



VistaGen Therapeutics Reports Fiscal 2017 Financial Results and Provides Corporate Update

June 29, 2017

SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 06/29/17 -- [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 fiscal year ended March 31, 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).

"With a team of industry experts and a focused strategy in place, we have established a strong foundation and embarked on paths to achieve several key catalysts within the next 18 months. We anticipate our first catalyst within the next 9 months as the NIMH completes its AV-101 Phase 2 monotherapy study in MDD, a study being conducted and fully funded by the NIH. Additionally, we are working closely with the FDA and our Principal Investigator, Dr. Maurizio Fava of Harvard University Medical School, on our AV-101 Phase 2 adjunctive treatment study in MDD, which we anticipate will begin enrollment in the first quarter of 2018 and be completed by the end of 2018, with topline results available in the first quarter of 2019," commented [Shawn Singh, Chief Executive Officer](#) of VistaGen.

In addition to MDD, AV-101 may have therapeutic potential in several other CNS indications where modulation of NMDA receptors, activation of AMPA pathways and/or active metabolites of AV-101 play a key role, including for treatment of epilepsy, as a non-opioid alternative for management of neuropathic pain, and to address certain symptoms associated with Parkinson's disease and Huntington's disease.

Mr. Singh continued, "Our MDD clinical program is our top priority, and will remain so. Additionally, however, recent peer-reviewed publications suggest that AV-101 may have significant therapeutic potential as a non-opioid treatment alternative for pain management. We are also excited about AV-101's potential to reduce dyskinesia associated with standard levodopa, or L-DOPA, therapy for Parkinson's disease, based on results from previous non-clinical studies. Without diverting our priority focus on MDD, we plan to expand our AV-101 Phase 2 clinical program during the next year to include these important CNS indications with significant unmet need."

"We are also pleased to have advanced our cardiac stem cell program during fiscal 2017, through both our participation in the FDA's CiPA initiative focused on using novel human stem cell models to predict cardiac toxicity of new drug candidates long before animal and human studies, as well as our exclusive sublicense agreement with BlueRock Therapeutics, an emerging force in cardiac regenerative medicine, founded and funded by Bayer AG and Versant Ventures. Our initial revenue-generating milestone with BlueRock Therapeutics was completed during fiscal 2017. We are optimistic about this relationship's potential and the future of cardiac regenerative medicine. We believe these significant events over the past year have positioned us to create substantial value for our stakeholders in fiscal 2018 and beyond."

Potential Near-Term Milestones:

- VistaGen is preparing to launch its study of AV-101 as a new generation adjunctive treatment for MDD (the Phase 2 Adjunctive Treatment Study), a 180-patient, multi-center, double-blind, placebo controlled efficacy and safety study evaluating AV-101 in MDD patients with an inadequate response to standard, FDA-approved antidepressants. The Company anticipates:
 - Receiving a response and approval from the FDA on the Company's Investigational New Drug application (IND) for the planned Phase 2 Adjunctive Treatment Study in the second half of 2017;
 - Commencing patient enrollment of the Phase 2 Adjunctive Treatment Study in January 2018, with Dr. Maurizio Fava as Principal Investigator; and
 - Completing the Phase 2 Adjunctive Treatment Study by the end of 2018, with topline results expected in the first quarter of 2019.
- FDA Fast Track designation for AV-101 as an adjunctive treatment of MDD by the end of 2017.
- Completion of the Phase 2 monotherapy study by the NIMH in 2017, with topline results during the first half of 2018.

Operational Highlights During Fiscal 2017:

Achievements Related to Stem Cell Technologies

- Execution of an [exclusive sublicense agreement with BlueRock Therapeutics L.P.](#), a next generation regenerative medicine company established by Bayer AG and Versant Ventures, for rights to VistaGen's proprietary stem cell 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.
- Additionally, VistaGen is selectively advancing its VistaStem Therapeutics subsidiary by:
 - Expansion of the predictive toxicology capabilities of *CardioSafe* 3D for internal small molecule NCE drug rescue and development;

- Participation in the FDA's Comprehensive in-vitro Proarrhythmia Assay (CiPA) initiative designed to change the landscape of preclinical drug development by providing a more complete and accurate in vitro assessment of potential drug effects on cardiac risk; and
- Execution of collaborative arrangements similar to the BlueRock Therapeutics agreement to advance regenerative medicine applications of our pluripotent stem cell technology platform.

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 for neuropathic pain. Safety data from both the 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 (AEs) at any dose between AV-101 and placebo. These recently published studies, statistically-significant positive results in four well-established preclinical models of pain associated with tissue inflammation and nerve injury, together with the excellent clinical safety profile, pharmacokinetic (PK) 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.
- AV-101 was found to have robust anti-nociceptive effects, similar to gabapentin, but with a better side effect profile in several preclinical models of hyperalgesia and allodynia, suggesting AV-101's potential for treating multiple hyperpathic pain states.

Bolstered Team with Industry Experts

- Clinical and Regulatory Advisory Board appointments include Dr. Maurizio Fava (Harvard University) as Chairman, Dr. Sanjay Matthew (Baylor University) and Dr. Thomas Laughren (former director, FDA's Division of Psychiatry), all distinguished opinion leaders in the field of depression.
- Jerry Gin, Ph.D., MBA, a veteran healthcare executive, was elected to serve as a member of VistaGen's Board of Directors.
- Key additions to VistaGen's management team include Mark A. Smith, MD, Ph.D., former Clinical Lead for Neuropsychiatry at Teva Pharmaceuticals, as Chief Medical Officer to lead clinical development of AV-101, and Mark A. McPartland as Vice President, Corporate Development, to expand awareness of VistaGen and its AV-101 development program among investors and potential partners.

Intellectual Property Accomplishments

- The European Patent Office issued a Notice of Intention to Grant VistaGen's European Patent Application for AV-101. The granted claims covering treatment of depression, reduction of dyskinesia associated with L-DOPA treatment of Parkinson's disease and multiple dosage forms of AV-101 will be in effect until at least January 2034.

Capital Market Highlights

- VistaGen's largest institutional stockholder, holding both common stock and 99.3% of VistaGen's outstanding preferred stock, entered into a 6-month lock-up agreement. Under the agreement, the stockholder and its affiliates agreed to not enter into any transaction involving VistaGen's securities during the term of the agreement, which runs through late-October 2017 and covers approximately 36% of the issued and outstanding equity securities on an as converted basis.
- Completed \$10M public offering in the first quarter of fiscal 2017, and listed our common stock for trading on the NASDAQ Capital Market.

Financial Results for the Fiscal Year Ended March 31, 2017:

Revenue for the fiscal year ended March 31, 2017 totaled \$1.25 million and was attributable to a sublicense agreement with BlueRock Therapeutics, for certain rights to the Company's proprietary technologies relating to the production of cardiac stem cells for the treatment of heart disease.

Research and development expense totaled \$5.2 million for the fiscal year ended March 31, 2017, an increase of approximately 33% compared with the \$3.9 million incurred for the fiscal year ended March 31, 2016. The increase in year-over-year research and development expense was attributable to increased focus on development of AV-101, including preparations to launch the Phase 2 Adjunctive Treatment Study in MDD.

General and administrative expense decreased to \$6.3 million in the fiscal year ended March 31, 2017, from \$13.9 million in the fiscal year ended March 31, 2016, primarily as a result of the decrease in non-cash stock compensation expense, partially offset by an increase in non-cash expense related to grants of equity securities in payment of certain professional services during fiscal 2017. Of the amounts reported, non-cash expenses, related primarily to grants or modifications of equity securities, totaled approximately \$3.1 million in fiscal 2017 and \$11.9 million in fiscal 2016.

Net loss for the fiscal years ended March 31, 2017 and 2016 was approximately \$10.3 million and \$47.2 million, respectively, the latter amount including a non-recurring, non-cash expense of approximately \$26.7 million attributable to the extinguishment of approximately \$15.9 million carrying value of prior indebtedness, including then-outstanding Senior Secured Convertible Notes, and conversion of such indebtedness into equity securities between May and September 2015 at a conversion price (stated value of the equity received) of \$7.00 per share.

At March 31, 2017, the Company had a cash and cash equivalents balance of \$2.9 million. Since late-March 2017, the Company sold units consisting

of unregistered common stock and common stock warrants to accredited investors in a self-placed private placement, yielding approximately \$1 million in cash proceeds to the Company.

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 in Phase 2 development, initially as a new generation oral antidepressant drug candidate for major depressive disorder (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. National Institute of Mental Health (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 University 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.

VistaStem Therapeutics is VistaGen's wholly owned subsidiary focused on applying human pluripotent stem cell technology, internally and with 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.

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 financing, 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 L-DOPA-induced dyskinesia associated with Parkinson's disease, protection of its intellectual property, and the availability of substantial additional capital to support its operations, including the Phase 2 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. VistaGen undertakes no obligation to publicly update or revise any forward-looking statements.

FINANCIAL TABLES FOLLOW

VISTAGEN THERAPEUTICS Condensed Consolidated Balance Sheets Amounts in Dollars

	<u>March 31, 2017</u>	<u>March 31, 2016</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 2,921,300	\$ 428,500
Prepaid expenses and other current assets	456,600	426,800
Total current assets	3,377,900	855,300
Property and equipment, net	286,500	87,600
Security deposits and other assets	47,800	46,900
Total assets	<u>\$ 3,712,200</u>	<u>\$ 989,800</u>
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	\$ 867,300	\$ 936,000
Accrued expenses	443,000	814,000
Current portion of notes payable and accrued interest	54,800	43,600
Capital lease obligations	2,400	1,100
Total current liabilities	1,367,500	1,794,700
Non-current liabilities:		
Notes payable	-	27,200
Accrued dividends on Series B Preferred Stock	1,577,800	2,089,600
Deferred rent liability	139,200	55,500
Capital lease obligations	11,900	-
Total non-current liabilities	1,728,900	2,172,300
Total liabilities	<u>3,096,400</u>	<u>3,967,000</u>
Commitments and contingencies		

Stockholders' equity (deficit):

Preferred stock, \$0.001 par value; 10,000,000 shares authorized at March 31, 2017 and March 31, 2016:

Series A Preferred, 500,000 shares authorized and outstanding at March 31, 2017 and March 31, 2016

500 500

Series B Preferred; 4,000,000 shares authorized at March 31, 2017 and March 31, 2016; 1,160,240 shares and 3,663,077 shares issued and outstanding at March 31, 2017 and March 31, 2016, respectively

1,200 3,700

Series C Preferred; 3,000,000 shares authorized at March 31, 2017 and March 31, 2016; 2,318,012 shares issued and outstanding at March 31, 2017 and March 31, 2016

2,300 2,300

Common stock, \$0.001 par value; 30,000,000 shares authorized at March 31, 2017 and March 31, 2016; 8,974,386 and 2,623,145 shares issued at March 31, 2017 and March 31, 2016, respectively

9,000 2,600

Additional paid-in capital

146,569,600 132,725,000

Treasury stock, at cost, 135,665 shares of common stock held at March 31, 2017 and March 31, 2016

(3,968,100) (3,968,100)

Accumulated deficit

(141,998,700) (131,743,200)

Total stockholders' equity (deficit)

615,800 (2,977,200)

Total liabilities and stockholders' equity (deficit)

\$ 3,712,200 \$ 989,800

**VISTAGEN THERAPEUTICS
STATEMENT OF OPERATIONS**

Amounts in Dollars, except share amounts

	Fiscal Years Ended March 31,	
	2017	2016
Revenues:		
Sublicense fees	\$ 1,250,000	\$ -
Total revenues	<u>1,250,000</u>	<u>-</u>
Operating expenses:		
Research and development	5,203,700	3,931,600
General and administrative	6,294,800	13,918,600
Total operating expenses	<u>11,498,500</u>	<u>17,850,200</u>
Loss from operations	(10,248,500)	(17,850,200)
Other expenses, net:		
Interest expense, net	(4,600)	(770,800)
Change in warrant liability	-	(1,894,700)
Loss on extinguishment of debt	-	(26,700,200)
Other expense	-	(2,300)
Loss before income taxes	(10,253,100)	(47,218,200)
Income taxes	(2,400)	(2,300)
Net loss and comprehensive loss	<u>(10,255,500)</u>	<u>(47,220,500)</u>
Accrued dividend on Series B Preferred stock	(1,257,000)	(2,140,500)
Deemed dividend on Series B Preferred Units	<u>(111,100)</u>	<u>(2,058,000)</u>
Net loss attributable to common stockholders	<u>\$ (11,623,600)</u>	<u>\$ (51,419,000)</u>
Basic and diluted net loss attributable to common stockholders per common share	<u>\$ (1.54)</u>	<u>\$ (29.08)</u>
Weighted average shares used in computing basic and diluted net loss attributable to common stockholders per common share	<u>7,531,642</u>	<u>1,767,957</u>

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