VistaGen Therapeutics Reports Fiscal Year 2022 Second Quarter Financial Results and Provides Corporate Update

November 10, 2021

PALISADE Phase 3 clinical trials of PH94B for rapid-onset acute treatment of anxiety in adults with social anxiety disorder (SAD) progressing on plan

PH94B Phase 2A clinical program targeting additional potential anxiety indications launched in adjustment disorder with anxiety (AjDA)

Newly appointed Directors add mental health, consumer engagement expertise to the Company's Board

SOUTH SAN FRANCISCO, Calif., Nov. 10, 2021 (GLOBE NEWSWIRE) -- VistaGen Therapeutics, Inc. (NASDAQ: VTGN), a late-stage biopharmaceutical company committed to developing and commercializing a new generation of medicines with the potential to go beyond the current standard of care for anxiety, depression, and other central nervous system (CNS) disorders, today reported its financial results for the fiscal year 2022 second quarter ended September 30, 2021 and provided a review of the Company's recent accomplishments.

"We continued our strong performance throughout the quarter with notable advances in all programs for our lead product candidate, PH94B. We advanced our PALISADE Phase 3 Program in social anxiety disorder with the initiation of a second Phase 3 study, PALISADE-2, and our PALISADE Long-term Safety Study," said Shawn Singh, Chief Executive Officer of VistaGen. "We also launched our exploratory Phase 2A clinical program for PH94B to begin to assess its therapeutic potential in anxiety indications beyond SAD. Our Phase 2A study of PH94B in its second potential indication, adjustment disorder with anxiety, is now underway. Adjustment disorder with anxiety is among several anxiety disorders which have emerged with greater prevalence during the COVID pandemic. In addition, we recently reported data from a PH94B preclinical study that strongly support its potential mechanism of action, suggesting that, in sharp contrast to all antidepressants, benzodiazepines and betablockers used to treat anxiety disorders, PH94B has the potential to achieve rapid-onset anti-anxiety effects without requiring systemic uptake or causing benzodiazepine-like side effects and safety concerns."

"These milestones are encouraging advances in our focused efforts to develop and commercialize PH94B, first and foremost for the acute treatment of anxiety in adults with social anxiety disorder, if our PALISADE Phase 3 Program is successful, and ultimately for anxiety indications beyond SAD," added Mr. Singh. "As we diligently pursue our goals for our CNS pipeline through 2022 and well beyond, we are well positioned to deliver on our mission to improve the mental health and daily lives of millions in the U.S. and around the world who are suffering from the debilitating effects of anxiety and depression."

PH94B Clinical Updates

During the quarter, VistaGen initiated PALISADE-2, the second Phase 3 trial in its PALISADE Phase 3 Program for PH94B in social anxiety disorder (SAD). PALISADE-2 is a U.S. multi-center, randomized, double-blind, placebo-controlled Phase 3 clinical study to evaluate the efficacy, safety, and tolerability of PH94B for the acute treatment of anxiety in adults with SAD. The Company also initiated its PALISADE Long-term Safety Study.

The Company expects topline data for PALISADE-1 in mid-2022 and PALISADE-2 topline data in the second half of 2022. The Company's PALISADE Phase 3 Program, if successful, is designed to provide the data required to support a potential submission of a PH94B U.S. New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in mid-2023. The FDA has granted PH94B Fast Track designation status for development in SAD.

VistaGen launched its exploratory Phase 2A clinical program for PH94B, designed to evaluate its therapeutic potential in several additional anxiety disorders beyond SAD. The first study in this program is a Phase 2A clinical trial evaluating PH94B in adults experiencing adjustment disorder with anxiety (AjDA), with topline results anticipated in the second half of 2022. The Company intends to expand the PH94B Phase 2A program in 2022 to include additional exploratory studies in other anxiety indications. PH94B has potential as a novel therapeutic for postpartum anxiety, post-traumatic stress disorder, and procedural anxiety.

New data from a preclinical study of radiolabeled PH94B in animal models demonstrated that PH94B's mechanism of action (MOA) involves binding to peripheral neurons in the nasal passages, thereby limiting the transport of molecules to the circulatory system and minimizing potential systemic exposure. These data support the fundamental differentiation of PH94B's MOA compared to that of currently marketed therapies for anxiety disorders, including antidepressants, benzodiazepines and beta blockers, all of which require systemic uptake and distribution and are associated with potential negative side effects and safety concerns.

Additional Corporate & Pipeline Updates

VistaGen expanded the expertise of its Board of Directors with the additions of Mary L. Rotunno, J.D. and Maggie Fitzpatrick. These two appointments bring patient-focused mental health and healthcare consumer engagement expertise to VistaGen's governorship. Ms. Rotunno's and Ms. Fitzpatrick's expertise will be particularly beneficial to the Company as it progresses through late-stage clinical studies and prepares for potential commercialization of PH94B. In addition, when combined with the prior appointments of Ann M. Cunningham, MBA and Joanne Curley Ph.D., VistaGen's Board holds a female-led majority, a significant distinction within the public biopharmaceutical space.

To advance beyond successful exploratory Phase 2A clinical development of PH10 nasal spray for treatment of major depressive disorder (MDD), VistaGen is currently preparing regulatory submissions necessary to initiate a U.S. Phase 2B multi-center, randomized, double-blind, placebo-

controlled study to evaluate the efficacy, safety, and tolerability of PH10 as a potential rapid-onset, stand-alone treatment for MDD in mid-2022. PH10 also has potential as a novel therapeutic for treatment-resistant depression, postpartum depression, and suicidal ideation.

VistaGen remains on track to initiate a Phase 1B clinical study to evaluate AV-101 in combination with probenecid during the current quarter. The FDA has granted Fast Track designation for development of AV-101 as a potential adjunctive treatment for MDD and as a non-opioid treatment for neuropathic pain. AV-101 also has the potential to be developed as a treatment for levodopa-induced dyskinesia associated with Parkinson's disease therapy, suicidal ideation, epilepsy, and other neurological disorders involving the NMDA (N-methyl-D-aspartate) receptor.

Fiscal Year 2022 Second Quarter Financial Results

***Revenue*:** During the quarter ended September 30, 2021, the Company recognized approximately $0.4 million in noncash sublicense revenue from the $5.0 million upfront payment received in the quarter ended September 30, 2020 related to its PH94B development and commercialization agreement with AffaMed Therapeutics, compared to approximately $0.3 million in the quarter ended September 30, 2020.

***Research and development (R&D) expense*:** Research and development expense increased by $7.7 million, from $2.4 million to $10.1 million for the quarters ended September 30, 2020 and 2021, respectively. The increase in R&D expense results primarily from the Company's PALISADE Phase 3 Program for PH94B in SAD, with the continuation of PALISADE-1 and the initiation of PALISADE-2 and the PALISADE Long-term Safety Study, as well as initiation of its Phase 2A study of PH94B in AjDA, in addition to continuing nonclinical developmental and outsourced manufacturing activities for both PH94B and PH10, which accounted for an increase of approximately $5.9 million during the quarter ended September 30, 2021, compared to expense in the same quarter in the prior year. Salaries and benefits expense for the quarter ended September 30, 2021 increased by approximately $1.6 million versus expense for the comparable prior-year quarter, primarily due to the hiring of additional senior management and other personnel focused on clinical operations, outsourced manufacturing activities, and regulatory affairs.

***General and administrative (G&A) expense*:** General and administrative expense increased to approximately $3.1 million for the quarter ended September 30, 2021, compared to approximately $1.3 million for the quarter ended September 30, 2020. Salaries and benefits expense for the quarter ended September 30, 2021 increased by approximately $0.9 million versus the comparable prior-year quarter, primarily due to the hiring of additional senior management personnel. Additionally, the Company incurred approximately $0.5 million in customary pre-commercialization expenses during the quarter ended September 30, 2021.

***Net loss*:** Net loss for the quarters ended September 30, 2021 and 2020 was approximately $12.8 million and $3.3 million, respectively.

***Cash position*:** At September 30, 2021, the Company had cash and cash equivalents of approximately $93.6 million.

At November 9, 2021, the Company had 199,702,333 shares of common stock outstanding.

Conference Call

VistaGen will host a conference call and live audio webcast this afternoon, Wednesday, November 10, 2021, at 5:00 p.m. Eastern Time to provide a corporate update and discuss its financial results for its fiscal year 2022 second quarter ended September 30, 2021.

U.S. Dial-in (Toll-Free): 1-877-407-9716
International Dial-in Number (Toll): 1-201-493-6779
Conference ID: 13724394
Webcast Link: https://viavid.webcasts.com/starthere.jsp?ei=1505931&tp_key=4eabb07e30

A telephone playback of the conference call will be available after approximately 8:00 p.m. Eastern Time on November 10, 2021. 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 13724394.

About VistaGen

VistaGen Therapeutics is a late-stage biopharmaceutical company committed to developing and commercializing innovative medicines with the potential to go beyond the current standard of care for anxiety, depression and other CNS disorders. Each of VistaGen's clinical-stage drug candidates has therapeutic potential in multiple CNS indications. For more information, please visit www.VistaGen.com and connect with VistaGen on Twitter, LinkedIn, and Facebook.

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. The Company's actual results or developments may differ materially from those projected or implied in these forward-looking statements. Factors that may cause such a difference include, without limitation, risks and uncertainties relating to delays in launching and/or conducting planned clinical trials, including delays due to the impact of the ongoing COVID-19 pandemic; fluctuating costs of materials and other resources required to conduct the Company's planned clinical and non-clinical trials; market conditions; the impact of general economic, industry or political conditions in the United States or internationally; adverse healthcare reforms and changes of laws and regulations; manufacturing and marketing risks, which may include, but are not limited to, unavailability of or delays in delivery of raw materials for manufacture of the Company's CNS drug candidates and difficulty in initiating or conducting clinical trials due to the ongoing COVID-19 pandemic or otherwise; inadequate and/or untimely supply of one or more of the Company's CNS drug candidates to meet demand; entry of competitive products; and other technical and unexpected hurdles in the development, manufacture and commercialization of the Company's CNS drug candidates; and the risks 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, 2021 and in the Company's most recent Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, 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 Company Contacts

Media:
Mark McPartland
Vice President, Corporate Development
Phone: (650) 577-3606
Email: markmcp@vistagen.com

Christy Curran
Sam Brown Inc.
Phone: (615) 414-8668
Email: ChristyCurran@sambrown.com

Investors:
Mark Flather
Vice President, Investor Relations
Phone: (650) 577-3617
Email: mflather@vistagen.com

VISTAGEN THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(Amounts in dollars, except share amounts)

	September 30, 2021 (unaudited)	March 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 93,627,100	$ 103,108,300
Receivable from collaboration partner	-	40,600
Prepaid expenses and other current assets	2,676,800	835,100
Deferred contract acquisition costs - current portion	133,500	133,500
Total current assets	96,437,400	104,117,500
Property and equipment, net	496,600	367,400
Right of use asset - operating lease	3,029,100	3,219,600
Deferred offering costs	321,600	294,900
Deferred contract acquisition costs - non-current portion	167,200	234,100
Security deposits	47,800	47,800
Total assets	$ 100,499,700	$ 108,281,300
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,659,600	$ 838,300
Accrued expenses	3,430,100	1,562,700
Deferred revenue - current portion	1,420,200	1,420,200
Operating lease obligation - current portion	401,000	364,800
Financing lease obligation - current portion	1,300	3,000
Total current liabilities	7,912,200	4,189,000
Non-current liabilities:		
Accrued dividends on Series B Preferred Stock	7,009,700	6,272,700
Deferred revenue - non-current portion	1,778,200	2,490,300
Operating lease obligation - non-current portion	3,139,900	3,350,800
Total non-current liabilities	11,927,800	12,113,800
Total liabilities	19,840,000	16,302,800
Commitments and contingencies		

Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at September 30, 2021 and March 31, 2021:		
Series A Preferred, 500,000 shares authorized, issued and outstanding at September 30, 2021 and March 31, 2021	500	500
Series B Preferred; 4,000,000 shares authorized at September 30, 2021 and March 31, 2021; 1,131,669 shares		
issued and outstanding at September 30, 2021 and March 31, 2021	1,100	1,100
Series C Preferred; 3,000,000 shares authorized at September 30, 2021 and March 31, 2021; 2,318,012 shares		
issued and outstanding at September 30, 2021 and March 31, 2021	2,300	2,300
Series D Preferred; 2,000,000 shares authorized at September 30, 2021 and March 31, 2021; no shares and 402,149		
shares issued and outstanding at September 30, 2021 and March 31, 2021, respectively	-	400
Common stock, $0.001 par value; 325,000,000 shares authorized at September 30, 2021 and March 31, 2021; 196,558,785		
and 180,751,234 shares issued at September 30, 2021 and March 31, 2021, respectively	196,500	180,800
Additional paid-in capital	324,808,000	315,603,100
Treasury stock, at cost, 135,665 shares of common stock held at September 30, 2021 and March 31, 2021	(3,968,100)	(3,968,100)
Accumulated deficit	(240,380,600)	(219,841,600)
Total stockholders' equity	80,659,700	91,978,500
Total liabilities and stockholders' equity	$ 100,499,700	$ 108,281,300

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

	Three Months Ended September 30,		Six Months Ended September 30,	
	2021	2020	2021	2020
Sublicense revenue	$ 358,000	$ 334,000	$ 712,100	$ 334,000
Total revenues	358,000	334,000	712,100	334,000
Operating expenses:				
Research and development	10,066,700	2,358,200	15,670,300	4,089,400
General and administrative	3,090,800	1,269,500	5,587,500	2,660,100
Total operating expenses	13,157,500	3,627,700	21,257,800	6,749,500
Loss from operations	(12,799,500)	(3,293,700)	(20,545,700)	(6,415,500)
Other income (expenses), net:				
Interest income (expense), net	5,100	(3,900)	10,200	(7,100)
Other income	-	-	-	600
Loss before income taxes	(12,794,400)	(3,297,600)	(20,535,500)	(6,422,000)
Income taxes	-	(200)	(3,400)	(2,600)
Net loss and comprehensive loss	$ (12,794,400)	$ (3,297,800)	(20,538,900)	(6,424,600)
Accrued dividends on Series B Preferred stock	(375,200)	(347,200)	(737,000)	(683,000)
Net loss attributable to common stockholders	$ (13,169,600)	$ (3,645,000)	$ (21,275,900)	$ (7,107,600)
Basic and diluted net loss attributable to common stockholders per common share	$ (0.07)	$ (0.05)	$ (0.11)	$ (0.12)
Weighted average shares used in computing basic and diluted net loss attributable to common stockholders per common share	193,227,841	67,082,935	191,585,026	59,245,209

Source: VistaGen Therapeutics, Inc.