Vistagen Provides Corporate Update and Reports Fiscal 2024 Second Quarter Financial Results

November 9, 2023

- *Fasedienol (PH94B) PALISADE Phase 3 Program for acute treatment of social anxiety disorder (SAD) advancing to build on recent positive PALISADE-2 Phase 3 results*
- *Preparations to initiate potential fasedienol NDA-enabling Phase 3 studies in 2024 underway*
- *Itruvone (PH10) staged for potential Phase 2B clinical development 2H 2024*
- *PH80 positive exploratory Phase 2A trial data reported in two separate women's health indications – vasomotor symptoms (hot flashes) due to menopause and premenstrual dysphoric disorder (PMDD)*
- *$137.7 million in gross proceeds secured since the beginning of fiscal 2024 second quarter, including $100 million from an underwritten public offering of equity securities led by BVF Partners LP, with participation from Commodore Capital, Great Point Partners, Logos Capital, Nantahala Capital, Surveyor Capital (a Citadel company), TCGX, and additional institutional investors*
- *Strong financial position provides adequate cash runway to a potential fasedienol U.S. New Drug Application for acute treatment of SAD*

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Nov. 9, 2023-- Vistagen (Nasdaq: VTGN), a late clinical-stage biopharmaceutical company aiming to transform the treatment landscape for individuals living with anxiety, depression, and other central nervous system (CNS) disorders, today provided a corporate update and reported financial results for its fiscal year 2024 second quarter ended September 30, 2023.

"Vistagen achieved multiple important milestones in recent months, significantly advancing our innovative pipeline, including positive Phase 3 results for fasedienol, our lead pherine nasal spray drug candidate," said Shawn Singh, Chief Executive Officer. "With a fortified balance sheet, a robust pipeline of drug candidates differentiated from the current standards of care, and a clear path forward in our potential U.S. New Drug Application-enabling PALISADE Phase 3 Program for fasedienol in social anxiety disorder, we are confident in our potential to improve the lives of millions of individuals affected by SAD and other large market mental health and CNS disorders."

Corporate Update and Pipeline Highlights

Fasedienol Nasal Spray – PALISADE Phase 3 Program

Positive results in August 2023 from PALISADE-2 Phase 3 study of fasedienol for the acute treatment of anxiety in adults with SAD advances the PALISADE Phase 3 development program and paves the way to initiate potential U.S. New Drug Application (NDA)-enabling studies in 2024.

- Primary endpoint met, with fasedienol demonstrating a statistically significant difference in average patient-reported Subjective Units of Distress Scale (SUDS) score during a public speaking challenge compared to placebo (p=0.015).
- Secondary endpoint met, demonstrating a statistically significant difference in the proportion of clinician-assessed responders between fasedienol and placebo as measured by the Clinical Global Impressions - Improvement (CGI-I) scale (p=0.033).
- Exploratory endpoint met, demonstrating a statistically significant difference in the proportion of patient-assessed responders between fasedienol and placebo as measured by the Patient Global Impression of Change (PGI-C) scale (p=0.003).
- Fasedienol was observed to be well-tolerated and demonstrated a favorable safety profile consistent with all prior trials.
- PALISADE Phase 3 Program studies to be initiated in 2024 are designed to build on the positive results observed from PALISADE-2 and enable a potential submission of a fasedienol U.S. NDA in SAD.

Preparing to initiate PALISADE-3 and PALISADE-4 Phase 3 studies.

To complement the positive top-line results from PALISADE-2, the Company is preparing to launch two similar Phase 3 clinical trials in 2024, PALISADE-3 in the first half of 2024 and PALISADE-4 in the second half of 2024. Like PALISADE-2, each study will be a randomized, double-blind, placebo-controlled, Phase 3 clinical trial designed to evaluate the efficacy, safety, and tolerability of the acute administration of fasedienol to relieve anxiety symptoms in adult patients with 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 SUDS as the primary efficacy endpoint.

Should it be successful, the Company believes its PALISADE Phase 3 Program may establish substantial evidence of fasedienol's effectiveness,

supporting a potential fasedienol NDA submission to the U.S. Food and Drug Administration (FDA) for the acute treatment of anxiety in adults with SAD in the first half of 2026.

The Company also plans to initiate a small (n= ca. 60) three-arm randomized, double-blind, placebo-controlled Phase 2B clinical trial designed to evaluate the efficacy, safety, and tolerability of a repeat dose of fasedienol (administered 10 minutes after an initial dose) to further relieve symptoms of acute anxiety in adult patients with SAD during a single simulated, anxiety-provoking public speaking challenge in a clinical setting.

The Company is preparing for the following milestones for fasedienol in SAD:

- Initiate PALISADE-3 Phase 3 study in the first half of 2024;
- Initiate PALISADE-4 Phase 3 study in the second half of 2024; and
- Initiate fasedienol Phase 2B repeat dose study in the second half of 2024.

Itruvone Nasal Spray

Itruvone staged for Phase 2B development as a monotherapy for major depressive disorder (MDD), by the Company or potentially with a strategic partner.

In June 2023, the Company completed a successful randomized, double-blind, placebo-controlled Phase 1 clinical trial to investigate the safety and tolerability of itruvone in healthy adult subjects. The trial was designed to confirm the favorable safety profile of itruvone established in three previous clinical trials conducted in Mexico, including a positive randomized, double-blind, placebo-controlled Phase 2A study of itruvone in MDD, and facilitate potential Phase 2B clinical development of itruvone in the U.S., either by Vistagen alone or potentially with a strategic development and commercialization partner, as a non-systemic monotherapy for MDD differentiated from all FDA-approved antidepressants.

The Company is preparing for the following milestone for itruvone in MDD:

- Initiate Phase 2B study in the second half of 2024.

PH80 Nasal Spray

Second positive exploratory Phase 2A trial of hormone-free PH80 nasal spray provides new optimism for the acute management of multiple indications in women's healthcare with high unmet medical need.

In September 2023, the Company announced previously unreported data of a randomized, double-blind, placebo-controlled exploratory Phase 2A clinical study designed to explore the efficacy, safety, and tolerability of intranasal administration of PH80 for the acute management of premenstrual dysphoric disorder (PMDD) in subjects with a regular menstrual cycle and at least a one-year history of PMDD.

- PH80 demonstrated statistically and clinically significant improvement versus placebo in symptoms of PMDD using the subject-rated Penn Daily Symptom Report (DSR) as early as Day 4 and continuing to Day 6 (p=0.008).
- PH80 demonstrated statistically and clinically significant improvement versus placebo at Day 6 on the clinician-rated Premenstrual Tension Scale (PMTS) (p=0.006).
- PH80 was well-tolerated with no serious adverse events.
- Along with the positive results reported during the Company's fiscal 2024 first quarter from a randomized, double-blind, placebo-controlled exploratory Phase 2A clinical study designed to explore the efficacy, safety, and tolerability of PH80 for the acute management of vasomotor symptoms (hot flashes) due to menopause, these PMDD data further support PH80's potential as a differentiated, non-systemic, hormone-free treatment option for multiple indications in women's healthcare with high unmet medical need.

The Company expects the following milestone for PH80:

- Finalize U.S. IND-enabling studies in the second half of 2024 to facilitate potential Phase 2B development in the U.S. for the acute treatment of vasomotor symptoms (hot flashes) due to menopause in the first half of 2025, potentially with a development and commercialization partner.

Corporate Update

$1.5 million payment received from Fuji Pharma for an exclusive negotiation agreement for a potential license to develop and commercialize hormone-free PH80 for vasomotor symptoms (hot flashes) due to menopause in Japan and potentially other indications.

In September 2023, Vistagen and Fuji Pharma entered into a time-limited (up to approximately eighteen months) agreement to negotiate exclusively with each other regarding a potential license to develop and commercialize PH80 in Japan, including for the acute treatment of moderate to severe vasomotor symptoms (hot flashes) due to menopause, PMDD, and potentially other indications. As consideration for this agreement, Fuji Pharma agreed to pay to Vistagen a cash fee of $1.5 million, which payment was received in November 2023.

Cindy Anderson appointed as Chief Financial Officer, succeeding Jerrold Dotson who retired after a distinguished decade-long career with the Company.

In August 2023, the Company 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 biotechnology sector. She joins Vistagen from Alnylam Pharmaceuticals where she served as the Chief Accounting Officer, focused on strategic and financial operations. Vistagen would like to extend its gratitude to Mr. Dotson for his substantial contributions during his tenure with the Company.

Fiscal Year 2024 Second Quarter Financial Results

***Research and development (R&D) expense*:** Research and development expense decreased by approximately $9.0 million, from $12.9 million to $3.9 million for the quarter ended September 30, 2022 and 2023, respectively. The decrease in R&D expense is primarily due to completing the initial studies in the Company's PALISADE Phase 3 Program for fasedienol in SAD, as well as reduced nonclinical development, regulatory and outsourced manufacturing, and regulatory activities for fasedienol and itruvone.

***General and administrative (G&A) expense*:** General and administrative expense decreased by approximately $0.5 million from $3.7 million for the quarter ended September 20, 2022, to $3.2 million for the quarter ended September 30, 2023, primarily due to decreased compensation, consulting, and professional services.

***Net loss*:** Net loss attributable to common stockholders for the second quarter ended September 30, 2023 was approximately $6.6 million compared to a net loss of $17.5 million for September 30, 2022.

***Cash position*:** At September 30, 2023, the Company had cash and cash equivalents of approximately $37.6 million. In addition, since September 30, 2023, the Company received approximately $93.5 million in net proceeds from an underwritten public offering of its equity securities and $1.5 million from Fuji Pharma for a time-limited exclusive negotiation agreement regarding a potential license to develop and commercialize PH80 in Japan.

Should its PALISADE Phase 3 Program be successful, the Company believes that the current cash position will be sufficient to fund its operations through its potential submission of a U.S. NDA for fasedienol for the acute treatment of anxiety in adults with SAD in the first half of 2026.

As of November 9, 2023, the Company had 27,023,038 shares of common stock 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): 1-800-245-3047
International Dial-in Number (Toll): 1-203-518-9765
Conference ID: VISTAGEN
Webcast Link: https://viavid.webcasts.com/starthere.jsp?ei=1641124&tp_key=2213157260

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 9, 2023. 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: 11153994.

About Vistagen

Vistagen (Nasdaq: VTGN) is a late clinical-stage biopharmaceutical company aiming to transform the treatment landscape for individuals living with anxiety, depression, and other CNS disorders. Vistagen is advancing therapeutics with the potential to be faster-acting, and with fewer side effects and safety concerns, than those currently available for the treatment of anxiety, depression, and multiple CNS disorders. Vistagen's pipeline contains six clinical-stage product candidates, including fasedienol (PH94B), itruvone (PH10), PH15, PH80, and PH284, each an investigational agent belonging to a new class of drugs known as pherines, as well as AV-101, which is an oral prodrug antagonist of the N-methyl-D-aspartate receptor (NMDAR). Pherines are neuroactive nasal sprays designed with an innovative and differentiated proposed mechanism of action (MOA) that activates chemosensory neurons in the nasal cavity and can beneficially impact key neural circuits in the brain without systemic absorption or direct activity on neurons in the brain. Vistagen is passionate about transforming mental health care and redefining what is possible in the treatment of anxiety, depression, and several other CNS 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, itruvone, AV-101 and/or PH80. Other factors that may cause such a difference include, without limitation, risks and uncertainties relating to the Company's submission of an U.S. NDA to the FDA for any product candidate, including fasedienol; the ability of any clinical trial information submitted by the Company to the FDA to support an U.S. NDA; risks and uncertainties related to the Company's ability to secure successful strategic global and/or regional development and commercialization partnerships; other risks and uncertainties related to delays in launching, conducting and/or completing ongoing and planned clinical trials; 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 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 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, 2023, and in the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2023, 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
(Amounts in dollars, except share amounts)

	September 30, 2023 (Unaudited)	March 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 37,608,400	$ 16,637,600
Prepaid expenses and other current assets	1,393,300	802,700
Deferred contract acquisition costs - current portion	74,500	67,100
Total current assets	39,076,200	17,507,400
Property and equipment, net	444,300	507,300
Right-of-use asset - operating lease	2,045,000	2,260,300
Deferred offering costs	362,000	495,700
Deferred contract acquisition costs - non-current portion	167,400	217,600
Security deposits	100,900	100,900
Total assets	$ 42,195,800	$ 21,089,200
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,305,000	$ 2,473,100
Accrued expenses	292,600	787,400
Note payable	-	105,300
Deferred revenue - current portion	793,000	714,300
Operating lease obligation - current portion	517,100	485,600
Financing lease obligation - current portion	1,800	1,700
Total current liabilities	2,909,500	4,567,400
Non-current liabilities:		

Deferred revenue - non-current portion	1,780,600	2,314,600
Operating lease obligation - non-current portion	1,854,000	2,119,800
Financing lease obligation - non-current portion	6,500	7,400
Total non-current liabilities	3,641,100	4,441,800
Total liabilities	6,550,600	9,009,200
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at September 30, 2023 and March 31, 2023; no shares outstanding at September 30, 2023 and March 31, 2023	-	-
Common stock, $0.001 par value; 325,000,000 shares authorized at September 30, 2023 and March 31, 2023; 12,016,750 and 7,315,583 shares issued at September 30, 2023 and March 31, 2023, respectively	12,000	7,300
Additional paid-in capital	379,943,800	342,892,500
Treasury stock, at cost, 4,522 shares of common stock held at September 30, 2023 and March 31, 2023	(3,968,100)	(3,968,100)
Accumulated deficit	(340,342,500)	(326,851,700)
Total stockholders' equity	35,645,200	12,080,000
Total liabilities and stockholders' equity	$ 42,195,800	$ 21,089,200

References to common shares and per share amounts have been retroactively restated to reflect the Company's 1-for-30 reverse stock split of its common stock effective on June 6, 2023.

VISTAGEN THERAPEUTICS
CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS
(Unaudited)
(Amounts in Dollars, except share amounts)

	Three Months Ended September 30,		**Six Months Ended September 30,**	
	2023	**2022**	**2023**	**2022**
Revenues:				
Sublicense revenue	$ 277,700	$ (892,500)	$ 455,300	$ (582,500)
Total revenues	277,700	(892,500)	455,300	(582,500)
Operating expenses:				
Research and development	3,850,600	12,894,500	8,047,800	28,185,800
General and administrative	3,207,300	3,702,300	6,185,500	8,494,100
Total operating expenses	7,057,900	16,596,800	14,233,300	36,679,900
Loss from operations	(6,780,200)	(17,489,300)	(13,778,000)	(37,262,400)

Other income, net:				
Interest income, net	192,500	6,100	289,700	8,400
Loss before income taxes	(6,587,700)	(17,483,200)	(13,488,300)	(37,254,000)
Income taxes	-	-	(2,500)	(5,500)
Net loss and comprehensive loss	$ (6,587,700)	$ (17,483,200)	$ (13,490,800)	$ (37,259,500)
Basic and diluted net loss per common share	$ (0.66)	$ (2.54)	$ (1.55)	$ (5.41)
Weighted average common share - basic and diluted	10,042,530	6,893,708	8,717,050	6,890,152

References to common shares and per share amounts have been retroactively restated to reflect the Company's 1-for-30 reverse stock split of its common stock effective on June 6, 2023.

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