VistaGen Therapeutics Reports First Quarter Financial Results and Provides Corporate Update

August 11, 2022

Evaluation of PALISADE-1 continues and interim analysis of PALISADE-2 begins

Preliminary data from nearly 200 subjects in the PALISADE open label safety study suggest that continued as-needed use of PH94B has potential to achieve cumulative functional improvement in the severity of social anxiety disorder (SAD)

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Aug. 11, 2022-- VistaGen Therapeutics, Inc. (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 reported its financial results for its first quarter of fiscal year 2023 ended June 30, 2022 and provided a corporate update.

“We remain steadfast in our commitment to change the trajectory of mental health care for millions of people affected by anxiety and depression disorders,” said Shawn Singh, Chief Executive Officer of VistaGen. “While we examine the results of our PALISADE-1 Phase 3 study in social anxiety disorder, we have paused enrollment in our PALISADE-2 Phase 3 study and have engaged an independent biostatistician to conduct an interim analysis of data collected to date. We then plan to meet with the FDA to pursue a consensus path forward for further Phase 3 development of PH94B in social anxiety disorder.

“We continue to believe in PH94B’s potential to help individuals suffering from social anxiety disorder. We are further encouraged by preliminary data from a cohort of nearly 200 patients in our PALISADE open label safety study who have completed three months of acute, as-needed use of PH94B. These preliminary data suggest that repeated acute, as-needed use of PH94B over an extended period of time has potential to increasingly relieve symptoms of social anxiety disorder, as measured by the Liebowitz Social Anxiety Scale, or LSAS, which historically has been the diagnostic gold standard for clinical assessment of social anxiety disorder. Taken together with encouraging published results from a prior Phase 2 study in social anxiety disorder which involved multiple administration assessment of PH94B over a two-week period measured by the LSAS, these preliminary data support the published findings and give us confidence in PH94B’s potential to reduce the severity of social anxiety on an acute, as-needed basis, while also achieving cumulative improvement in everyday social functioning, with continued use in a real-world environment.”

“Having deferred a large portion of our NDA-enabling activities, we have reduced our expected cash requirements for our operations over the next year. Our mission is to transform lives, and we have a strong pipeline and team in place to accomplish that goal,” added Singh.

First Quarter Fiscal Year 2023 & Recent Business Highlights

Below is an update on the Company’s pipeline of CNS product candidates— the nasal spray, pherine-based platform consisting of PH94B and PH10, and our NMDA (N-methyl-D-aspartate) receptor program, involving orally available AV-101.

PALISADE Clinical Development Program for PH94B in Social Anxiety Disorder (*SAD*) – On July 22, 2022, the Company announced that PH94B did not achieve its primary efficacy endpoint during PALISADE-1, a single administration assessment Phase 3 trial, as measured by change from baseline using the Subjective Units of Distress Scale (*SUDS*) as compared to placebo. The Company continues to evaluate the results of this study. In response to the topline results from PALISADE-1, the Company has paused enrollment in PALISADE-2, a replicate Phase 3 clinical study in our PALISADE clinical development program, while an independent third-party biostatistician conducts an interim analysis of available data from PALISADE-2.

Although PALISADE-1 did not meet its primary efficacy endpoint, the tolerability of PH94B in PALISADE-1 was favorable and consistent with reported results from previous clinical trials. No severe or serious adverse events were reported for PH94B in PALISADE-1 or in other clinical trials.

In addition, the Company is encouraged by preliminary data from a cohort of nearly 200 subject in its PALISADE open label safety study which suggest an excellent safety profile for PH94B consistent with all previous studies, as well as cumulative functional improvement as measured by the Liebowitz Social Anxiety Scale (*LSAS*). In this study, which mirrors real world use, this cohort of study participants has used PH94B acutely, as-needed, multiple times for three months. Given these data, along with positive indications from the prior Phase 2 studies, the Company believes that continued Phase 3 clinical development of PH94B as a potential treatment for SAD is appropriate, particularly with repeated and longer-term use of PH94B evaluated by multiple administration assessments using the LSAS as the primary endpoint and SUDS as the secondary endpoint.

The Company is evaluating potential study design modifications in its PALISADE Phase 3 program, including an extended exposure period, and is preparing to meet with the FDA to discuss potential next steps for the late-stage clinical development of PH94B.

Phase 2 Trial of PH94B in Adjustment Disorder with Anxiety and Future Opportunities – The Company has an ongoing exploratory Phase 2A clinical trial designed to evaluate the efficacy, safety and tolerability of PH94B as a potential treatment of adults with adjustment disorder with anxiety (*AjDA*). The study protocol involves multiple administration assessments of PH94B, which is administered four times per day for 28 days. We anticipate topline data from this AjDA trial in late 2022.

PH10 Nasal Spray Development Continues for Multiple Depression Disorders – Following positive results from an exploratory Phase 2A study of PH10 in major depressive disorder (*MDD*) conducted in Mexico City, the Company is preparing to submit an Investigational New Drug (*IND*) application to the FDA for further clinical development of PH10 in MDD in the U.S. The Company anticipates submission of its PH10 IND in MDD in

2022 and initiation of a small U.S. Phase 1 study in 2022 to facilitate potential Phase 2B development of PH10 as a rapid-onset, stand-alone treatment of MDD in 2023.

AV-101 + Probenecid Phase 1B Trial Progressing – Following positive preclinical data, VistaGen initiated a Phase 1B drug-drug interaction study of AV-101 in combination with probenecid in late 2021. The Company is considering the evaluation of AV-101 in combination with probenecid as a potential oral treatment for several distinct neurological disorders.

Fiscal Year 2023 First Quarter Financial Results

***Research and development (R&D) expense*:** Research and development expense increased by $9.8 million, from $5.5 million to $15.3 million for the quarters ended June 30, 2021 and 2022, respectively. The increase in R&D expense is primarily due to expenses related to conducting the PALISADE Phase 3 Program for PH94B, including PALISADE-1, PALISADE-2 and the PALISADE open label safety study, and the PH94B Phase 2A Study in AjDA, as well as nonclinical development and outsourced manufacturing activities for both PH94B and PH10.

***General and administrative (G&A) expense*:** General and administrative expense increased to approximately $4.8 million for the quarter ended June 30, 2022 compared to approximately $2.6 million for the quarter ended June 30, 2021. The increase in G&A expense was primarily due to the addition of senior management and other personnel during calendar year 2021 and the first half of calendar 2022, as well as PH94B pre-launch commercialization market research studies and analyses.

***Net loss*:** Net loss attributable to common stockholders for the fiscal quarters ended June 30, 2022 and 2021 was approximately $19.8 million and $8.1 million, respectively.

***Cash position*:** At June 30, 2022, the Company had cash and cash equivalents of approximately $52.0 million.

As a result of the deferral of several research and development and pre-commercial activities involving PH94B, the Company anticipates a considerable reduction in external spending to conserve cash and extend the Company's cash runway covering at least the next 12 months.

As of August 10, 2022, the Company had 206,836,345 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 and discuss its financial results for its first quarter fiscal year 2023 ended June 30, 2022.

U.S. Dial-in (Toll-Free): 1-888-999-5318
International Dial-in Number (Toll): 1-848-280-6460
Conference ID: 4956626
Webcast Link: https://viavid.webcasts.com/starthere.jsp?ei=1558823&tp_key=7de8cd8f64

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 Thursday, August 11, 2022. 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 151563.

About VistaGen

VistaGen (Nasdaq: VTGN) is a late clinical-stage, CNS-focused biopharmaceutical company striving 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. VistaGen's clinical-stage candidates are targeting multiple forms of anxiety and depression. PH94B and PH10 belong to a new class of drugs known as pherines, which are odorless and tasteless investigational neuroactive steroids designed with a novel rapid-onset mechanism of action that activates chemosensory neurons in the nasal passages and can impact the olfactory-amygdala 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 any 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 other 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 results of the Company's interim analysis of data currently available from the PALISADE-2 Phase 3 clinical trial; the completion and results of 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; delays in launching, conducting and/or completing other ongoing and planned clinical trials, including delays or other adverse effects due to the impact of the ongoing 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 June 30, 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)

	June 30, 2022 (unaudited)	March 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 51,986,400	$ 68,135,300
Prepaid expenses and other current assets	2,890,300	2,745,800
Deferred contract acquisition costs - current portion	116,900	116,900
Total current assets	54,993,600	70,998,000
Property and equipment, net	567,600	414,300
Right-of-use asset - operating lease	2,565,000	2,662,000
Deferred offering costs	381,200	321,800
Deferred contract acquisition costs - non-current portion	117,300	146,400
Security deposits	100,900	100,900
Total assets	$ 58,725,600	$ 74,643,400
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,473,000	$ 2,758,600
Accrued expenses	727,300	1,329,200
Notes payable	1,037,800	-
Deferred revenue - current portion	1,244,000	1,244,000
Operating lease obligation - current portion	442,600	433,300
Financing lease obligation - current portion	1,500	-
Total current liabilities	8,926,200	5,765,100
Non-current liabilities:		

Deferred revenue - non-current portion	1,247,500	1,557,600
Operating lease obligation - non-current portion	2,491,200	2,605,400
	8,700	-
Total non-current liabilities	3,747,400	4,163,000
Total liabilities	12,673,600	9,928,100
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at June 30, 2022 and March 31, 2022: no shares outstanding at June 30, 2022 and March 31, 2022		
Common stock, $0.001 par value; 325,000,000 shares authorized at June 30, 2022 and March 31, 2022; 206,851,620 and 206,676,620 shares issued at June 30, 2022 and March 31, 2022, respectively	206,900	206,700
Additional paid-in capital	337,193,500	336,080,700
Treasury stock, at cost, 135,665 shares of common stock held at June 30, 2022 and March 31, 2022	(3,968,100)	(3,968,100)
Accumulated deficit	(287,380,300)	(267,604,000)
Total stockholders' equity	46,052,000	64,715,300
Total liabilities and stockholders' equity	$ 58,725,600	$ 74,643,400

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

	Three Months Ended June 30,	
	2022	**2021**
Revenues:		
Sublicense revenue	$ 310,100	$ 354,100
Total revenues	310,100	354,100
Operating expenses:		
Research and development	$ 15,291,400	$ 5,457,200
General and administrative	4,791,800	2,643,100
Total operating expenses	20,083,200	8,100,300
Loss from operations	(19,773,100)	(7,746,200)
Other income, net:		
Interest income, net	2,300	5,100
Loss before income taxes	(19,770,800)	(7,741,100)

Income taxes	(5,500)	(3,400)
Net loss and comprehensive loss	$ (19,776,300)	$ (7,744,500)
Accrued dividend on Series B Preferred stock	-	(361,800)
Net loss attributable to common stockholders	$ (19,776,300)	$ (8,106,300)
Basic and diluted net loss attributable to common stockholders per common share	$ (0.10)	$ (0.04)
Weighted average shares used in computing basic and diluted net loss attributable to common stockholders per common share	206,596,724	189,924,158

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