

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 13, 2019

Commission File Number: 001-37761

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:

- 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)
Emerging growth company

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.

On February 13, 2019, VistaGen Therapeutics, Inc. (the "Company") announced that the U.S. Patent and Trademark Office provided a Notice of Allowance for a patent related to methods of treating depression with PH10, the Company's investigational new generation CNS nasal spray in Phase 2 development for major depressive disorder ("MDD"). A copy of this press release is attached to this Current Report on Form 8-K as Exhibit 99.1.

On February 19, 2019, the Company announced that the Japan Patent Office issued to the Company a patent related to methods of treating depression with AV-101, the Company's oral NMDA receptor glycine site antagonist in Phase 2 development for treatment of MDD. The patent also relates to methods of treating hyperalgesia, which is extreme sensitivity to pain. A copy of this press release is attached to this Current Report on Form 8-K as Exhibit 99.2.

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 hereunto duly authorized.

VistaGen Therapeutics, Inc.

Date: *February 19, 2019*

By: /s/ Shawn K. Singh

Name: Shawn K. Singh
Title: Chief Executive Officer

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
EX-99.1	Press release issued by VistaGen Therapeutics Inc., dated February 13, 2019.
EX-99.2	Press release issued by VistaGen Therapeutics Inc., dated February 19, 2019.



VistaGen Therapeutics Receives Notice of Allowance for U.S. Patent for Treatment of Depression with PH10

SOUTH SAN FRANCISCO, Calif., Feb 13, 2019 - VistaGen Therapeutics (NASDAQ: VTGN), a clinical-stage biopharmaceutical company developing new generation medicines for depression and other central nervous system (CNS) diseases and disorders with high unmet need, today announced that the U.S. Patent and Trademark Office (USPTO) has provided a Notice of Allowance for a patent related to methods of treating depression with PH10, VistaGen's investigational new generation CNS nasal spray in Phase 2 development for major depressive disorder (MDD). Counterpart foreign patents have already issued in Europe, Japan and several other countries. In a small exploratory Phase 2a clinical study, at microgram doses, PH10 nasal spray was observed to have rapid-onset antidepressant effects, without systemic exposure, psychological side effects or safety concerns.

"Currently approved antidepressants are not sufficient for millions of patients who suffer with depression. For many with an inadequate response to current antidepressants, living with depression is not living. Unfortunately, there is no one-size-fits-all treatment solution, and inadequate response to current antidepressants is among the key reasons MDD remains one of the leading public health concerns in the U.S.," said Shawn Singh, Chief Executive Officer. "With mechanisms of action that are fundamentally differentiated from current antidepressants, we believe both oral AV-101 and PH10 nasal spray have the potential to address the significant unmet medical need for new antidepressant agents with rapid-onset activity, convenient at-home administration, and an acceptable safety and tolerability profile."

Singh continued, "Once issued, this patent will be a key component of our commercial protection strategy for PH10 in the U.S., in a manner similar to our issued U.S. patent for therapeutic uses to treat depression with AV-101, which will not expire until at least 2034."

About PH10

PH10 is a potential first-in-class, CNS neurosteroid nasal spray administered in microgram doses for MDD. PH10 nasal spray activates nasal chemosensory receptors that, in turn, engage GABA (gamma-aminobutyric acid) and CRH (corticotropin-releasing hormone) neurons in the limbic amygdala system. The activation of these neural circuits is believed to have the potential to lead to a rapid antidepressant effects without psychological side effects, systemic exposure or safety concerns often associated with current antidepressants. Based on positive results of a small exploratory Phase 2a study in MDD in which rapid-onset antidepressant effects were observed without psychological side effects or systemic exposure, VistaGen is preparing for planned Phase 2b clinical development of PH10 for MDD.

About Major Depressive Disorder (MDD)

MDD affects nearly 300 million people of all ages globally and is the leading cause of disability worldwide. Individuals with depression, including major depressive disorder, experience continuous suffering from a serious, biologically based disease which has a significant negative impact on all aspects of life, including quality of life and function. While antidepressants are widely used for treatment, large-scale studies have suggested the U.S. drug-treated MDD market is substantially underserved by current medications.

About VistaGen

VistaGen Therapeutics is a clinical-stage biopharmaceutical company developing new generation medicines with rapid-onset potential for multiple CNS diseases and disorders with high unmet need. Each of VistaGen's CNS pipeline candidates, AV-101, PH10 and PH94B has potential to provide rapid-onset therapeutic benefits without the psychological side effects, inconvenient clinical administration or safety concerns often associated with many current and potential new generation medications for CNS diseases and disorders, such as MDD and SAD. Each drug candidate in VistaGen's pipeline is either currently in, or has completed, Phase 2 clinical development. AV-101, an oral NMDA receptor glycine B antagonist, is in Phase 2 development, initially as an adjunctive treatment of MDD. The FDA has granted Fast Track designation for development of AV-101, both as a potential adjunctive treatment of MDD and a non-opioid treatment for neuropathic pain. PH10 nasal spray, a potential first-in-class CNS neuroactive steroid with rapid onset effects observed at microgram doses, is in Phase 2 development for MDD. PH94B nasal spray, also a potential first-in-class CNS neuroactive steroid with rapid onset effects observed at microgram doses, has completed Phase 2 development and is now being prepared for Phase 3 clinical development as an on-demand PRN treatment of SAD.

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 and commercialization of our drug candidates, including AV-101 for MDD, neuropathic pain and suicidal ideation, PH94B for SAD, and PH10 for MDD, as well as our intellectual property and commercial protection of our drug candidates, all of which 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 during our clinical development of any product candidate that cause us to discontinue further development, (ii) we may not be able to successfully demonstrate the safety and efficacy of our product candidates 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 studies, and ongoing or future preclinical and clinical results may not support further development of, or be sufficient to gain regulatory approval to market AV-101, PH94B, and/or PH10, (iv) decisions or actions of regulatory agencies may negatively affect the progress of, and our ability to proceed with, further clinical studies or to obtain marketing approval for our drug candidates, (v) we may not be able to obtain or maintain adequate intellectual property protection and other forms of marketing and data exclusivity for our product candidates, (vi) we may not have access to or be able to secure substantial additional capital to support our operations, including our ongoing clinical development activities; and (vii) we may encounter technical and other unexpected hurdles in the manufacturing and development of any of our product candidates. 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

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VistaGen Therapeutics Receives AV-101 Japanese Patent for Treatment of Depression and Hyperalgesia

SOUTH SAN FRANCISCO, Calif., Feb 19, 2019 - VistaGen Therapeutics (NASDAQ: VTGN), a clinical-stage biopharmaceutical company developing new generation medicines for depression and other central nervous system (CNS) diseases and disorders with high unmet need, today announced that the Japan Patent Office (JPO) has issued a patent related to methods of treating depression with AV-101, VistaGen's oral NMDA receptor glycine site antagonist in Phase 2 development for treatment of major depressive disorder (JP 6436913B). This patent also relates to methods of treating hyperalgesia, which is extreme sensitivity to pain. The new AV-101 Japanese patent will not expire until at least 2034.

“Development and commercialization of our CNS pipeline in Japan, together with the U.S., China and the European Union, is among our top corporate priorities, stated Shawn Singh, Chief Executive Officer. “Together with our previously obtained Japanese patent for the synthesis of AV-101, this key patent now expands commercial protection of AV-101 in Japan, one of the world’s largest pharmaceutical markets, a market with a strong long-term track record of innovative and successful neuropsychiatry products.”

About AV-101

VistaGen's AV-101 (4-Cl-KYN) is an investigational, oral NMDA receptor glycine site antagonist with potential to be a treatment for multiple CNS indications with high unmet need. AV-101 is currently in Phase 2 clinical development in the U.S. for major depressive disorder (MDD) and in a first-step target engagement study in healthy volunteer U.S. military Veterans for suicidal ideation. The U.S. Food and Drug Administration (FDA) has granted Fast Track designation for development of AV-101 as both a potential adjunctive treatment of MDD and as a non-opioid treatment for neuropathic pain.

About Major Depressive Disorder (MDD)

MDD affects nearly 300 million people of all ages globally and is the leading cause of disability worldwide. Individuals with depression, including MDD, experience continuous suffering from a serious, biologically based disease which has a significant negative impact on all aspects of life, including quality of life. While current antidepressants are widely used for treatment, large-scale studies have suggested that the drug-treated MDD market is substantially underserved by current medications.

About VistaGen

VistaGen Therapeutics is a clinical-stage biopharmaceutical company developing new generation medicines with for multiple CNS diseases and disorders with high unmet need. Each of VistaGen's CNS pipeline candidates has potential as a convenient, at-home treatment with rapid-onset therapeutic benefits and an exceptional safety profile - without psychological or other side effects and safety concerns often associated with current and potential new generation medications for certain highly-prevalent CNS diseases and disorders, such as major depressive disorder, neuropathic pain and social anxiety disorder. Each CNS drug candidate in VistaGen's pipeline is either currently in, or has completed, Phase 2 clinical development. AV-101, an oral NMDA receptor glycine antagonist, is in Phase 2 development in the U.S. for treatment of MDD and in a first-step target engagement study in healthy volunteer U.S. military Veterans for suicidal ideation. The FDA has granted Fast Track designation for development of AV-101, both as a potential adjunctive treatment of MDD and as a non-opioid treatment for neuropathic pain. PH10 nasal spray is a potential first-in-class CNS neuroactive steroid with rapid onset effects observed at microgram doses and without systemic exposure. PH10 is in Phase 2 development for MDD. PH94B nasal spray also is a potential first-in-class CNS neuroactive steroid with rapid onset effects observed at microgram doses and without systemic exposure. Phase 2 development has been completed successfully, and PH94B is now being prepared for Phase 3 as an on-demand PRN treatment of Social Anxiety Disorder (SAD).

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 and commercialization of our drug candidates, including AV-101 for MDD, neuropathic pain and suicidal ideation, PH94B for SAD, and PH10 for MDD, as well as our intellectual property and commercial protection of our drug candidates, all of which 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 during our clinical development of any product candidate that cause us to discontinue further development, (ii) we may not be able to successfully demonstrate the safety and efficacy of our product candidates 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 studies, and ongoing or future preclinical and clinical results may not support further development of, or be sufficient to gain regulatory approval to market AV-101, PH94B, and/or PH10, (iv) decisions or actions of regulatory agencies may negatively affect the progress of, and our ability to proceed with, further clinical studies or to obtain marketing approval for our drug candidates, (v) we may not be able to obtain or maintain adequate intellectual property protection and other forms of marketing and data exclusivity for our product candidates, (vi) we may not have access to or be able to secure substantial additional capital to support our operations, including our ongoing clinical development activities; and (vii) we may encounter technical and other unexpected hurdles in the manufacturing and development of any of our product candidates. 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
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Investor Contact

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

Media Contact

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Phone: +1 (212) 896-1241/+1 (508) 843-6428
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