VistaGen Therapeutics Reports Second Quarter 2017 Financial Results and Business Update

November 14, 2016

SOUTH SAN FRANCISCO, Calif., Nov. 14, 2016 /PRNewswire/ -- VistaGen Therapeutics Inc. (NASDAQ: VTGN), a clinical-stage biopharmaceutical company focused on developing new generation therapies for depression and other central nervous system (*CNS*) disorders, today reported financial results for the second quarter of fiscal 2017 ended September 30, 2016.

The Company also provided an update on its corporate progress, including clinical status and anticipated milestones for AV-101, its new generation, orally available prodrug candidate in Phase 2 development, initially for the adjunctive treatment of major depressive disorder *(MDD)* in patients with an inadequate response to standard, U.S. Food and Drug Administration (*FDA*)-approved antidepressants.

"We continue to make great strides in 2016, achieving milestones which have been fundamental to our plans for 2017, which we believe will be another dynamic and transformative year for our shareholders," commented Shawn Singh, Chief Executive Officer of VistaGen.

Recent Corporate Highlights:

- Appointed Mark A. Smith M.D., Ph.D. as Chief Medical Officer, former Clinical Lead for Neuropsychiatry at Teva Pharmaceuticals, to lead late-stage clinical development of AV-101;
- Appointed Mark A. McPartland as Vice President, Corporate Development and Investor Relations, to expand awareness of VistaGen and its AV-101 development program among investors, patients, researchers, clinicians and potential partners;
- Uplisted to the NASDAQ Capital Market; and
- Completed $10.9 million public offering, led by institutional investors.

AV-101 is currently being evaluated in an ongoing Phase 2a monotherapy study for the treatment of MDD. This study is being fully funded by the U.S. National Institute of Mental Health (*NIMH*), part of the U.S. National Institutes of Health (*NIH*). The Principal Investigator of the study is Dr. Carlos Zarate Jr., Chief, Section on the Neurobiology and Treatment of Mood Disorders and Chief of Experimental Therapeutics and Pathophysiology Branch at the NIMH.

The Company is preparing to advance AV-101 into a 280-patient, U.S. multi-center, Phase 2b adjunctive treatment study in MDD in the first half of 2017, prior to the completion of the ongoing NIMH-sponsored AV-101 Phase 2a monotherapy study. Dr. Maurizio Fava of Harvard University will be the Principal Investigator of the Phase 2b study, which will be a double-blind, placebo controlled efficacy and safety study of AV-101 as adjunctive treatment of MDD patients with inadequate response to standard antidepressants. The Phase 2b study will utilize a Sequential Parallel Comparison Design (*SPCD*), which is a clinical study design intended to mitigate potential placebo effects. The Company anticipates topline results from this Phase 2b study to be reported in the second half of 2018.

Expected Near-Term Milestones:

- Submission of an Investigational New Drug application (IND) to the FDA for a Phase 2b study of AV-101 as adjunctive treatment of MDD in the first half of calendar 2017;
- Launch of AV-101 Phase 2b study as adjunctive treatment of MDD in patients with inadequate response to standard antidepressants, in the first half of 2017;
- FDA Fast Track designation for AV-101 as adjunctive treatment of MDD in the first half of 2017; and
- Topline results from NIMH-sponsored AV-101 Phase 2a MDD monotherapy study in the first half of 2017.

Summary of Financial Results for the Second Quarter of Fiscal 2017 Ended September 30, 2016

For the second fiscal quarter ended September 30, 2016, the Company reported a net loss of approximately $3.1 million, or a net loss attributable to common stockholders of $0.42 per common share, compared to a net loss of approximately $5.1 million, or a net loss attributable to common stockholders of $0.91 per common share for the same period in the prior year. Research and development expense totaled $1.61 million for the quarter ended September 30, 2016, a 3% decrease compared with the $1.66 million reported for the quarter ended September 30, 2015, reflecting our increasing focus on the continued development of AV-101 and preparations to launch our AV-101 Phase 2b study in MDD, which we currently anticipate to begin in the first half of 2017, offset by a reduction in noncash stock compensation expense compared to the same period in the prior year. General and administrative expense decreased to $1.5 million for the second quarter ended September 30, 2016, from $3.7 million for the same period in the prior year. The changes in G&A are the result of a decrease in noncash stock compensation expense attributable to option and fully-vested warrant grants to employees, members of our Board of Directors and consultants and noncash expense related to grants of equity securities in payment of certain professional services, offset by a combination of corporate expenses, including investor relations and corporate development initiatives, our Nasdaq listing fees and compensation and headcount increases.

As of September 30, 2016, the Company had approximately $6.3 million of cash and cash equivalents. The Company believes it has sufficient financial resources to fund its expected operations through the first half of 2017.

About AV-101
AV-101 *(4-Cl-KYN)* is an orally available prodrug candidate, currently in Phase 2 development, initially for the adjunctive treatment of MDD in patients with an inadequate response to standard, FDA-approved antidepressants. AV-101 has broad potential utility in other CNS diseases and disorders, including chronic neuropathic pain, epilepsy and neurodegenerative diseases, such as Parkinson's disease and Huntington's disease. Orally available AV-101 is rapidly absorbed through the gut, and then actively transported across the blood-brain barrier. Astrocytes in the brain rapidly convert AV-101 into its active metabolite, 7-chlorokynurenic acid (*7-Cl-KYNA*), a well-characterized, potent and selective antagonist of N-methyl-D-aspartate *(NMDA)* receptors, acting by blocking the glycine-binding co-agonist site of the NMDA receptor. AV-101 is a member of a new generation of fast-acting glutamatergic drug candidates in development for adjunctive treatment of MDD. These fast-acting drug candidates act through the AMPA receptor pathway increasing the production of nerve connections in the brain, often referred to as "synaptogenesis." The increase in synaptogenesis is thought to be the mechanism by which these new generation antidepressant drug candidates have potential to provide therapeutic benefit for MDD.

AV-101's mechanism of action is fundamentally differentiated from all FDA-approved antidepressants and atypical antipsychotics, with potential to drive a paradigm shift towards new generation safer and faster-acting antidepressants. Unlike most currently approved antidepressants, which act on serotonin and related neurotransmitter pathways in the brain, AV-101 works through an entirely different mechanism, mobilizing glutamate pathways to enhance neuronal plasticity and improve the communication between neuronal cells. Dysfunction in these activities is increasingly recognized by scientists as an important contributor to depression and other serious disorders of the CNS.

About VistaGen
VistaGen Therapeutics, Inc. (NASDAQ: VTGN) is a clinical-stage biopharmaceutical company dedicated to developing and commercializing innovative therapies for CNS diseases and disorders. VistaGen's lead CNS product candidate, AV-101, is a new generation, orally available prodrug in Phase 2 development, initially for the adjunctive treatment of MDD in patients with inadequate response to standard antidepressants. AV-101 is currently being evaluated in an ongoing Phase 2a clinical study being conducted by Principal Investigator, Dr. Carlos Zarate Jr., of the NIMH, and fully funded by the NIMH. VistaGen is also preparing to initiate a Phase 2b clinical study of AV-101 as an adjunctive treatment of MDD in patients with inadequate response to standard, FDA-approved antidepressants in the first half of 2017.

For more information, please visit www.vistagen.com and connect with VistaGen on Twitter, LinkedIn and Facebook.

Forward-Looking Statements
The statements in this press release that are not historical facts may constitute forward-looking statements that are based on current expectations and are subject to risks and uncertainties that could cause actual future results to differ materially from those expressed or implied by such statements. Those risks and uncertainties include, but are not limited to, risks related to the successful launch, continuation and results of Phase 2a (monotherapy) and/or Phase 2b (adjunctive therapy) clinical studies of AV-101 in MDD, and other CNS diseases and disorders, protection of its intellectual property, and the availability of substantial additional capital to support its operations, including the development activities described above. These and other risks and uncertainties are identified and described in more detail in VistaGen's filings with the Securities and Exchange Commission (*SEC*). These filings are available on the SEC's website at www.sec.gov. VistaGen undertakes no obligation to publicly update or revise any forward-looking statements.

Condensed Consolidated Financial Statements (Unaudited)

VISTAGEN THERAPEUTICS, INC.

Condensed Consolidated Balance Sheets
Amounts in Dollars

	September 30, 2016	March 31, 2016

	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,257,100	$ 428,500
Prepaid expenses and other current assets	648,900	426,800
Total current assets	6,906,000	855,300
Property and equipment, net	69,200	87,600
Security deposits and other assets	47,800	46,900
Total assets	$ 7,023,000	$ 989,800
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 930,200	$ 936,000
Accrued expenses	795,000	814,000
Current portion of notes payable and accrued interest	71,100	43,600
Capital lease obligations	600	1,100
Total current liabilities	1,796,900	1,794,700
Non-current liabilities:		
Notes payable	-	27,200
Accrued dividends on Series B Preferred Stock	1,101,600	2,089,600
Deferred rent liability	37,400	55,500
Total non-current liabilities	1,139,000	2,172,300
Total liabilities	2,935,900	3,967,000
Commitments and contingencies		
Stockholders' equity (deficit):		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at September 30, 2016 and March 31, 2016:		
Series A Preferred, 500,000 shares authorized and outstanding at September 30, 2016 and March 31, 2016	500	500
Series B Preferred; 4,000,000 shares authorized at September 30, 2016 and March 31, 2016; 1,160,240 shares and 3,663,077 shares issued and outstanding at September 30, 2016 and March 31, 2016, respectively	1,200	3,700
Series C Preferred; 3,000,000 shares authorized at September 30, 2016 and March 31, 2016; 2,318,012 shares issued and outstanding at September 30, 2016 and March 31, 2016	2,300	2,300
Common stock, $0.001 par value; 30,000,000 shares authorized at September 30, 2016 and March 31, 2016; 8,405,128 and 2,623,145 shares issued at September 30, 2016 and March 31, 2016, respectively	8,400	2,600
Additional paid-in capital	144,854,200	132,725,000
Treasury stock, at cost, 135,665 shares of common stock held at September 30, 2016 and March 31, 2016	(3,968,100)	(3,968,100)
Accumulated deficit	(136,811,400)	(131,743,200)
Total stockholders' equity (deficit)	4,087,100	(2,977,200)
Total liabilities and stockholders' equity (deficit)	$ 7,023,000	$ 989,800

VISTAGEN THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)
(Amounts in dollars, except share amounts)

	Three Months Ended September 30,		Six Months Ended September 30,	
	2016	2015	2016	2015
Operating expenses:				
Research and development	1,606,100	1,656,100	2,431,800	2,028,700
General and administrative	1,493,600	3,730,500	2,631,200	5,179,000
Total operating expenses	3,099,700	5,386,600	5,063,000	7,207,700
Loss from operations	(3,099,700)	(5,386,600)	(5,063,000)	(7,207,700)
Other expenses, net:				
Interest expense, net	(1,400)	(12,200)	(2,800)	(767,300)
Change in warrant liability	-	-	-	(1,894,700)
Loss on extinguishment of debt	-	(1,649,300)	-	(26,700,200)
Loss before income taxes	(3,101,100)	(7,048,100)	(5,065,800)	(36,569,900)
Income taxes	-	-	(2,400)	(2,300)
Net loss	$ (3,101,100)	$ (7,048,100)	$ (5,068,200)	$ (36,572,200)

Accrued dividend on Series B Preferred stock	(241,000)	(614,700)	(780,800)	(828,000)
Deemed dividend on Series B Preferred Units	-	(886,900)	(111,100)	(1,143,100)
Net loss attributable to common stockholders	$ (3,342,100)	$ (8,549,700)	$ (5,960,100)	$ (38,543,300)
Basic and diluted net loss attributable to common stockholders per common share	$ (0.42)	$ (5.26)	$ (0.91)	$ (24.21)
Weighted average shares used in computing basic and diluted net loss attributable to common stockholders per common share	8,041,619	1,624,371	6,577,769	1,592,104
Comprehensive loss	$ (3,101,100)	$ (7,048,100)	$ (5,068,200)	$ (36,572,200)

Logo - https://photos.prnewswire.com/prnh/20160321/346644LOGO

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/vistagen-therapeutics-reports-second-quarter-2017-financial-results-and-business-update-300362434.html

SOURCE VistaGen Therapeutics, Inc.

Released November 14, 2016