

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 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): February 10, 2016

Commission File Number: 000-54014

VistaGen Therapeutics, Inc.
(Exact name of registrant as specified in its charter.)

Nevada
(State or other jurisdiction of incorporation or organization)

205093315
(IRS Employer Identification No.)

343 Allerton Avenue, South San Francisco, California 94080
(Address of principal executive offices)

650-577-3600
(Registrant's Telephone number)

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)
- 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))
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Item 7.01 Regulation FD Disclosure.

On February 10, 2016, VistaGen Therapeutics, Inc. (the "Company") issued its 2015 Letter to Stockholders, in which the Company provides its business outlook and key corporate, clinical and regulatory milestones it expects to achieve in 2016. A copy of the Company's 2015 Letter to Stockholders is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

See Exhibit Index.

Disclaimer.

The information included under Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1 hereto) is being furnished and shall not be deemed filed for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, is not subject to the liabilities of that section and is not deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except as shall be expressly set forth by specific reference in such a filing.

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.

VistaGen Therapeutics, Inc.

Date: *February 10, 2016*

By: */s/ Shawn Singh*

Name: Shawn Singh
Title: Chief Executive Officer

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
EX-99.1	2015 Stockholder Letter

2015 Letter to Stockholders

February 2016

Dear Fellow Stockholders:

2015 was a year marked by significant accomplishments on the clinical, regulatory and operational fronts which we believe will enable VistaGen to achieve key milestones and position the Company for a strong 2016 and beyond. Especially noteworthy was the advancement of our lead candidate, AV-101, into an NIH-funded Phase 2a clinical study involving patients with treatment-resistant major depressive disorder (MDD), an indication that was recognized by the pharmaceutical industry through meaningful M&A activity late in the year. In addition, we expanded our intellectual property estate related to AV-101 and exciting near- and long-term opportunities in drug rescue and regenerative medicine.

Over the course of the year, we bolstered our Clinical and Scientific Advisory Board with the additions of Dr. Maurizio Fava and Dr. Gerald Sanacora, preeminent thought leaders in the depression space. Dr. Fava, Professor of Psychiatry at Harvard Medical School, is Director of the Division of Clinical Research of the Massachusetts General Hospital (MGH) Research Institute. Dr. Sanacora, Associate Professor at Yale School of Medicine, is Director of the Yale Depression Research Program. We are privileged to add them both to the VistaGen team.

Looking ahead, we expect 2016 to be a year where we will focus on continuing to execute on our strategy culminating in the achievement of transformational milestones, including ensuring our financial stability and listing of our common stock on a National Exchange, continued advancement of our Phase 2a study towards completion and the initiation of a Phase 2b study of AV-101 for MDD, the diversification and expansion of opportunities relating to our stem cell platform, and importantly, substantially heightened awareness of VistaGen among the pharmaceutical and investment communities.

AV-101 Advanced to NIH-Funded Phase 2a Study

One of the key highlights for VistaGen in 2015 was the advancement of our unique, lead clinical candidate, AV-101, into a Phase 2a study for MDD. AV-101 is a new generation, **orally-available** N-methyl-D-aspartate receptor (NMDAR) antagonist binding selectively at the glycine binding (GlyB) co-agonist site of the NMDAR.

MDD is among the most common mental disorders in the United States today, and one which impairs the daily functioning of approximately 6.7% of the adult population. As a result, MDD is a significant area of unmet medical need, because initial treatment with standard antidepressants is effective in only approximately one-third of depression patients and requires many weeks to months to achieve therapeutic benefits.

In February 2015, we were pleased to announce that VistaGen had entered into a Cooperative Research and Development Agreement (CRADA) with the U.S. National Institute of Mental Health (NIMH), under which the NIMH agreed to fully fund and lead our Phase 2a study of up to 28 adults in treatment-resistant MDD. The study was initiated in October 2015, with Dr. Carlos Zarate, Jr., Chief of the NIMH's Experimental Therapeutics & Pathophysiology Branch, serving as Principal Investigator. Dr. Zarate is an internationally recognized expert in the field of depression and was among the first clinical researchers in the world to discover the therapeutic potential of the NMDAR antagonist ketamine in treatment-resistant MDD.

Current evidence suggests that AV-101's unique mechanism of action may provide rapid, dose-dependent and persistent ketamine-like antidepressant benefits without the negative side effects seen with ketamine. Preclinical data illustrating these key findings were published in the October 2015 issue of the peer-reviewed *Journal of Pharmacology and Experimental Therapeutics*. We are excited about the potentially vast market opportunity for AV-101, and strongly believe that it is fundamentally differentiated from all standard antidepressants currently approved by the U.S. Food and Drug Administration (FDA), and also from those in clinical development.

Our optimism with the AV-101 opportunity is underscored by the considerable M&A attention that anti-depression drugs, in particular, drugs with similar mechanisms of action to ketamine, have received of late. As an example, in September 2015, a major pharmaceutical company, Allergan plc, acquired Naurex Inc. to gain access to Naurex's pipeline candidates rapastinel (administered intravenously), which had completed a Phase 2b clinical study in MDD, and NRX-1074, an earlier stage drug candidate. According to the terms of the acquisition, Allergan paid \$560 million in upfront cash, plus potential R&D and sales-based milestones. In November, Pfizer Inc. and Allergan plc agreed to merge, resulting in one of the largest M&A transactions in the history of the pharmaceutical industry, with rapastinel cited as a key development program for the combined company.

VistaGen believes that AV-101's emerging efficacy and safety profile, supported by a favorable oral formulation over rapastinel's IV administration, represents a potential "game changer" and major shift in the treatment paradigm among the current next-generation anti-depression drug candidates. As such, we believe that the Company's recent market valuation does not fully reflect our progress and the exceptional opportunities that are ahead of us in the near- and long-term.

More than one billion people worldwide suffer from diseases of the central nervous system (CNS). The annual economic burden of these disorders is staggering, estimated at \$2 trillion in the United States and the European Union alone, a figure that RAND Corporation estimates is expected to triple to \$6 trillion by 2030. We are excited, not only about AV-101's potential as a disruptive

new generation antidepressant, but also about its potential to impact several other CNS-related conditions and neurodegenerative diseases with high unmet need. Moving forward, we are committed to pursuing these additional opportunities.

Stem Cell Program Progress

During 2015, we also advanced our pluripotent stem cell technology platform to enable potential commercial applications involving drug rescue and regenerative medicine. With that in mind, in late-2015, VistaGen licensed three patent-pending stem cell technologies from University Health Network (UHN), Canada's largest research hospital. The newly licensed technologies were discovered and developed by distinguished UHN researcher and VistaGen co-founder, Dr. Gordon Keller, Director of UHN's McEwen Centre for Regenerative Medicine (McEwen Centre), one of the world's leading centers for stem cell and regenerative medicine research. VistaGen now holds five licenses from UHN, and anticipates that these new licenses will enable the further application of our technology platform to develop stem cells into blood, heart, liver and cartilage cells for multiple potential commercial applications, including drug rescue and regenerative therapies for cancer, heart disease, liver disease and osteoarthritis. Our intent is to further develop these applications collaboratively and as quickly as we can obtain the requisite funding.

Transformed Capital Structure

On the business front, we significantly transformed VistaGen's capital structure in 2015 through a series of transactions that, we believe, will vastly improve our liquidity profile, raise awareness in the global marketplace, and drive stockholder value. Among these transactions was the conversion of nearly 90% of our debt (approximately \$17.2 million), including all secured promissory notes, into equity. We believe this improved capital structure will enable VistaGen to obtain sufficient financing to satisfy crossover listing requirements to facilitate our transition from the OTC Markets to a National Exchange as quickly as possible in 2016.

Tangible Catalytic Events We Expect to Transform VistaGen in the Year Ahead:

- Uplisting to a National Exchange;
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Strengthening our capital position;

- Potential for the FDA to award “Fast Track Designation” to AV-101 in connection with our Phase 2b MDD development program;
- Commencing patient dosing in a new AV-101 Phase 2b MDD study in patients with an inadequate response to standard antidepressant therapies;
- Diversifying and expanding opportunities relating to our stem cell technology platform;
- Substantially heightening awareness of VistaGen among potential pharmaceutical partners and broadly throughout the investment communities; and
- Reporting top-line results from the ongoing Phase 2a study of AV-101 in treatment-resistant MDD by early next year.

At VistaGen, our entire team is dedicated to capitalizing on significant value-creating opportunities for our stockholders. We are confident in AV-101’s potential to emerge as a leader among next-generation treatments for MDD and other CNS indications resulting in new solutions for physicians and patients. And finally, we are encouraged by recent M&A interest for such assets among global pharmaceutical industry leaders.

We are grateful to you, our stockholders, for your continued interest and support. We very much look forward to updating you on our progress in what we believe will be an exciting year ahead.

Very truly yours,

/s/ Shawn K. Singh

Shawn K. Singh
Chief Executive Officer