
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 24, 2018

VistaGen Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

NEVADA
(State or other jurisdiction of incorporation)

000-54014
(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 1.01 Entry into a Material Definitive Agreement.

On October 24, 2018, VistaGen Therapeutics, Inc. (the “*Company*”) exercised the option (the “*PH10 Option*”) previously granted to the Company by Pherin Pharmaceuticals, Inc. (“*Pherin*”) to acquire an exclusive license for the worldwide rights to develop and commercialize PH10 (the “*PH10 License*”), a first-in-class investigational neuroactive steroid drug candidate administered as a nasal spray, currently in Phase 2 development for the treatment of major depressive disorder (“*MDD*”). As a part of the Company’s acquisition of the PH10 License, the Company and Pherin executed the license agreement that was previously negotiated by the parties and attached to the PH10 Option as Exhibit B (the “*PH10 Agreement*”).

As consideration for the exercise of the option and acquisition of the PH10 License, the Company issued to Pherin \$2.0 million of the Company’s unregistered common stock, par value \$0.001 per share (“*Common Stock*”), or a total of 925,926 shares, which was based on the closing price of the Company’s Common Stock on October 23, 2018, as reported on the Nasdaq Capital Market (the “*PH10 Shares*”). In the event certain regulatory-based milestones are achieved, the Company will also pay to Pherin cash payments and royalties upon attainment of the applicable milestones.

The foregoing description of the PH10 Agreement, does not purport to be complete, and is qualified in its entirety by reference to the PH10 Agreement, a copy of which will be filed as an exhibit to the Company’s next periodic report filed under the Securities Exchange Act of 1934, as amended (the “*Exchange Act*”).

Item 3.02 Unregistered Sales of Equity Securities.

See Item 1.01 above with respect to the issuance of the PH10 Shares.

The issuance of the the PH10 Shares was exempt from the registration requirements of the Securities Act of 1933, as amended (the “*Securities Act*”), in reliance on the exemptions provided by Section 4(a)(2) of the Securities Act. The PH10 Shares have not been registered under the Securities Act or any other applicable securities laws, and unless so registered, may not be offered or sold in the United States except pursuant to an exemption from the registration requirements of the Securities Act.

Item 8.01 Other Events.

The Company today issued a press release announcing the acquisition of the PH10 License. A copy of the press release is attached hereto as Exhibit 99.1, and is incorporated by reference herein. The information in this Item 8.01 and the press release attached hereto as Exhibit 99.1 shall not be deemed “filed” for purposes of Section 18 of the Exchange Act, nor shall such information be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act.

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, 2018

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

EXHIBIT INDEX

Exhibit Number	Description
<u>99.1</u>	Press release issued by VistaGen Therapeutics Inc., dated October 25, 2018.



VistaGen Therapeutics Acquires Worldwide Rights to Develop and Commercialize PH10, a First-in-Class Intranasally Administered Neuroactive Steroid with Rapid-onset Antidepressant Effects for Major Depressive Disorder Demonstrated in Phase 2a Study

PH10 demonstrated in Phase 2a study significant antidepressant effects without psychological side effects after only one week of administration

South San Francisco, Calif. (October 25, 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 Company has exercised its option to acquire from Pherin Pharmaceuticals, Inc. (Pherin) the exclusive license for worldwide rights to develop and commercialize PH10, a first-in-class, intranasally administered neuroactive steroid (a “pherine”), with rapid-onset antidepressant effects for treatment of major depressive disorder (MDD) demonstrated in a phase 2a study. The Company secured the option for PH10 concurrently with its previously announced [license agreement with Pherin](#) for worldwide rights to develop and commercialize PH94B, also a first-in-class neuroactive pherine, which VistaGen is preparing for pivotal Phase 3 development as a nasal spray for acute on-demand treatment of social anxiety disorder (SAD).

PH10 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 effect.

Michael Liebowitz, M.D., a member of VistaGen’s CNS Clinical and Regulatory Advisory Board, has acted as an advisor to Pherin in connection with its clinical trials of PH10 and PH94B and previously presented results for PH10’s eight-week, double-blind, single-center, 30-patient, Phase 2a study for MDD. Results in the Phase 2a study demonstrated that self-administered doses of PH10 as a nasal spray resulted in significant decreases in depression as measured by the Hamilton Rating Scale for Depression, a widely used clinician-administered depression assessment scale. In this study, PH10 was very well tolerated with minimal side effects.

“After extensive due diligence and guidance from Dr. Liebowitz, we exercised our option to acquire exclusive rights to develop and commercialize PH10 for depression and other CNS diseases,” said [Shawn Singh, Chief Executive Officer of VistaGen](#). “Depression is a complicated disease, without a one-size-fits-all solution. Development of promising treatment alternatives with fundamentally different mechanisms of action from current antidepressants is a core competency of our team. We are excited to build upon the notable and steadfast efforts of Dr. Louis Monti, Dr. Liebowitz and Pherin’s entire team in developing PH10 to date. PH10 marks yet another valuable asset in our growing pipeline, with compelling data and complementary to our core focus on developing innovative rapid-onset treatments for MDD beyond ketamine with convenient administration and without debilitating or psychological side effects and safety concerns. We believe that having yet another potentially safe, fast-acting, new generation mechanism of action treatment in play, in addition to AV-101 with its NMDAR GlyB and AMPAR targets, adds strength to strength, allowing us to provide patients with an even broader range of potential solutions to treat MDD, and expands our potential opportunities to monetize our assets to the benefit of our stockholders.”

“Depression is a pervasive mental illness and currently available treatments fall short for many individuals with the disease. Ultra-low doses of intranasal PH10, with its novel mechanism of action, rapid onset activity and excellent safety and tolerability profile demonstrated in a phase 2a study, may represent another life-changing opportunity to address the growing unmet need among individuals suffering from MDD,” stated Dr. Liebowitz.

Pherines inhibit nerve circuits mediating behavioral and physiological effects of anxiety. This mechanism of action, rapid onset of efficacy and excellent safety and tolerability profile have been shown in multiple previous clinical trials, including a pilot Phase 3 feasibility study evaluating the safety and efficacy of PH94B for SAD and Phase 2 feasibility study evaluating the safety and efficacy of PH10 for MDD.

In connection with the consummation of the license and option agreements, VistaGen issued to Pherin \$2.0 million of its unregistered common stock (925,926 unregistered shares).

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 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 in 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 ca. 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.

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