Vistagen Reports Fiscal Year 2026 First Quarter Financial Results and Corporate Update

August 7, 2025

Topline results of PALISADE-3 Phase 3 Trial of fasedienol for acute treatment of social anxiety disorder expected in the fourth quarter of 2025

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

Vistagen continues to advance diverse intranasal pherine pipeline targeting treatments in psychiatry, women's health, and cancer supportive care

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Aug. 7, 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 2026 first quarter ended June 30, 2025, and provided a corporate update.

"We had another productive quarter, advancing key programs across our pipeline," said Shawn Singh, President and Chief Executive Officer of Vistagen. "Our lead program, fasedienol, for acute treatment of social anxiety disorder, continues to progress, with topline results from our PALISADE-3 Phase 3 trial anticipated later this year, and topline results from our PALISADE-4 Phase 3 trial expected in the first half of 2026. With no FDA-approved acute treatment, we remain optimistic about fasedienol's potential to impact the lives of over 30 million U.S. adults affected by social anxiety disorder. As the PALISADE trials near completion, we're encouraged by growing support for our pherine platform, including itruvone for MDD and PH80 for hot flashes, from patients, clinicians, and key opinion leaders. With multiple near-term catalysts and a differentiated pipeline, we remain focused on delivering long-term impact for patients and value for stockholders."

Clinical-stage Neuroscience Product Candidates

Vistagen is developing a broad and diverse pipeline of five clinical-stage intranasal pherine product candidates spanning three key therapeutic areas: psychiatry, women's health, and cancer supportive care.

Lead Program Highlights

Fasedienol for the Acute Treatment of Social Anxiety Disorder

- Vistagen's lead clinical development program – the U.S. registration-directed PALISADE Program evaluating intranasal fasedienol for the acute treatment of Social Anxiety Disorder (SAD) – is moving closer to key milestones. The PALISADE-3 Phase 3 trial is expected to provide 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, may establish substantial evidence of the effectiveness of fasedienol in support of a potential New Drug Application (NDA) submission to the U.S. Food and Drug Administration (FDA) for the acute treatment of social anxiety in adults.
- There is no FDA-approved acute treatment for SAD, a serious and potentially life-threatening mental health disorder often associated with co-morbidities such as major depressive disorder and suicidal ideation. SAD affects more than 30 million U.S. adults, with rising prevalence, especially among those aged 18-22.

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

- Following positive results from exploratory Phase 2A studies in women's health conditions, including vasomotor symptoms (hot flashes) due to menopause and premenstrual dysphoric disorder (PMDD), Vistagen is preparing its U.S. Investigational New Drug Application (IND) to facilitate further Phase 2 clinical development of PH80 for treatment of vasomotor symptoms (VMS), also known as hot flashes, due to menopause.
- An estimated 60% - 80% of menopausal women in the U.S. experience VMS, according to SWAN (Study of Women Across the Nation) and other published studies.

Itruvone for Major Depressive Disorder

- Following positive results from an exploratory Phase 2A, Vistagen is also planning for further Phase 2 development of itruvone for Major Depressive Disorder (MDD) under its U.S. IND in MDD.
- Depression is a serious medical condition and a global public health concern that can arise at any time during a person's life. According to the World Health Organization (WHO), depression is the leading cause of disability worldwide, affecting over 250 million people. Statistics reported by the U.S. National Institute of Mental Health (NIMH) indicate that approximately 21 million adults in the U.S., or approximately 8.4% of all adults in the U.S., experienced at least one major depressive episode in 2020.

Corporate Updates

In June, Vistagen announced the appointment of Elissa Cote as its Chief Corporate Development Officer, responsible for overseeing strategic, commercial, and business development functions.

Financial Results for Fiscal Year 2026 First Quarter Ended June 30, 2025

Research and development (R&D) expense

- R&D expense was $11.7 million for the three months ended June 30, 2025, as compared to $7.6 million for the three months ended June 30, 2024. The increase in R&D expense was primarily due to an increase in research, development, contract manufacturing expenses, and headcount related to the U.S. registration-directed PALISADE Program for fasedienol in SAD.

General and administrative (G&A) expense

- G&A expense was $4.4 million for the three months ended June 30, 2025, as compared to $4.6 million for the three months ended June 30, 2024.

Net loss

- Net loss was $15.1 million for the three months ended June 30, 2025, as compared to $10.7 million for the three months ended June 30, 2024.

Other financial highlights

- Cash, cash equivalents, and marketable securities were $63.2 million as of June 30, 2025.

Conference Call and Webcast

Vistagen will host a conference call and live audio webcast today, August 7, 2025, at 5:00 p.m. Eastern Time to provide a corporate update of the Company'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. Please click on the webcast link and follow the prompts for registration and access at least 10 minutes before the call. The webcast will be archived on Vistagen's website shortly after the call and will be available for at least 90 days.

For participants interested in participating in the call via dial-in, please follow the link below to pre-register. After registering, you will be provided with access details via email.

https://registrations.events/direct/NTM6228373

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 activate peripheral receptors in human nasal chemosensory neurons and are designed to rapidly activate nose-to-brain neurocircuits, believed to modulate brain areas, without requiring systemic absorption or uptake into the brain to achieve desired therapeutic benefits and differentiated safety.

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 activate peripheral receptors on human nasal chemosensory neurons and are designed to rapidly trigger 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 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 results 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, PALISADE-4 and/or any other clinical trial conducted by Vistagen as a part of its PALISADE program, as currently expected or at all; completing IND-enabling programs for *applicable product candidates, including itruvone and/or PH80; submission of a NDA to the FDA for any of Vistagen's product candidates, including fasedienol; the ability of any clinical trial information from the PALISADE program or otherwise submitted by Vistagen to the 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, and Quarterly Report on Form 10-Q for the period ended June 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.*

VISTAGEN THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share and par value amounts)

	June 30, 2025	**March 31, 2025**
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 48,985	$ 67,131
Marketable securities	14,195	13,351
Prepaid expenses and other current assets	3,536	1,594
Total current assets	66,716	82,076
Property and equipment, net	530	476
Right-of-use asset - operating lease	1,206	1,335
Other assets	472	454
Total assets	$ 68,924	$ 84,341
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 486	$ 653
Accrued expenses	6,582	8,810
Note payable	933	—

Deferred revenue - current portion	2,514	2,588
Operating lease obligation - current portion	640	561
Total current liabilities	11,155	12,612
Deferred revenue - non-current portion	221	391
Operating lease obligation - non-current portion	783	948
Total liabilities	12,159	13,951
Commitments and contingencies		
Stockholders’ equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at June 30, 2025 and March 31, 2025; no shares outstanding at June 30, 2025 and March 31, 2025	-	-
Common stock, $0.001 par value; 325,000,000 shares authorized at June 30, 2025 and March 31, 2025; 29,286,585 and 29,001,481 shares issued at June 30, 2025 and March 31, 2025, respectively	29	29
Additional paid-in capital	483,430	481,956
Treasury stock, at cost, 4,522 shares of common stock held at June 30, 2025 and March 31, 2025	(3,968)	(3,968)
Accumulated other comprehensive income	1	5
Accumulated deficit	(422,727)	(407,632)
Total stockholders’ equity	56,765	70,390
Total liabilities and stockholders’ equity	$ 68,924	$ 84,341

VISTAGEN THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(unaudited)

(in thousands, except share and per share data)

	Three Months Ended June 30,	
	2025	**2024**
Revenues:		
Sublicense and other revenue	$ 244	$ 84
Total revenues	244	84
Operating expenses:		

Research and development	11,678	7,648
General and administrative	4,370	4,567
Total operating expenses	16,048	12,215
Loss from operations	(15,804)	(12,131)
Other income, net:		
Interest income, net	711	1,398
Other expense	(2)	—
Loss before income taxes	(15,095)	(10,733)
Income taxes	—	—
Net loss	$ (15,095)	$ (10,733)
Unrealized gain (loss) on marketable securities	(4)	2,000
Comprehensive loss	$ (15,099)	$ (10,731)
Basic and diluted net loss per common share	$ (0.47)	$ (0.35)
Weighted average common shares outstanding, basic and diluted	31,930,665	30,603,435

View source version on businesswire.com: https://www.businesswire.com/news/home/20250807014578/en/

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