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

August 12, 2021

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

Additional potential NDA-enabling clinical studies expected to initiate in 2021

SOUTH SAN FRANCISCO, Calif., Aug. 12, 2021 (GLOBE NEWSWIRE) -- VistaGen Therapeutics, Inc. (NASDAQ: VTGN), a 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 financial results for its fiscal year 2022 first quarter ended June 30, 2021 and provided a corporate update.

“The strong momentum we generated in fiscal 2021 leading up to the launch of our PALISADE Phase 3 Program for PH94B as a potential rapid-onset acute treatment of anxiety in adults with social anxiety disorder continued throughout the first quarter of fiscal 2022. The initiation of PALISADE-1 was a major milestone in the program. That study is proceeding as planned, with topline data anticipated in mid-2022. We remain on track to initiate PALISADE-2, which will be a counterpart of PALISADE-1, later this year, together with several other planned clinical studies we believe will be supportive of a potential U.S. New Drug Application for PH94B if our PALISADE Phase 3 Program is successful. We have also made progress in our Phase 2A clinical development program for PH94B, which is focused on additional anxiety disorders beyond SAD. We recently received from the U.S. Food and Drug Administration notice that we may proceed with our proposed exploratory Phase 2A clinical study of PH94B for treatment of adjustment disorder with anxiety. We expect to initiate that study in the U.S. before year end,” said Shawn Singh, Chief Executive Officer of VistaGen.

“Our core mission is to improve mental health and well-being for individuals around the world. As we continue to advance on that goal and into the next phases of our corporate development, we have enhanced diversity and collective expertise on our Board and across all key internal functions. We are well-positioned to drive our clinical-stage programs through multiple development and regulatory milestones, as well as appropriately-timed pre-commercial activities, and, if our PALISADE Phase 3 Program is successful, PH94B commercial launch operations in the U.S.,” continued Singh.

Recent Corporate Highlights

- Initiated PALISADE Phase 3 Program for PH94B with PALISADE-1, 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. Topline results from PALISADE-1 are anticipated in mid-2022.
- Received notice from the U.S. Food and Drug Administration (FDA) that we may proceed with our exploratory Phase 2A clinical study of PH94B in adults experiencing adjustment disorder with anxiety (AjDA).
- Appointed Mary L. Rotunno, J.D. to our Board of Directors, adding significant healthcare industry expertise as a leader and strategist as we advance late-stage development of our CNS product candidates for anxiety and depression disorders.
- Appointed Maggie FitzPatrick to our Board of Directors, bringing extensive leadership in healthcare consumer-focused engagement, marketing and public relations. Ms. FitzPatrick has driven marketing communications initiatives for some of the world’s largest and most successful companies, including Johnson & Johnson and Cigna.
- Included in the Russell 2000® Index, one of the most cited performance benchmarks for small-cap companies, increasing overall awareness and exposure for VistaGen within the investment community.

CNS Pipeline Updates

PH94B Nasal Spray

In May, VistaGen initiated its PALISADE Phase 3 Program with PALISADE-1, 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 expects to initiate PALISADE-2, a replicate of PALISADE-1, in the second half of calendar 2021. If successful, these clinical studies are designed to be among the studies necessary to support a potential PH94B U.S. New Drug Application (NDA) to the FDA. PH94B has been granted Fast Track designation status by the FDA for development as an acute treatment of anxiety in adults with SAD.

Recently, the Company received a notice from the FDA allowing commencement of its exploratory Phase 2A clinical study of PH94B in adults experiencing AjDA. The study is expected to start by the end of 2021. In addition to studies of PH94B in SAD and AjDA, the Company is also preparing for exploratory Phase 2A clinical studies of PH94B in adults experiencing other anxiety disorders, including postpartum anxiety, post-traumatic stress disorder and pre-procedural anxiety.

PH10 Nasal Spray

Exploratory Phase 2A clinical development of PH10 as a potential rapid-onset treatment of major depressive disorder (MDD) has been completed. VistaGen is preparing 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 treatment for treatment-resistant depression, postpartum depression and suicidal ideation.

AV-101

VistaGen is currently preparing to initiate a Phase 1B clinical study to evaluate AV-101 in combination with probenecid during the second half of calendar 2021. 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, suicidal ideation, epilepsy and other neurological disorders involving the NMDA (N-methyl-D-aspartate) receptor.

Fiscal Year 2022 First Quarter Financial Results

Revenue: The Company recognized $0.4 million in sublicense revenue from its $5 million upfront payment pursuant to its PH94B development and commercialization agreement with EverInsight Therapeutics (now AffaMed Therapeutics) during the quarter ended June 30, 2021, compared to none in the quarter ended June 30, 2020.

Research and development (R&D) expense: Research and development expense increased by $3.9 million, from $1.7 million to $5.6 million for the quarters ended June 30, 2020 and 2021, respectively. The increase in R&D expense is primarily related to the commencement of our PALISADE Phase 3 Program for PH94B in SAD with PALISADE-1, as well as other clinical and nonclinical developmental and manufacturing activities for both PH94B and PH10, which accounted for increased expenses of approximately $2.7 million during the quarter ended June 30, 2021 in comparison to the same quarter in the prior year. Salaries and benefits expense for the quarter ended June 30, 2021 increased by approximately $1.0 million versus 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 $2.5 million for the quarter ended June 30, 2021 compared to approximately $1.4 million for the quarter ended June 30, 2020. Salaries and benefits expense for the quarter ended June 30, 2021 increased by approximately $0.6 million versus the comparable prior-year quarter, primarily due to the hiring of additional senior management and other administrative personnel.

Net loss: Net loss for the quarters ended June 30, 2021 and 2020 was approximately $7.7 million and $3.1 million, respectively.

Cash Position: At June 30, 2021, the Company had cash and cash equivalents of approximately $97.8 million.

As of August 11, 2021, the Company had 192,903,896 shares of common stock outstanding.

Conference Call

VistaGen will host a conference call and live audio webcast this afternoon at 2:00 p.m. Pacific Time to provide a corporate update and discuss its financial results for its fiscal year 2022 first quarter ended June 30, 2021.

U.S. Dial-in (Toll Free): 1-800-935-5014
International Dial-in Number (Toll): 1-212-231-2920
Conference ID: 21996610
Webcast Link: **http://public.viavid.com/index.php?id=146257**

A telephone playback of the conference call will be available after approximately 5:00 p.m. Pacific Time on August 12, 2020. 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 21996610.

About VistaGen
VistaGen Therapeutics is a 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 drug candidates has a differentiated potential mechanism of action, has been well-tolerated in all clinical studies to date and 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 us and our management, are inherently uncertain. Our 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 our 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 our 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 our 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 our CNS drug candidates to meet demand; entry of competitive products; and other technical and unexpected hurdles in the development, manufacture and commercialization of our CNS drug candidates; and the risks more fully discussed in the section entitled "Risk Factors" in our most recent Annual Report on Form 10-K for the fiscal year ended March 31, 2021 and in our most recent Quarterly Report on Form 10-Q for the quarter ended June 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). Our 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 our views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements, other than as may be required by law. If we do update one or more forward-looking statements, no inference should be made that we will make additional updates with respect to those or other forward-looking statements.

VistaGen Company Contacts
Media:
Mark McPartland
Phone: (650) 577-3606
Email: markmcp@vistagen.com

Investors:
Mark Flather
Phone: (650) 577-3617
Email: mflather@vistagen.com

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

	June 30, 2021	March 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 97,776,900	$ 103,108,300
Receivable from collaboration partner	44,000	40,600
Prepaid expenses and other current assets	1,871,400	835,100
Deferred contract acquisition costs - current portion	133,500	133,500
Total current assets	99,825,800	104,117,500
Property and equipment, net	482,800	367,400
Right of use asset - operating lease	3,125,300	3,219,600
Deferred offering costs	224,700	294,900
Deferred contract acquisition costs - non-current portion	200,800	234,100
Security deposits and other assets	47,800	47,800
Total assets	$ 103,907,200	$ 108,281,300
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,316,200	$ 838,300
Accrued expenses	2,150,000	1,562,700
Deferred revenue - current portion	1,420,200	1,420,200
Operating lease obligation - current portion	378,400	364,800
Financing lease obligation - current portion	2,200	3,000
Total current liabilities	6,267,000	4,189,000
Non-current liabilities:		
Accrued dividends on Series B Preferred Stock	6,634,500	6,272,700
Deferred revenue - non-current portion	2,136,200	2,490,300
Operating lease obligation - non-current portion	3,252,700	3,350,800
Total non-current liabilities	12,023,400	12,113,800
Total liabilities	18,290,400	16,302,800
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at June 30, 2021 and March 31, 2021:		

Series A Preferred, 500,000 shares authorized, issued and outstanding at June 30, 2021 and March 31, 2021	500	500
Series B Preferred; 4,000,000 shares authorized at June 30, 2021 and March 31, 2021; 1,131,669 shares issued and outstanding at June 30, 2021 and March 31, 2021	1,100	1,100
Series C Preferred; 3,000,000 shares authorized at June 30, 2021 and March 31, 2021; 2,318,012 shares issued and outstanding at June 30, 2021 and March 31, 2021	2,300	2,300
Series D Preferred; 2,000,000 shares authorized at June 30, 2021 and March 31, 2021; no shares and 402,149 shares issued and outstanding at June 30, 2021 and March 31, 2021, respectively	-	400
Common stock, $0.001 par value; 325,000,000 shares authorized at June 30, 2021 and March 31, 2021; 191,632,008 and 180,751,234 shares issued at June 30, 2021 and March 31, 2021, respectively	191,600	180,800
Additional paid-in capital	316,975,600	315,603,100
Treasury stock, at cost, 135,665 shares of common stock held at June 30, 2021 and March 31, 2021	(3,968,100)	(3,968,100)
Accumulated deficit	(227,586,200)	(219,841,600)
Total stockholders' equity	85,616,800	91,978,500
Total liabilities and stockholders' equity	$ 103,907,200	$ 108,281,300

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

	Three Months Ended June 30,	
	2021	**2020**
Sublicense revenue	$ 354,100	$ -
Total revenues	354,100	-
Operating expenses:		
Research and development	5,603,600	1,731,200
General and administrative	2,496,700	1,390,600
Total operating expenses	8,100,300	3,121,800
Loss from operations	(7,746,200)	(3,121,800)
Other income (expenses), net:		
Interest income (expense), net	5,100	(3,200)
Other income	-	600
Loss before income taxes	(7,741,100)	(3,124,400)
Income taxes	(3,400)	(2,400)
Net loss and comprehensive loss	(7,744,500)	(3,126,800)
Accrued dividends on Series B Preferred stock	(361,800)	(335,800)
Net loss attributable to common stockholders	$ (8,106,300)	$ (3,462,600)
Basic and diluted net loss attributable to common stockholders per common share	$ (0.04)	$ (0.07)
Weighted average shares used in computing basic and diluted net loss attributable to common stockholders per common share	189,924,158	51,321,355

Source: VistaGen Therapeutics, Inc.