VistaGen Therapeutics, Inc.
Form S-8
December 04, 2015

As filed with the Securities and Exchange Commission on December 4, 2015

Registration No. 333- _____

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM S-8
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

VistaGen Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Nevada	20-5093315
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

343 Allerton Avenue
South San Francisco, California 94080
(Address of Principal Executive Offices)

1999 Stock Incentive Plan

and

2008 Stock Incentive Plan
(Full title of the plan)

Shawn K. Singh
Chief Executive Officer
VistaGen Therapeutics, Inc.
343 Allerton Avenue
South San Francisco, California 94080
(Name and address of agent for service)

(650) 577-3600
(Telephone number, including area code, of agent for service)

Copies to:
Daniel W. Rumsey
Managing Partner
Disclosure Law Group

600 W. Broadway, Suite 700
San Diego, California 92101

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act.

Large Accelerated filer Accelerated filer [ ] Non-accelerated filer [ ] Smaller reporting company [X]
[ ]

CALCULATION OF REGISTRATION FEE

Title of Securities to be Registered (1)	Amount to be Registered (2)	Proposed Maximum Offering Price per Share (3)	Proposed Maximum Aggregate Offering Price (3)	Amount of Registration Fee
Common Stock, $0.001 par value per share: To be issued under the 2008 Stock Incentive Plan	700,491	$6.65	$4,658,265.15	$541.29
Common Stock, $0.001 par value per share: Outstanding options to purchase shares of Common Stock issued by the Registrant under the 1999 Stock Incentive Plan	12,229	$6.65	$81,322.85	$9.45
Common Stock, $0.001 par value per share: Outstanding options to purchase shares of Common Stock issued by the Registrant under the 2008 Stock Incentive Plan	284,509	$6.65	$1,891,984.85	$219.84
Total	997,229		$6,631,572.85	$770.58

(1) The securities to be registered include options to acquire shares of the Registrant's common stock.

(2) In accordance with Rule 416 under the Securities Act of 1933, as amended, this registration statement shall also be deemed to cover any additional securities that may from time to time be offered or issued to prevent dilution resulting from stock splits, stock dividends or similar transactions.

(3) Estimated solely for the purpose of calculating the amount of the registration fee pursuant to Rules 457(c) and (h) under the Securities Act of 1933, as amended.

EXPLANATORY NOTE

This Registration Statement includes a reoffer prospectus in Part I (the "Reoffer Prospectus"), which has been prepared in accordance with General Instruction C of Form S-8 and the requirements of Part I of Form S-3, and may be used for reoffers of shares of common stock (acquired or to be acquired pursuant to awards granted under the 1999 Stock Incentive Plan (the "1999 Plan") and the 2008 Stock Incentive Plan (the "2008 Plan" and, together with the 1999 Plan, the "Plans")) that are defined as "control securities" or "restricted securities" under General Instruction C of Form S-8.

The names of persons selling shares under the Reoffer Prospectus and the amount of such shares are set forth below under the caption "Selling Stockholders" to the extent we presently have such information. However, other affiliate selling stockholders may elect to sell shares under the Reoffer Prospectus as they receive them from time to time in the future in which case, as their names and amounts of shares to be reoffered become known, we will supplement the Reoffer Prospectus with that information. In addition, as permitted by General Instruction C of Form S-8, certain non-affiliates holding less than the lesser of 1,000 shares or 1% of our common stock issuable under the Plans may resell restricted securities issued under each respective Plan up to that amount under the Reoffer Prospectus without being named therein. Any securities covered by the Reoffer Prospectus which qualify for sale pursuant to Rule 144 may be sold under Rule 144 rather than pursuant to the Reoffer Prospectus.

PART I

INFORMATION REQUIRED IN THE SECTION 10(a) PROSPECTUS

The document(s) containing the information concerning the Registrant's 1999 Plan and the 2008 Plan specified in Part I will be sent or given to participants of the Plans as specified by Rule 428(b)(1). Such documents are not filed as part of this Registration Statement in accordance with the Note to Part I of the Form S-8 Registration Statement.

REOFFER PROSPECTUS

VISTAGEN THERAPEUTICS, INC.

296,738 Shares of Common Stock

This Reoffer Prospectus relates to the sale of up 296,738 shares of our common stock, par value $0.001 per share, that may be offered and resold from time to time by existing selling stockholders (the "Selling Stockholders") identified in this Reoffer Prospectus for his own account issuable pursuant to the Company's 1999 Stock Incentive Plan (the "1999 Plan") and the 2008 Stock Incentive Plan (the "2008 Plan" and, together with the 1999 Plan, the "Plans"). It is anticipated that the Selling Stockholders will offer common stock for sale at prevailing prices on the OTCQB on the date of sale. We will receive no part of the proceeds from sales made under this Reoffer Prospectus. The Selling Stockholders will bear all sales commissions and similar expenses. Any other expenses incurred in connection with the registration and offering of the shares will be borne by the Company.

The shares of common stock will be issued pursuant to stock options previously granted under the Plans. This Reoffer Prospectus has been prepared for the purposes of registering the common stock under the Securities Act of 1933, as amended, to allow for future sales by the Selling Stockholders on a continuous or delayed basis to the public without restriction.

Our common stock is quoted on OTCQB under the symbol "VSTA." The closing sale price for our common stock on December 2, 2015, was $6.50 per share.

Investing in our common stock involves risks. See "Risk Factors" on page 4 of this Reoffer Prospectus.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS REOFFER PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this Reoffer Prospectus is December 4, 2015

VISTAGEN THERAPEUTICS, INC.

TABLE OF CONTENTS

	PAGE NO.
PROSPECTUS SUMMARY	1
THE OFFERING	2
RISK FACTORS	3
CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS	42
DETERMINATION OF OFFERING PRICE	43
USE OF PROCEEDS	43
SELLING STOCKHOLDERS	43
PLAN OF DISTRIBUTION	45
LEGAL MATTERS	47
EXPERTS	47
INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE	47
WHERE YOU CAN FIND ADDITIONAL INFORMATION	48

You should rely only on the information contained in this Reoffer Prospectus or any related prospectus supplement. We have not authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. The information contained in this Reoffer Prospectus or incorporated by reference herein is accurate only on the date of this Reoffer Prospectus. Our business, financial condition, results of operations and prospects may have changed since such date. Other than as required under the federal securities laws, we undertake no obligation to publicly update or revise such information, whether as a result of new information, future events or any other reason.

This Reoffer Prospectus is not an offer to sell, nor is it an offer to buy, these securities in any jurisdiction where the offer or sale is not permitted.

Table of Contents

PROSPECTUS SUMMARY

This summary highlights certain information that we present more fully in the rest of this Reoffer Prospectus. This summary does not contain all of the information you should consider before investing in the securities offered pursuant to this Reoffer Prospectus. You should read the entire prospectus carefully, including the section titled "Risk Factors," before making an investment decision.

Except where the context otherwise requires and for purposes of this Reoffer Prospectus only, "we," "us," "our," "Company," "our Company," and "VistaGen" refer to VistaGen Therapeutics, Inc., a Nevada corporation, and its consolidated subsidiaries.

Overview

We are a clinical-stage biopharmaceutical company committed to developing and commercializing innovative product candidates for patients with depression, cancer, other diseases involving the central nervous system (CNS), as well as certain neurodegenerative diseases.

AV-101, our new generation, orally available prodrug candidate is in Phase 2 development, initially for the adjunctive treatment of Major Depressive Disorder (MDD) in patients with an inadequate response to standard antidepressants. AV-101's novel mechanism of action, as an N-methyl D aspartate receptor (NMDAR) antagonist binding selectively at the glycine binding (GlyB) co-agonist site of the NMDAR, is fundamentally differentiated from all antidepressants currently approved by the U.S. Food and Drug Administration (FDA). A Phase 2A clinical study of AV-101 in subjects with treatment-resistant MDD is being conducted and funded by the National Institutes of Mental Health (NIMH) under a Cooperative Research and Development Agreement (CRADA). The Principal Investigator of this NIMH-funded Phase 2A study, which was initiated in October 2015, is Dr. Carlos Zarate, Jr., Chief of the NIMH's Experimental Therapeutics & Pathophysiology Branch and its Section on Neurobiology and Treatment of Mood and Anxiety Disorders.

Beyond MDD, we believe that AV-101 has therapeutic potential in additional CNS indications, including neuropathic pain and epilepsy, and in neurodegenerative diseases such as Parkinson's disease and Huntington's disease.

In addition to our focus on CNS and neurology, we are applying our proprietary, human pluripotent stem cell (hPSC) technology for drug rescue to develop proprietary new chemical entities (NCEs) for our internal drug candidate pipeline. Initial drug rescue programs are focused on NCEs for the treatment of cancer.

We are also considering regenerative medicine applications of our stem cell technology platform. Using hPSC-derived blood, cartilage, heart and liver cells in collaborative arrangements with academic research partners, including our co-founder and the Chairman of our Scientific Advisory Board, Gordon Keller, Ph.D., the Director of the University Health Network's McEwen Centre for the Regenerative Medicine in Toronto, we may pursue development of novel in vitro human disease models with produce for our pipeline NCEs and biologics with regenerative potential and nonclinical proof of concept studies focused on cell therapy.

Table of Contents

THE OFFERING

By this Reoffer Prospectus, the Selling Stockholders are offering up to 296,738 shares of our common stock, which are issuable pursuant to our 1999 Plan and 2008 Plan. The Selling Stockholders are not required to sell their shares, and any sales of common stock by the Selling Stockholders are entirely at the discretion of the Selling Stockholders. We will receive no proceeds from the sale of the shares of common stock in this offering.

Securities Registered:	296,738 shares of common stock, par value $0.001
Shares Outstanding Prior to Completion of the Offering:	1,764,149
OTCQB Symbol:	VSTA
Transfer Agent:	ComputerShare, Jersey City, New Jersey.
Risk Factors:	Our business operations are subject to numerous risks, including the risk of delays in, or discontinuation of, our research and development due to lack of financing, poor results, inability to commercialize our technologies or to obtain necessary regulatory approvals to market the products, unforeseen safety issues relating to the products and dependence on third party collaborators to conduct research and development of the products. Because we are an early stage company with a limited history of operations, we are also subject to many risks associated with early-stage companies. For a more detailed discussion of some of the risks you should consider, you are urged to carefully review and consider the section titled “Risk Factors” of this Reoffer Prospectus.
Use of Proceeds:	We will not receive any proceeds from the sale of the shares of common stock registered pursuant to this Reoffer Prospectus. To the extent that we receive any funds from the exercise of options issued to the Selling Stockholders, such funds will be used to fund the research and development of our product candidates, including AV-101, and for working capital and general corporate purposes.
Sales by Affiliates and Sales of Restricted Securities	Selling Stockholders who are considered “affiliates” of the Company, as defined in Rule 405 under the Securities Act, or who are selling “restricted securities”, as defined in Rule 144(a)(3) under the Securities Act, may not sell an amount of shares pursuant to this reoffer prospectus which exceeds in any three month period the amount specified in Rule 144(e) under the Securities Act.

Table of Contents

RISK FACTORS

Investing in our securities involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this Prospectus before investing in our securities. The risks described below are not the only risks facing our Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also materially adversely affect our business, financial condition and/or operating results. If any of the following risks are realized, our business, financial condition and results of operations could be materially and adversely affected.

Risks Related to Product Development, Regulatory Approval and Commercialization

We depend heavily on the success of AV-101. We cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize AV-101, or any product candidate.

We currently have no drug products for sale and may never be able to develop and commercialize marketable drug products. Our business depends heavily on the successful non-clinical and clinical development, regulatory approval and commercialization of AV-101 for depression, including for Major Depressive Disorder (MDD), and various other diseases and disorders involving the central nervous system (CNS), as well as our ability to produce, develop and commercialize new chemical entities (NCEs) from our drug rescue programs. AV-101 will require substantial additional Phase 2 and Phase 3 clinical development, testing and regulatory approval before we are permitted to commence its commercialization. Each drug rescue NCE will require substantial non-clinical development, all phases of clinical development, and regulatory approval before we are permitted to commence its commercialization. The non-clinical studies and clinical trials of our product candidates are, and the manufacturing and marketing of our product candidates will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and, if approved, market any product candidate. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must demonstrate through non-clinical studies and clinical trials that the product candidate is safe and effective for use in each target indication. Drug development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our non-clinical studies or clinical trials. This process can take many years and may also include post-marketing studies and surveillance, which will require the expenditure of substantial resources beyond the proceeds we have raised to date. Of the large number of drugs in development in the United States, only a small percentage will successfully complete the U.S. Food and Drug Administration, or FDA, regulatory approval process and will be commercialized. Accordingly, even if we are able to obtain the requisite financing to continue to fund our non-clinical studies and clinical trials, we cannot assure you that AV-101 or any other product candidate will be successfully developed or commercialized.

We are not permitted to market our product candidates in the United States until we receive approval of a New Drug Application, or an NDA, from the FDA, or in any foreign countries until we receive the requisite approval from such countries. In October 2015, we began a Phase 2 clinical trial involving AV-101, to study its safety, tolerability and efficacy in patients with MDD. If our Phase 2 clinical trial of AV-101 is successful, we expect the FDA to require us to complete at least one pivotal Phase 2b clinical trial and at least one pivotal Phase 3 clinical trial in order to submit an NDA for AV-101 as a treatment for MDD. However, the FDA may require that we conduct more than one Phase 2b clinical study and more than one Phase 3 pivotal trial of AV-101 before we can submit an NDA. The FDA may also require that we conduct additional toxicity studies and additional non-clinical studies before submitting an NDA for AV-101.

Table of Contents

Obtaining FDA approval of an NDA is a complex, lengthy, expensive and uncertain process, and the FDA may delay, limit or deny approval of AV-101 or any of our product candidates for many reasons, including, among others:

- we may not be able to demonstrate that our product candidate is safe and effective in treating a human disease or disorder, to the satisfaction of the FDA;
- the results of our non-clinical studies and clinical trials may not meet the level of statistical or clinical significance required by the FDA for marketing approval;
- the FDA may disagree with the number, design, size, conduct or implementation of our non-clinical studies and clinical trials;
- the FDA may require that we conduct additional non-clinical studies and clinical trials;
- the FDA or the applicable foreign regulatory agency may not approve the formulation, labeling or specifications of any of our product candidates;
- the contract research organizations, or CROs, that we retain to conduct our non-clinical studies and clinical trials may take actions outside of our control that materially adversely impact our non-clinical studies and clinical trials;
- the FDA may find the data from non-clinical studies and clinical trials insufficient to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- the FDA may disagree with our interpretation of data from our non-clinical studies and clinical trials;
- the FDA may not accept data generated at our non-clinical studies and clinical trial sites;
- if our NDA, if and when submitted, is reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional non-clinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
- the FDA may require development of a Risk Evaluation and Mitigation Strategy, or REMS, as a condition of approval or post-approval;
- the FDA or the applicable foreign regulatory agency may determine that the manufacturing processes or facilities of third-party contract manufacturers with which we contract do not conform to applicable requirements, including current Good Manufacturing Practices, or cGMPs; or

- the FDA or applicable foreign regulatory agency may change its approval policies or adopt new regulations.

Any of these factors, many of which are beyond our control, could jeopardize our ability to obtain regulatory approval for and successfully commercialize AV-101 or any other product candidate we may develop, including drug rescue NCEs. Any such setback in our pursuit of regulatory approval would have a material adverse effect on our business and prospects.

Table of Contents

A Fast Track designation by the FDA may not actually lead to a faster development or regulatory review or approval process.

We intend to seek FDA Fast Track designation for AV-101 for treatment of MDD, and we may do so for other product candidates as well. If a product candidate is intended for the treatment of a serious or life-threatening condition and the product candidate demonstrates the potential to address unmet medical needs for this condition, the sponsor may apply for the FDA Fast Track designation. The FDA has broad discretion whether or not to grant this designation, and even if we believe AV-101 and other product candidates are eligible for this designation, we cannot be sure that the review or approval will compare to conventional FDA procedures. Even if granted, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development programs.

The number of patients suffering from MDD has not been established with precision. If the actual number of patients with MDD is smaller than we anticipate, we or our collaborators may encounter difficulties in enrolling patients in AV-101 clinical trials, including our recently-initiated NIH-funded Phase 2 clinical study of AV-101 in MDD, thereby delaying or preventing clinical development. Further, if AV-101 is approved for treatment of MDD, and the market for this indication is smaller than we anticipate, our ability to achieve profitability could be limited.

Results of earlier clinical trials may not be predictive of the results of later-stage clinical trials.

The results of preclinical studies and early clinical trials of AV-101 and other product candidates may not be predictive of the results of later-stage clinical trials. AV-101 or other product candidates in later stages of clinical trials may fail to show the desired safety and efficacy results despite having progressed through preclinical studies and initial clinical trials. Many companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to adverse safety profiles or lack of efficacy, notwithstanding promising results in earlier studies. Similarly, our future clinical trial results may not be successful for these or other reasons.

This drug candidate development risk is heightened by any changes in planned clinical trials compared to completed clinical trials. As product candidates are developed through preclinical to early and late stage clinical trials towards approval and commercialization, it is customary that various aspects of the development program, such as manufacturing and methods of administration, are altered along the way in an effort to optimize processes and results. While these types of changes are common and are intended to optimize the product candidates for later stage clinical trials, approval and commercialization, such changes do carry the risk that they will not achieve these intended objectives.

For example, the results of planned clinical trials may be adversely affected if we or our collaborator seek to optimize and scale-up production of a product candidate. In such case, we will need to demonstrate comparability between the newly manufactured drug substance and/or drug product relative to the previously manufactured drug substance and/or drug product. Demonstrating comparability may cause us to incur additional costs or delay initiation or completion of our clinical trials, including the need to initiate a dose escalation study and, if unsuccessful, could require us to complete additional preclinical or clinical studies of our product candidates.

If serious adverse events or other undesirable side effects are identified during the use of AV-101 in clinical trials, it may adversely effect our development of AV-101 for MDD and other CNS indications.

AV-101 is currently being tested in an NIH investigator sponsored Phase 2 clinical trial for the treatment of MDD and may be subjected to testing in the future for other CNS indications in additional investigator sponsored clinical trials. If serious adverse events or other undesirable side effects, or unexpected characteristics of AV-101 are observed in investigator sponsored clinical trials of AV-101 or our clinical trials, it may adversely affect or delay our clinical

development of AV-101, and the occurrence of these events would have a material adverse effect on our business.

Table of Contents

Positive results from early pre-clinical studies and clinical trials of AV-101 or other product candidates are not necessarily predictive of the results of later pre-clinical studies and clinical trials of such product candidates. If we cannot replicate the positive results from our earlier pre-clinical studies and clinical trials of AV-101 or other product candidates in our later pre-clinical studies and clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize our product candidates.

Positive results from pre-clinical studies of our product candidates, and any positive results we may obtain from early clinical trials of our product candidates, may not necessarily be predictive of the results from required later pre-clinical studies and clinical trials. Similarly, even if we are able to complete our planned pre-clinical studies or clinical trials of our product candidates according to our current development timeline, the positive results from our pre-clinical studies and clinical trials of our product candidates may not be replicated in subsequent pre-clinical studies or clinical trial results. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, pre-clinical findings made while clinical trials were underway or safety or efficacy observations made in pre-clinical studies and clinical trials, including previously unreported adverse events. Moreover, pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials nonetheless failed to obtain FDA approval. We have not yet completed a Phase 2 clinical trial for AV-101, and if we fail to produce positive results in our NIH-sponsored Phase 2 clinical trial of AV-101 in MDD, the development timeline and regulatory approval and commercialization prospects for AV-101 and, correspondingly, our business and financial prospects, could be materially adversely affected.

Failures or delays in the commencement or completion of our planned clinical trials of our product candidates could result in increased costs to us and could delay, prevent or limit our ability to generate revenue and continue our business.

We and the NIH have commenced an NIH-funded Phase 2 clinical trial of AV-101 as a treatment for MDD. We will need to complete at least two additional large clinical trials prior to the submission of an NDA for AV-101 as a treatment for MDD. Successful completion of our clinical trials is a prerequisite to submitting an NDA to the FDA and, consequently, the ultimate approval and commercial marketing of AV-101 for MDD and any other product candidates we may develop. We do not know whether the NIH-funded Phase 2 study of AV-101 or any of our future-planned clinical trials will be completed on schedule, if at all, as the commencement and completion of clinical trials can be delayed or prevented for a number of reasons, including, among others:

- the FDA may deny permission to proceed with our planned clinical trials or any other clinical trials we may initiate, or may place a clinical trial on hold;
- delays in filing or receiving approvals of additional INDs that may be required;
- negative results from our ongoing pre-clinical studies;
- delays in reaching or failing to reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- inadequate quantity or quality of a product candidate or other materials necessary to conduct clinical trials, for example delays in the manufacturing of sufficient supply of finished drug product;

difficulties obtaining Institutional Review Board, or IRB, approval to conduct a clinical trial at a prospective site or sites;

Table of Contents

challenges in recruiting and enrolling patients to participate in clinical trials, including the proximity of patients to trial sites;

eligibility criteria for the clinical trial, the nature of the clinical trial protocol, the availability of approved effective treatments for the relevant disease and competition from other clinical trial programs for similar indications;