# UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

# FORM 8-K

# CURRENT REPORT Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) June 29, 2017

# VistaGen Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

**Nevada** (State or other jurisdiction of incorporation)

**000-54014** (Commission File Number)

**20-5093315** (I.R.S. Employer Identification No.)

343 Allerton Ave.
South San Francisco, California 94090
(Address of principal executive offices) (Zip Code)

(650) 577-3600 (Registrant's telephone number, including area code)

Not applicable.

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

 $\square$  Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### Item 2.02 Results of Operations and Financial Condition.

See Item 8.01.

#### Item 8.01 Other Events.

Today, VistaGen Therapeutics Inc. (the "Company") issued a press release to provide investors with a corporate update and to announce the Company's financial results for its fiscal year ended March 31, 2017. A copy of the press release is attached hereto as Exhibit 99.1.

The information furnished herein and therein shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, or incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

#### Item 9.01 Financial Statements and Exhibits.

#### (d) Exhibits Index

Exhibit No. Description

99.1 Press release issued by VistaGen Therapeutics Inc. dated June 29, 2017.

#### Disclaimer.

This Current Report on Form 8-K may contain, among other things, certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, without limitation, (i) statements with respect to the Company's plans, objectives, expectations and intentions; and (ii) other statements identified by words such as "may", "could", "would", should", "believes", "expects", "anticipates", "estimates", "intends", "plans" or similar expressions. These statements are based upon the current beliefs and expectations of the Company's management and are subject to significant risks and uncertainties.

# **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: June 29, 2017

VistaGen Therapeutics Inc.

By: /s/ Shawn K. Singh Name: Shawn K. Singh

Title: Chief Executive Officer

### EXHIBIT INDEX

Exhibit Number	Description
00.1	
99.1	Press release issued by VistaGen Therapeutics Inc. dated June 29, 2017.



# VistaGen Therapeutics Reports Fiscal 2017 Financial Results and Provides Corporate Update

SOUTH SAN FRANCISCO, CA -- (Marketwired – June 29, 2017) -- 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:
  - o 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:
  - o Commencing patient enrollment of the Phase 2 Adjunctive Treatment Study in January 2018, with Dr. Maurizio Fava as Principal Investigator; and
  - o 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:
  - o Expansion of the predictive toxicology capabilities of CardioSafe 3D for internal small molecule NCE drug rescue and development;
  - o 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
  - o 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 fasteracting 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.

#### **Company Contact:**

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# VISTAGEN THERAPEUTICS, INC.

### **Condensed Consolidated Balance Sheets**

Amounts in Dollars

		March 31, 2017		March 31, 2016	
ASSETS					
Current assets:	ф	2.024.200	ф	100 500	
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	\$	3,712,200	\$	989,800	
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		55,500	
Total non-current liabilities	_	1,728,900	_	2,172,300	
			_		
Total liabilities		3,096,400	_	3,967,000	
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, 2017; 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, INC. STATEMENT OF OPERATIONS

Amounts in dollars, except share amounts

Fiscal Years Ended
March 31,

Total revenues  Operating expenses: Research and development General and administrative Total operating expenses  Loss from operations Other expenses, net: Interest expense, net Change in warrant liability Loss on extinguishment of debt Other expense Loss before income taxes  1,25	murch 51,		
Sublicense fees \$ 1,25 Total revenues 1,25 Operating expenses: Research and development 5,20 General and administrative 6,29 Total operating expenses 11,49 Loss from operations (10,24 Other expenses, net: Interest expense, net (Change in warrant liability Loss on extinguishment of debt Other expense Loss before income taxes (10,25)	,	2016	
Total revenues Operating expenses: Research and development General and administrative Total operating expenses  Loss from operations Other expenses, net: Interest expense, net Change in warrant liability Loss on extinguishment of debt Other expense Loss before income taxes  1,25			
Operating expenses: Research and development 5,20 General and administrative 6,29 Total operating expenses 11,49 Loss from operations (10,24 Other expenses, net: Interest expense, net (Change in warrant liability Loss on extinguishment of debt Other expense Loss before income taxes (10,25)	0,000 \$	-	
Research and development 5,20 General and administrative 6,29 Total operating expenses 11,49 Loss from operations (10,24 Other expenses, net: Interest expense, net (Change in warrant liability Loss on extinguishment of debt Other expense (10,25)	0,000	-	
General and administrative 6,29 Total operating expenses 11,49 Loss from operations (10,24 Other expenses, net: Interest expense, net Change in warrant liability Loss on extinguishment of debt Other expense Loss before income taxes (10,25)			
Total operating expenses  Loss from operations  Other expenses, net:  Interest expense, net  Change in warrant liability  Loss on extinguishment of debt  Other expense  Loss before income taxes  11,49  (10,24	3,700	3,931,600	
Loss from operations (10,24) Other expenses, net: Interest expense, net Change in warrant liability Loss on extinguishment of debt Other expense Loss before income taxes (10,25)	4,800	13,918,600	
Other expenses, net: Interest expense, net Change in warrant liability Loss on extinguishment of debt Other expense Loss before income taxes  (10,25)	8,500	17,850,200	
Interest expense, net Change in warrant liability Loss on extinguishment of debt Other expense Loss before income taxes  (10,25	8,500)	(17,850,200)	
Change in warrant liability Loss on extinguishment of debt Other expense Loss before income taxes  (10,25)			
Loss on extinguishment of debt Other expense Loss before income taxes  (10,25)	(4,600)	(770,800)	
Other expense  Loss before income taxes (10,25)	-	(1,894,700)	
Loss before income taxes (10,25	-	(26,700,200)	
		(2,300)	
Income taxes	3,100)	(47,218,200)	
	(2,400)	(2,300)	
Net loss and comprehensive loss (10,25)	5,500)	(47,220,500)	
Accrued dividend on Series B Preferred stock (1,25	7,000)	(2,140,500)	
Deemed dividend on Series B Preferred Units (11	1,100)	(2,058,000)	
Net loss attributable to common stockholders \$ (11,62	3,600) \$	(51,419,000)	
Basic and diluted net loss attributable to common stockholders			
per common share	(1.54) \$	(29.08)	
Weighted average shares used in computing basic and diluted net loss attributable  to common stockholders per common share  7,53	1,642	1,767,957	