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): January 7, 2019

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))

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 7.01 Regulation FD Disclosure.

On January 7, 2019, VistaGen Therapeutics, Inc. (the "*Company*") began utilizing a new corporate presentation. A copy of the Corporate Presentation is attached hereto as Exhibit 99.1.

The information in this Item 7.01 of this Current Report on Form 8-K, including the information set forth in Exhibit 99.1, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "*Exchange Act*"), nor shall Exhibit 99.1 filed herewith be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

In addition, this Current Report on Form 8-K and the exhibit(s) attached hereto 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.

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: January 11, 2019

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Corporate Presentation, dated January 2019

VistaGen®
Therapeutics

Nasdaq: VTGN

Corporate Presentation
January 2019
San Francisco, California

www.vistagen.com

Forward-looking Statements

This presentation contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements concern our product candidates, our development efforts, our collaborations, our intellectual property, our financial condition, our plans and our development programs. These statements involve risks, uncertainties and assumptions, and are based on the current estimates and assumptions of the management of VistaGen Therapeutics, Inc. (Company) as of the date of this presentation and are subject to uncertainty and changes. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

Important factors that could cause actual results to differ materially from those indicated by such forward-looking statements include, among others, those set forth in our Annual Report on Form 10-K for the year ended March 31, 2018, filed with the Securities and Exchange Commission (SEC) on June 26, 2018, as well as any updates to those risk factors filed with the SEC from time to time in our periodic and current reports on Forms 8-K and 10-Q. All statements contained in this presentation are made only as of the date of this presentation, and the Company undertakes no duty to update this information unless required by law.

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VistaGen Overview

NASDAQ: VTGN

VistaGen Therapeutics

CNS-focused, clinical-stage (in or through Phase 2 clinical development)

3 novel CNS candidates, 2 with Phase 2 POC efficacy data, each with fast-acting activity and potential to be safer and better tolerated than current drugs

5 large and addressable CNS target markets with high and growing clinical need

3 clinical data readouts during next 9 months

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Pipeline

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Product Candidate	Indication	Preclinical	Phase 1	Phase 2	Pivotal Phase 3
PH94B	Social Anxiety Disorder	Phase 2 completed; Pivotal Phase 3 preparation in process			
AV-101	Major Depressive Disorder†			ELEVATE Study	
	Major Depressive Disorder			U.S. National Institute of Mental Health Study	
	Suicidal Ideation			Baylor/VA First-Step Study	
	Neuropathic Pain†			IND active; Phase 2a protocol in process	
	Parkinson's Disease Dyskinesia			IND and Phase 2a protocol in process	
PH10	Major Depressive Disorder			Phase 2a complete; Phase 2b IND submission planned	

† FDA Fast Track Designation

Social Anxiety Disorder

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DEVELOPING NEXT GENERATION MEDICINES FOR CNS DISEASES AND DISORDERS WITH HIGH UNMET NEED

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Social Anxiety Disorder in the U.S.

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Intense, persistent fear of being watched and judged by others, causing people to avoid everyday social situations for fear of being scrutinized, judged, humiliated or embarrassed

One of the most prevalent mental health conditions in the U.S.

Affects as many as

22 million

7%
of U.S. adults

9%
of U.S. adolescents

Individuals can feel symptoms of anxiety or fear in certain or all social and/or performance situations, such as...

- giving a speech
- making a work presentation
- meeting new people
- interviewing for a job
- eating/drinking in front of others

Individuals recognize their fear is excessive and irrational, but feel powerless to do anything about it

Can interfere with daily routines and job performance and make it difficult to maintain social relationships

6

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Current Drug Treatments for SAD Fall Short

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FDA APPROVED

- Antidepressants
  - SSRIs such as paroxetine and sertraline and SNRIs such as venlafaxine
    - ✖ Take weeks to months to work and may worsen anxiety initially
    - ✖ Many patients are reluctant to take long-term, daily SSRIs or SNRIs with significant side effects for a disorder that may be situational

Off-label

- Benzodiazepines such as alprazolam (Xanax)
  - ✖ Addiction
  - ✖ Tolerance
  - ✖ Sedation
  - ✖ Cognitive impairment
- Beta blockers such as propranolol
  - May relieve physical symptoms such as racing heart etc.

7

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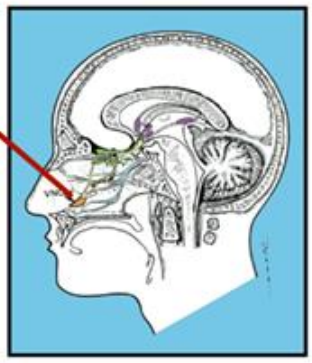
PH94B

Novel, Fast-Acting, On-Demand Treatment for SAD

Phase 3-ready

- ✓ First-in-class, synthetic neurosteroid
- ✓ Novel MOA targets nasal chemosensory neurons in the amygdala to suppress anxiety
- ✓ Self-administered on-demand, as needed (PRN) prior to a feared event
- ✓ Microdose (3.2 µg) delivered directly to receptors in nasal passages
- ✓ Fast-acting efficacy in 10 - 15 minutes
- ✓ Non-sedating, non-addictive
- ✓ Well-tolerated in multiple clinical studies
- ✓ No systemic exposure



Potential to be the first FDA-approved on-demand PRN treatment for SAD

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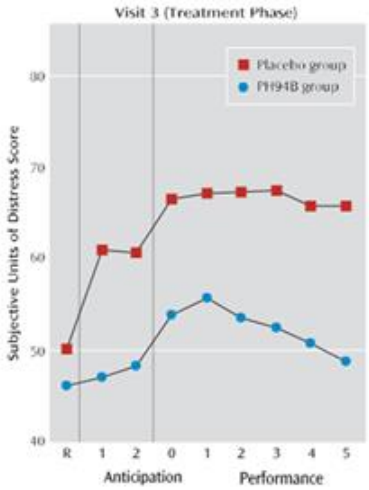
PH94B Phase 2 Efficacy Data

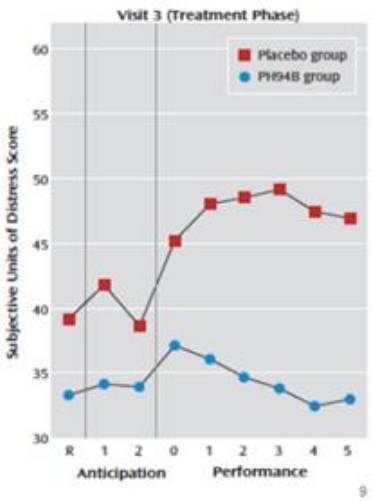
- Multicenter, randomized, double-blind, placebo-controlled, single-dose study (n=91)
- Significantly and rapidly reduced anxiety produced by laboratory-simulated public speaking and social interaction challenges in female SAD patients
- Well-tolerated, no systemic exposure, toxicity or sedating or addictive effects observed

(MR Liebowitz et al, Am J Psych, 2014)

Public Speaking Challenge



Social Interaction Challenge



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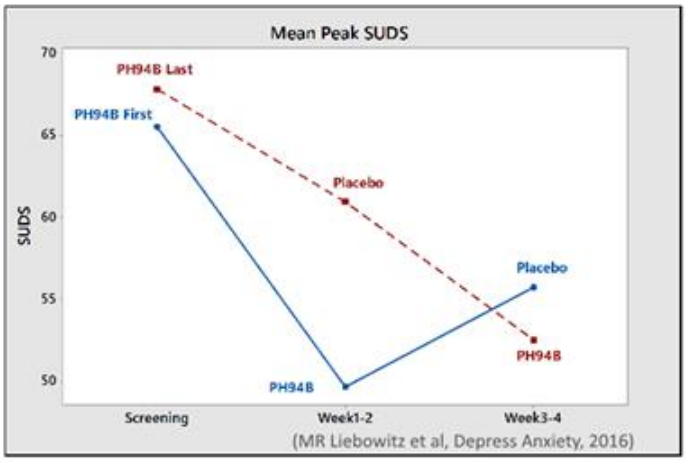
PH94B "Real World" Pilot Phase 3 Efficacy Data

- "Real-world" placebo-controlled, cross-over study in patients with SAD who confronted stressful situations in their workplaces and social situations (n=22)
- Significant difference observed for subjects while on PH94B vs. placebo on primary outcome measure (Subjective Units of Distress Scale (SUDS)) and robust effects seen on secondary outcome measures, including Liebowitz Social Anxiety Scale (LSAS)
- Carryover efficacy observed in second period of crossover. Parallel design will be used in pivotal Phase 3 studies



(MR Liebowitz et al, Depress Anxiety, 2016)

Major Depressive Disorder

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Nasdaq: VTGN

DEVELOPING NEXT GENERATION MEDICINES FOR CNS DISEASES AND DISORDERS WITH HIGH UNMET NEED

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Depression in the U.S.

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1 in 4 women

diagnosed with depressive disorders

1 in 6 men

>

1 in 8

age 12 and over takes an antidepressant[1]

DEPRESSION, LARGE ADDRESSABLE MARKET WITH HIGH UNMET NEED[2,3]

11.6M	7.3M	5.1M
Drug-treated patients with Major Depressive Disorder	Inadequate response to 1st antidepressant	Treatment-resistant after 2nd antidepressant

1. CDC – NCHS – National Center for Health Statistics, August 2017; 2. Rush AJ, et al. Am J. Psychiatry. 2006, 163(11): 1905-1917 (STAR*D Study); 3. Decision Resources 2016.

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Current Approved Drug Treatments for Depression Fall Short

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Current Antidepressants

- **Often do not work**
  - – First antidepressant effective in only 1 of 3 patients
- **Slow to work**
  - – May take 4 to 6 weeks for antidepressant effects
- **Numerous side effects**
  - – Anxiety, sexual dysfunction, insomnia, fatigue

Adjunctive Atypical Antipsychotics

- **Often do not work**
  - – Only 10 to 20% of patients respond to augmentation
- **Safety concerns**
  - – "Black Box" warnings
- **Numerous side effects**
  - – Weight gain, akathisia, tardive dyskinesia

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Ketamine: Breakthrough in MDD Treatment

Antidepressant Effects Within 1 Day of a Single IV Infusion

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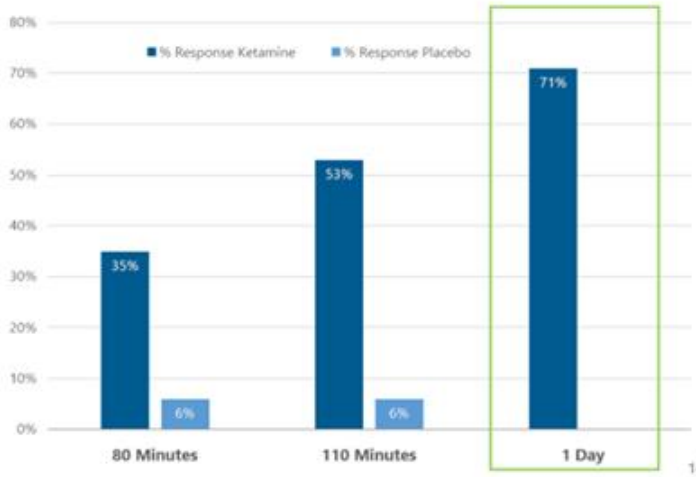
Responder[¥] Rates at 1 Day with Ketamine in Treatment-resistant MDD

[¥] Proportion of patients with treatment-resistant MDD with at least 50% improvement in depression rating

[1]Zarate, C. A., Jr., et al. (2006) "A randomized trial of an N-methyl-D-aspartate antagonist in treatment-resistant major depression." Arch Gen Psychiatry 63:856-864.



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Potential Limitations of Long-Term Ketamine Therapy

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"...[I]t is necessary to recognize the major gaps that remain in our knowledge about the longer-term efficacy and safety of ketamine infusions." [1]

The American Psychiatric Association (APA) Council of Research Task Force on Novel Biomarkers and Treatments, March 2017

POTENTIAL SIDE EFFECTS & SAFETY CONCERNS

- DEA Schedule III Drug
- Risk of Abuse
- Dissociation
- Hallucinations
- Confusion
- Dizziness
- Increased BP

1. Sanacora G, Frye MA, McDonald W, et al. A Consensus Statement on the Use of Ketamine in the Treatment of Mood Disorders. JAMA Psychiatry. 2017;74(4):399-405. doi:10.1001/jamapsychiatry.2017.0080

Beyond Ketamine for MDD
AV-101 and PH10

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AV-101

New Generation Adjunctive Treatment for MDD

- ✓ Oral NMDAR GlyB antagonist
- ✓ Ketamine-like antidepressant effects in published preclinical studies
- ✓ Well-tolerated in two Phase 1 studies and two ongoing Phase 2 studies
- ✓ No psychological side effects observed to date
- ✓ FDA Fast Track designation

- ELEVATE and NIMH-sponsored Phase 2 MDD studies ongoing
- Clinical data readouts in 2019
- Initial objective: displace atypical antipsychotics in current MDD treatment paradigm

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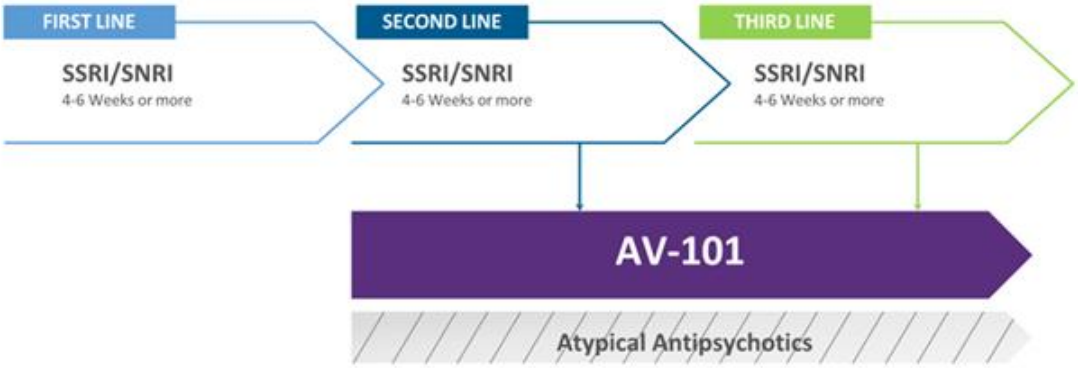
Initial Regulatory and Commercial Objective

Adjunctive Treatment for Inadequate Response to SSRIs/SNRIs



DISPLACE ATYPICAL ANTIPSYCHOTICS IN CURRENT DRUG TREATMENT PARADIGM

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AV-101 vs. Ketamine in Published Preclinical Studies

Rapid-acting, Antidepressant-like Effects	AV-101	Ketamine
Forced-swim	COMPARABLE	
Tail-suspension	COMPARABLE	
Learned-helplessness	COMPARABLE	
Novelty-suppressed feeding	COMPARABLE	
Side Effects	**AV-101**	**Ketamine**
Psychotomimetic and rewarding	No	Yes
Hyper movement	No	Yes
Movement sensitization	No	Yes
Circling and rearing	No	Yes
Sensory-motor gating	No	Yes

1. Zanos, P., et al. (2015). "The Prodrug 4-Chlorokynurenine Causes Ketamine-Like Antidepressant Effects, but Not Side Effects, by NMDA/Glycine$_B$-Site Inhibition." J Pharmacol Exp Ther 355(1): 76-85.

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AV-101 Published Phase 1 Safety Studies

- Two NIH-funded Phase 1 safety studies conducted in 86 normal volunteers
- Phase 1A: Single ascending dose – 30 to 1440 mg of AV-101 administered once
- Phase 1B: Multiple ascending dose – 360, 1080 and 1440 mg administered daily for 14 days
- Excellent safety profile, similar to placebo

Multiple subjects on AV-101 (none on placebo) reported positive feelings of well-being similar to antidepressant effects reported with ketamine, but without ketamine's psychological side-effects

Wallace, M., et al. (2017) "Randomized, double-blind, placebo-controlled, dose-escalation study: Investigation of the safety, pharmacokinetics, and antihyperalgesic activity of L-4-chlorokynurenine in healthy volunteers." Scandinavian Journal of Pain 17(1): 243-251.

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AV-101 NIMH Phase 2 Clinical Study

NIH National Institute of Mental Health

Principal Investigator: Dr. Carlos Zarate, Jr., National Institute of Mental Health

- NIH-sponsored; ongoing at NIMH
- Double-blind, placebo-controlled, crossover design
- Monotherapy in patients with treatment-resistant depression, once per day for 14 days
- Blinded adverse events suggest that AV-101 continues to be exceptionally well-tolerated
- CSF measurements of AV-101, 7-Cl-KYNA, quinolinic acid, etc. will be measured
- Glutamate levels in the brain measured by MR spectroscopy in response to AV-101
- Target enrollment, ca. 20 adults; target topline results, 1H 2019

Primary Endpoint: Change in HDRS (HAM-D) from baseline compared to placebo

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AV-101 ELEVATE Phase 2 Clinical Study

Adjunctive Treatment for Major Depressive Disorder

Principal Investigator: Dr. Maurizio Fava, Harvard Medical School

- Company-sponsored
- Adjunctive treatment for inadequate response to current SSRI/SNRI therapy
- Oral dose (1440 mg), once per day for 14 days
- 20 U.S. clinical sites
- Target enrollment, ca. 180 patients
- Target completion, 1H 2019
- Target topline results, mid-2019

Primary Endpoint: Change in MADRS from baseline compared to placebo

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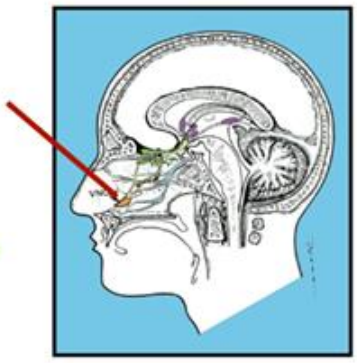
PH910

Novel, Fast-Acting Intranasal Treatment for MDD

Phase 2a POC Completed

- ✓ First-in-class, synthetic neurosteroid
- ✓ Novel MOA activates nasal chemosensory receptors that in turn engage GABA in the limbic amygdala system
- ✓ Self-administered, at-home
- ✓ Microdose (3.2 µg) delivered directly to receptors in nasal passages
- ✓ Fast-acting antidepressant efficacy observed in Phase 2a POC study (n=30)
- ✓ Non-sedating, non-addictive
- ✓ Well-tolerated, no systemic exposure



Fast-acting antidepressant effects, without psychological side effects or safety concerns

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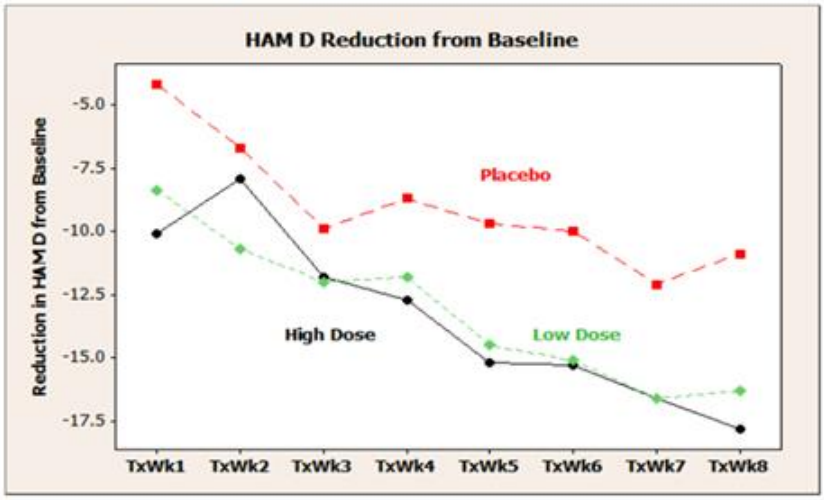
PH10 Phase 2 Efficacy Data



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Potential Additional AV-101 and PH10 Depression Indications

- Prevent relapse following successful ketamine therapy
- Front-line monotherapy

Suicidal Ideation

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Baylor / VA Phase 1b Clinical Study

U.S. Department of Veterans Affairs

Baylor College of Medicine

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Investigating AV-101 as a Potential Treatment for Suicidal Ideation

Principal Investigator: Dr. Marijn Lijffijt, Baylor College of Medicine

- Sponsored by U.S. Department of Veteran's Affairs (VA); ongoing at Baylor University
- First-step study testing for potential anti-suicidal effects of AV-101 in healthy U.S. Veterans
- Double-blind, placebo-controlled, crossover design
- Two single doses of AV-101 (720mg and 1440 mg) and placebo over three weeks
- Purpose: Define neurophysiological markers and further evaluate safety and tolerability
- Study completion anticipated 1H 2019; topline results anticipated 2H 2019

Primary Objective: Test dose-dependent target engagement using kynurenine markers and electrophysiological measures relevant to NMDA antagonism and suicidal ideation

Neuropathic Pain and Parkinson's LID

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DEVELOPING NEXT GENERATION MEDICINES FOR CNS DISEASES AND DISORDERS WITH HIGH UNMET NEED

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AV-101 for Neuropathic Pain

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Oral, Non-opioid, Non-addictive, Non-sedating Treatment Option

[W]e've undertaken new efforts to support novel product innovation. This includes ... steps to advance the development of non-addictive treatments for pain."[1]
-Scott Gottlieb, M.D.,
FDA Commissioner

FDA granted Fast Track designation for development of AV-101 as a non-opioid, non-sedating treatment for neuropathic pain

NEXT STEP → Phase 2a study of AV-101 vs placebo in patients with neuropathic pain

1. FDA Commissioner Scott Gottlieb, M.D., https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm618831.htm

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AV-101 for Parkinson's Dyskinesia

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Replace oral amantadine in treatment paradigm to reduce dyskinesia induced by levodopa therapy, without amantadine-like side effects

Levodopa-induced dyskinesia occurs in 80% of patients with PD after 10 years

AV-101 reduced mean dyskinesia scores by 30% in Parkinsonian monkeys with LID, without worsening Parkinson's symptoms

NEXT STEP → Phase 2a study of AV-101 vs placebo in Parkinson's patients

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Experienced Team Leading Execution

VistaGen Therapeutics

Shawn K. Singh
Chief Executive Officer
- 25 years of experience with biopharmaceutical companies, a healthcare venture capital firm and a profitable CRO
- Artemis Neuroscience; SciClone Pharmaceuticals; Cato BioVentures; Cato Research: Morrison & Foerster

Ralph Snodgrass, Ph.D. Pres[illegible] Chief
Scientific Officer
- 23 years of experience in senior [illegible] management
- Progenitor; Lineberger Comprehensive Cancer Center

Jerrold D. Dotson, CPA
Chief Financial Officer, Secretary
- 20 years of experience in senior management finance and administration
- Calypte Biomedical; Discovery Foods; California & Hawaiian Sugar; Clorox

Mark A. Smith, M.D., Ph.D.
Chief Medical Officer
- 20 years of large Pharma CNS drug development experience
- Teva Pharmaceuticals; Shire Pharmaceuticals; AstraZeneca Pharmaceuticals; DuPont Pharmaceutical Company; U.S. National Institute of Mental Health

Mark A. McPartland
Vice President, Corporate Development
- 20 years of experience in corporate development, capital markets and management consulting
- Stellar Biotechnologies; MZ Group; Hayden Communications: Alliance Advisors

Preeminent CNS Clinical and Regulatory Advisors

VistaGen Therapeutics

Maurizio Fava, M.D.
Professor of Psychiatry, Harvard Medical School; Director, Division of Clinical Research, Massachusetts General Hospital (MGH) Research Institute; Executive Director, MGH Clinical Trials Network and Institute

Sanjay Mathew, M.D.
Associate Professor of Psychiatry and Behavioral Sciences, Marjorie Bintliff Johnson and Raleigh White Johnson; Jr. Chair for Research in Psychiatry and Menninger Department of Psychiatry & Behavioral Sciences, Baylor College of Medicine

Michael Liebowitz, M.D.
Professor of Clinical Psychiatry, Columbia University; Managing Director and Founder, The Medical Research Network, LLC; Director (retired), Anxiety Disorders Clinic at the New York State Psychiatric Institute

Gerard Sanacora, Ph.D., M.D.
Professor of Psychiatry, Yale School of Medicine; Director, Yale Depression Research Program; Scientific Director, Yale-New Haven Hospital Interventional Psychiatry Service

Thomas Laughren, M.D.
Director (retired), U.S. Food and Drug Administration (FDA) Division of Psychiatry Products, Office of New Drugs, Center for Drug Evaluation and Research (CDER)

Mark Wallace, M.D.
Professor of Clinical Anesthesiology, Chair of the Division of Pain Medicine, Medical Director and Director at the University of California, San Diego

VistaGen Summary

NASDAQ: VTGN

VistaGen Therapeutics

- Focused on large addressable CNS markets where current medications fall short
- Multiple shots on goal with 3 late-stage CNS pipeline candidates
- Highly-experienced team leading execution
- Potentially transformative clinical, corporate and regulatory catalysts in 2019

DEVELOPING NEW GENERATION MEDICINES FOR DEPRESSION AND OTHER CNS DISORDERS