



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

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SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 08/14/17 -- [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 first fiscal quarter ended June 30, 2017.

The Company also provided an update on its corporate progress, clinical status and anticipated milestones for AV-101, its orally available CNS prodrug candidate in Phase 2 development, initially as a new generation treatment for major depressive disorder (MDD).

"We anticipate several catalytic milestones in our clinical development, intellectual property and regulatory programs for AV-101 within the next 6 to 18 months. We remain highly focused on satisfying standard regulatory requirements and completing preparations for our planned AV-101 Phase 2 adjunctive treatment study in MDD. Our primary goal is to launch the study in January 2018 and complete it during 2018 to advance our efforts to provide a new generation treatment alternative to millions battling depression every day," commented Shawn Singh, Chief Executive Officer of VistaGen.

Mr. Singh continued, "In conjunction with our focused efforts to advance our AV-101 Phase 2 development program, we have continued to expand our intellectual property portfolio. Earlier this year the European Patent Office issued a Notice of Intention to Grant our European Patent Application regarding AV-101 for treatment of depression and reduction of dyskinesias associated with levodopa therapy for Parkinson's disease, a patent that will be in effect until at least January 2034. In addition, the U.S. Patent and Trademark Office recently allowed another important U.S. patent relating to stem cell technology held by VistaStem Therapeutics, our subsidiary using stem cell technology for drug rescue and regenerative medicine. The breakthrough technology under the allowed U.S. patent involves the stem cells from which all blood cells and most bone marrow cells are derived, technology with the potential to reach patients with a broad range of life-threatening diseases, including cancer, with CAR-T cell applications and foundational technology we believe may ultimately provide approaches for producing bone marrow stem cells for bone marrow transfusions. We are confident in our path forward through strategic collaborations, such as our agreement with the U.S. National Institute of Mental Health covering its full financial sponsorship of the ongoing Phase 2 study of AV-101 for MDD that Dr. Carlos Zarate Jr. and his team are conducting at the NIH's clinic in Bethesda, as well as our sublicense arrangement with BlueRock Therapeutics, a company established by Bayer AG and Versant Ventures, focused on regenerative medicine for heart disease. As we have historically, we believe we have surrounded ourselves with partners, supportive stockholders and corporate development and finance experts who share our confidence in our future and will assist us in securing key collaborations and raising sufficient capital to achieve our objectives, most notably the launch and completion in 2018 of our Phase 2 adjunctive treatment study of AV-101 for MDD. We look forward to creating value for our stakeholders in fiscal 2018 and beyond."

### **Potential Near-Term Milestones:**

During the second half of 2017, the Company is pursuing the following objectives:

- Receiving U.S. Food and Drug Administration (FDA) approval to commence its planned 180-patient, multi-center, double-blind, placebo controlled efficacy and safety study evaluating AV-101 as a new generation adjunctive treatment for MDD patients with an inadequate response to standard, FDA-approved antidepressants, with Dr. Maurizio Fava of Harvard Medical School as Principal Investigator; and
- Receiving FDA Fast Track designation for AV-101 as an adjunctive treatment for MDD.

Further, the Company anticipates that the U.S. National Institute of Mental Health (NIMH) will complete the NIH-sponsored Phase 2 study of AV-101 in depression, with topline results during the first half of 2018.

### **Recent Operational Highlights:**

*Advancement of AV-101 as a Potential, Non-Opioid Treatment Alternative for Chronic Pain*

- Two Phase 1 studies of AV-101 were published in the peer-reviewed *Scandinavian Journal of Pain* supporting the effect of AV-101 as a potential non-opioid treatment alternative for neuropathic pain. Safety data from both single and multi-dose Phase 1 studies indicated that oral AV-101 was extremely safe and well tolerated, with no meaningful difference in adverse events at any dose between AV-101 and placebo. These recently published studies, as well as statistically-significant positive results in four well-established preclinical models of pain associated with tissue inflammation and nerve injury, AV-101's excellent clinical safety profile, pharmacokinetic characteristics and consistent reductions in three pain measures (allodynia, mechanical and heat hyperalgesia), support future Phase 2 clinical studies of AV-101 as a potential non-opioid treatment alternative for neuropathic pain.

*Bolstered Clinical Team with Industry Expert*

- The Company appointed Mark Wallace, M.D., Distinguished Professor of Clinical Anesthesiology at the University of California, San Diego, to its Clinical Advisory Board to assist in advancing the potential development of AV-101 as a non-opioid treatment for neuropathic pain. Dr. Wallace is an internationally recognized leader in the field of multi-modal pain management, with over 30 years of professional experience, board certifications, licensures, honors/awards, grants, articles and abstracts.

#### *Intellectual Property Accomplishments*

- The Company received a Notice of Allowance from the U.S. Patent and Trademark Office for U.S. Patent Application No. 14/359,517 regarding proprietary methods for producing hematopoietic precursor stem cells, which are stem cells that give rise to all blood cells and most bone marrow cells in the body, with potential to impact both direct and supportive therapy for autoimmune disorders and cancer.

#### *Capital Market Highlights*

- The Company's largest institutional stockholder, holding common stock and 99.3% of the Company's outstanding preferred stock, entered into a 6-month lock-up agreement. Under the agreement, the stockholder and its affiliates agreed not to enter into any transaction involving the Company's securities during the term of the agreement, which runs through late-October 2017 and covers approximately 36% of the Company's issued and outstanding equity securities on an as-converted basis.

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

At June 30, 2017, the Company had a cash and cash equivalents balance of \$1.6 million, compared to \$2.9 million as of March 31, 2017. Between late-March 2017 and late-June 2017, in self-placed private placement transactions, the Company sold units consisting of unregistered common stock and common stock warrants to accredited investors, yielding approximately \$1 million in net cash proceeds.

Net loss for the fiscal quarters ended June 30, 2017 and 2016 was approximately \$2.3 million and \$2.0 million, respectively, including non-cash expenses of approximately \$0.5 million in each period.

Research and development expense totaled \$1.1 million for the fiscal quarter ended June 30, 2017, compared with \$0.8 million for the fiscal quarter ended June 30, 2016. The increase in year-over-year research and development expense was attributable to the Company's increased focus on the continuing non-clinical and clinical development of AV-101 and ongoing preparations to launch its AV-101 Phase 2 Adjunctive Treatment Study.

General and administrative expense increased slightly to \$1.2 million in the fiscal quarter ended June 30, 2017, from \$1.1 million in the fiscal quarter ended June 30, 2016 primarily because of increased headcount and employee-related expenses and non-cash stock compensation expense attributable to recent stock option grants, partially offset by a reduction in professional services fees.

#### **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 prodrug candidate for MDD. 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. NIMH in a 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 inadequate response to standard, FDA-approved antidepressants. Dr. Maurizio Fava of Harvard Medical School will be the Principal Investigator of the Company's Phase 2 adjunctive treatment study. 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, L-Dopa-induced dyskinesia associated with Parkinson's disease 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 launch, continuation and results of the NIMH's Phase 2 (monotherapy) and/or the Company's planned Phase 2 (adjunctive therapy) clinical studies of AV-101 in MDD, and other CNS diseases and disorders, including neuropathic pain and levodopa (L-DOPA)-induced dyskinesia associated with Parkinson's disease, the potential for the Company's stem cell technology to produce NCEs, cellular therapies, regenerative medicine or bone marrow stem cells to treat any medical condition, including autoimmune disorders and cancer, protection of its intellectual property, and the availability of substantial additional capital to support its operations, including the 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, except share amounts)

	<u>June 30, 2017</u>	<u>March 31, 2017</u>
	<i>(Unaudited)</i>	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 1,628,200	\$ 2,921,300
Prepaid expenses and other current assets	498,000	456,600
Total current assets	<u>2,126,200</u>	<u>3,377,900</u>
Property and equipment, net	262,900	286,500
Security deposits and other assets	47,800	47,800
Total assets	<u>\$ 2,436,900</u>	<u>\$ 3,712,200</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
Current liabilities:		
Accounts payable	\$ 632,000	\$ 867,300
Accrued expenses	204,900	443,000
Current portion of notes payable and accrued interest	165,500	54,800
Capital lease obligations	2,400	2,400
Total current liabilities	<u>1,004,800</u>	<u>1,367,500</u>
Non-current liabilities:		
Accrued dividends on Series B Preferred Stock	1,825,100	1,577,800
Deferred rent liability	202,500	139,200
Capital lease obligations	11,300	11,900
Total non-current liabilities	<u>2,038,900</u>	<u>1,728,900</u>
Total liabilities	<u>3,043,700</u>	<u>3,096,400</u>
Commitments and contingencies		
Stockholders' deficit:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized at June 30, 2017 and March 31, 2017:		
Series A Preferred, 500,000 shares authorized and outstanding at June 30, 2017 and March 31, 2017	500	500
Series B Preferred; 4,000,000 shares authorized at June 30, 2017 and March 31, 2017; 1,160,240 shares issued and outstanding at June 30, 2017 and March 31, 2017	1,200	1,200
Series C Preferred; 3,000,000 shares authorized at June 30, 2017 and March 31, 2017; 2,318,012 shares issued and outstanding at June 30, 2017 and March 31, 2017	2,300	2,300
Common stock, \$0.001 par value; 30,000,000 shares authorized at June 30, 2017 and March 31, 2017; 9,437,137 and 8,974,386 shares issued at June 30, 2017 and March 31, 2017, respectively	9,400	9,000
Additional paid-in capital	147,611,900	146,569,600
Treasury stock, at cost, 135,665 shares of common stock held at June 30, 2017 and March 31, 2017	(3,968,100)	(3,968,100)
Accumulated deficit	(144,264,000)	(141,998,700)
Total stockholders' equity (deficit)	<u>(606,800)</u>	<u>615,800</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 2,436,900</u>	<u>\$ 3,712,200</u>

**VISTAGEN THERAPEUTICS**

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**

**(Unaudited)**  
**(Amounts in dollars, except share amounts)**

	<b>Three Months Ended June 30,</b>	
	<b>2017</b>	<b>2016</b>
Operating expenses:		
Research and development	\$ 1,096,200	\$ 825,700
General and administrative	1,164,300	1,137,600
Total operating expenses	2,260,500	1,963,300
Loss from operations	(2,260,500)	(1,963,300)
Other expenses, net:		
Interest expense, net	(2,400)	(1,400)
Loss before income taxes	(2,262,900)	(1,964,700)
Income taxes	(2,400)	(2,400)
Net loss and comprehensive loss	(2,265,300)	(1,967,100)
Accrued dividend on Series B Preferred stock	(247,300)	(539,800)
Deemed dividend on Series B Preferred Units	-	(111,100)
Net loss attributable to common stockholders	\$ (2,512,600)	\$ (2,618,000)
Basic and diluted net loss attributable to common stockholders per common share	\$ (0.28)	\$ (0.51)
Weighted average shares used in computing basic and diluted net loss attributable to common stockholders per common share	9,034,213	5,097,832

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