

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): March 16, 2015

Commission File Number: 000-54014

**VistaGen Therapeutics, Inc.**

(Exact name of small business issuer as specified in its charter)

Nevada

(State or other jurisdiction of incorporation or organization)

20-5093315

(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 (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))

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**Item 7.01 Regulation FD Disclosure**

On March 16, 2015, VistaGen Therapeutics, Inc., a Nevada corporation (the “Company”), intends to meet with certain investors and other stakeholders, and will provide them with, among other information, certain information regarding AV-101. The Company's presentation is furnished hereto as Exhibit 99.1.

The information in this Current Report on Form 8-K (including Exhibit 99.1 hereto) is being furnished and shall not be deemed filed for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, is not subject to the liabilities of that section and is not deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except as shall be expressly set forth by specific reference in such a filing.

**Item 9.01 Financial Statements and Exhibits.**

See Exhibit Index.

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## 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: March 16, 2015

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

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## EXHIBIT INDEX

Exhibit Number	Description
99.1	Investor Presentation of VistaGen Therapeutics, Inc.

**VistaGen**<sup>TM</sup>

OTCQB: VSTA



# Forward-looking Statements



This presentation contains forward-looking statements. These statements relate to future events and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. Each of these statements is based only on current information, assumptions and expectations that are inherently subject to change and involve a number of risks and uncertainties. Forward-looking statements include, but are not limited to, statements about: (i) our plans for, including timing and progress of, clinical development of AV-101; (ii) benefits to be derived from and efficacy of AV-101 in Major Depressive Disorder (MDD) and other neurological indications, (iii) potential advantages of AV-101 versus existing antidepressants and other potential rapid-acting antidepressants, (iv) estimates regarding the prevalence of MDD, (iv) potential markets for any of our product candidates, (v) potential development of proprietary new chemical entities from our drug rescue programs and (v) estimates regarding potential note conversions and cash requirements.

In some cases you can identify forward-looking statements by terms such as “may,” “will,” “should,” “could,” “would,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “projects,” “predicts,” “potential,” and similar expressions (and the negative thereof) intended to identify forward-looking statements. Given the risks and uncertainties, you should not place undue reliance on forward-looking statements. For a discussion of the risks and other factors that may cause our actual results, performances or achievements to differ, please refer to our quarterly report on SEC Form 10-Q for the nine months ended December 31, 2014, as well as our subsequent filings with the SEC. The forward-looking statements contained herein are made as of the date hereof, and we undertake no obligation to update them for future events.

# Company Overview



- Clinical-stage biopharmaceutical company based in South San Francisco
- Products
  - **AV-101 (L-4-chlorokynurenine)**
    - New generation, orally-active Central Nervous System drug candidate
    - Phase 2a depression study in 2015 sponsored by National Institutes of Health
    - Potential to transform depression treatment paradigm
    - Broad opportunity to expand into range of neurological indications
  - **CardioSafe 3D™ and LiverSafe 3D™**
    - Drug rescue candidates
- \$57 million invested (excluding ~\$10 million NIH sponsorship for Phase 2a)

## Recent Developments



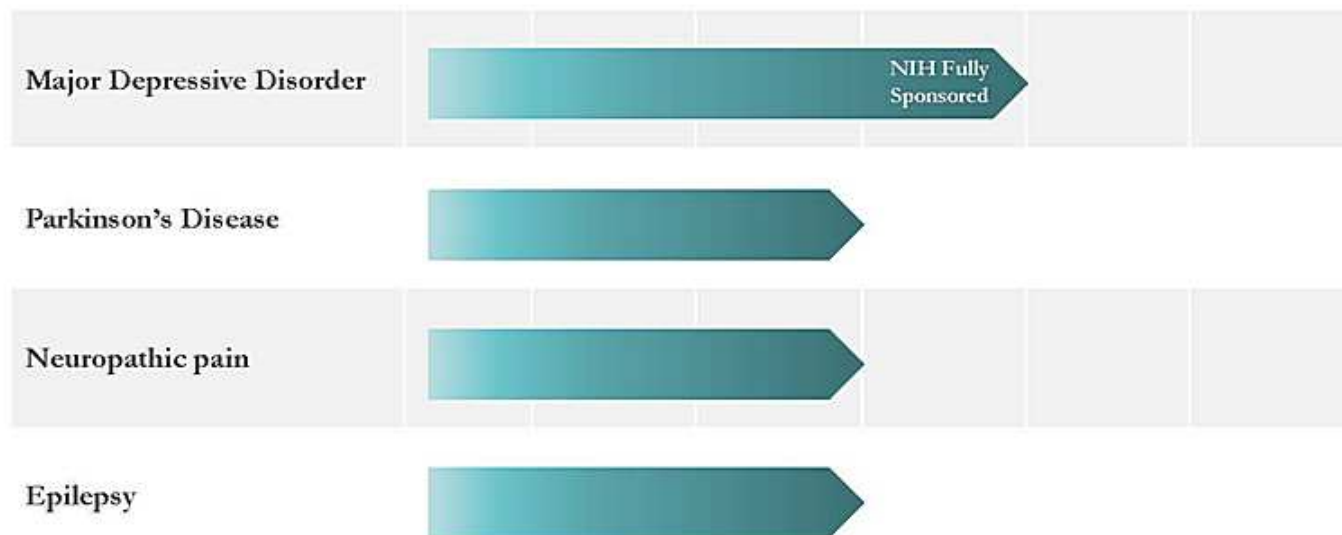
- NIH Phase 2a Cooperative Research and Development Agreement
  - NIH to conduct and fully-fund Phase 2a efficacy and safety study of AV-101 in Major Depressive Disorder (~ \$10mm)
  - NIH previously awarded ~\$9mm for AV-101 preclinical and Phase 1 development
- Appointment of key opinion leader to Clinical Advisory Board
  - Gerard Sanacora, PhD, MD
    - Professor of Psychiatry, Yale School of Medicine
    - Director, Yale Depression Research Program



# AV-101 Pipeline



AV-101	Preclinical	Phase 1a	Phase 1b	Phase 2a	Phase 2b	Phase 3
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# Founders and Management



Shawn Singh	Chief Executive Officer, Director	Cato BioVentures, Cato Research; SciClone; Echo; Artemis
Ralph Snodgrass, Ph.D.	Co-founder, President, CSO, Director	Progenitor; Lineberger Comprehensive Cancer Center; Basel Institute for Immunology
Gordon Keller, Ph.D.	Co-founder, Head, Stem Cell Research (pt), Chair, SAB	Director, McEwen Centre for Regenerative Medicine, University Health Network
Jon Saxe	Chair, Board of Directors	Ret., CEO or senior executive roles at Roche, PDL BioPharma, Synergen
Brian Underdown, Ph.D.	Independent Director	Managing Director, Lumira Capital
Jerrold Dotson, CPA	Vice President, CFO, Secretary	Calypte Biomedical Corporation (OTCBB: CBMC); Discovery Foods

## Depression: Global Problem & Multi-Billion Dollar Market



- 350 million worldwide suffer from depression (WHO)
  - 1-in-10 in U.S. aged 12+ takes antidepressant medication (CDC)
  - Medical need has remained high over the past several decades, but total market value has declined due to generic pricing
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- As it was before the introduction of products now under pressure from generic pricing (SSRIs and SNRIs), the global depression marketed is poised for a new generation of antidepressants with a fundamentally novel mechanism versus all currently-approved medications

# Problems of Current Antidepressants



- Up to 10 weeks before patients experience significant therapeutic benefit
- Only ~33% of depression sufferers benefit from initial treatment
- Likelihood of achieving remission of depressive symptoms declines with each successive treatment attempt
- Effects of multiple treatments increase risk of serious side effects, including suicidal thoughts and behaviors

## **WARNING: SUICIDAL THOUGHTS AND BEHAVIORS**

Antidepressants increased the risk of suicidal thoughts and behavior in children, teenagers, and young adults. In patients of all ages who are started on antidepressant therapy, watch closely for worsening depression and for suicidal thoughts and behaviors. Families and caregivers of patients on antidepressants should talk with the patient's doctor if depression becomes worse.



## NIH Ketamine Study Revolutionizes Depression Treatment Paradigm



- In 2006, NIH single-dose ketamine studies demonstrated robust, rapid-onset antidepressant effects in patients with treatment-resistant Major Depressive Disorder
  - Ketamine is an NMDA antagonist used widely as an anesthetic in surgical settings
- Negative attributes of ketamine:
  - Hallucinations
  - High risk of abuse
  - Requires i.v. administration in a clinical setting
- NIH single-dose ketamine studies also inspired development of a new generation of antidepressants targeting the rapid-acting antidepressant benefits of ketamine without ketamine's side effects and limitations

# VistaGen's Solution: AV-101



- NMDA receptor glycine-binding site antagonist
  - Fundamentally novel mechanism of action versus all current FDA-approved antidepressants
  - Modulates (down-regulates) NMDA receptor channel activity
  - Similar, and potentially superior, to Naurex's GLYX-13 (i.v.) and NRX-1074
- Orally-active, non-sedating, non-hallucinogenic
- Strong preclinical data indicates ketamine-like antidepressant effects without ketamine's undesirable side effects
- Safe and well-tolerated in two NIH-funded Phase 1 studies
- NIH-sponsored Phase 2 efficacy study in Major Depressive Disorder in 2015
  - **Anticipate rapid-acting antidepressant effects similar to ketamine, without ketamine's side effects or required i.v. administration**

# AV-101 vs. Ketamine Preclinical Studies



Benefits in preclinical models of depression	VistaGen's AV-101	Ketamine
Forced-swim		equivalent
Tail-suspension		equivalent
Learned-helplessness		equivalent
Novelty-suppressed feeding		equivalent
Negative effects in preclinical models	VistaGen's AV-101	Ketamine
Hyper movement	—	✓
movement sensitization	—	✓
circling and rearing	—	✓
sensory-motor gating	—	✓
abusive potential	—	✓

- AMPA receptor activation supports “glutamate surge” premise for rapid-onset, NMDA receptor-mediated antidepressant effects

## AV-101 is positioned to become a transformative advancement in the treatment of depression



Negative Clinical Attributes	AV-101	Ketamine
Requires IV delivery	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Narrow therapeutic range	not anticipated	<input checked="" type="checkbox"/>
Hallucinogenic	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Schizophrenia-like effects	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Positive Clinical Attributes	AV-101	Ketamine
Positive effects on mood	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Direct modulator of NMDA-R	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Non-channel blocker	<input checked="" type="checkbox"/>	<input type="checkbox"/>
More potent GlyB site modulator	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Wide safe dose range	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Orally-available	<input checked="" type="checkbox"/>	<input type="checkbox"/>



# AV-101 Phase 1a Safety Study Results and Observations



- NIH-funded
- Single-site (University of California, San Diego), randomized, double-blind, placebo controlled
- Single oral dose (capsule) with sequential dose-escalation
- Six single dose levels: 30, 120, 360, 720, 1,080, and 1,440 mg
- 36 subjects: 18 treatment and 18 placebo; 6 per cohort
- Well-tolerated; good bioavailability; no serious adverse events
- At higher doses, some subjects on AV-101 (and none on placebo) reported positive feelings of well-being similar to the antidepressant effects of Ketamine, but without any of Ketamine's side effects

# AV-101 Phase 1b Safety Study Results and Observations



- NIH-funded
- Single-site (University of California, San Diego), randomized, double-blind, placebo controlled
- Daily oral dose for 14 days, with sequential dose-escalation
- Three dose levels: 360, 1,080 and 1,440 mg
- 48 subjects: 36 treatment and 12 placebo; 16 per cohort
- Well-tolerated; good bioavailability; no serious adverse events
- Multiple subjects on AV-101 (and none on placebo) reported positive feelings of well-being similar to the antidepressant effects of ketamine, but without any of ketamine's side effects

# AV-101 Phase 2a Study

## Major Depressive Disorder



- NIH-sponsored, beginning in 2Q concluding in Q4 2015
- Principal Investigator
  - Carlos Zarate, MD, Chief of Experimental Therapeutics and Pathophysiology at the NIH's National Institute of Mental Health
  - Principal investigator on NIH studies of ketamine in Major Depressive Disorder
- Single-site (NIH), double-blind, placebo-controlled, crossover study
- 26 to 28 adult subjects with Major Depressive Disorder
- Single oral dose (1,440 mg) once per day for 14 days
- Primary objective is to evaluate efficacy and safety of AV-101 using standard Hamilton Depression Rating Scale and other widely-accepted measures of mood and depression

# AV-101: Broad Opportunity to Expand into Range of Neurological Indications



- **Parkinson's disease**
  - Monkey studies support potential to reduce L-DOPA dosing, thereby reducing dyskinesias associated with L-DOPA therapy
- **Epilepsy**
  - Reduced frequency of seizures and neuronal damage in well-established animal models
- **Chronic Neuropathic Pain**
  - Reduced chronic neuropathic pain due to inflammation and nerve damage in well-established live animal pain models
- **Huntington's disease**
  - A key metabolite of AV-101 (4-Cl-3-HANA) is a potent inhibitor of quinolinic acid synthesis associated with neurodegeneration

# Drug Rescue Opportunities



- One-third of new drug candidates fail due to unexpected heart or liver toxicity
- CardioSafe 3D™ and LiverSafe 3D™
  - Customized human cell-based bioassay systems to predict potential heart and liver toxicity of new chemical entities (NCEs) and optimized drug rescue candidates, before animal or human studies
- Multiple drug rescue candidates identified, screened and with potential to expand proprietary NCE pipeline in 2016



# VistaGen Summary



- AV-101 has the potential to be a transformative advancement in the treatment of depression
- Secured NIH sponsorship funding and management for AV-101 Phase 2a clinical efficacy study to be conducted by a leading investigator at the NIH's National Institute of Mental Health
- Working with key opinion leaders in depression from Yale and the NIH
- FDA Fast Track Designation for AV-101 in Major Depressive Disorder anticipated in 2015
- Significantly undervalued to comparable companies with clinical-stage new generation antidepressant drug candidates