

November 9, 2017



# VistaGen Therapeutics Reports Second Fiscal Quarter 2018 Financial Results and Provides Business Update

SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 11/09/17 -- [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 its financial results for its second fiscal quarter ended September 30, 2017.

The Company also provided an update on its corporate progress and recently achieved milestone for AV-101, its oral CNS drug candidate in Phase 2 development, initially as a new generation adjunctive treatment for major depressive disorder (MDD).

"The FDA's recent authorization to proceed under our AV-101 IND application is a significant milestone in our Phase 2 program focused on MDD," commented [Shawn Singh, Chief Executive Officer of VistaGen](#). "With that authorization, we are now one step closer towards our goal of commencing our 180-patient, multi-center, double-blind, placebo-controlled Phase 2 adjunctive treatment study in the first quarter of 2018."

## ***Milestones achieved during the quarter:***

In October 2017, the U.S. Food and Drug Administration (FDA) [authorized the Company to proceed under its Investigational New Drug \(IND\) application](#) with its planned 180-patient, multi-center, double-blind, placebo-controlled Phase 2 study to assess the safety, tolerability and efficacy of AV-101 as an orally administered adjunctive treatment for adult MDD patients with an inadequate response to standard, FDA-approved antidepressants. Dr. Maurizio Fava of Harvard Medical School will be the Principal Investigator of this study, expected to begin in the first quarter of 2018 with completion expected at the end of 2018.

## ***Recent Operational Highlights:***

### *Intellectual Property Accomplishments*

- The European Patent Office [granted a European Patent for AV-101](#) relating to the treatment of depression, Parkinson's disease levodopa-induced dyskinesia (PD LID) and use of multiple dosage forms to treat these CNS disorders. The patent has been validated in Belgium, Denmark, France, Germany, Ireland, Italy, Portugal, Spain, Switzerland and the United Kingdom. It will be in effect until January 2034.
- The Company [received a Notice of Allowance](#) from the U.S. Patent and Trademark Office for U.S. Patent Application No. 14/775,287 related to certain methods of production for AV-101.

- The corresponding patent application related to methods of production for AV-101 was also granted in China.

*Bolstered Clinical Team with Industry Expert*

- The Company [appointed David Rotella, Ph.D. to the Scientific Advisory Board of VistaStem Therapeutics](#), the Company's wholly owned subsidiary focused on utilizing the Company's stem cell technology, to assist in advancing VistaStem's small molecule drug rescue objectives and in evaluating other CNS-focused programs intended to expand VistaGen's drug development pipeline. Dr. Rotella has extensive academic research and pharmaceutical industry experience in both medicinal chemistry and drug discovery, including key leadership roles on teams at Wyeth, Pfizer and Bristol-Meyers focused on drug candidates to fight cancer, cardiovascular disease, metabolic disorders, and neurodegenerative diseases.

***Financial Results for the Fiscal Quarter Ended September 30, 2017:***

Net loss for the fiscal quarter ended September 30, 2017 was approximately \$5.0 million, including non-cash expenses of approximately \$2.1 million, compared to \$3.1 million for the fiscal quarter ended September 30, 2016, which included non-cash expenses of approximately \$0.7 million.

Research and development expense totaled approximately \$2.4 million for the fiscal quarter ended September 30, 2017, compared with approximately \$1.6 million for the fiscal quarter ended September 30, 2016. The increase in year-over-year research and development expense was attributable to the Company's increased focus on the continuing nonclinical and clinical development of AV-101 and ongoing preparations to launch its AV-101 MDD Phase 2 adjunctive treatment study.

General and administrative expense was approximately \$2.6 million in the fiscal quarter ended September 30, 2017, compared to approximately \$1.5 million in the fiscal quarter ended September 30, 2016, reflecting increased professional services expenses and noncash expense attributable to the grant of common stock for services, noncash warrant modification expense and, to a lesser extent, salary and benefits and noncash stock compensation expenses.

At September 30, 2017, the Company had cash of approximately \$1.76 million, compared to approximately \$1.63 million as of June 30, 2017. In September 2017, the Company completed an underwritten public offering of shares of its common stock and warrants. The gross proceeds from this offering were approximately \$2.4 million, resulting in net proceeds of \$2.0 million, after deducting the underwriting discount and offering expenses.

***About VistaGen***

VistaGen Therapeutics, Inc. (NASDAQ: VTGN) is a clinical-stage biopharmaceutical company focused on developing new generation medicines for depression and other CNS disorders. VistaGen's lead CNS product candidate, AV-101, is in Phase 2 development, initially as a new generation oral antidepressant drug candidate for MDD. AV-101's mechanism of action is fundamentally different 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 NIMH in a small Phase 2 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 180-patient Phase 2 study of AV-101 as an adjunctive treatment for MDD patients with an inadequate response to standard, FDA-approved antidepressants, with Dr. Maurizio Fava of Harvard University as Principal Investigator. AV-101 may also have the potential to treat multiple CNS disorders and neurodegenerative diseases in addition to MDD, including neuropathic pain, epilepsy, Huntington's disease, PD LID and other disorders where modulation of the NMDA receptors, activation of AMPA pathways and/or key active metabolites of AV-101 may achieve therapeutic benefit.

### **About VistaStem**

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 (i) proprietary new chemical entities (NCEs), including NCEs with regenerative potential, for CNS and other diseases and (ii) cellular therapies involving stem cell-derived blood, cartilage, heart and liver cells. VistaStem's internal drug rescue programs are designed to utilize CardioSafe 3D, its customized cardiac bioassay system, to develop NCEs for VistaGen's pipeline. To advance potential regenerative medicine (RM) applications of its cardiac stem cell technology, in December 2016, VistaStem exclusively sublicensed to BlueRock Therapeutics LP, a next generation regenerative medicine company established in 2016 by Bayer AG and Versant Ventures, rights to certain proprietary technologies relating to the production of cardiac cells for the treatment of heart disease. In a manner similar to its exclusive sublicense agreement with BlueRock Therapeutics, VistaStem may pursue additional collaborations and potential RM applications of its stem cell technology platform, including using blood, cartilage, and/or liver cells derived from hPSCs, for (i) cell-based therapy, (ii) cell repair therapy, and/or (iii) tissue engineering.

For more information, please visit [www.vistagen.com](http://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 funding, launch, continuation and results of the NIMH's Phase 2 (monotherapy) and/or the Company's planned Phase 2 (adjunctive treatment) clinical studies of AV-101 in MDD, and other CNS diseases and disorders, including neuropathic pain and PD LID, protection of its intellectual property, and the availability of substantial additional capital to support its operations, including the AV-101 Phase 2 adjunctive treatment study and other potential AV-101 clinical 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](http://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

	<b>September 30, 2017</b>	<b>March 31, 2017</b>		
	<b>(Unaudited)</b>			
<b>ASSETS</b>				
Current assets:				
Cash and cash equivalents	\$ 1,764,400	\$ 2,921,300		
Prepaid expenses and other current assets	563,300	456,600		
Total current assets	<u>2,327,700</u>	<u>3,377,900</u>		
Property and equipment, net	242,000	286,500		
Security deposits and other assets	47,800	47,800		
Total assets	<u>\$ 2,617,500</u>	<u>\$ 3,712,200</u>		
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>				
Current liabilities:				
Accounts payable	\$ 1,151,000	\$ 867,300		
Accrued expenses	625,600	443,000		
Current notes payable	105,200	54,800		
Capital lease obligations	2,500	2,400		
Total current liabilities	<u>1,884,300</u>	<u>1,367,500</u>		
Non-current liabilities:				
Accrued dividends on Series B Preferred Stock	2,081,400	1,577,800		
Deferred rent liability	312,700	139,200		
Capital lease obligations	10,700	11,900		
Total non-current liabilities	<u>2,404,800</u>	<u>1,728,900</u>		
Total liabilities	<u>4,289,100</u>	<u>3,096,400</u>		
Commitments and contingencies				
Stockholders' equity (deficit):				
Preferred stock, \$0.001 par value; 10,000,000 shares authorized at September 30, 2017 and March 31, 2017:				
Series A Preferred, 500,000 shares authorized, issued and outstanding at September 30, 2017 and March 31, 2017	500	500		
Series B Preferred; 4,000,000 shares authorized at September 30, 2017 and March 31, 2017; 1,160,240 shares issued and outstanding at September 30, 2017 and March 31, 2017	1,200	1,200		

Series C Preferred; 3,000,000 shares authorized at September 30, 2017 and March 31, 2017; 2,318,012 shares issued and outstanding at September 30, 2017 and March 31, 2017	2,300	2,300
Common stock, \$0.001 par value; 100,000,000 and 30,000,000 shares authorized at September 30, 2017 and March 31, 2017, respectively; 11,764,639 and 8,974,386 shares issued at September 30, 2017 and March 31, 2017, respectively		
Additional paid-in capital	11,800	9,000
Treasury stock, at cost, 135,665 shares of common stock held at September 30, 2017 and March 31, 2017	151,541,700	146,569,600
Accumulated deficit	<u>(3,968,100)</u>	<u>(3,968,100)</u>
Total stockholders' equity (deficit)	<u>(149,261,000)</u>	<u>(141,998,700)</u>
Total liabilities and stockholders' equity (deficit)	<u><u>\$ 1,671,600</u></u>	<u><u>615,800</u></u>
	<u><u>\$ 2,617,500</u></u>	<u><u>\$ 3,712,200</u></u>

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

**UNAUDITED**

	<i>Three Months Ended September 30,</i>		<i>Six Months Ended September 30,</i>	
	<i>2017</i>	<i>2016</i>	<i>2017</i>	<i>2016</i>
Operating expenses:				
Research and development	\$ 2,426,600	\$ 1,606,100	\$ 3,522,800	\$ 2,431,800
General and administrative	<u>2,567,100</u>	<u>1,493,600</u>	<u>3,731,400</u>	<u>2,631,200</u>
Total operating expenses	<u>4,993,700</u>	<u>3,099,700</u>	<u>7,254,200</u>	<u>5,063,000</u>
Loss from operations	<u>(4,993,700)</u>	<u>(3,099,700)</u>	<u>(7,254,200)</u>	<u>(5,063,000)</u>
Other expenses, net:				
Interest expense, net	<u>(3,300)</u>	<u>(1,400)</u>	<u>(5,700)</u>	<u>(2,800)</u>
Loss before income taxes	<u>(4,997,000)</u>	<u>(3,101,100)</u>	<u>(7,259,900)</u>	<u>(5,065,800)</u>
Income taxes	<u>-</u>	<u>-</u>	<u>(2,400)</u>	<u>(2,400)</u>
Net loss and comprehensive loss	<u>(4,997,000)</u>	<u>(3,101,100)</u>	<u>(7,262,300)</u>	<u>(5,068,200)</u>
Accrued dividend on Series B Preferred stock	<u>(256,300)</u>	<u>(241,000)</u>	<u>(503,600)</u>	<u>(780,800)</u>
Deemed dividend on Series B Preferred Units	<u>-</u>	<u>-</u>	<u>-</u>	<u>(111,100)</u>

Net loss attributable to common stockholders	<u>\$ (5,253,300)</u>	<u>\$ (3,342,100)</u>	<u>\$ (7,765,900)</u>	<u>\$ (5,960,100)</u>
Basic and diluted net loss attributable to common stockholders per common share	<u>\$ (0.53)</u>	<u>\$ (0.42)</u>	<u>\$ (0.82)</u>	<u>\$ (0.91)</u>
Weighted average shares used in computing basic and diluted net loss attributable to common stockholders per common share	<u>9,892,016</u>	<u>8,041,619</u>	<u>9,465,459</u>	<u>6,577,769</u>

***Three Months Ended September 30,***  
***2017***      ***2016***

Operating expenses:				
Research and development		\$ 2,427		\$ 1,606
General and administrative		2,567		1,494
Total operating expenses		4,994		3,100
Loss from operations		(4,994)		(3,100)
Interest expense, net		(3)		(1)
Loss before income taxes		(4,997)		(3,101)
Income taxes		-		-
Net loss		\$ (4,997)		\$ (3,101)
Accrued dividend on Series B Preferred Stock		(256)		(241)
Deemed dividend on Series B Preferred Stock		-		-
Net loss attributable to common stockholders		\$ (5,253)		\$ (3,342)

***Six Months Ended September 30,***  
***2017***      ***2016***

Operating expenses:				
Research and development		\$ 3,523		\$ 2,432
General and administrative		3,731		2,631
Total operating expenses		7,254		5,063
Loss from operations		(7,254)		(5,063)
Interest expense (net)		(6)		(3)
Loss before income taxes		(7,260)		(5,066)

Income taxes	(2)	(2)
Net loss	\$ (7,262)	\$ (5,068)
Accrued dividend on Series B Preferred Stock	(504)	(781)
Deemed dividend on Series B Preferred Stock	-	(111)
Net loss attributable to common stockholders	<u>\$ (7,766)</u>	<u>\$ (5,960)</u>

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