen is currently preparing its U.S. IND to facilitate further Phase 2 clinical development of PH80 for women's health conditions.

Additional Program Highlights

- PH80 showed efficacy for the treatment of Premenstrual Dysphoric Disorder (PMDD), a condition with limited effective treatment options, in an exploratory Phase 2A trial.
- PH15 showed potential for improvement of psychomotor impairment caused by mental fatigue in a pilot Phase 2A study.

- PH284 demonstrated positive results on appetite from an exploratory Phase 2A study in cancer cachexia.

Corporate Update

Workplace Recognition

- Recognized for its workplace culture, Vistagen was awarded the highest level of recognition, the Platinum Bell Seal for Workplace Mental Health, from Mental Health America for the third consecutive year. The company was certified by Great Place To Work® for the second year in a row.

Financial Results for Fiscal Year Ended March 31, 2025

Research and development (R&D) expenses

- R&D expenses were $39.4 million and $20.0 million for the fiscal years ended March 31, 2025, and 2024, respectively. The increase in R&D expense was primarily due to an increase in research, clinical and nonclinical development, and contract manufacturing expenses and headcount related to the U.S. registration-directed PALISADE Program for fasedienol in SAD and U.S. IND-enabling program for PH80 in women's health.

General and administrative (G&A) expenses

- G&A expenses were $17.1 million and $14.1 million for the fiscal years ended March 31, 2025, and 2024, respectively. The increase in G&A expense was primarily due to an increase in headcount and consulting and professional services fees.

Net loss

- Net loss was $51.4 million for the year ended March 31, 2025, as compared to $29.4 million for the year ended March 31, 2024.

Other financial highlights

- Cash, cash equivalents and marketable securities were $80.5 million as of March 31, 2025.

Conference Call and Webcast:

Vistagen will host a conference call and live audio webcast today, June 17, 2025, at 5:00 p.m. Eastern Time to provide a corporate update of Vistagen's progress. The conference call is being webcast live, and a link can be found under "Events" in the Investors section of Vistagen's website.

Participants may register to join the live call by following the link **here** to receive the dial-in numbers and unique PIN to access the call. Those who plan on participating are advised to join 15 minutes prior to the start time. A webcast replay of the call will be available on Vistagen's website about 24 hours after the end of the live conference call and will be accessible for at least 30 days.

About Pherines

Vistagen's neuroscience pipeline currently consists of five investigational pherine product candidates, each with a novel mechanism of action (MOA) and positive clinical data in their targeted indications. Pherines are agonists on peripheral receptors in human nasal chemosensory neurons and are designed to rapidly activate nose-to-brain neurocircuits believed to regulate brain areas without requiring systemic absorption or uptake into the brain to achieve desired therapeutic benefits and differentiated safety.

About Social Anxiety Disorder

Social anxiety disorder (SAD) is a highly prevalent, serious, and sometimes life-threatening psychiatric mental health disorder affecting over 30 million adults in the U.S. With onset typically early in life, usually during adolescence, SAD persists for many years thereafter, with a reported mean duration of about 20 years. While often a long-term disorder, SAD can manifest acutely when triggered by anxiety-provoking social and performance situations during which individuals with SAD experience extreme anxiety, distress, fear, and impairment due to their feelings of embarrassment, judgment, humiliation, negative evaluation, and scrutiny. The disorder can significantly disrupt family and social life, diminish self-esteem, and hinder work performance. Anxiety associated with SAD often results in avoidance of everyday interactions and opportunities in academic, social, and vocational settings and an increased risk of serious and life-threatening co-morbid depression, substance abuse, suicidal ideation, and suicide.

About Vistagen

Headquartered in South San Francisco, CA, 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 intranasal product candidates called pherines. Pherines specifically and selectively bind as agonists on peripheral receptors on human nasal chemosensory neurons and are designed to rapidly activate olfactory bulb-to-brain neurocircuits believed to regulate brain areas involved in behavior and autonomic nervous system activity. They 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 neuroscience pipeline also includes an oral prodrug with potential to treat 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 indications, including social anxiety disorder, major depressive disorder, and multiple women's health conditions, including 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 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 will successfully complete ongoing or future clinical trials within estimated timelines or at all, receive regulatory approval or be commercially successful, or that Vistagen will be able to successfully replicate the result of past studies of any of its product candidates. Other factors that may cause such a difference include, without limitation, risks and uncertainties relating to conducting and/or completing ongoing clinical trials, including PALISADE-3 and/or PALISADE-4, as currently expected or at all; completing IND-enabling programs for applicable product candidates, including itruvone and PH80; submission of a new drug application (NDA) to the U.S. FDA for any of Vistagen's product candidate, including fasedienol; the ability of any clinical trial information submitted by Vistagen to the U.S. FDA to support a 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 and uncertainties resulting from disruptions and personnel turnover, staff reductions or otherwise, at the FDA, other government agencies and comparable foreign regulatory authorities; risks associated with current and potential future healthcare reforms; the scope and enforceability of Vistagen's patents, including patents related to Vistagen's pherine product candidates and AV-101; 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, 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.

VISTAGEN THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and par value amounts)

	March 31, 2025	2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 67,131	$ 119,166
Marketable securities	13,351	—
Prepaid expenses and other current assets	1,594	1,506
Total current assets	82,076	120,672
Property and equipment, net	476	435
Right-of-use asset - operating lease	1,335	1,820
Other assets	454	726
Total assets	$ 84,341	$ 123,653

LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 653	$ 1,547
Accrued expenses	8,810	2,235
Deferred revenue - current portion	2,588	791
Operating lease liability - current portion	561	550
Total current liabilities	12,612	5,123
Deferred revenue - non-current portion	391	2,674
Operating lease liability - non-current portion	948	1,570
Total liabilities	13,951	9,367
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at March 31, 2025 and March 31, 2024; no shares outstanding at March 31, 2025 and March 31, 2024	—	—
Common stock, $0.001 par value; 325,000,000 shares authorized at March 31, 2025 and March 31, 2024; 29,001,481 and 27,029,731 shares issued at March 31, 2025 and March 31, 2024, respectively	29	27
Additional paid-in capital	481,956	474,441
Treasury stock, at cost, 4,522 shares of common stock held at March 31, 2025 and March 31, 2024	(3,968)	(3,968)
Accumulated other comprehensive gain	5	—
Accumulated deficit	(407,632)	(356,214)
Total stockholders' equity	70,390	114,286
Total liabilities and stockholders' equity	$ 84,341	$ 123,653

VISTAGEN THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share data)

	Year Ended March 31,	
	2025	**2024**

Revenues:		
Sublicense and other revenue	$ 486	$ 1,064
Total revenues	486	1,064
Operating expenses:		
Research and development	39,375	20,022
General and administrative	17,084	14,063
Total operating expenses	56,459	34,085
Loss from operations	(55,973)	(33,021)
Other income, net:		
Interest income, net	4,557	3,351
Other income, net	5	312
Loss before income taxes	(51,411)	(29,358)
Income taxes	(7)	(4)
Net loss	$ (51,418)	$ (29,362)
Unrealized gain on marketable securities	$ 5	$ —
Comprehensive loss	$ (51,413)	$ (29,362)
Basic and diluted net loss per common share	$ (1.67)	$ (1.52)
Weighted average common shares outstanding, basic and diluted	30,877,029	19,354,500

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