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): May 2, 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. [ ]

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value $0.001 per share	VTGN	Nasdaq Capital Market

Item 7.01 Regulation FD Disclosure.

VistaGen Therapeutics, Inc. (the "*Company*") today 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.

Item 8.01 Other Items.

The Company today announced topline results from an exploratory clinical study of AV-101 as a monotherapy in patients with treatment-resistant depression ("*TRD*"). The 19-patient study was sponsored and conducted by the U.S National Institute of Mental Health ("*NIMH*"). A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.2.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits Index

Exhibit No.	Description
99.1	Corporate Presentation, dated May 2, 2019
99.2	Press Release issued by VistaGen Therapeutics, Inc., dated May 2, 2019.

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: May 2, 2019

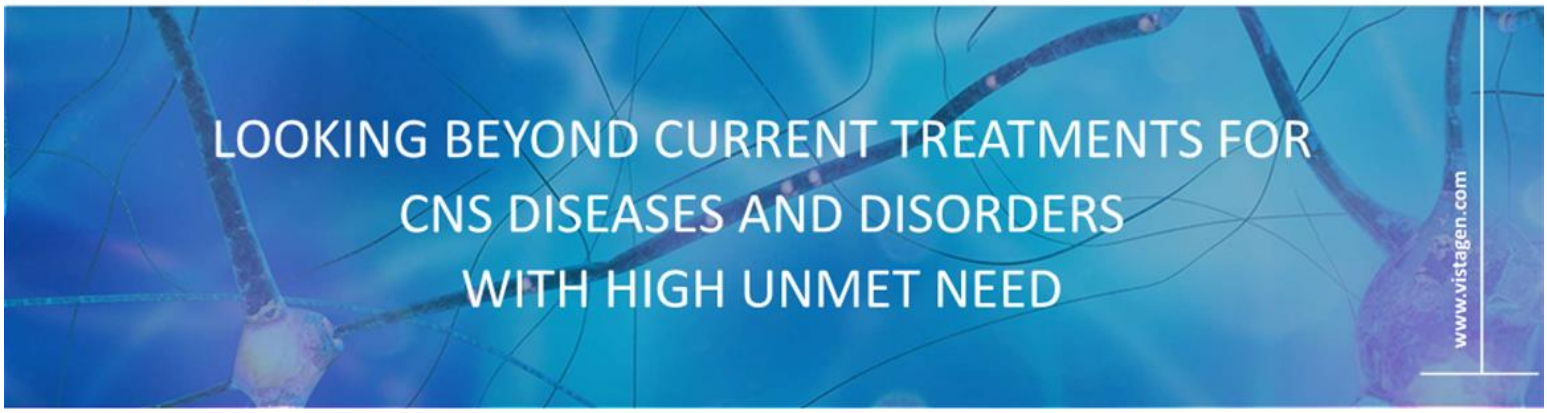
By: */s/ Shawn K. Singh*
Shawn K. Singh
Chief Executive Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Corporate Presentation, dated May 2, 2019
99.2	Press Release issued by VistaGen Therapeutics, Inc., dated May 2, 2019.

Exhibit 99.1

VistaGen® Therapeutics



Nasdaq: VTGN

Spring 2019

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.

www.vistagen.com

Looking beyond current therapies for CNS diseases and disorders with high unmet need

VistaGen Therapeutics

3 late-stage CNS product candidates

Multiple large target markets where current treatments fall short

New generation MOAs

Rapid-onset potential

Exceptional safety

At-home convenience

Pipeline

VistaGen Therapeutics

Product Candidate	Indication	Preclinical	Phase 1	Phase 2	Phase 3
PH94B	Social Anxiety Disorder	Pivotal Phase 3 Study preparation in process			
AV-101	Major Depressive Disorder† (inadequate response to current ADT)	ELEVATE Phase 2 Study ongoing			
	Major Depressive Disorder (ketamine therapy responders)	RELAY Phase 2 Study preparation in process			
	Suicidal Ideation	Baylor 1st-step Study ongoing			
	Neuropathic Pain†	Phase 2 Study preparation in process			
	Parkinson's LID	Phase 2 Study preparation in process			
PH10	Major Depressive Disorder	2nd Phase 2 Study preparation in process			

† FDA Fast Track Designation

Most Advanced Clinical Program
* Preparing to Enter
Pivotal Phase 3 *

PH94B
for
Social Anxiety Disorder

www.vistagen.com

VistaGen®
Therapeutics

Nasdaq: VTGN

LOOKING BEYOND CURRENT TREATMENTS FOR CENTRAL NERVOUS SYSTEM (CNS) DISEASES AND DISORDERS WITH HIGH UNMET NEED

VistaGen Therapeutics

Social Anxiety Disorder in the U.S.

SAD is More than Just Shyness

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

Affects as many as

22 million

7% of adults and **9%** of adolescents

NIH National Institute of Mental Health

Individuals feel anxiety or fear in everyday social and performance situations, such as…

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

https://www.nimh.nih.gov/health/publications/social-anxiety-disorder-more-than-just-shyness/index.shtml

Current SAD Drug Treatments Fall Short

VistaGen Therapeutics

FDA APPROVED

Not FDA-Approved
*** Used Off-label ***

Antidepressants

- Slow onset, chronic administration
- May worsen anxiety initially
- Significant side effects
- Potential drug-drug interaction

Benzodiazepines & Beta Blockers

- Addiction risk
- Sedation
- Cognitive impairment
- Cardiac concerns

There is no FDA-approved as-needed (PRN) treatment for SAD

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PH94B

Rapid-Onset Efficacy, Exceptional Safety

VistaGen Therapeutics

- Novel CNS neuroactive steroid nasal spray
- Activates nasal chemosensory receptors that trigger neural circuits in the brain that suppress fear and anxiety
- PRN treatment prior to a fear/anxiety-producing situation
- Rapid-onset efficacy (10 to 15 minutes)
- Microgram dose, no systemic exposure
- Well-tolerated
- Non-sedating, non-addictive

Phase 2 and pilot Phase 3 Complete
Preparing for U.S. Pivotal Phase 3 program launch in 2020

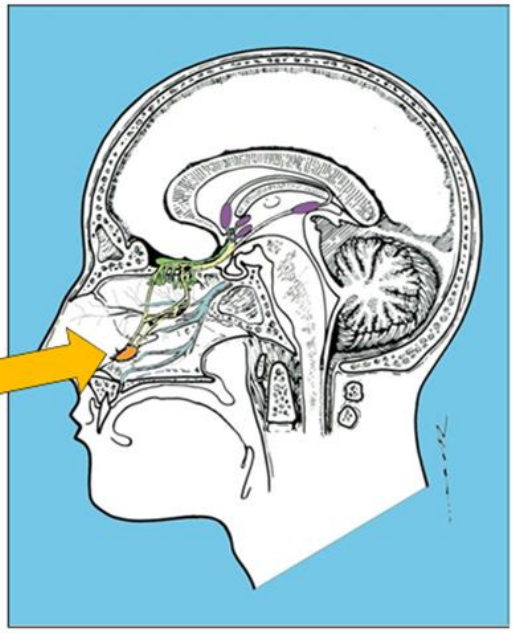
Potential to be the first FDA-approved PRN treatment for SAD

PH94B Mechanism of Action

Activates Neural Circuits that Suppress Fear and Anxiety

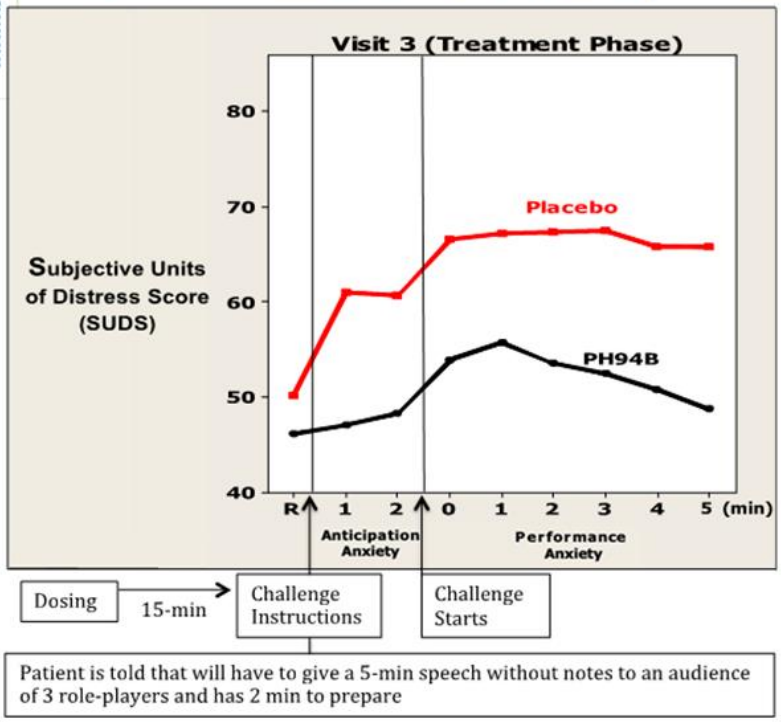
VistaGen Therapeutics

- **Fundamentally different from all current SAD treatments**
- **Activates nasal chemosensory receptors that trigger neural circuits in the brain that suppress fear and anxiety**
  - Engages nasal chemosensory receptors that trigger a subset of neurons in the main olfactory bulbs (OB)
  - OB neurons stimulate inhibitory GABAergic neurons in the amygdala, decreasing release of norepinephrine, and facilitating fear extinction and activity of the limbic-hypothalamic parasympathetic system



PH94B Phase 2 POC Study – Public Speaking (n = 91)

VistaGen Therapeutics



PH94B Rapidly Reduced Anxiety in Response to Public Speaking Challenge

Active Group:	Placebo Group:
Mean Difference = 26.7	Mean Difference = 14.0
Standard Deviation = 21.6	Standard Deviation = 16.3
Number of Subjects = 45	Number of subjects = 46

t = 3.16	p = 0.002	Cohen's d (Effect Size) .72

Liebowitz, MR, Salman, E, Nicolini, H, Rosenthal, N, Hanover, R, Monti, L (2014). Effect of an acute intranasal aerosol dose of PH94B on social and performance anxiety in women with social anxiety disorder. *Am. J. Psychiatry* 171:675-682.

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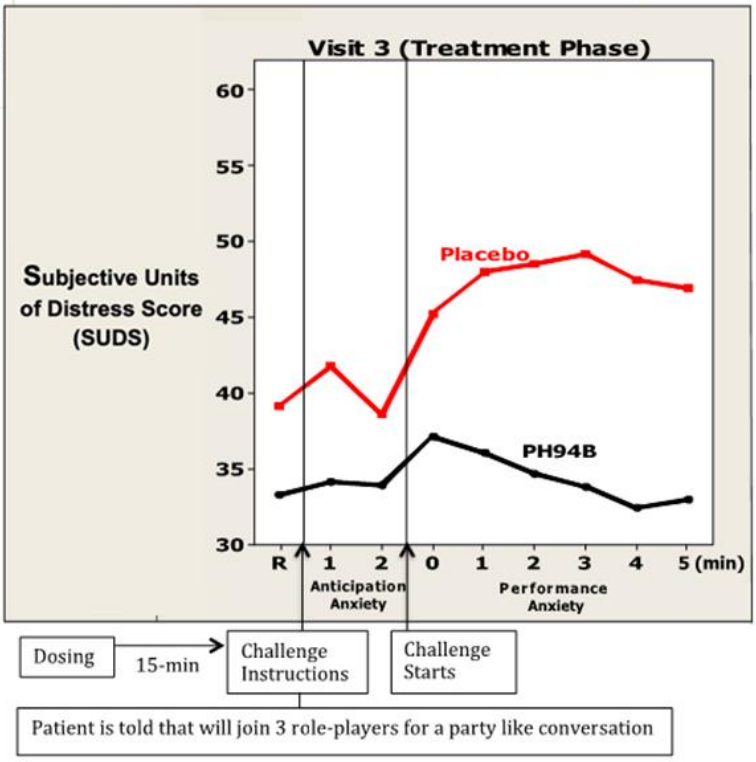
PH94B Phase 2 POC Study – Social Interaction (n = 91)

VistaGen Therapeutics



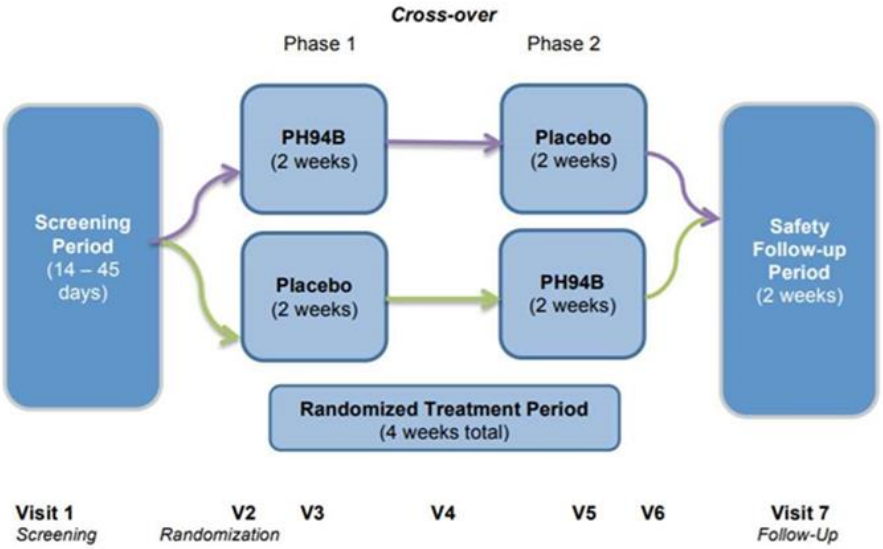
PH94B Rapidly Reduced Anxiety in Response to Social Interaction Challenge

Active Group:	Placebo Group:
Mean Difference = 18.3	Mean Difference = 6.6
Standard Deviation = 17.4	Standard Deviation = 23.6
Number of Subjects = 45	Number of Subjects = 46

t = 2.67	p = 0.009	Cohen's d (Effect size) .56

VistaGen® Therapeutics

PH94B Pilot Phase 3 Crossover Study (n = 22)

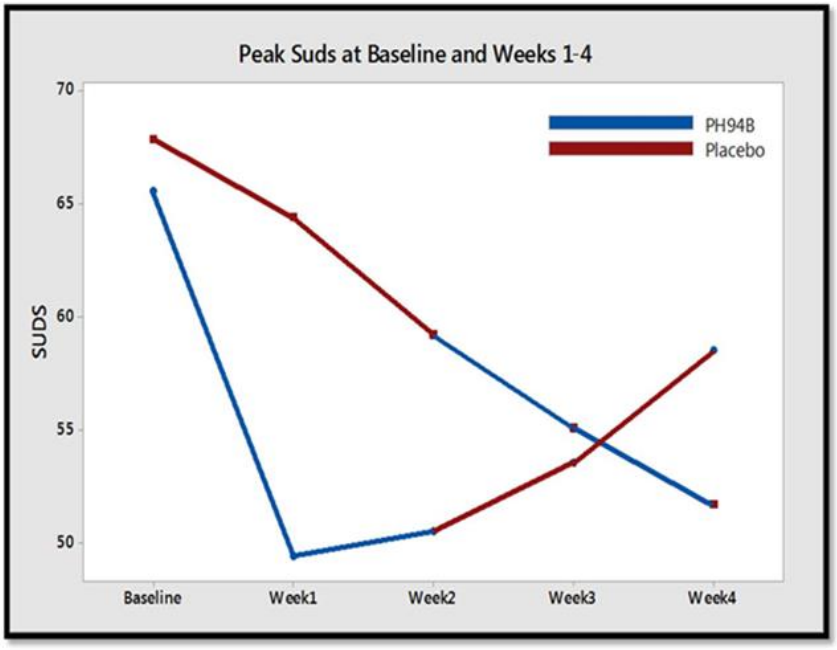


Adult subjects were randomized on a 1:1 basis to PH94B or placebo for two weeks, and then crossed over to the opposite treatment for an additional two weeks.

Liebowitz, M.R., Hanover, R., Draine, A., Careri, J., Monti, L., Smith, M., Moran, M., & Burnetta, D. (2019). Effect of As-Needed Use of Intranasal PH94B on Social and Performance Anxiety in Individuals with Social Anxiety Disorder. 2019 Anxiety and Depression Association of America (ADAA) Annual Conference Poster Session.

PH94B Pilot Phase 3 Crossover Study

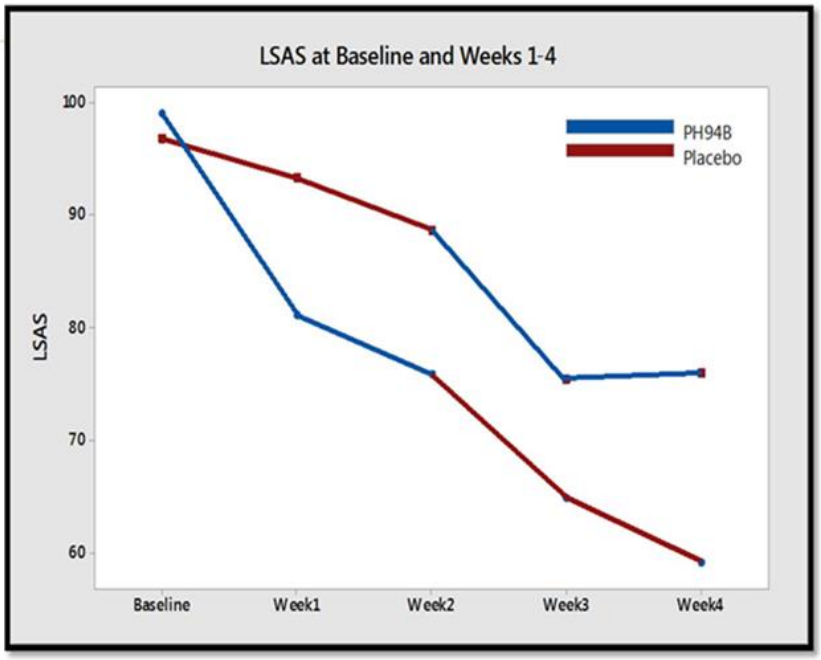
VistaGen Therapeutics



- Early suggestions of drug/placebo differences were seen in Week 1 and 2 SUDS scores: average change in SUDS at week 1 was 16.1 for PH94B versus 3.4 for placebo (t=1.86, p=.078, ES .79), and at week 2, the average change was 15.9 for PH94B and 6.9 for placebo (t= 1.35, p=0.192, ES .576)
- Peak SUDS score for the PH94B group increased when crossed over to placebo, though not back to the baseline level, due to increased confidence from PH94B treatment prior to crossover

PH94B Pilot Phase 3 Crossover Study

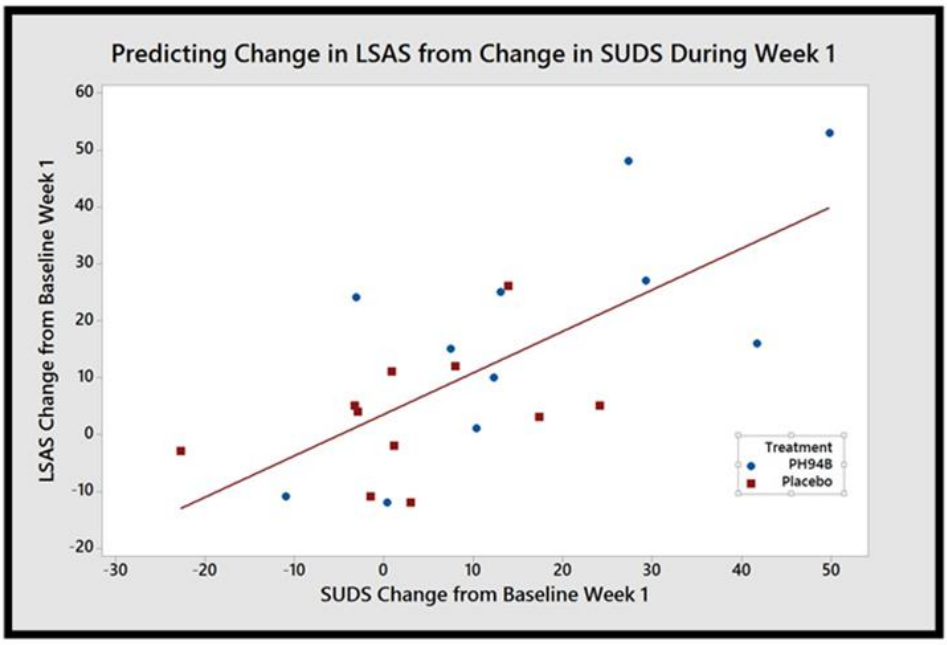
VistaGen Therapeutics



- In the sample as a whole, drop in LSAS scores after treatment did not differ between groups because subjects receiving PH94B before receiving placebo continued to improve when crossed over to placebo
- After the first 2 weeks of treatment, subjects who received PH94B dropped an average of 23.2 points on the LSAS, while those who received placebo dropped only 8.2 points, showing a trend difference (t=1.9, p=.07) with a large effect size of .812
- Similar trend differences on total LSAS scores were seen after 1 week of treatment, where the PH94B group showed a 17.8 point drop compared to a 3.5 point drop with placebo (t=2.02, p=.057, ES .86)

PH94B Pilot Phase 3 Crossover Study

VistaGen Therapeutics



Changes in total LSAS scores were closely associated with change in SUDS peak anxiety scores at Week 1 (R-sq (adj) 45.2%) and at Week 2 (R-sq (adj) 34.95%). Looking at LSAS subscales, the strongest associations for SUDS peak anxiety scores were with the LSAS avoidance subscale at Week 1 (R-sq (adj) 58.78%) and Week 2 (R-sq (adj) 42.74%), and LSAS performance at Week 1 (R-sq (adj) 50.33%)

PH94B Development for SAD – Next Step

First U.S. Pivotal Phase 3 Study

Principal Investigator: Dr. Michael Liebowitz, Columbia University, New York

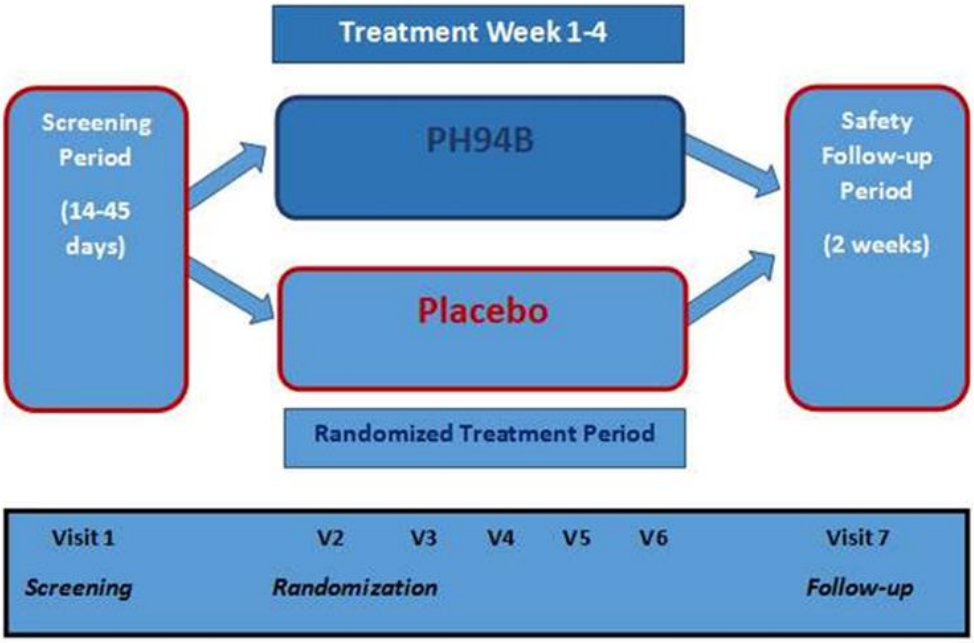
- Randomized, double-blind, placebo-controlled, monotherapy study
- As-needed (PRN) self-administration of PH94B (3.2 μg) or placebo for 4 Weeks
- Multi-center, ca. 15 sites in North America
- Target enrollment, ca. 200 patients
- Target launch, mid-2020
- Target completion, end of 2021

Primary Endpoint: Change in LSAS from baseline compared to placebo

PH94B Development for SAD – Next Step

First U.S. Pivotal Phase 3 Study (n = ca. 200)

VistaGen Therapeutics



Phase 2 Clinical Programs

AV-101 and PH10
for
Major Depressive Disorder

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VistaGen® Therapeutics

Nasdaq: VTGN

LOOKING BEYOND CURRENT TREATMENTS FOR CENTRAL NERVOUS SYSTEM (CNS) DISEASES AND DISORDERS WITH HIGH UNMET NEED

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Major Depressive Disorder - A Global Challenge

VistaGen Therapeutics

300 million
suffer from depression worldwide[1]

Depression is the leading cause of disability worldwide[1]

Depression and anxiety disorders cost the global economy an estimated US$1 trillion each year in lost productivity[1]

The total estimated number of people living with depression increased by 18.4% between 2005 and 2015[1]

1. World Health Organization

www.vistagen.com

VistaGen Therapeutics

Major Depressive Disorder in the U.S.

1 in 4 women and **1 in 6 men** diagnosed with depressive disorders

1 in 8 age 12 and over takes an antidepressant[1]

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

11.6M
Drug-treated patients with Major Depressive Disorder

7.3M
Inadequate response to 1st antidepressant

5.1M
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.

VistaGen® Therapeutics

Current FDA-Approved MDD Drug Treatments Fall Short

Antidepressants

- **Often do not work; slow to work**
  - Initial ADT effective in 1 of 3 patients
  - May take 4 to 6 weeks or more for antidepressant effects
- **Significant side effects**
  - Anxiety, sexual dysfunction, insomnia

Atypical Antipsychotics

- **Often do not work**
  - Only ca. 20% of patients respond to augmentation
- **Significant side effects**
  - Weight gain, akathisia, insomnia, dizziness, tardive dyskinesia

VistaGen Therapeutics

Ketamine-based Therapy for MDD

Intravenous ketamine

"Ketamine offers lifeline for people with severe depression, suicidal thoughts"

CNN

Intranasal ketamine

The New York Times

"Fast-Acting Depression Drug, Newly Approved, Could Help Millions"

CNBC

"J&J's new ketamine-like depression drug Spravato off to 'very, very strong start,' company says"

VistaGen® Therapeutics

Ketamine-based therapy for MDD offers new hope to millions, but is it a long-term solution?

> "…[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]
>
> American Psychiatric Association (APA)

- Safety Concerns?
- Durability?
- Side Effects?
- Convenience?
- Compliance?
- Cost?

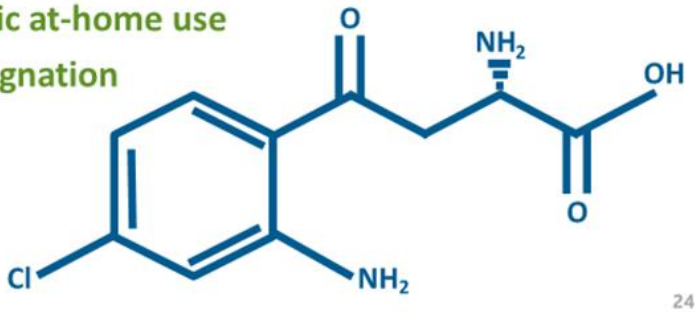
1. Sanacora G, Frye MA, McDonald W, et al. A Consensus Statement on the Use of Ketamine in the Treatment of Mood Disorders. *JAMA Psychiatry*. 2017;74(4):399–405. doi:10.1001/jamapsychiatry.2017.0080

AV-101 for MDD: Transformative Potential

Rapid-onset Potential, Exceptional Safety

VistaGen Therapeutics

- Oral prodrug of 7-Cl-KYNA
- NMDA receptor glycine site antagonist (a full antagonist)
- Rapid-onset antidepressant effects and neurogenesis in preclinical studies
- Well-tolerated in all clinical studies to date
- No psychological side effects or treatment-related SAEs
- Intended for chronic at-home use
- FDA Fast Track designation

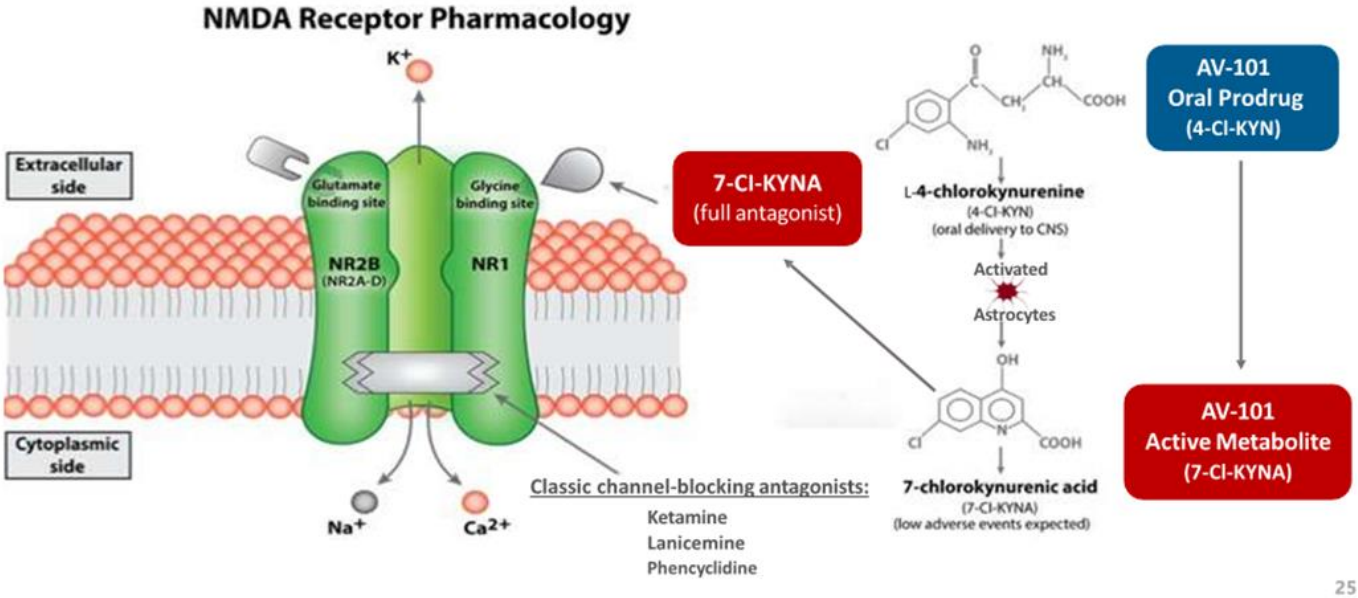


Phase 2 study ongoing
Topline results in 2019

VistaGen Therapeutics

AV-101's Mechanism of Action

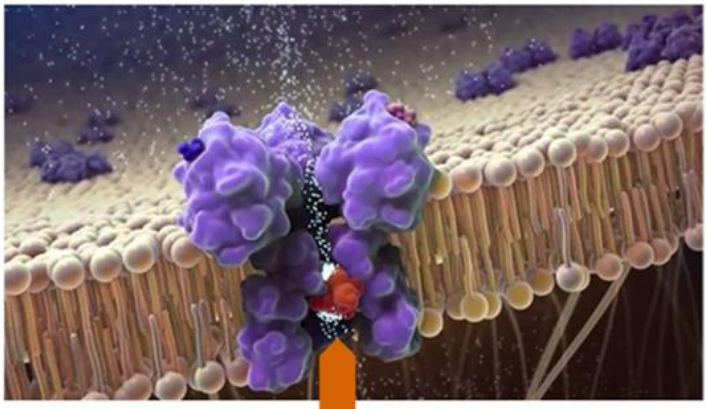
Inhibits NMDA Receptor Activity



AV-101's Mechanism of Action

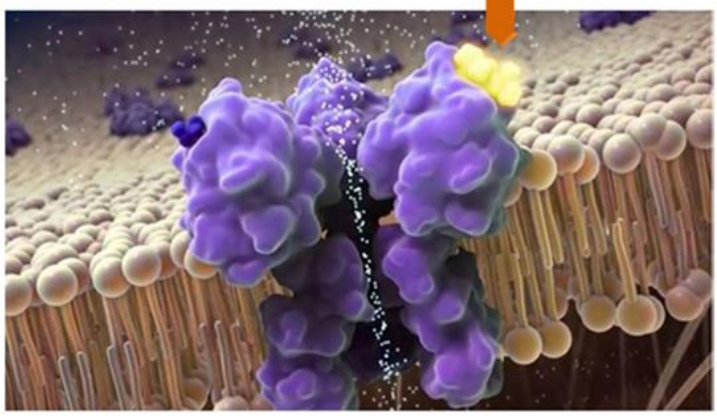
Inhibits NMDA Receptor Activity

VistaGen Therapeutics



Ketamine completely blocks the ion channel of the NMDA receptor

AV-101's active metabolite (7-Cl-KYNA) does not block NMDA receptor activity; it inhibits it



AV-101 vs. Ketamine in Published Preclinical Studies

VistaGen Therapeutics

"The Prodrug 4-Chlorokynurenine Causes Ketamine-Like Antidepressant Effects, but Not Side Effects, by NMDA/GlycineB-Site Inhibition."

Zanos, P., et al. (2015). *J Pharmacol Exp Ther* 355(1): 76-85.

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

The ELEVATE Study

AV-101 Phase 2 Adjunctive Treatment Study for MDD

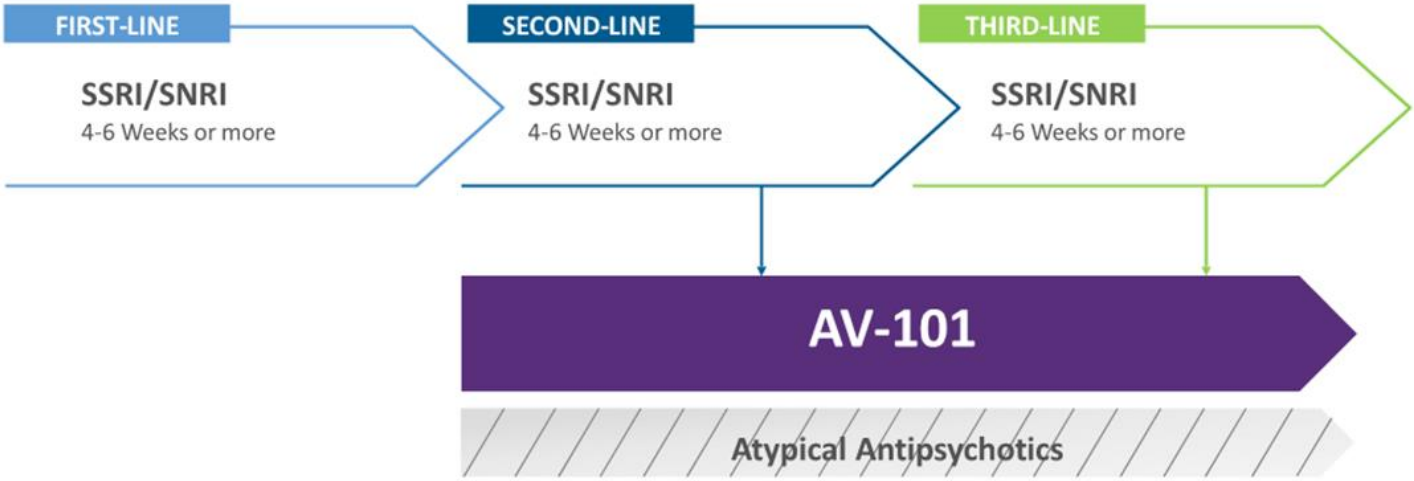
Principal Investigator: Dr. Maurizio Fava, Harvard Medical School

- Adjunctive treatment for MDD patients with an inadequate response to a current FDA-approved oral antidepressant (with a current depressive episode of not more than 2 years)
- Oral dose of AV-101 + current oral antidepressant vs. placebo + current oral antidepressant
- Once per day for 14 days
- Target enrollment, ca. 180 patients
- Target topline results, end of Q3 2019

Primary Endpoint: Change in MADRS-10 from baseline compared to placebo

Initial Objective for AV-101 in MDD

Displace atypical antipsychotics in current MDD drug treatment paradigm



VistaGen Therapeutics

Proposed Next Step: The RELAY Study

Prevent relapse following ketamine-based therapy

- Multi-center, double blind, placebo-controlled, adjunctive treatment study
- AV-101 + standard antidepressant vs. placebo + standard antidepressant in patients who have responded to IV ketamine or intranasal esketamine + standard antidepressant
- Oral dose, once per day for 12 weeks
- Target enrollment: ca. 200 patients
- Target start: 2H 2020

Primary Endpoint: Kaplan-Maier survival analysis for time to relapse following response to IV ketamine or intranasal esketamine

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PH10 for MDD

Rapid-Onset, Exceptional Safety

VistaGen Therapeutics

- Novel CNS neuroactive steroid nasal spray
- Activates nasal chemosensory receptors that trigger neural circuits in the brain leading to antidepressant effects
- Rapid-onset antidepressant efficacy in Phase 2A
- Microgram dose, no systemic exposure
- Well-tolerated, minimal side effects

Phase 2A POC Completed

Preparing to Launch U.S. Phase 2B in 2H 2020

Potential for fast-acting, esketamine-like antidepressant effects, without its psychological side effects and safety concerns

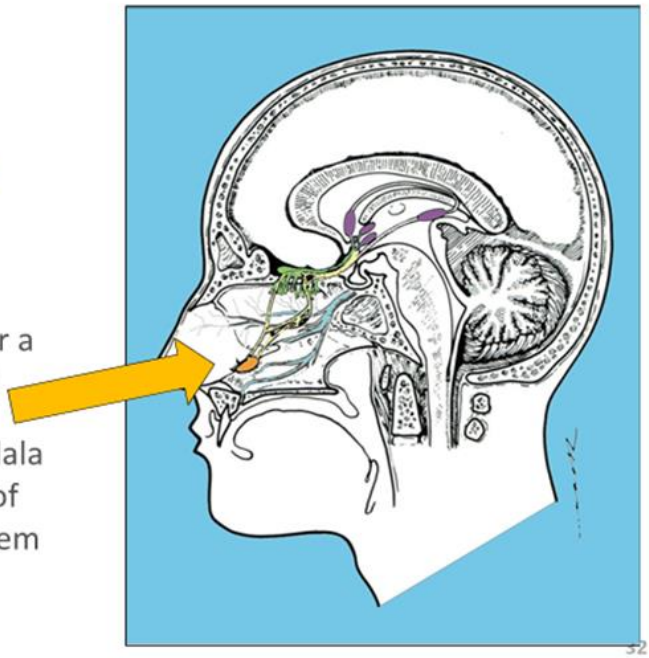
www.vistagen.com

PH10 Mechanism of Action

Activates Neural Circuits Leading to Antidepressant Effects

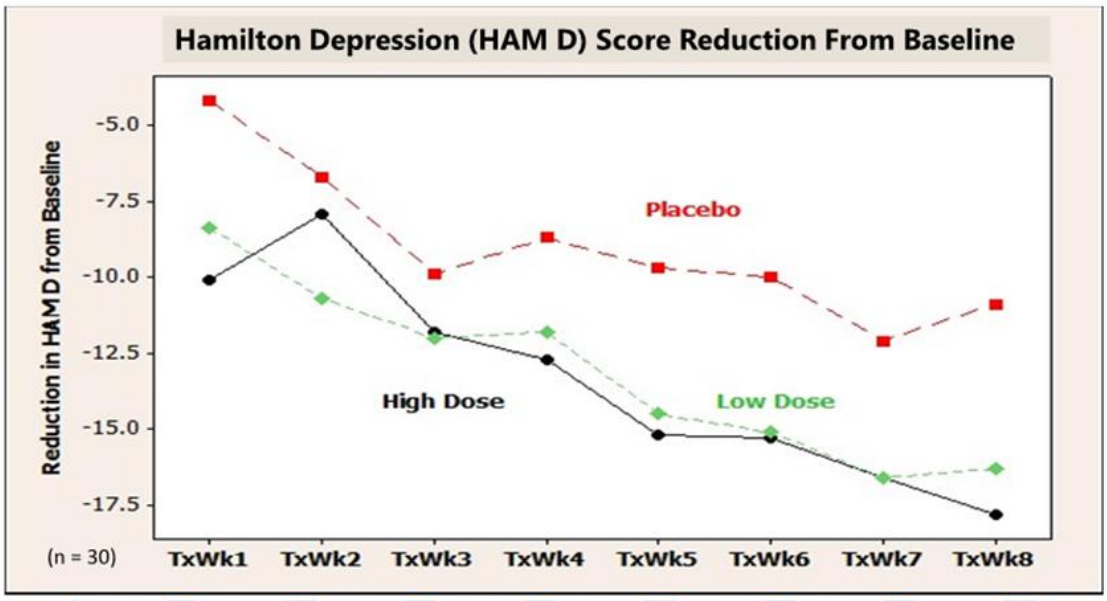
VistaGen Therapeutics

- **Fundamentally different from all current treatments**
- **Activates nasal chemosensory receptors that trigger neural circuits in the brain leading to antidepressant effects**
  - Engages nasal chemosensory receptors that trigger a subset of neurons in the main olfactory bulbs (OB)
  - OB neurons stimulate neurons in the limbic amygdala that release norepinephrine and increase activity of the limbic-hypothalamic sympathetic nervous system



PH10 Phase 2A MDD Study – Monotherapy (n = 22)

VistaGen Therapeutics



PH10 Dose	HAM D Score	P (PH10 vs Placebo)	Cohen's D (Effect Size)
3.2 µg (Low Dose)	16.3	.101	0.74
6.4 µg (High Dose)	17.8	.022	0.95
Placebo	10.9		

Microgram doses of PH10 neuroactive nasal spray improved MDD symptoms with rapid-onset efficacy

PH10 Development for MDD – Next Step

Phase 2B Study

VistaGen Therapeutics

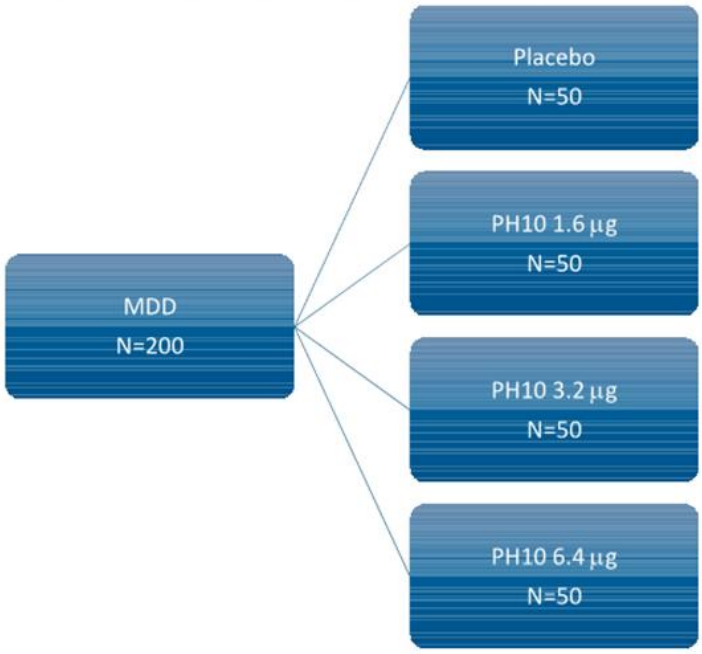
Principal Investigator: Dr. Michael Liebowitz, Columbia University, New York

- Randomized, double-blind, placebo-controlled, multi-center monotherapy study
- MDD patients with zero or 1 prior failure on a standard antidepressant
- Twice a day administration of PH10 (1.6, 3.2 or 6.4 μg) or placebo for 4 Weeks
- Target enrollment, ca. 200 patients
- Target start, 2H 2020
- Target completion, 1H 2022

Primary Endpoint: Change in MADRS from baseline compared to placebo

PH10 Phase 2B MDD Monotherapy Study

4-week study in MDD patients after zero or one standard ADT failure



Summary: AV-101 and PH10 for MDD

Multiple Shots on Goal

Augmentation for inadequate response to SSRIs/SNRIs

- **AV-101 ELEVATE Study (ongoing, topline results in 2019)**

Relapse prevention after successful ketamine-based therapy

- **AV-101 RELAY Study (preparing for launch in 2H 2020)**

First-line monotherapy

- **PH10 Phase 2B Study (preparing for launch in 2H 2020)**

Phase 1B Clinical Program

AV-101

for

Suicidal Ideation

www.vistagen.com

VistaGen® Therapeutics

Nasdaq: VTGN

LOOKING BEYOND CURRENT TREATMENTS FOR CENTRAL NERVOUS SYSTEM (CNS) DISEASES AND DISORDERS WITH HIGH UNMET NEED

AV-101 for Suicidal Ideation

U.S. Department of Veterans Affairs

Baylor College of Medicine

VistaGen Therapeutics

Baylor / VA Phase 1B Clinical Study

- Sponsored by U.S. Department of Veteran's Affairs (VA)
- Ongoing at Baylor University
- First-step target engagement study
- Double-blind, placebo-controlled, crossover design
- Two single doses of AV-101 (720 mg and 1440 mg) and placebo over three weeks
- Target enrollment, 12 healthy U.S. Military Veterans
- Topline results, end of Q4 2019

Primary Objective: Target engagement relevant to NMDA antagonism and suicidal ideation

Additional Potential Programs

AV-101

for

Neuropathic Pain

and

Parkinson's LID

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VistaGen® Therapeutics

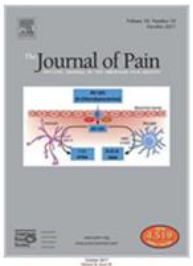
Nasdaq: VTGN

LOOKING BEYOND CURRENT TREATMENTS FOR CENTRAL NERVOUS SYSTEM (CNS) DISEASES AND DISORDERS WITH HIGH UNMET NEED

VistaGen Therapeutics

AV-101 for Neuropathic Pain

- Potential oral non-opioid treatment option
- Non-addictive and non-sedating in published preclinical studies
- FDA Fast Track designation



"[W]e've undertaken … steps to advance the development of non-addictive treatments for pain."[1]

Scott Gottlieb, M.D., FDA Commissioner

Potential Next Step: Phase 2A study

AV-101 for Parkinson's LID

- Parkinson's disease (PD) levodopa-induced dyskinesia (LID)
- Reduced mean dyskinesia scores in Parkinsonian monkeys with LID, without worsening Parkinson's symptoms
- Potential to replace oral amantadine for PD LID

Potential Next Step: Phase 2A study

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

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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.
President, Chief Scientific Officer
- 23 years of experience in senior biotechnology 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

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Board of Directors

VistaGen Therapeutics

Jon Saxe Chairman

- 35 years of biopharmaceutical experience, director of multiple public and private healthcare companies
- Former President and Director, PDL BioPharma; CEO, Synergen (acquired by Amgen for $262M); VP, Licensing and Corporate Development, Head of Patent Law, Hoffmann-La Roche

Jerry Gin, Ph.D., MBA

- 45 years of healthcare industry experience; Co-Founder of Oculex (acquired by Allergan for $230M)
- Co-Founder, President and CEO of Nuvora

Ann Cunningham, MBA

- 20 years of experience including commercial and leadership roles at multiple global companies in the pharmaceutical industry
- Teva Pharmaceuticals; Otsuka America Pharmaceutical; Eli Lilly and Company

Shawn Singh, JD, CEO

- 25 years of experience with biopharmaceutical companies, a venture capital firm and a profitable CRO
- Artemis Neuroscience; SciClone Pharmaceuticals; Cato BioVentures; Cato Research

Brian Underdown, Ph.D.

- 30 years of leadership experience in biopharmaceutical sector; key player in growth of 10 Life Science companies
- Former VP, Research, Pasteur Merieux Connaught (now Sanofi Pasteur); Venture Partner, Lumira Capital

Ralph Snodgrass, Ph.D. President, CSO

- 23 years of experience in senior biotechnology management
- Progenitor; Lineberger Comprehensive Cancer Center

Distinguished 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

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Looking beyond current therapies for CNS diseases and disorders with high unmet need

VistaGen Therapeutics

3 late-stage CNS product candidates

Multiple large target markets where current treatments fall short

New generation MOAs

Rapid-onset potential

Exceptional safety

At-home administration

VistaGen® Therapeutics

LOOKING BEYOND CURRENT TREATMENTS FOR CNS DISEASES AND DISORDERS WITH HIGH UNMET NEED

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VistaGen Reports Top Line Results from NIMH's Exploratory Study of AV-101 Monotherapy for Treatment-Resistant Depression

SOUTH SAN FRANCISCO, Calif., May 2, 2019 - VistaGen Therapeutics (NASDAQ: VTGN), a clinical-stage biopharmaceutical company developing new generation medicines for depression, social anxiety disorder and other central nervous system (CNS) diseases and disorders with high unmet need, today announced top line results from an exploratory Phase 2 clinical study of AV-101 as a monotherapy (which is treatment without a concurrent FDA-approved antidepressant) in patients with treatment-resistant depression (TRD). In the 19-patient study sponsored and conducted by the U.S National Institute of Mental Health (NIMH), AV-101 did not demonstrate significant separation from placebo on the primary outcome measure, the change from baseline in the Hamilton Depression Rating Scale (HDRS) total score compared to placebo. A key objective of the study was to evaluate safety in TRD patients, and, consistent with VistaGen's Phase 1 studies, AV-101 was very well-tolerated with no ketamine-like psychological side effects or safety concerns and no treatment-related serious adverse events.

"Although this small NIMH monotherapy study did not meet its primary endpoint in this very difficult-to-treat TRD population, we remain firmly committed to developing novel treatments for those suffering from MDD. In contrast to the NIMH study, our ongoing ELEVATE study is designed to evaluate AV-101 as a novel adjunctive therapy in a significantly different population of MDD patients, namely those whose current depressive episode is less than 2 years. ELEVATE is on track and we will announce top line results later this year," stated Shawn Singh, VistaGen's CEO. "We greatly appreciate our long-standing relationship with the NIMH and are grateful for their efforts conducting and providing financial sponsorship for this exploratory study. In addition, we appreciate receiving additional positive safety data from this study and are encouraged that AV-101 was very well-tolerated, without any troubling side effects or safety concerns, in TRD patients suffering from one of the most debilitating forms of depression."

The double-blind, placebo-controlled, crossover study was conducted at the National Institutes of Health (NIH) Clinical Center in Bethesda, Maryland. Patients with TRD were required to taper off all antidepressant medications, including all adjunctive atypical antipsychotics, for 2 to 5 weeks, and then remain medication free for an additional 2 weeks prior to dosing. Patients were then randomized to receive either a daily dose of AV-101 for 14 days (1080 mg for 7 days followed by 1440 mg for 7 days) or placebo for 14 days. After a 2- to 3-week washout period following the initial 14-day dosing phase, patients were crossed over to the opposite arm of the study.

People who are currently struggling with Major Depressive Disorder (MDD) are considered to have TRD if they have not responded adequately to at least 2 different antidepressants of adequate dose and duration in their current depressive episode. Patients in this NIMH study had serious, long-lasting episodes of depression. The average length of the current depressive episode of the TRD patients in this study was 8.6 years. Prior to participating in this study, patients had undergone an average of 7.8 attempts to treat their TRD over their lifetime, using multiple different antidepressant drugs.

The NIMH plans to present detailed results from this study at a scientific meeting later this year.

About Major Depressive Disorder (MDD)
Major depressive disorder is a serious neurobiologically-based mood disorder, affecting approximately 16 million adults in the U.S., according to the NIMH. Individuals diagnosed with MDD exhibit depressive symptoms, such as a depressed mood or a loss of interest or pleasure in daily activities, for more than a two-week period, as well as impaired social, occupational, educational or other important functioning which has a negative impact on their quality of life. Globally, MDD affects nearly 300 million people of all ages and is the leading cause of disability worldwide.

About Treatment-Resistant Depression (TRD)
People who are currently struggling with MDD are considered to have TRD if they have not responded adequately to at least 2 different antidepressants of adequate dose and duration in their current depressive episode. TRD is a chronic condition that places an ongoing emotional, functional, and economic burden on the individual, their loved ones and society.

About AV-101
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 a Phase 2 clinical study (the ELEVATE study) for adjunctive treatment of MDD and a first-step target engagement study in healthy volunteer U.S. military Veterans. The FDA has granted Fast Track designation for development of AV-101 as both a potential adjunctive treatment for MDD and as a non-opioid treatment for neuropathic pain.

About ELEVATE
Among VistaGen's core objectives for AV-101 is to displace atypical antipsychotics, such as aripiprazole and brexpiprazole, in the current MDD drug treatment paradigm. The Company's ELEVATE study is designed to advance on that objective. The ELEVATE study is an ongoing randomized, double-blind, placebo-controlled, multi-center U.S. Phase 2 clinical study to evaluate the efficacy and safety of adjunctive use of AV-101 in adult MDD patients who have an inadequate response to standard FDA-approved antidepressant therapy, either a selective serotonin reuptake inhibitor (SSRI), a serotonin norepinephrine reuptake inhibitor (SNRI), or bupropion. Only patients whose current depression episode is less than 2 years will be randomized to receive either AV-101 or placebo, in addition to their ongoing standard FDA-approved antidepressant. The primary endpoint of the study is the change from baseline on the Montgomery-Åsberg Depression Rating Scale (MADRS) total score.

About VistaGen

VistaGen Therapeutics is a clinical-stage biopharmaceutical company developing new generation medicines for depression, social anxiety disorder and other CNS diseases and disorders with high unmet need. VistaGen's current CNS pipeline includes three drug candidates, AV-101, PH10, and PH94B, with potential for at-home use, rapid-onset therapeutic benefits and exceptional safety. 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, 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 our drug candidates, including AV-101, (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.

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