Vistagen Reports Fiscal Year 2025 Third Quarter Financial Results and Corporate Update

February 13, 2025

Fasedienol U.S. registration-directed PALISADE Phase 3 Program for acute treatment of social anxiety disorder progressing with ongoing PALISADE-3, PALISADE-4 and Repeat Dose trials

Vistagen highlights clinical-stage pipeline with five novel pherine product candidates with positive efficacy signals and potential to transform standards of care for multiple high prevalence indications

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Feb. 13, 2025-- Vistagen (Nasdaq: VTGN), a 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 2025 third quarter ended December 31, 2024, and provided a corporate update.

"We had a very productive quarter, with both PALISADE-3 and PALISADE-4 advancing towards expected top-line results later this year," said Shawn Singh, President and Chief Executive Officer of Vistagen. "We are also pleased to report positive results from an exploratory Phase 2A trial of PH284 in cancer cachexia. PH284 is our fifth neurocircuitry-focused pherine product candidate with a positive efficacy signal and differentiated safety, and this announcement underscores the breadth and diversity of our pherine pipeline. As always, we remain optimistic about the potential of our product candidates to transform standards of care and address multiple significant unmet needs. We continue to believe that 2025 has the potential to be a monumental year, between multiple anticipated data readouts for fasedienol in acute treatment of social anxiety disorder and further advancement of additional pherine product candidates for treatment of major depressive disorder and menopausal hot flashes."

Neuroscience Pipeline Highlights

- Fasedienol PALISADE-3 and PALISADE-4 Phase 3 trials for the acute treatment of social anxiety disorder (SAD) progressing to produce top-line results in 2025.
- Initiated fasedienol Phase 2 Repeat Dose Study for the acute treatment of SAD.
- Announced positive results from an exploratory Phase 2A study of PH284 in cancer cachexia.

Vistagen is also continuing:

- Ongoing U.S. Investigational New Drug Application (IND)-enabling program for PH80, designed to support its planned submission of a U.S. IND to build on a previously reported positive exploratory Phase 2A studies of PH80 in women's health indications and facilitate further Phase 2 clinical development of PH80 in the U.S. as a potential novel non-hormonal, non-systemic treatment option for millions of women affected by vasomotor symptoms (hot flashes) due to menopause.
- Preparations and planning for Phase 2B development of itruvone as a potential novel non-systemic, stand-alone treatment for major depressive disorder, without the weight gain, sexual side effects, and safety concerns associated with currently available depression therapies.

Financial Results for Fiscal Year 2025 Third Quarter Ended December 31, 2024

Research and development (R&D) expense

- R&D expense was $11.3 million for the three months ended December 31, 2024, as compared to $4.5 million for the three months ended December 31, 2023. The increase in R&D expense was primarily due to an increase in research, development, and contract manufacturing expenses related to the PALISADE Phase 3 Program for fasedienol in SAD and U.S. IND-enabling programs for itruvone in MDD and PH80 in menopausal hot flashes.

General and administrative (G&A) expense

- G&A expense was $4.0 million for the three months ended December 31, 2024, as compared to $3.8 million for the three months ended December 31, 2023. The increase in G&A expense was primarily due to an increase in headcount.

Net loss

- Net loss was $14.1 million for the three months ended December 31, 2024, as compared to $6.4 million for the three months ended December 31, 2023.

Other financial highlights

- Cash, cash equivalents, and marketable securities were $88.6 million as of December 31, 2024.

Conference Call and Webcast:

Vistagen will host a conference call and live audio webcast today February 13, 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 the Company's website.

Participants may register for the live call link HERE to receive the dial-in numbers and unique PIN to access the call. It is recommended that you join 15 minutes prior to the start of the event.

A webcast replay of the call will be available on Vistagen's website within 24 hours after the end of the live conference call and will be accessible for at least 90 days.

About Fasedienol for the Acute Treatment of Social Anxiety Disorder

Fasedienol, the lead clinical-stage product candidate, is a synthetic neuroactive intranasal pherine in an ongoing U.S. registration-directed Phase 3 clinical development program for the acute treatment of anxiety in adults with social anxiety disorder (SAD), a highly prevalent, serious, and life-threatening psychiatric mental health disorder affecting over 30 million adults in the U.S. The proposed mechanism of action (MOA) of fasedienol is fundamentally differentiated from all FDA-approved anti-anxiety medications. When administered intranasally in microgram-level doses, fasedienol activates nasal chemosensory neurons connected to olfactory bulb neurons that, in turn, connect to neural circuits in the limbic amygdala involved in SAD. Fasedienol is pharmacologically active without requiring apparent systemic absorption or direct binding on neurons in the brain to achieve its rapid-onset anxiolytic effects. Because of its innovative non-systemic neurocircuitry-focused MOA, fasedienol has the potential to achieve rapid-onset anxiolytic effects for individuals with SAD on an acute, as-needed basis, with a significantly reduced risk of unwanted side effects and safety concerns, such as potential drug-drug interactions, sedation, abuse, misuse, withdrawal symptoms, 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 SAD. There is no U.S. FDA-approved acute treatment for SAD. The U.S. FDA has granted Fast Track designation for the development of fasedienol for the acute treatment of SAD.

About Itruvone for the Treatment of Major Depressive Disorder

Itruvone is an investigational, non-systemic intranasal pherine product candidate with a novel, rapid-onset neurocircuitry-focused proposed mechanism of action (MOA) that is fundamentally differentiated from the MOA of all currently approved pharmacological treatments for depression disorders. Itruvone is administered intranasally at microgram-level doses and is designed to regulate olfactory-to-amygdala neural circuitry believed to produce antidepressant effects, without systemic absorption or brain penetration and without many of the side effects and safety concerns potentially associated with currently approved antidepressants. Unlike antidepressants which rely on single or double-receptor occupancy in the brain, itruvone activates neural circuits that regulate the amygdala, hypothalamus, entorhinal area and hippocampus, prefrontal cortex, locus coeruleus, and raphe nucleus, all involved in the pathophysiology of depression. The scope of itruvone's neural circuit activation, and potential impact on the brain, appears wider, faster and safer than can be achieved with therapies targeting binding to any specific brain receptor. Vistagen is developing itruvone as a potential new non-systemic, stand-alone treatment for major depressive disorder, and the FDA has granted Fast Track designation for the development of itruvone for that indication.

About PH80 for the Treatment of Vasomotor Symptoms (Hot Flashes) Due to Menopause

PH80 is an investigational non-hormonal, non-systemic, neurocircuitry-focused intranasal pherine product candidate with a novel, rapid-onset proposed MOA that is fundamentally differentiated from all currently approved treatments for vasomotor symptoms (hot flashes) due to menopause. Rapid activation of peripheral nasal chemosensory neurons via self-administration of low microgram doses of PH80 rapidly stimulates neurocircuits in the olfactory bulbs that are connected to the limbic amygdala and hypothalamus, which are involved in the regulation of the autonomic nervous system and thermoregulatory areas of the hypothalamus. Vistagen is developing PH80 as a potential new non-hormonal, non-systemic treatment for the management of moderate to severe vasomotor symptoms (hot flashes) due to menopause.

About Vistagen

Headquartered in South San Francisco, CA, Vistagen (Nasdaq: VTGN) is a clinical-stage biopharmaceutical company leveraging a deep understanding of nose-to-brain neurocircuitry to develop and commercialize a broad and diverse pipeline of clinical-stage product candidates from a new class of intranasal therapies called pherines. Pherines specifically and selectively bind to peripheral receptors in human nasal chemosensory neurons, which activate olfactory bulb-to-brain neurocircuits without requiring systemic absorption or uptake into the brain to achieve desired therapeutic benefits and differentiated safety. Vistagen's neuroscience pipeline also includes an oral prodrug 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 indications, 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 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; launching planned

clinical trials for any of Vistagen's product candidates; 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 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, 2024, and Quarterly Report on Form 10-Q for the period ended December 31, 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. 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)

	December 31, 2024	March 31, 2024
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 74,715	$ 119,166
Marketable securities	13,845	-
Prepaid expenses and other current assets	1,381	1,506
Total current assets	89,941	120,672
Property and equipment, net	428	435
Right-of-use asset - operating lease	1,461	1,820
Other assets	477	726
Total assets	$ 92,307	$ 123,653
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,039	$ 1,547
Accrued expenses	5,469	2,235
Deferred revenue - current portion	2,510	791

Operating lease obligation - current portion	603	550
Total current liabilities	9,621	5,123
Deferred revenue - non-current portion	454	2,674
Operating lease obligation - non-current portion	1,110	1,570
Total liabilities	11,185	9,367
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at December 31, 2024 and March 31, 2024; no shares outstanding at December 31, 2024 and March 31, 2024	-	-
Common stock, $0.001 par value; 325,000,000 shares authorized at December 31, 2024 and March 31, 2024; 28,321,216 and 27,029,731 shares issued at December 31, 2024 and March 31, 2024, respectively	28	27
Additional paid-in capital	479,048	474,441
Treasury stock, at cost, 4,522 shares of common stock held at December 31, 2024 and March 31, 2024	(3,968)	(3,968)
Accumulated other comprehensive income	11	-
Accumulated deficit	(393,997)	(356,214)
Total stockholders' equity	81,122	114,286
Total liabilities and stockholders' equity	$ 92,307	$ 123,653

VISTAGEN THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(unaudited)

(in thousands, except share and per share data)

	Three Months Ended December 31,		**Nine Months Ended December 31,**	
	2024	**2023**	**2024**	**2023**
Revenues:				
Sublicense and other revenue	$ 234	$ 411	$ 501	$ 867
Total revenues	234	411	501	$ 867
Operating expenses:				

Research and development	11,305	4,537	29,168	$ 12,586
General and administrative	4,049	3,758	12,811	$ 9,943
Total operating expenses	15,354	8,295	41,979	$ 22,529
Loss from operations	(15,120)	(7,884)	(41,478)	$ (21,662)
Other income, net:				
Interest income, net	1,031	1,534	3,702	$ 1,824
Loss before income taxes	(14,089)	(6,350)	(37,776)	$ (19,838)
Income taxes	—	—	(7)	$ (3)
Net loss	$ (14,089)	$ (6,350)	$ (37,783)	$ (19,841)
Unrealized gain (loss) on marketable securities	(11)	—	11	—
Comprehensive loss	$ (14,100)	$ (6,350)	$ (37,772)	$ (19,841)
Basic and diluted net loss per common share	$ (0.46)	$ (0.22)	$ (1.23)	$ (1.27)
Weighted average common shares outstanding, basic and diluted	30,711,872	29,388,085	30,649,384	15,632,451

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