Vistagen Provides Corporate Update and Reports Fiscal 2023 Third Quarter Financial Results

February 7, 2023

Pherin acquisition completed; all future royalty payment obligations related to PH94B and PH10 eliminated, three new drug candidates added to Vistagen's pipeline

PH94B Phase 3 program for social anxiety disorder advancing towards important next steps

PH10 Phase 1 study initiated to facilitate plans for Phase 2B development of PH10 for major depressive disorder; FDA Fast Track designation granted

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Feb. 7, 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 2023 third quarter ended December 31, 2022.

"Since our last quarterly update, Vistagen has met several important business objectives," said Shawn Singh, Chief Executive Officer of Vistagen. "Our recent acquisition of Pherin Pharmaceuticals, and now full ownership of PH94B and PH10, puts the company in a position to significantly enhance the commercial profile of these two promising pipeline assets. In addition, over the past two quarters, we advanced core clinical programs in social anxiety disorder, adjustment disorder and major depressive disorder. Both PH94B and PH10 have the potential to offer novel, fast-acting treatment for millions of patients confronting the effects of debilitating mental health challenges without the side effects and safety concerns often associated with current FDA-approved products. We believe Vistagen is now well-positioned to reach several important milestones during 2023."

Corporate Update

Company remains confident in PH94B Phase 3 development program for treatment of social anxiety disorder (SAD).

After further analysis of PALISADE-1, a single administration Phase 3 public speaking challenge study, the Company has identified several potential explanations for the unexpected results of the study, primarily complexities associated with the single-dose assessment public speaking challenge methodology and conducting the study during surges in the COVID-19 pandemic. The Company recently submitted to the U.S. Food and Drug Administration (FDA) proposed adjustments to the PALISADE-2 study protocol. Should Vistagen resume PALISADE-2, the proposed amendments are intended to address various methodological issues believed to have contributed to the unexpected results of PALISADE-1.

Upon reviewing information and data available this time, the Company believes it is not yet advisable to make a decision about resuming PALISADE-2 before discussing its broader Phase 3 development plan for PH94B with the FDA and before further assessing the potential impact of the proposed adjustments to the PALISADE-2 protocol in light of two recently completed public speaking challenge SAD studies conducted by peers, each of which did not achieve its primary efficacy endpoint. Vistagen is currently preparing to meet with the FDA to discuss its broader Phase 3 development plan for PH94B, which plan includes the possibility of a multiple-administration, randomized, double-blind, placebo-controlled Phase 3 study of PH94B in adults, using the Liebowitz Social Anxiety Scale (LSAS) as the primary efficacy outcome measure to support a potential New Drug Application. The LSAS was the primary efficacy endpoint in all registration studies for the three currently FDA-approved treatments for SAD. Given that LSAS measures overall improvement in disease severity by measuring the reduction in fear and anxiety over time (rather than from only a single dose assessment), as well as the avoidance of anxiety-provoking social and performance situations in a real-world environment, Vistagen believes the LSAS is appropriate to measure and reflect the true impact of PH94B on patients' lives. The Company expects to announce its plans regarding PALISADE-2 concurrently with other updates to its PH94B Phase 3 development plan.

Encouraging preliminary data from PALISADE Open Label Study inform Phase 3 path forward in SAD.

Preliminary analysis of the final data set from nearly 400 subjects observed in the Company's PALISADE Open Label Study (PALISADE OLS) provide important additional information about the safety and tolerability of PH94B in adult subjects with SAD as well as potential improvement in SAD over time, as measured by the LSAS. The Company expects to release safety and tolerability results from the PALISADE OLS, as well as results observed using the LSAS over time, during the first quarter of calendar 2023.

Exploratory Phase 2A trial of PH94B in adjustment disorder with anxiety (AjDA) completed.

The Company has completed its exploratory double-blind, placebo-controlled Phase 2A clinical trial of PH94B to evaluate the efficacy, safety and tolerability of PH94B as a potential treatment of adults with AjDA. The study protocol involves multiple administration assessments of PH94B administered four times per day for 28 days. Vistagen anticipates reporting topline results from this exploratory Phase 2A AjDA trial by the end of the first quarter of calendar 2023.

PH10 receives Fast Track designation in major depressive disorder (MDD) from FDA; Phase 1 clinical trial underway to facilitate Phase 2B program.

In December 2022, Vistagen was advised by the FDA that the Company may proceed with its Phase 1 program following submission of its U.S. Investigational New Drug (IND) application for clinical development of PH10 in the U.S. in healthy volunteers. In addition, the FDA has granted Fast Track designation (FTD) for the development of PH10 for the treatment of MDD.

The small (n=12) randomized, double-blinded, placebo-controlled Phase 1 trial is underway and is intended to investigate the safety and tolerability of PH10 in healthy adult subjects, confirm the favorable safety profile of PH10 established in three previous clinical studies conducted in Mexico,

including a published Phase 2A study for the treatment of MDD, and facilitate plans for Phase 2B development of PH10 as a stand-alone treatment for MDD. The Company anticipates completion of the Phase 1 study by the end of the first quarter of calendar 2023.

AV-101 + Probenecid Phase 1B trial progressing.

Based on observations and findings from preclinical studies, Vistagen believes that AV-101, alone or in combination with FDA-approved oral probenecid, has the potential to become a new oral treatment alternative for certain CNS indications involving the NMDA receptor. The Company is currently conducting an exploratory Phase 1B drug-drug interaction clinical study of AV-101 in combination with probenecid and expects to complete the study in the first half of 2023. Upon completion of the study, the Company plans to consider exploratory Phase 2A development of AV-101, alone or in combination with probenecid, on its own or with a collaborator, as a potential oral treatment for one or more CNS disorders involving the NMDA receptor.

Acquisition of Pherin Pharmaceuticals, Inc. completed.

Vistagen recently completed the acquisition of Pherin Pharmaceuticals, Inc. (Pherin), resulting in Pherin becoming a wholly-owned subsidiary of the Company. Vistagen secured full ownership of intellectual property rights to PH94B and PH10 and all future royalty payment obligations related to those assets have been eliminated, significantly enhancing the potential commercial profile of these two late-stage assets. In addition, the Company now has three new early clinical-stage pherine product candidates: PH15 for cognition improvement; PH80 for migraine and hot flashes; and PH284 for appetite-related disorders.

Fiscal Year 2023 Third Quarter Financial Results

***Research and development (R&D) expense*:** Research and development expense decreased by $0.9 million, from $7.8 million to $6.9 million for the quarters ended December 31, 2021 and 2022, respectively. The decrease in R&D expense is primarily due the reduction in expenses related to the PALISADE Phase 3 Program for PH94B in SAD, including PALISADE-1, PALISADE-2 and the PALISADE OLS, and the exploratory Phase 2A study of PH94B in AjDA, as well as nonclinical development, regulatory and outsourced manufacturing activities for both PH94B and PH10.

***General and administrative (G&A) expense*:** General and administrative expense was flat at approximately $3.1 million for each of the quarters ended December 31, 2022 and 2021.

***Net loss*:** Net loss attributable to common stockholders for the fiscal quarters ended December 31, 2022 and 2021 was approximately $9.8 million and $10.7 million, respectively.

***Cash position*:** At December 31, 2022, the Company had cash and cash equivalents of approximately $25.0 million.

As of February 7, 2023, the Company had 219,326,526 shares of common stock outstanding, which reflects the issuance of approximately 12.4 million unregistered shares of common stock associated with the Pherin Pharmaceuticals transaction.

Conference Call

Vistagen will host a conference call and live audio webcast this afternoon at 5:00 p.m. Eastern Time to discuss its financial results for its third quarter fiscal year 2023 ended December 31, 2022 and 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: 13735532
Webcast Link: https://viavid.webcasts.com/starthere.jsp?ei=1593644&tp_key=b10e7e1927

A live audio webcast of the conference call will also be available via the link provided above. 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, February 7, 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 PIN number 13735532.

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. The Company is advancing therapeutics with the potential to be faster-acting, and with fewer side effects and safety concerns, than those that are currently available for treatment of anxiety and depression. Vistagen's product candidates belong to a new class of drugs known as pherines, which are designed with a novel rapid-onset mechanism of action that activates chemosensory neurons in the nasal passages and can impact key neural circuits without systemic uptake or direct activity on CNS neurons in the brain. Vistagen is passionate about transforming mental health care and redefining what is possible in the treatment of anxiety and depression. 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 future clinical trials, receive regulatory approval or be commercially successful. Other factors that may cause such a difference include, without limitation, risks and uncertainties relating to the Company's continued clinical development program of PH94B in SAD, including the Company's plan for continuing PALISADE-2, if at all, and its broader Phase 3 development program; the completion and results the Company's ongoing clinical studies of PH94B, including the Company's Phase 2A clinical trial of PH94B in adults experiencing adjustment disorder

with anxiety, and ongoing studies of the Company's other product candidates, PH10 and AV-101; incorporation of PH50, PH80 and PH284 into the Company's pre-clinical and clinical development plans and other risks and uncertainties related to the Company's recent acquisition of Pherin Pharmaceuticals, Inc.; delays in launching, conducting and/or completing other ongoing and planned clinical trials, including adverse effects resulting from the COVID-19 pandemic; fluctuating costs of materials and other resources 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 CNS drug 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, 2022 and in the Company's most recent Quarterly Report on Form 10-Q for the quarter ended December 31, 2022, 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)

	December 31, 2022 (unaudited)	**March 31, 2022**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 25,037,300	$ 68,135,300
Prepaid expenses and other current assets	953,200	2,745,800
Deferred contract acquisition costs - current portion	67,000	116,900
Total current assets	26,057,500	70,998,000
Property and equipment, net	540,700	414,300
Right-of-use asset - operating lease	2,364,100	2,662,000
Deferred offering costs	411,400	321,800
Deferred contract acquisition costs - non-current portion	234,200	146,400
Security deposits	100,900	100,900
Total assets	$ 29,708,800	$ 74,643,400
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,598,800	$ 2,758,600
Accrued expenses	1,085,200	1,329,200
Note payable	419,100	-
Deferred revenue - current portion	712,300	1,244,000

Operating lease obligation - current portion	470,400	433,300
Financing lease obligation - current portion	1,600	-
Total current liabilities	4,287,400	5,765,100
Non-current liabilities:		
Non-current portion of notes payable	-	-
Accrued dividends on Series B Preferred Stock	-	-
Deferred revenue - non-current portion	2,492,200	1,557,600
Operating lease obligation - non-current portion	2,246,800	2,605,400
Financing lease obligation - non-current portion	7,900	-
Total non-current liabilities	4,746,900	4,163,000
Total liabilities	9,034,300	9,928,100
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at December 31, 2022 and March 31, 2022:		
no shares outstanding at December 31, 2022 and March 31, 2022	-	-
Common stock, $0.001 par value; 325,000,000 shares authorized at December 31, 2022 and March 31, 2022;		
207,052,010 and 206,676,620 shares issued at December 31, 2022 and March 31, 2022, respectively	207,100	206,700
Additional paid-in capital	339,060,200	336,080,700
Treasury stock, at cost, 135,665 shares of common stock held at December 31, 2022 and March 31, 2022	(3,968,100)	(3,968,100)
Accumulated deficit	(314,624,700)	(267,604,000)
Total stockholders' equity	20,674,500	64,715,300
Total liabilities and stockholders' equity	$ 29,708,800	$ 74,643,400

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

	Three Months Ended December 31,		Nine Months Ended December 31,	
	2022	**2021**	**2022**	**2021**
Revenues:				
Sublicense revenue	$ 179,600	$ 357,900	$ (402,900)	$ 1,070,000

Total revenues	179,600	357,900	(402,900)	1,070,000
Operating expenses:				
Research and development	6,854,000	7,780,000	35,039,800	23,173,600
General and administrative	3,092,100	3,118,100	11,586,200	8,982,300
Total operating expenses	9,946,100	10,898,100	46,626,000	32,155,900
Loss from operations	(9,766,500)	(10,540,200)	(47,028,900)	(31,085,900)
Other income, net:				
Interest income, net	5,300	5,100	13,700	15,300
Loss before income taxes	(9,761,200)	(10,535,100)	(47,015,200)	(31,070,600)
Income taxes	-	-	(5,500)	(3,400)
Net loss and comprehensive loss	(9,761,200)	(10,535,100)	(47,020,700)	(31,074,000)
Accrued dividend on Series B Preferred stock	-	(208,100)	-	(945,100)
Net loss attributable to common stockholders	$ (9,761,200)	$ (10,743,200)	$ (47,020,700)	$ (32,019,100)
Basic and diluted net loss attributable to common stockholders per common share	$ (0.05)	$ (0.05)	$ (0.23)	$ (0.16)
Weighted average shares used in computing basic and diluted net loss attributable to common stockholders per common share	206,838,084	202,328,683	206,749,238	195,179,267

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