Vistagen Reports Fiscal Year 2024 Financial Results and Provides Corporate Update

June 11, 2024

Registration-directed fasedienol PALISADE Phase 3 program for the acute treatment of social anxiety disorder progressing on track

PALISADE-3 Phase 3 trial recently initiated; PALISADE-4 Phase 3 trial initiation anticipated in 2H 2024

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jun. 11, 2024-- Vistagen (Nasdaq: VTGN), a neuroscience-focused biopharmaceutical company dedicated to pursuing a pioneering approach to the development of groundbreaking therapies for psychiatric and neurological disorders based on nose-to-brain neurocircuitry, today reported financial results for its fiscal year ended March 31, 2024, and provided a corporate update.

“Vistagen’s fiscal 2024 proved to be a year full of remarkable accomplishments. Most notably, with our PALISADE-2 trial of fasedienol, we became the first company to report positive results of a Phase 3 trial for the acute treatment of social anxiety disorder, a mental health disorder affecting the lives of over 30 million adults in the U.S for which there is no FDA-approved acute treatment option. In addition, we recently initiated our PALISADE-3 Phase 3 trial, which, if successful, has the potential to complement PALISADE-2 in support of a fasedienol U.S. New Drug Application submission,” said Shawn Singh, Chief Executive Officer of Vistagen. “Our primary focus is on the high-quality execution of our registration-directed PALISADE Phase 3 program for fasedienol in social anxiety disorder, as well as the further progression of our non-systemic, neurocircuitry-focused pherine development programs involving itruvone for major depressive disorder and hormone-free PH80 for menopausal hot flashes. We are well-positioned on a path toward achieving multiple potential value-creating catalysts during the year ahead as we pursue our mission to develop and commercialize differentiated neuroscience therapies to improve patients' lives worldwide.”

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

- **Reported Positive PALISADE-2 Phase 3 Trial Results**. In the second quarter of fiscal 2024, Vistagen announced positive top-line results from PALISADE-2, a U.S. multi-center, randomized, double-blind, placebo-controlled Phase 3 trial designed to evaluate the efficacy, safety, and tolerability of fasedienol for the acute treatment of SAD after a single dose of fasedienol during a simulated, anxiety-provoking public speaking challenge in a clinical setting, as measured using the patient-reported Subjective Units of Distress Scale (SUDS) as the primary efficacy endpoint. Fasedienol is Vistagen’s lead investigational neuroactive pherine formulated as a rapid-onset nasal spray to activate olfactory and brain neural circuits without requiring systemic uptake or binding to neurons in the brain. Fasedienol’s proposed MOA is fundamentally differentiated from the MOA of all currently approved treatments for anxiety disorders. Currently, there is no FDA-approved drug therapy for the acute treatment of SAD. With PALISADE-2, Vistagen became the first company to report a positive Phase 3 trial of a drug candidate for the acute treatment of SAD.
- **Initiated PALISADE-3 Phase 3 Trial; Preparation for PALISADE-4 Phase 3 Trial Underway.** In the fourth quarter of fiscal 2024, Vistagen launched its PALISADE-3 Phase 3 trial of fasedienol for the acute treatment of SAD. With PALISADE-3 initiated, the Company is now preparing to launch its PALISADE-4 Phase 3 trial in the second half of calendar 2024. PALISADE-3 and PALISADE-4 are designed similarly to PALISADE-2, including an open-label extension for a period of up to 12 months with subjects able to use fasedienol up to 6 times per day in their everyday lives prior to anxiety-provoking social and performance stressors.

Itruvone for Major Depressive Disorder (MDD)

- **Completed Successful U.S. Phase 1 Trial to Enable U.S. Phase 2B Development**. In the first quarter of fiscal 2024, Vistagen announced favorable safety and tolerability data from its U.S. Phase 1 clinical trial of itruvone to build on successful Phase 1 and Phase 2A clinical studies of itruvone previously conducted outside the U.S. Leveraging positive results from an exploratory Phase 2A trial in MDD, preparations and planning are underway for U.S. Phase 2B development of itruvone as a novel, non-systemic stand-alone treatment for MDD.
- **Reported Key Pherine Mechanism of Action (MOA) Data**. In the second quarter of fiscal 2024, the Company reported preclinical data demonstrating that a single intranasal administration of radiolabeled itruvone ([14C]PH10) was essentially undetectable in the brain and most other tissues, including blood and plasma. Similar to previously reported preclinical MOA data of fasedienol, these new preclinical data for itruvone further support its unique proposed MOA as involving binding to receptors of peripheral chemosensory neurons in the nasal cavity, but not to neuronal receptors in the central nervous system, and thereby limiting transport of molecules to the circulatory system and minimizing potential systemic exposure. Itruvone’s proposed MOA is fundamentally differentiated from the MOA of all currently approved treatments for depression disorders.

PH80 for Women’s Health Indications

- **Announced Positive Exploratory Phase 2A Data Study for the Treatment of Vasomotor Symptoms (Hot Flashes) due to Menopause**. In the first quarter of fiscal 2024, Vistagen announced positive data from a previously unreported exploratory Phase 2A clinical trial conducted outside the U.S. in which PH80, Vistagen's rapid-onset, hormone-free neuroactive pherine nasal spray, demonstrated statistically significant efficacy versus placebo for the treatment of vasomotor symptoms (hot flashes) due to menopause. Potential U.S. IND-enabling studies are underway to facilitate further Phase 2 development of PH80 in the U.S. for the treatment of menopausal hot flashes. PH80's proposed MOA is fundamentally differentiated from the MOA of all currently approved treatments for menopausal hot flashes.
- **Announced Positive Exploratory Phase 2A Data Study for Treatment of Premenstrual Dysphoric Disorder (PMDD).** In the second quarter of fiscal 2024, the Company announced positive data from a previously unreported exploratory Phase 2A clinical trial conducted outside the U.S. in which PH80 demonstrated statistically significant efficacy versus placebo for the treatment of PMDD.

Corporate Updates

- In the first quarter of fiscal 2024, Vistagen was awarded Mental Health America's Platinum Bell Seal for workplace mental health, an award the Company received again in the first quarter of fiscal 2025. Receipt of this prestigious award demonstrates Vistagen's ongoing commitment to bringing mental health awareness and action to the forefront of its workplace and corporate objectives.
- In the second quarter of fiscal 2024, Vistagen announced the appointment of Cindy Anderson as Chief Financial Officer. Ms. Anderson brings almost two decades of financial and operating strength from her experiences in the biopharmaceutical sector.
- In the second quarter of fiscal 2024, Vistagen entered into an Exclusive Negotiation Agreement with Fuji Pharma Co., Ltd. (Fuji Pharma), a leading company in Japan focused on women's health, to negotiate exclusively with Fuji Pharma for a potential agreement to develop and commercialize Vistagen's hormone-free pherine nasal spray, PH80, in Japan for the treatment of vasomotor symptoms (hot flashes) due to menopause.
- In the third quarter of fiscal 2024, Vistagen closed an underwritten public offering, providing the Company with cash runway to execute critical milestones in its registration-directed PALISADE Phase 3 program for fasedienol in SAD and across other programs in its neuroscience pipeline.

Financial Results for Fiscal Year 2024

Research and development (R&D) expenses

- R&D expenses were $20.0 million for the year ended March 31, 2024, as compared to $44.4 million for the year ended March 31, 2023. The decrease in R&D expenses was primarily due to a decrease in clinical and development expenses related to the timing of expenses incurred for the Company's Phase 3 trials of fasedienol in SAD.

General and administrative (G&A) expenses

- G&A expenses were $14.1 million for the year ended March 31, 2024, as compared to $14.7 million for the year ended March 31, 2023. The decrease in G&A expenses was primarily due to a decrease in professional fees and stock-based compensation expense, offset by an increase in compensation and related expenses.

Net loss

- Net loss was $29.4 million for the year ended March 31, 2024, as compared to $59.2 million for the year ended March 31, 2023.

Other financial highlights

- Cash and cash equivalents were $119.2 million as of March 31, 2024.
- As of June 10, 2024, the Company had 27,029,731 shares of common stock issued and 3,577,240 pre-funded warrants outstanding.

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): 1-877-407-9716
International Dial-in Number (Toll): 1-201-493-6779
Conference ID: 13746589
Webcast: https://viavid.webcasts.com/starthere.jsp?ei=1670447&tp_key=0236806001

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 Tuesday, June 11, 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 13746589.

About Vistagen

Headquartered in South San Francisco, CA, Vistagen (Nasdaq: VTGN) is a neuroscience-focused biopharmaceutical company dedicated to pursuing a pioneering approach to the development and commercialization of groundbreaking therapies for psychiatric and neurological disorders based on its deep understanding of nose-to-brain neurocircuitry. Designed exclusively as nasal sprays, Vistagen's diversified pipeline of pherine product candidates rapidly activate chemosensory neurons in the nasal cavity to impact fundamental neurocircuitry in the olfactory system and the brain, with favorable safety profiles observed in all clinical studies completed to date. Vistagen's pipeline also includes an oral prodrug with potential to modulate NMDA receptor activity. At Vistagen, we are passionate about creating novel and differentiated treatments that set new standards of care for millions of people living with anxiety, depression, and other neurological disorders. 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 the Company's drug candidates will successfully complete ongoing or, if initiated, future clinical trials, receive regulatory approval or be commercially successful, or that the Company will be able to successfully replicate the result of past studies of its product candidates, including fasedienol, ituruvone, PH80 or its other drug candidates. Other factors that may cause such a difference include, without limitation, risks and uncertainties relating to delays in launching, conducting and/or completing ongoing and planned nonclinical studies and clinical trials, including PALISADE-3 and PALISADE-4 or additional Phase 2 clinical trials of ituruvone or PH80; the period over which the Company anticipates its available financial resources will fund its operating expense; the timing of completion of preclinical studies and clinical trials and related preparatory work required to apply for an maintain regulatory approval for any of our product candidates; the scope and enforceability of the Company's patents, including patents related to the Company's pherine drug candidates and AV-101; fluctuating costs of materials and other resources and services required to conduct the Company's ongoing and/or planned clinical and nonclinical 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 the Company's product candidates. These risks are more fully discussed in the section entitled "Risk Factors" in the Company's most recent Annual Report on Form 10-K for the fiscal year ended March 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). The Company'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 the Company's views as of any subsequent date. The Company explicitly disclaims any obligation to update any forward-looking statements other than as may be required by law. If the Company does update one or more forward-looking statements, no inference should be made that the Company 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, 2024	2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 119,166	$ 16,638
Prepaid expenses and other current assets	1,432	802
Deferred contract acquisition costs - current portion	74	67
Total current assets	120,672	17,507
Property and equipment, net	435	507
Right-of-use asset - operating lease	1,820	2,260
Deferred offering costs	495	496
Deferred contract acquisition costs - non-current portion	130	218

Security deposits	101	101
Total assets	$ 123,653	$ 21,089
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,547	$ 2,473
Accrued expenses	2,235	796
Note payable	-	105
Deferred revenue - current portion	791	714
Operating lease obligation - current portion	550	486
Total current liabilities	5,123	4,574
Deferred revenue - non-current portion	2,674	2,315
Operating lease obligation - non-current portion	1,570	2,120
Total liabilities	9,367	9,009
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at March 31, 2024 and March 31, 2023; no shares outstanding at March 31, 2024 and March 31, 2023	-	-
Common stock, $0.001 par value; 325,000,000 shares authorized at March 31, 2024 and March 31, 2023; 27,029,731 and 7,315,583 shares issued at March 31, 2024 and March 31, 2023, respectively	27	7
Additional paid-in capital	474,441	342,893
Treasury stock, at cost, 4,522 shares of common stock held at March 31, 2024 and March 31, 2023	(3,968)	(3,968)
Accumulated deficit	(356,214)	(326,852)
Total stockholders' equity	114,286	12,080
Total liabilities and stockholders' equity	$ 123,653	$ 21,089

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

	Year Ended March 31,	
	2024	**2023**
Revenues:		
Sublicense and other revenue	$ 1,064	$ (227)
Total revenues	1,064	(227)
Operating expenses:		

Research and development	20,022	44,377
General and administrative	14,063	14,664
Total operating expenses	34,085	59,041
Loss from operations	(33,021)	(59,268)
Other income, net:		
Interest income, net	3,351	26
Other income	312	-
Loss before income taxes	(29,358)	(59,242)
Income taxes	(4)	(6)
Net loss and comprehensive loss	$ (29,362)	$ (59,248)
Basic and diluted net loss per common share	$ (1.52)	$ (8.51)
Weighted average common shares outstanding, basic and diluted	19,354,500	6,958,749

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