
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): April 10, 2018

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 (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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR 230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR 240.12b-2)

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act

Item 8.01 Other Events.

VistaGen Therapeutics, Inc. (the “*Company*”) today announced that the European Patent Office has issued a Notice of Intention to grant a patent related to certain methods of production for AV-101, the Company’s oral CNS drug candidate. AV-101 is in Phase 2 clinical development in the United States under ELEVATE, the Company’s ongoing randomized, double-blind, multi-center, placebo-controlled Phase 2 clinical study to evaluate the efficacy and safety of AV-101 (L-4-chlorokynurenine) as an adjunctive treatment of Major Depressive Disorder (“*MDD*”) in patients with an inadequate response to current antidepressants approved by the U.S. Food and Drug Administration (“*FDA*”). A copy of the Company’s press release is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01 Financial Statements and 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: April 10, 2018

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

EXHIBIT INDEX

Exhibit No.

Description

[99.1](#)

Press Release issued by VistaGen Therapeutics, Inc., dated April 10, 2018



VistaGen Therapeutics Receives European Patent regarding Methods of Production for AV-101

South San Francisco, CA (April 10, 2018) – [VistaGen Therapeutics, Inc.](#) (NASDAQ: VTGN), a clinical-stage biopharmaceutical company developing new generation medicines for depression and other central nervous system (CNS) disorders, today announced the European Patent Office has issued a Notice of Intention to grant a patent related to certain methods of production for AV-101, the Company's oral CNS drug candidate. AV-101 is in Phase 2 clinical development in the United States as a new adjunctive treatment of Major Depressive Disorder in patients with an inadequate response to current antidepressants that have been approved by the U.S. Food and Drug Administration (FDA).

AV-101, an oral N-methyl-D-aspartate (NMDA) receptor glycine B (GlyB) antagonist, belongs to a new generation of investigational medicines in neuropsychiatry known as glutamate receptor modulators having the potential to treat MDD faster than current FDA-approved antidepressants commonly known as SSRIs and SNRIs, which target the neurotransmitters serotonin and/or norepinephrine, respectively.

"This patent will be the European counterpart to [U.S. Patent No. 9,834,801](#) granted to us by the U.S. Patent and Trademark Office (USPTO) in December 2017," stated [Shawn Singh, Chief Executive Officer of VistaGen](#). "We are pleased that VistaGen will also have multiple patents relating to AV-101 in Europe. This is another important step in our strategy to secure long-term intellectual property protection for AV-101 in the world's major pharmaceutical markets, thereby enhancing its commercial potential."

About AV-101

AV-101 is an oral N-methyl-D-aspartate (NMDA) receptor glycine B (GlyB) antagonist in Phase 2 clinical development in the United States. ELEVATE, VistaGen's ongoing Phase 2, randomized, double-blind, multi-center, placebo-controlled clinical trial, is designed to evaluate the efficacy and safety of adjunctive use of oral AV-101 for MDD in patients with an inadequate response to standard antidepressant therapy with either an FDA-approved selective serotonin reuptake inhibitor (SSRI) or serotonin norepinephrine reuptake inhibitor (SNRI).

AV-101 has a novel mechanism of action (MOA), meaning its MOA is fundamentally different from all current FDA-approved SSRIs and SNRIs for depression, most of which, if effective, take many weeks to achieve therapeutic benefits. AV-101 targets glutamate, the most prevalent neurotransmitter in the brain. AV-101 inhibits NMDA receptor activity, activates AMPA pathways and has the potential to achieve ketamine-like antidepressant effects with an oral drug candidate that does not cause ketamine's side effects and safety concerns. AV-101 may also have the potential to treat neuropathic pain, epilepsy, Parkinson's disease levodopa-induced dyskinesia, suicidal ideation and other CNS diseases and disorders where modulation of the NMDA receptors and activation of AMPA pathways may achieve therapeutic benefits. The FDA has granted Fast Track designation to AV-101 for development as a potential adjunctive treatment of MDD.

About VistaGen

VistaGen Therapeutics, Inc. (NASDAQ: VTGN) is a clinical-stage biopharmaceutical company developing new generation medicines for depression and other CNS disorders. VistaGen's lead CNS product candidate, AV-101, is an oral NMDA receptor GlyB antagonist in Phase 2 clinical development in the United States, initially as a new adjunctive treatment of MDD in patients with an inadequate response to current FDA-approved antidepressants.

For more information, please visit www.vistagen.com and connect with VistaGen on [Twitter](#), [LinkedIn](#) and [Facebook](#).

Forward-Looking Statements

Various statements in this release concerning VistaGen's future expectations, plans and prospects, including without limitation, our expectations regarding development of AV-101, the potential of AV-101 for the treatment of MDD and various other CNS diseases and disorders and our intellectual property and commercial protection of AV-101 constitute forward-looking statements for the purposes of the safe harbor provisions under the Private Securities Litigation Reform Act of 1995. These forward-looking statements are neither promises nor guarantees of future performance, and are subject to a variety of risks and uncertainties, many of which are beyond our control, which could cause actual results to differ materially from those contemplated in these forward-looking statements. Among these risks is the possibility that we may encounter unexpected adverse events in patients in our ELEVATE study that cause us to discontinue further development of AV-101; we may not be able to successfully demonstrate the safety and efficacy of AV-101 at each stage of clinical development; success in preclinical studies or in early-stage clinical trials may not be repeated or observed in ongoing or future AV-101 studies, and ongoing or future preclinical and clinical results may not support further development of AV-101 or be sufficient to gain regulatory approval to market AV-101; decisions or actions of regulatory agencies may negatively affect the progress of the ELEVATE study or the initiation, timing and progress of future AV-101 clinical trials, and our ability to proceed with further clinical studies or to obtain marketing approval; we may not be able to obtain or maintain adequate intellectual property protection and other forms of marketing and data exclusivity for AV-101; we may not have access or be able to secure substantial additional capital to support our operations, including clinical development of AV-101 activities described above; and we may encounter technical and other unexpected hurdles in the manufacturing and development of AV-101 or other product candidates, as well as those risks more fully discussed in the section entitled "Risk Factors" in our most recent annual report on Form 10-K, and subsequent quarterly reports on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in our other filings with the Securities and Exchange Commission (SEC). Our SEC filings are available on the SEC's website at www.sec.gov. In addition, any forward-looking statements represent our views only as of today, and should not be relied upon as representing our views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.

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