VistaGen Therapeutics Reports Fiscal Third Quarter 2017 Financial Results and Provides Corporate Update

February 13, 2017

SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 02/13/17 -- VistaGen Therapeutics Inc. (NASDAQ: VTGN), a clinical-stage biopharmaceutical company focused on developing new generation medicines for depression and other central nervous system (*CNS*) disorders, today reported financial results for the third quarter of fiscal 2017 ended December 31, 2016.

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

"We are excited about our progress during the last quarter, with several key advances related to our MDD-focused programs for AV-101, as well as potential regenerative medicine and drug rescue applications of our cardiac stem cell technology. Following productive discussions with the FDA last quarter, our team and key advisors have been working diligently to complete the diverse regulatory and technical activities necessary to support the planned launch of our Phase 2b study of AV-101 next quarter, a study we believe has game-changing potential for the millions of patients who battle MDD every day with inadequate therapies," commented Shawn Singh, Chief Executive Officer of VistaGen. "Also, our recent sublicense agreement with BlueRock Therapeutics was an important advance in our cardiac stem cell program while we remain primarily focused on our Phase 2 programs for AV-101. With potentially catalytic milestones in the coming quarters, we believe we are poised to unlock significant value for our shareholders throughout 2017," added Mr. Singh.

Recent Corporate Highlights:

- Completed successful pre-IND communications with the FDA regarding the Company's planned 280-patient, multi-center, double-blind, placebo controlled Phase 2b efficacy and safety study to evaluate AV-101 as a new generation adjunctive treatment for MDD patients with an inadequate response to standard, FDA-approved antidepressants (*Phase 2b Study*), and continued progress towards commencement of the Phase 2b Study in the second quarter of 2017;
- Signed an exclusive sublicense agreement with BlueRock Therapeutics L.P, a next generation regenerative medicine company established by Bayer AG and Versant Ventures, for VistaGen's rights to proprietary technologies relating to the production of cardiac stem cells for the treatment of heart disease, recognizing an upfront payment of $1.25 million; with potential additional milestone payments and royalties in the future; and
- Submitted to the FDA predictive toxicology data generated using *CardioSafe* 3D, VistaGen's next generation human heart cell-based cardiac toxicity assay system, as a participant in the FDA's Comprehensive in-vitro Proarrhythmia Assay (*CiPA*) initiative. CiPA is an FDA-initiated program, with participants including many large pharmaceutical and biotechnology companies, designed to change the landscape of nonclinical drug development by providing a more complete and accurate assessment of potential drug effects on cardiac risk through the use of stem cell-derived heart cells and in vitro ion channel data.

The U.S. National Institute of Mental Health (*NIMH*) is currently conducting and fully funding a 20 to 25-patient Phase 2a study of AV-101 as a monotherapy for treatment-resistant MDD under VistaGen's Cooperative Research and Development Agreement (*CRADA*) with the NIMH (*Phase 2a Study*). 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 and a leading clinical expert on the use of ketamine for treatment-resistant MDD, is the Principal Investigator of the Phase 2a Study. Following recent guidance from the NIMH, the Company currently anticipates that the NIMH will complete the Phase 2a Study by the end of 2017.

VistaGen is preparing to launch a 280-patient, multi-center, double-blind, placebo controlled Phase 2b efficacy and safety study evaluating AV-101 as a new generation adjunctive treatment for MDD patients with an inadequate response to standard, FDA-approved antidepressant therapies. The Company currently anticipates commencing patient enrollment in the Phase 2b Study in the second quarter of 2017. Dr. Maurizio Fava of Harvard University Medical School will serve as the Principal Investigator of VistaGen's AV-101 Phase 2b Study. Topline clinical results from the Phase 2b Study are currently anticipated by the end of 2018.

Dr. Mark Smith, Chief Medical Officer of VistaGen, commented, "We look forward to starting patient enrollment in our Phase 2b study of AV-101 as an adjunctive therapy in the treatment of MDD. We believe we have significantly de-risked this Phase 2b study with a clinical trial methodology that is designed to overcome the challenge of placebo effects in psychiatric clinical trials. Based on the study protocol we have designed in collaboration with key opinion leaders in depression and neuroscience, including our Principal Investigator, Dr. Fava, we expect that achieving a successful outcome of our Phase 2b study will be integral in realizing AV-101's potential to displace atypical antipsychotics and non-drug interventions in the current depression treatment paradigm, representing a much needed treatment solution for physicians and patients, as well as an enormous opportunity for VistaGen."

Expected Near-Term Milestones:

- Filing of the Company's Investigational New Drug application (*IND*) with the FDA for the Company's planned Phase 2b Study of AV-101 as an adjunctive treatment of MDD patients with an inadequate response to standard FDA-approved antidepressant therapies; response from the FDA expected in the first half of 2017;
- Commencement of patient enrollment in the Company's planned Phase 2b Study of AV-101 as an adjunctive treatment of MDD, in the second quarter of 2017;
- Application for FDA Fast Track designation for AV-101 as an adjunctive treatment of MDD, in the first half of 2017; and
- Completion of the NIMH-sponsored Phase 2a Study of AV-101 as a monotherapy for MDD, by the end of 2017.

"The NIMH recently updated us on their timelines for the completion of the Phase 2a study of AV-101 as a monotherapy for MDD. The Phase 2a study protocol requires considerable time and dedication from both the study participants and the multi-disciplinary NIMH teams involved. Patient enrollment for the Phase 2a study remains ongoing and we currently anticipate the NIMH's completion of the study by the end of 2017. Our top priority is to execute our plans for our Phase 2b study of AV-101 as a new generation adjunctive treatment of MDD, and we remain on track to launch that important study in the second quarter. As part of our Phase 2 program, this Phase 2b study has been specifically designed to achieve important outcomes that will be key to advancing AV-101 into a pivotal program in MDD and more broadly beyond MDD, as we continue to advance our global commercialization strategy. We are confident that our Phase 2 program is a major step forward in positioning AV-101 as a potentially transformative adjunctive treatment of MDD and other CNS disorders," concluded Mr. Singh.

Summary of Financial Results for the Third Quarter of Fiscal 2017 Ended December 31, 2016

Revenue

The Company recognized $1.25 million in sublicense revenue pursuant to its cardiac stem cell technology sublicense agreement with BlueRock Therapeutics, a next generation regenerative medicine company established by Bayer AG and Versant Ventures, in the third fiscal quarter ended December 31, 2016.

Research and Development Expenses

Research and development expense totaled $1.61 million for the third fiscal quarter ended December 31, 2016, compared to $806,300 for the quarter ended December 31, 2015, reflecting increasing focus on nonclinical and clinical development of AV-101 and preparations for launch of the AV-101 Phase 2b Study in the second quarter of 2017.

General and Administrative Expenses

General and administrative expense increased to $2.3 million in the third fiscal quarter ended December 31, 2016, from $1.3 million for the same period in the prior year. The increase in G&A expense is the result of increased noncash stock compensation expense attributable to option and warrant grants in the period to employees, independent members of the Company's Board of Directors and consultants and other noncash expense related to grants of equity securities in payment of certain professional services, and a combination of corporate expenses, including investor relations and corporate development initiatives.

Net Loss

For the third fiscal quarter ended December 31, 2016, the Company reported a net loss of approximately $2.6 million, or a net loss attributable to common stockholders of $0.34 per common share, compared to a net loss of approximately $2.1 million, or a net loss attributable to common stockholders of $1.95 per common share for the same period in the prior year.

Cash and Cash Equivalents

As of December 31, 2016, the Company had approximately $5.6 million of cash, cash equivalents and short term receivables, including a $1.25 million short term sublicense fee receivable from BlueRock Therapeutics pursuant to the Company's December 2016 technology sublicense agreement with BlueRock Therapeutics. In January 2017, the Company received the $1.25 million sublicense fee payment from BlueRock Therapeutics and currently believes it has sufficient financial resources to fund its expected operations at least through the first half of 2017, including preparation for and launch of its planned AV-101 Phase 2b Study in MDD.

About VistaGen

VistaGen Therapeutics, Inc. (NASDAQ: VTGN), is a clinical-stage biopharmaceutical company focused on developing new generation medicines for depression and other central nervous system (*CNS*) disorders. VistaGen's lead CNS product candidate, AV-101, is a new generation oral antidepressant drug candidate in Phase 2 development. AV-101's mechanism of action is fundamentally differentiated from all FDA-approved antidepressants and atypical antipsychotics used adjunctively to treat MDD, with potential to drive a paradigm shift towards a new generation of safer and faster-acting antidepressants. AV-101 is currently being evaluated by the U.S. National Institute of Mental Health (*NIMH)* in a Phase 2a monotherapy study in MDD being fully funded by the NIMH and conducted by 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. VistaGen is preparing to launch a 280-patient Phase 2b study of AV-101 as an adjunctive treatment for MDD patients with inadequate response to standard, FDA-approved antidepressant therapies. Dr. Maurizio Fava of Harvard University will be the Principal Investigator of the Phase 2b study. AV-101 may also have the potential to treat multiple CNS disorders and neurodegenerative diseases in addition to MDD, including chronic neuropathic pain, epilepsy, Parkinson's disease and Huntington's disease, where modulation of the NMDAR, AMPA pathway and/or key active metabolites of AV-101 may achieve therapeutic benefit.

VistaStem Therapeutics is VistaGen's wholly owned subsidiary focused on applying human pluripotent stem cell *(hPSC)* technology, internally and with third-party collaborators, to discover, rescue, develop and commercialize proprietary new chemical entities *(NCEs),* including small molecule NCEs with regenerative potential, for CNS and other diseases, and cellular therapies involving stem cell-derived blood, cartilage, heart and liver cells. In December 2016, VistaGen exclusively sublicensed to BlueRock Therapeutics LP, a next generation regenerative medicine company established by Bayer AG and Versant Ventures, rights to certain proprietary technologies relating to the production of cardiac stem cells for the treatment of heart disease.

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 the NIMH's Phase 2a (monotherapy) and/or the Company's planned 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.

VISTAGEN THERAPEUTICS
Condensed Consolidated Balance Sheets
Amounts in Dollars

	December 31 2016	***March 31, 2016***
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,372,000	$ 428,500
Sublicense fee receivable	1,250,000	-
Prepaid expenses and other current assets	146,400	426,800
Total current assets	5,768,400	855,300
Property and equipment, net	59,900	87,600
Security deposits and other assets	47,800	46,900
Total assets	$ 5,876,100	$ 989,800
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 874,400	$ 936,000
Accrued expenses	961,800	814,000
Current portion of notes payable and accrued interest	35,800	43,600
Capital lease obligations	300	1,100
Total current liabilities	1,872,300	1,794,700
Non-current liabilities:		
Notes payable	-	27,200
Accrued dividends on Series B Preferred Stock	1,339,300	2,089,600
Deferred rent liability	75,900	55,500
Total non-current liabilities	1,415,200	2,172,300
Total liabilities	3,287,500	3,967,000
Commitments and contingencies		
Stockholders' equity (deficit):		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at December 31, 2016 and March 31, 2016:		
Series A Preferred, 500,000 shares authorized and outstanding at December 31, 2016 and March 31, 2016	500	500
Series B Preferred; 4,000,000 shares authorized at December 31, 2016 and March 31, 2016; 1,160,240 shares and 3,663,077 shares issued and outstanding at December 31, 2016 and March 31, 2016, respectively	1,200	3,700
Series C Preferred; 3,000,000 shares authorized at December 31, 2016 and March 31, 2016; 2,318,012 shares issued and outstanding at December 31, 2016 and March 31, 2016	2,300	2,300
Common stock, $0.001 par value; 30,000,000 shares authorized at December 31, 2016 and March 31, 2016;8,717,136 and 2,623,145 shares issued at December 31, 2016 and March 31, 2016, respectively	8,700	2,600
Additional paid-in capital	145,993,900	132,725,000
Treasury stock, at cost, 135,665 shares of common stock held at December 31, 2016 and March 31, 2016	(3,968,100)	(3,968,100)
Accumulated deficit	(139,449,900)	(131,743,200)
Total stockholders' equity (deficit)	2,588,600	(2,977,200)

Total liabilities and stockholders' equity (deficit)	$ 5,876,100	$ 989,800
	-	-

VISTAGEN THERAPEUTICS
STATEMENT OF OPERATIONS
Amounts in Dollars, except share amounts

UNAUDITED

	Three Months Ended December 31,		***Nine Months Ended December 31,***	
	2016	***2015***	***2016***	***2015***
Revenues:				
Sublicense fees	1,250,000	-	1,250,000	-
Total revenues	1,250,000	-	1,250,000	-
Operating expenses:				
Research and development	1,611,000	806,300	4,042,800	2,835,000
General and administrative	2,276,600	1,335,500	4,907,800	6,514,500
Total operating expenses	3,887,600	2,141,800	8,950,600	9,349,500
Loss from operations	(2,637,600)	(2,141,800)	(7,700,600)	(9,349,500)
Other expenses, net:				
Interest expense, net	(900)	(2,500)	(3,700)	(769,800)
Change in warrant liability	-	-	-	(1,894,700)
Loss on extinguishment of debt	-	-	-	(26,700,200)
Other income (expense)	-	(2,300)	-	(2,300)
Loss before income taxes	(2,638,500)	(2,146,600)	(7,704,300)	(38,716,500)
Income taxes	-	-	(2,400)	(2,300)
Net loss	$ (2,638,500)	$ (2,146,600)	$ (7,706,700)	$ (38,718,800)
Accrued dividend on Series B Preferred stock	(237,700)	(631,300)	(1,018,500)	(1,459,300)
Deemed dividend on Series B Preferred Units	-	(668,700)	(111,100)	(1,811,800)
Net loss attributable to common stockholders	$ (2,876,200)	$ (3,446,600)	$ (8,836,300)	$ (41,989,900)
Basic and diluted net loss attributable to common stockholders per common share	$ (0.34)	$ (1.95)	$ (1.23)	$ (25.45)
Weighted average shares used in computing basic and diluted net loss attributable to common stockholders per common share	8,381,824	1,765,641	7,181,307	1,650,160
Comprehensive loss	$ (2,638,500)	$ (2,146,600)	$ (7,706,700)	$ (38,718,800)

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