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): September 22, 2016

VistaGen Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

NEVADA	**000-54014**	**20-5093315**
(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 offices)

(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:

☐ 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))

Item 7.01 Regulation FD Disclosure.

VistaGen Therapeutics, Inc. (the "*Company*") today issued a press release that provided a business outlook regarding the clinical status of its flagship central nervous system ("*CNS"*) product candidate, AV-101 (L-4-chlorokyurenine or 4-CI-KYN), and an overview of anticipated events and near-term corporate, business, clinical and regulatory milestones expected through the first half of 2017. A copy of the press release is attached hereto as Exhibit 99.1.

In accordance with General Instruction B.2 for Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, 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, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

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.

Item 9.01 Financial Statements and Exhibits.

(d) 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: September 22, 2016

By: */s/ Shawn K. Singh*
Shawn K. Singh
Chief Executive Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, dated September 22, 2016

Exhibit 99.1

VistaGen Therapeutics Provides Business Outlook and Sets Corporate Milestones

- Company poised to achieve multiple key corporate, business, clinical and regulatory milestones in the near-term -

South San Francisco, CA (September 22, 2016) – VistaGen Therapeutics Inc. (NASDAQ: VTGN) (*VistaGen* or the *Company*), a clinical-stage biopharmaceutical company dedicated to developing and commercializing innovative product candidates for patients with diseases and disorders involving the central nervous system (*CNS*), today provided a business outlook including the clinical status of its flagship CNS product candidate, AV-101 (L-4-chlorokyurenine or 4-CI-KYN), currently in Phase 2 development for the treatment of major depressive disorder (*MDD*), and an overview of anticipated events and near-term corporate, business, clinical and regulatory milestones expected through the first half of 2017.

"During the first half of 2016, we have achieved notable progress on corporate, clinical and regulatory fronts, and I believe we are now rapidly heading into the most exciting time for VistaGen to date," commented Shawn Singh, Chief Executive Officer of VistaGen.

Recent Corporate Highlights

- Appointed Mark A. Smith M.D., Ph.D. as Chief Medical Officer, former Clinical Lead for Neuropsychiatry at Teva Pharmaceuticals, to lead clinical development of AV-101 in MDD and additional CNS pipeline programs;
- Completed $10M public offering, led by institutional investors;
- Uplisted to NASDAQ Capital Markets under new ticker "VTGN";
- Appointed veteran healthcare executive, Jerry Gin, Ph.D., MBA, to Board of Directors; and
- Bolstered Clinical and Regulatory Advisory Board (*CRB*) with the appointment of existing member, Maurizio Fava, M.D., as Chairman, and new members, Sanjay Matthew, M.D. and Thomas Laughren M.D.

"These achievements were transformational for VistaGen. The Company is fundamentally stronger than it ever has been, and we are positioned to strategically expand our pipeline of opportunities in the future," stated Mr. Singh.

Mr. Singh added, "The key appointments of our Chief Medical Officer, Mark A. Smith, M.D., Ph.D., as well as the preeminent members to our Clinical and Regulatory Advisory Board, position VistaGen at the forefront in the development of the new generation of safer and orally available antidepressants. Leveraging the strength and expertise of our expanded team will prove to be an integral factor in unlocking and building shareholder value, in both the short-term and long-term."

AV-101 for the Adjunctive Treatment of MDD - Clinical Development Overview

The Company also provided an update to its corporate progress and clinical status for AV-101, its new generation, orally available prodrug candidate in Phase 2 development, initially for the adjunctive treatment of MDD in patients with an inadequate response to standard antidepressants.

AV-101 is currently being evaluated in an ongoing Phase 2a monotherapy study for the treatment of MDD, a study being conducted and funded by the U.S. National Institute of Mental Health (*NIMH*), part of the U.S. National Institutes of Health (*NIH*). Dr. Carlos Zarate of the NIMH is the Principal Investigator of the study. AV-101's mechanism of action is fundamentally differentiated from all FDA-approved antidepressants and atypical antipsychotics, with potential to drive a paradigm shift towards new generation safer and faster-acting antidepressants. VistaGen's development strategy for AV-101 is focused on establishing it as the primary augmentation option for individuals with MDD with inadequate response to standard antidepressants, displacing atypical antipsychotics in the current depression treatment paradigm. VistaGen expects to report topline data from its NIMH-sponsored Phase 2a study in the second quarter of 2017.

The Company is also preparing to advance AV-101 into a Phase 2b study for adjunctive treatment of MDD in the first quarter of 2017. Dr. Maurizio Fava of Harvard University will be the Principal Investigator of this study. The double-blind, placebo controlled efficacy and safety study of AV-101 as adjunctive treatment of MDD for individuals with inadequate response to standard antidepressants is expected to enroll approximately 280 patients at 20-25 sites across the US. The study will involve a Sequential Parallel Comparison Design (*SPCD*), a study design intended to mitigate placebo effects. The Company anticipates topline results from this Phase 2b study to be reported in the third quarter of 2018.

The Company expects to receive FDA Fast Track Designation for AV-101 as adjunctive treatment for MDD during the first half of 2017.

Pipeline Expansion Opportunities

VistaGen believes it has the potential to expand AV-101 into multiple additional CNS indications beyond adjunctive treatment of MDD, including neuropsychiatric disorders (depression and bipolar depression), neurological disorders (chronic neuropathic pain and epilepsy) and neurodegenerative disorders (Huntington's disease and Parkinson's disease), each representing potential blockbuster opportunities.

The Company also evaluates opportunities to acquire or license synergistic CNS product candidates to expand its pipeline.

Near-Term Milestones Expected to Drive Value

- Meet with FDA and submit Investigational New Drug application (IND) to the FDA regarding Phase 2b study of AV-101 as adjunctive treatment of MDD in Q4 2016 (October – December 2016);
- Commence Phase 2b study of AV-101 as adjunctive treatment of MDD in Q1 2017 (January - March 2017);
- Obtain FDA Fast Track Designation for AV-101 as adjunctive treatment of MDD in Q1 2017 (January – March 2017); and
- Report topline data from NIMH-sponsored Phase 2a monotherapy study of AV-101 in MDD in Q2 2017 (April - June 2017).

"We fully intend to build upon the significant momentum we have created this year and will continue to focus on operational excellence as we drive AV-101 towards late-stage clinical development and commercialization. We believe AV-101 has the potential to be a game-changing therapy for individuals living with MDD where there remain significant shortcomings in current treatment alternatives, and we are committed to advancing our development programs as rapidly as possible. We believe AV-101 will have an important role in the global depression market, a market that is large and growing at staggering rates," Mr. Singh concluded.

About Major Depressive Disorder
Depression is a serious medical illness and a global public health concern that can occur at any time over a person's life. While most people will experience depressed mood at some point during their lifetime, MDD is different. MDD is the chronic, pervasive feeling of utter unhappiness and suffering, which impairs daily functioning. Symptoms of MDD include diminished pleasure in activities, changes in appetite that result in weight changes, insomnia or oversleeping, psychomotor agitation, loss of energy or increased fatigue, feelings of worthlessness or inappropriate guilt, difficulty thinking, concentrating or making decisions, and thoughts of death or suicide and attempts at suicide. Suicide is estimated to be the cause of death in up to 15% individuals with MDD. For many people, depression cannot be controlled for any length of time without treatment. Standard antidepressant medications currently available include commonly prescribed selective serotonin reuptake inhibitors (*SSRIs*) and serotonin-norepinephrine reuptake inhibitors (*SNRIs*). However, about two out of every three drug-treated patients suffering from MDD do not receive adequate therapeutic benefit from their initial treatment with a standard, FDA-approved antidepressant, and the likelihood of achieving remission declines with each successive treatment attempt.

About AV-101

AV-101 (L-4-chlorokyurenine or 4-CI-KYN) is an orally available prodrug candidate, currently in Phase 2 development, initially for the adjunctive treatment of major depressive disorder (MDD) in patients with an inadequate response to standard antidepressants. AV-101 has broad potential utility in other CNS diseases and disorders, including chronic neuropathic pain, epilepsy and neurodegenerative diseases, such as Parkinson's disease and Huntington's disease. Orally available AV-101 is rapidly absorbed through the gut, and then actively transported across the blood-brain barrier. Astrocytes in the brain rapidly convert AV-101 into its active metabolite, 7-chlorokynurenic acid (7-Cl-KYNA), a well-characterized, potent and selective antagonist of N-methyl-D-aspartate (NMDA) receptors, acting by blocking the glycine-binding co-agonist site of the NMDA receptor. AV-101 is a member of a new generation of fast-acting glutamatergic drug candidates in development for adjunctive treatment of MDD. These fast-acting drug candidates act through the AMPA receptor pathway increasing the production of nerve connections in the brain, often referred to as "synaptogenesis." The increase in synaptogenesis is thought to be the mechanism by which these new generation antidepressant drug candidates have potential to provide therapeutic benefit for MDD.

About VistaGen

VistaGen Therapeutics, Inc. is a clinical-stage biopharmaceutical company dedicated to developing and commercializing innovative product candidates for patients with diseases and disorders involving the central nervous system (CNS). VistaGen's lead CNS product candidate, AV-101, is a new generation, orally available prodrug in Phase 2 development, initially for the adjunctive treatment of MDD in patients with inadequate response to standard antidepressants. AV-101 is currently being evaluated in an ongoing Phase 2a clinical study being conducted by Principal Investigator, Dr. Carlos Zarate, Chief, Section on the Neurobiology and Treatment of Mood Disorders and Chief of Experimental Therapeutics and Pathophysiology Branch at the NIMH, and fully funded by the NIMH. VistaGen is also preparing to initiate a Phase 2b clinical study of AV-101 as an adjunctive treatment of MDD in the first quarter of 2017.

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 VistaGen's successful Phase 2 clinical development of AV-101 for the treatment of MDD and other CNS diseases and disorders, protection of its intellectual property, and the availability of substantial additional capital to support its operations, including the 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.

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