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

November 7, 2024

Fasedienol U.S. registration-directed PALISADE Phase 3 Program for acute treatment of social anxiety disorder progressing

PALISADE-3 and PALISADE-4 Phase 3 trials initiated and underway

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Nov. 7, 2024-- Vistagen (Nasdaq: VTGN), a late clinical-stage company dedicated to pioneering neuroscience based on nose-to-brain neurocircuitry, today reported financial results for its fiscal year 2025 second quarter ended September 30, 2024, and provided a corporate update.

"We initiated our PALISADE-4 Phase 3 trial during our second quarter, achieving yet another significant milestone in our fasedienol U.S. registration-directed Phase 3 Program for the acute treatment of social anxiety disorder," said Shawn Singh, Chief Executive Officer of Vistagen. "We are actively recruiting for both our PALISADE-3 and PALISADE-4 Phase 3 trials and remain primarily focused on execution. Our broad and diverse neuroscience pipeline is based on our novel, non-systemic, neurocircuitry-focused approaches to treating multiple challenging disorders in high-prevalence markets with inadequate current treatment options. As we head into 2025, we expect data from multiple Phase 3 clinical trials in social anxiety disorder and further advancement of our non-systemic pherine product candidates in Phase 2 programs for treatment of major depressive disorder and hormone-free treatment of menopausal hot flashes, each with potential to set a new standard of care."

Neuroscience Pipeline Highlights

Leveraging its pioneering neuroscience and deep understanding of nose-to-brain neurocircuitry, Vistagen is advancing a broad and diverse pipeline of innovative non-systemic intranasal pherine product candidates.

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

- During the second quarter, Vistagen announced initiation of its PALISADE-4 Phase 3 trial of fasedienol for the acute treatment of SAD.
- Vistagen's PALISADE-3 and PALISADE-4 Phase 3 trials remain on track to produce top-line results in 2025.

Itruvone for Major Depressive Disorder (MDD)

- Vistagen continues preparations and planning for Phase 2B development of itruvone as 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 Vasomotor Symptoms (Hot Flashes) due to Menopause

- Vistagen's ongoing U.S. Investigational New Drug Application (IND)-enabling program for PH80 is designed to support its planned submission of a U.S. IND to facilitate further Phase 2 clinical development of PH80 in the U.S. as a novel non-systemic, hormone-free treatment option for millions of women affected by vasomotor symptoms (hot flashes) due to menopause.

Corporate Highlight

Raising Awareness at Nasdaq on World Mental Health Day

- Vistagen partnered with The Goldie Hawn Foundation's MindUP to raise awareness of global mental health challenges and the power of partnership and shared commitment to advance neuroscience-based innovation in a Nasdaq Closing Bell ceremony in New York City on World Mental Health Day.

Financial Results for Fiscal Year 2025 Second Quarter Ended September 30, 2024

Research and development (R&D) expense

- R&D expense was $10.2 million for the three months ended September 30, 2024, as compared to $3.9 million for the three months ended September 30, 2023. The increase in R&D expense was primarily due to an increase in research, development, and contract manufacturing expenses related to our PALISADE Phase 3 Program for fasedienol in SAD, an increase in headcount, and an increase in consulting and professional service fees.

General and administrative (G&A) expense

- G&A expense was $4.2 million for the three months ended September 30, 2024, as compared to $3.2 million for the three months ended September 30, 2023. The increase in G&A expense was primarily due to an increase in headcount and professional service fees.

Net loss

- Net loss was $13.0 million for the three months ended September 30, 2024, as compared to $6.6 million for the three months ended September 30, 2023.

Other financial highlights

- Cash, cash equivalents, and marketable securities were $97.6 million as of September 30, 2024.

Conference Call:

Vistagen will host a conference call and live audio webcast this afternoon at 5:00 p.m. Eastern Time to provide a corporate update.

U.S. Dial-in (Toll-Free): 1-800-717-1738

International Dial-in Number (Toll): 1-646-307-1865

Conference ID: 1196845

Webcast: https://viavid.webcasts.com/starthere.jsp?ei=1692083&tp_key=a59cae127b

A live audio conference call webcast will also be available via the above link. Participants should access this webcast site 10 minutes before the start of the call. In addition, a telephone playback of the call will be available after approximately 8:00 p.m. Eastern Time on Thursday, November 7, 2024. To listen to the replay, call toll-free 1-844-512-2921 within the United States or 1-412-317-6671 when calling internationally (toll). Please use the replay access ID number 1196845.

About Fasedienol Nasal Spray for Acute Treatment of Social Anxiety Disorder

Fasedienol is a potential first-in-class, investigational neuroactive pherine nasal spray designed to have rapid onset with a novel mechanism of action (MOA) that is differentiated from all currently approved anxiety medications. Fasedienol is designed to regulate the olfactory-amygdala neural circuits of fear and anxiety and attenuate the tone of the sympathetic autonomic nervous system, without systemic absorption, potentiation of GABA-A receptors, or binding to neurons in the brain. Vistagen's U.S. registration-directed PALISADE Phase 3 program for fasedienol is focused on the acute treatment of SAD. Fasedienol has not demonstrated any signals of abuse potential or suggested any potential for psychological and physical dependence in any clinical trial conducted to date. 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 Nasal Spray for Major Depressive Disorder

Itruvone is an investigational pherine nasal spray designed to have rapid onset, with a novel proposed neurocircuitry-focused mechanism of action (MOA) that is fundamentally differentiated from the MOA of all currently approved treatments for depression disorders. Itruvone is administered intranasally at microgram-level doses and is designed to regulate olfactory-to-amygdala neural circuitry believed to increase the activity of the limbic-hypothalamic sympathetic nervous system and increase the release of catecholamines 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. 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 Nasal Spray for Vasomotor Symptoms (Hot Flashes) Due to Menopause

PH80 is a hormone-free investigational neuroactive pherine nasal spray with a novel neurocircuitry-focused mechanism of action (MOA) that is fundamentally differentiated from all currently approved treatment options for women's health indications. PH80's proposed MOA does not require systemic absorption or binding to neurons in the brain. Vistagen is developing PH80 as a potential new non-systemic, hormone-free treatment for the management of vasomotor symptoms (hot flashes) due to menopause.

About Vistagen

Headquartered in South San Francisco, CA, Vistagen (Nasdaq: VTGN) is a late clinical-stage company leveraging its pioneering neuroscience and deep understanding of nose-to-brain neurocircuitry to develop and commercialize a broad and diverse pipeline of intranasal product candidates called pherines. Each pherine product candidate in Vistagen's neuroscience pipeline is designed to rapidly activate olfactory system and brain neurocircuitry to achieve desired therapeutic benefits and differentiated safety without requiring systemic absorption or binding to neurons in the brain. Vistagen's neuroscience pipeline also includes an oral prodrug, AV-101, 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 disorders, 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. Among other things, there can be no guarantee that any of Vistagen's product candidates will successfully complete ongoing or future clinical trials, receive regulatory approval or be commercially successful, or that Vistagen will be able to successfully replicate the result of past studies of its product candidates, including fasedienol, itruvone, PH80 or its other 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; completing IND-enabling programs for applicable product candidates, including PH80; launching planned clinical trials for any of our product candidates, including fasedienol; Vistagen's submission of a new drug application (NDA) to the U.S. FDA for any product candidate, including fasedienol; the ability of any clinical trial information submitted by the Company to the U.S. FDA to support a NDA; 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 September 30, 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

	September 30, 2024	**March 31, 2024**
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 84,246	$ 119,166
Marketable securities	13,332	-
Prepaid expenses and other current assets	2,370	1,506
Total current assets	99,948	120,672
Property and equipment, net	467	435
Right-of-use asset - operating lease	1,583	1,820
Other assets	498	726
Total assets	$ 102,496	$ 123,653
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 715	$ 1,547
Accrued expenses	3,815	2,235

Deferred revenue - current portion	2,468	791
Operating lease obligation - current portion	525	550
Total current liabilities	7,523	5,123
Deferred revenue - non-current portion	730	2,674
Operating lease obligation - non-current portion	1,269	1,570
Total liabilities	9,522	9,367
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at September 30, 2024 and March 31, 2024; no shares outstanding at September 30, 2024 and March 31, 2024	-	-
Common stock, $0.001 par value; 325,000,000 shares authorized at September 30, 2024 and March 31, 2024; 27,059,629 and 27,029,731 shares issued at September 30, 2024 and March 31, 2024, respectively	27	27
Additional paid-in capital	476,801	474,441
Treasury stock, at cost, 4,522 shares of common stock held at September 30, 2024 and March 31, 2024	(3,968)	(3,968)
Accumulated other comprehensive income	22	-
Accumulated deficit	(379,908)	(356,214)
Total stockholders' equity	92,974	114,286
Total liabilities and stockholders' equity	$ 102,496	$ 123,653

VISTAGEN THERAPEUTICS

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(unaudited)

	Three Months Ended September 30,		**Six Months Ended September 30,**	
	2024	**2023**	**2024**	**2023**
Revenues:				
Sublicense and other revenue	$ 183	$ 278	$ 267	$ 455
Total revenues	183	278	267	$ 455
Operating expenses:				
Research and development	10,215	3,851	17,863	$ 8,048

General and administrative	4,195	3,207	8,762	$ 6,185
Total operating expenses	14,410	7,058	26,625	$ 14,233
Loss from operations	(14,227)	(6,780)	(26,358)	$ (13,778)
Other income, net:				
Interest income, net	1,273	192	2,671	$ 290
Loss before income taxes	(12,954)	(6,588)	(23,687)	$ (13,488)
Income taxes	(7)	—	(7)	$ (3)
Net loss	$ (12,961)	$ (6,588)	$ (23,694)	$ (13,491)
Unrealized gain on marketable securities	20	—	22	—
Comprehensive loss	$ (12,941)	$ (6,588)	$ (23,672)	$ (13,491)
Basic and diluted net loss per common share	$ (0.42)	$ (0.66)	$ (0.77)	$ (1.55)
Weighted average common shares outstanding, basic and diluted	30,632,347	10,042,530	30,617,970	8,717,050

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