
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): October 26, 2017

VistaGen Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

NEVADA
*(State or other jurisdiction of
incorporation)*

001-37761
(Commission File Number)

20-5093315
(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))
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Item 8.01 Other Events.

VistaGen Therapeutics, Inc. (the “*Company*”) today announced that the U.S. Food and Drug Administration has authorized the Company to proceed, under its Investigational New Drug application, with its planned Phase 2 clinical study of AV-101 as a new generation oral treatment for major depressive disorder. 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: October 26, 2017

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

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press release issued by VistaGen Therapeutics Inc., dated October 26, 2017.



VistaGen Announces FDA Authorization to Initiate Phase 2 Study of AV-101 for Major Depressive Disorder

South San Francisco, CA (October 26, 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 U.S. Food and Drug Administration (FDA) has authorized the Company to proceed, under its Investigational New Drug (IND) application, with its planned Phase 2 clinical study of AV-101 as a new generation oral treatment for major depressive disorder (MDD).

VistaGen is preparing to launch a 180-patient, multi-center, double-blind, placebo-controlled Phase 2 study to assess the safety, tolerability and efficacy of AV-101 as an orally administered adjunctive treatment for adult MDD patients with an inadequate response to standard, FDA-approved antidepressants. Dr. Maurizio Fava of Harvard Medical School will be the Principal Investigator of this study, expected to begin in the first quarter of 2018.

“This is a significant milestone in our AV-101 clinical development program,” stated Shawn Singh, Chief Executive Officer of VistaGen. “With the FDA’s authorization to proceed under our IND application now in hand, our primary goal remains to launch and complete our Phase 2 study of AV-101 for major depressive disorder in 2018, further advancing our efforts to develop and commercialize AV-101 as a new generation oral treatment alternative for depression, one with a mechanism of action that is fundamentally differentiated from all FDA-approved antidepressants and atypical antipsychotics often used adjunctively to augment them.”

About AV-101

AV-101 (4-CI-KYN) is an oral CNS drug candidate in Phase 2 development in the U.S., initially as a new generation adjunctive treatment for MDD. AV-101 also has broad potential utility in several other CNS indications where modulation of NMDA receptors, activation of AMPA pathways and/or key active metabolites of AV-101 may achieve therapeutic benefit, including neuropathic pain and epilepsy, as well as addressing symptoms associated with neurodegenerative diseases, such as Parkinson's disease levodopa-induced dyskinesia (PD LID) and Huntington's disease.

AV-101 is currently being evaluated in a Phase 2 monotherapy study in MDD, a study being fully funded by the U.S. National Institute of Mental Health (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, as Principal Investigator.

VistaGen is preparing to advance AV-101 into a 180-patient, U.S. multi-center, Phase 2 adjunctive treatment study in adult MDD patients with an inadequate response to standard, FDA-approved antidepressants, with Dr. Maurizio Fava of Harvard University as Principal Investigator.

About VistaGen

VistaGen Therapeutics, Inc. (NASDAQ: VTGN) is a clinical-stage biopharmaceutical company focused on developing new generation medicines for depression and other 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 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 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, with Dr. Maurizio Fava of Harvard University as Principal Investigator. 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, PD LID 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.



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 funding, launch, continuation and results of the NIMH's Phase 2 (monotherapy) and/or the Company's planned Phase 2 (adjunctive treatment) clinical studies of AV-101 in MDD, and other CNS diseases and disorders, including neuropathic pain and PD L1D, protection of its intellectual property, and the availability of substantial additional capital to support its operations, including the AV-101 Phase 2 adjunctive treatment study and other potential 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 www.sec.gov. VistaGen undertakes no obligation to publicly update or revise any forward-looking statements.

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