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 3, 2018

VistaGen Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

NEVADA	**001-37761**	**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 8.01 Other Events.

On October 3, 2018, the Company announced that the U.S. Food and Drug Administration ("*FDA*") granted Fast Track designation for development of AV-101 as a non-opioid, non-sedating treatment for neuropathic pain, the second FDA Fast Track designation granted to the Company for development of AV-101 since December 2017. 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.

(d) Exhibits Index

Exhibit No.	Description
99.1	Press release issued by VistaGen Therapeutics Inc. dated October 3, 2018.

Disclaimer.

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.

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 5, 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 October 3, 2018.

Exhibit 99.1

VistaGen Therapeutics Receives FDA Fast Track Designation for Development of AV-101 as a Non-Opioid Treatment for Neuropathic Pain

Designation highlights serious unmet need for new treatment options for patients suffering from neuropathic pain

Second FDA Fast Track designation for AV-101 since December 2017 marks another milestone for VistaGen's R&D pipeline

SOUTH SAN FRANCISCO, Calif., October 3, 2018 – VistaGen Therapeutics, Inc. (NASDAQ: VTGN), a clinical-stage biopharmaceutical company developing new generation medicines for central nervous system (CNS) diseases and disorders with high unmet need, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for development of AV-101 as a non-opioid, non-sedating treatment for neuropathic pain. This is the second FDA Fast Track designation granted to VistaGen since December 2017.

The FDA's Fast Track designation is designed to facilitate the development, and potentially expedite the review, of drugs to treat serious or life-threatening conditions and fill an unmet medical need.

AV-101 is an investigational, orally bioavailable, small molecule NMDA (N-methyl-D-aspartate) receptor glycine B antagonist without psychological or sedative side effects.

"Every day in the U.S., more than 115 people die from overdosing on opioids. We have evaluated AV-101 in multiple models of serious CNS conditions, including those that cause patients to suffer from neuropathic pain, for which current treatment options are inadequate. After considering peer-reviewed data published last year in *The Journal of Pain*, together with published safety data from our Phase 1 program, we believe AV-101 has the potential to address the high unmet need for a new non-opioid, non-sedating treatment for neuropathic pain," said Shawn Singh, Chief Executive Officer of VistaGen. "This important designation is especially timely given the FDA's forceful commitment to address our nation's opioid epidemic. The FDA's Fast Track designation for development of AV-101 for neuropathic pain, together with the previously granted Fast Track designation for major depressive disorder, will allow our team to work closely with the FDA to bring AV-101 to patients affected by two of our country's most debilitating and widespread healthcare concerns as soon as possible."

VistaGen's receipt of the FDA's Fast Track designation for the development of AV-101 for neuropathic pain comes on the heels of the recent official statement made by FDA Commissioner Scott Gottlieb, stating that the FDA plans to issue guidance documents to assist sponsors with the development of new non-opioid pain medications, such as AV-101, as therapeutic alternatives to the use of opioids. More specifically, over the next 6 to 12 months, the FDA has stated it anticipates issuing several documents intended to stimulate the development of medications for specific types of pain, resulting in smaller clinical trials, faster approvals and quicker launches of novel therapies.[1]

About Neuropathic Pain
Neuropathic pain (NP) affects approximately 33 million people in the United States (excluding patients with back pain).[2] It is characterized by a steady burning or "pins and needles" or "electric shock" sensation that results in abnormal neuronal function after trauma to the nerve, viral infections, certain medications, or metabolic insults.

About AV-101
AV-101 is an investigational, orally bioavailable, small molecule NMDA (N-methyl-D-aspartate) receptor glycine B antagonist without psychological or sedative side effects. AV-101 has potential to be a new at-home treatment for multiple CNS indications with high unmet need. AV-101 is currently in Phase 2 clinical development in the United States for major depressive disorder (MDD). ELEVATE ELEVATEis VistaGen's ongoing Phase 2 clinical trial designed to evaluate the efficacy and safety of adjunctive use of AV-101 for MDD in individuals with an inadequate response to standard antidepressant therapy with either an FDA-approved SSRI or SNRI. The FDA has granted Fast Track designation for development of AV-101 as a potential treatment of MDD and neuropathic pain.

About VistaGen
VistaGen Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing new generation medicines for multiple CNS diseases and disorders with high unmet need. For more information, please visit www.vistagen.com and connect with VistaGen on Twitter, LinkedIn and Facebook.

Forward-Looking Statements
This release contains various statements concerning VistaGen's future expectations, plans and prospects, including without limitation, our expectations regarding development of AV-101 and the potential of AV-101 for the treatment of MDD, NP and various other CNS diseases and disorders 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, and may cause actual results to differ materially from those contemplated in these forward-looking statements. Among these risks is the possibility that (i) we may encounter unexpected adverse events in patients in our ELEVATE study or other clinical studies that cause us to discontinue further development of AV-101, (ii) we may not be able to successfully demonstrate the safety and efficacy of AV-101 at each stage of clinical development, (iii) 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, (iv) decisions or actions of regulatory agencies may negatively affect the initiation or progress of ongoing or future AV-101 clinical trials, and our ability to proceed with further clinical studies or to obtain marketing approval, (v) we may not be able to obtain or maintain adequate intellectual property protection and other forms of marketing and data exclusivity for AV-101, (vi) we may not have access to or be able to secure substantial additional capital required to support our operations, including clinical development of AV-101 activities described above; and (vii) we may encounter technical and other unexpected hurdles in the manufacturing and development of AV-101. Certain other risks are 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 the issuance of this release 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.

Company Contact
Mark A. McPartland
VistaGen Therapeutics Inc.
Phone: +1 (650) 577-3600
Email: IR@vistagen.com

Investor Contact
Valter Pinto / Allison Soss
KCSA Strategic Communications
Phone: +1 (212) 896-1254/+1 (212) 896-1267
Email: VistaGen@KCSA.com

Media Contact
Caitlin Kasunich / Lisa Lipson
KCSA Strategic Communications
Phone: +1 (212) 896-1241/+1 (508) 843-6428
Email: VistaGen@KCSA.com

[1] https://www.washingtonpost.com/news/to-your-health/wp/2018/08/29/fda-pushes-for-development-of-non-opioid-pain-medications/?noredirect=on&utm_term=.99fa0f10ec06
[2] DiBonaventura MD, Sadosky A, Concialdi K, Hopps M, Kudel I, Parsons B, et al. The prevalence of probable neuropathic pain in the US: results from a multimodal general-population health survey. J Pain Res 2017;10:2525-2538.