# 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): August 8, 2017

### VistaGen Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

**NEVADA** 

**001-37761** 

<u>20-5093315</u>

(State or other jurisdiction of incorporation)

(Commission File Number)

(IRS Employer Identification Number)

343 Allerton Ave. South San Francisco, California 94090

 $(Address\ of\ principal\ executive\ of fices)$ 

(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 rovisions:
☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425) ☐ 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 13a 4(c) under the Exchange Act (17 CFR 240.13a 4(c))
□ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e -4(c))

### Item 8.01 Other Events.

On August 8, 2017, VistaGen Therapeutics, Inc. (the "*Company*") announced that the Company received a Notice of Allowance from the U.S. Patent and Trademark Office ("*USPTO*") for U.S. Patent Application No. 14/359,517 regarding proprietary methods for producing hematopoietic precursor stem cells. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1, and is incorporated herein by reference.

### Item 9.01 Exhibits.

See Exhibit Index.

### **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 thereunto duly authorized.

VistaGen Therapeutics, Inc.

Date: August 9, 2017 By: /s/ Shawn K. Singh

Shawn K. Singh Chief Executive Officer

## EXHIBIT INDEX

Exhibit Number	Description
<u>99.1</u>	Press release issued by VistaGen Therapeutics Inc., dated August 8, 2017.



# VistaGen Receives Notice of Allowance from U.S. Patent and Trademark Office for U.S. Patent regarding Breakthrough Methods for Producing Blood Cells, Platelets and Bone Marrow Stem Cells with Potential to Treat Autoimmune Disorders and Cancer

**South San Francisco, CA (August 8, 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, announced today that the Company has received a Notice of Allowance from the U.S. Patent and Trademark Office (USPTO) 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 of the blood cells and most of the bone marrow cells in the body, with potential to impact both direct and supportive therapy for autoimmune disorders and cancer.

The breakthrough technology covered by the allowed U.S. patent was discovered and developed by distinguished stem cell researcher, Dr. Gordon Keller, Director of the UHN's McEwen Centre for Regenerative Medicine in Toronto, one of the world's leading centers for stem cell and regenerative medicine research and part of the University Health Network (UHN), Canada's largest research hospital. Dr. Keller is a co-founder of VistaGen and a member of the Company's Scientific Advisory Board. VistaGen holds an exclusive worldwide license from UHN to the stem cell technology covered by the allowed U.S. patent.

"We are pleased to report that the USPTO has allowed another important U.S. patent relating to our stem cell technology platform, stated Shawn Singh, Chief Executive Officer of VistaGen. "Because the technology under this allowed patent involves the stem cells from which all blood cells are derived, it has the potential to reach the lives of millions battling a broad range of life-threatening medical conditions, including cancer, with CAR-T cell applications and foundational technology we believe ultimately will provide approaches for producing bone marrow stem cells for bone marrow transfusions. As we continue to expand the patent portfolio of VistaStem Therapeutics, our stem cell technology-focused subsidiary, we enhance our potential opportunities for additional regenerative medicine transactions similar to our December 2016 sublicense of cardiac stem cell technology to BlueRock Therapeutics, while focusing VistaStem's internal efforts on using stem cell technology for cost-efficient small molecule drug rescue to expand our drug development pipeline."

#### 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 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 U.S. National Institute of Mental Health (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. 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, and levodopa-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 small molecule 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 small molecule 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 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 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 <a href="https://www.sec.gov">www.sec.gov</a>. VistaGen undertakes no obligation to publicly update or revise any forward-looking statements.

### **Company Contact**

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