

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

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): **October 8, 2019**

VistaGen Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

NEVADA
(State or other jurisdiction of incorporation)

000-54014
(Commission File Number)

20-5093315
(IRS Employer Identification Number)

343 Allerton Ave.
South San Francisco, California 94090
(Address of principal executive offices)

(650) 577-3600
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$0.001 per share	VTGN	Nasdaq Capital Market

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 October 8, 2019, VistaGen Therapeutics, Inc. (the “Company”) began utilizing a new corporate presentation, a copy of which is attached to this Current Report on Form 8-K as Exhibit 99.1.

The information in 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 Events.

On October 8, 2019, the Company issued a press release announcing that the last patient completed dosing in the Company's ELEVATE Phase 2 clinical study of AV-101 as an adjunctive treatment with an FDA-approved oral antidepressant for major depressive disorder. The Company remains on track to report top line results of the ELEVATE study before the end of 2019. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.2.

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: October 8, 2019

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

EXHIBIT INDEX

Exhibit Number	Description
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99.1	VistaGen Therapeutics, Inc. Corporate Presentation, dated October 2019.
99.2	Press Release issued by VistaGen Therapeutics, Inc., dated October 8, 2019.



VistaGen®
Therapeutics

www.vistagen.com

 Nasdaq: VTGN

Fall 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, 2019, filed with the Securities and Exchange Commission (SEC) on June 25, 2019, 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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Looking Beyond Current Treatments for CNS Diseases and Disorders with High Unmet Need

VistaGen is developing differentiated new generation medications for large and growing mental health and neurology markets where current treatments are inadequate to meet the needs of millions of patients worldwide.


VistaGen®
Therapeutics

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

New generation MOAs

3 differentiated clinical-stage product candidates

Fast-acting, exceptional safety

Multiple large and growing CNS markets

Potentially transformative milestones in 2H 2019

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Our Pipeline

Product Candidate	Indication	Preclinical	Phase 1	Phase 2	Phase 3
PH94B [*]	Social Anxiety Disorder ¹				
	Generalized Anxiety Disorder ¹				
	Peripartum Anxiety ¹				
	Preoperative Anxiety ¹				
	Panic Disorder ¹				
	PTSD ¹				
AV-101 [*]	Major Depressive Disorder ^{1,2}				
	Neuropathic Pain ^{1,3}				
	LID associated with Parkinson's Therapy ¹				
	Suicidal Ideation ^{1,3}				
	Epilepsy ¹				
PH10 [*]	Major Depressive Disorder ¹				
	Treatment-Resistant Depression ¹				
	Suicidal Ideation ¹				
	Peripartum Depression ¹				

* All potential future studies are subject to securing sufficient internal and/or collaborative third-party funding
 1 FDA Fast Track designation

1. Preparing for initial Phase 3 study
2. Assessing for potential Phase 2b study
3. Assessing for potential Phase 2a study

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PH94B neuroactive nasal spray

(3 β)-androsta-4,16-dien-3-ol

Novel, fast-acting, non-systemic therapy for:

- Social Anxiety Disorder
- Generalized Anxiety Disorder
- Peripartum Anxiety
- Preoperative Anxiety
- Panic Disorder
- Post-Traumatic Stress Disorder



VistaGen[®]
Therapeutics



Social Anxiety Disorder (SAD) in the U.S.

More than Just Shyness



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

Affects as many as
20 million¹
Americans



¹Harvard Medical School, 2007. National Comorbidity Survey (NCS). (Update - 2017, August 21). Kessler, et al, US National Comorbidity Survey Replication, 2005. <https://www.nimh.nih.gov/health/publications/social-anxiety-disorder-more-than-just-shyness/index.shtml>

Current SAD Drug Treatments Fall Short



Not FDA-Approved
*** Prescribed Off-label ***

Antidepressants (2 SSRIs, 1 SNRI)

- ✗ Slow onset, chronic administration
- ✗ May worsen anxiety initially
- ✗ Significant potential side effects
 - ❖ Nausea and vomiting
 - ❖ Weight gain
 - ❖ Sleepiness
 - ❖ Sexual problems
- ✗ Potential drug-drug interaction

Benzodiazepines & Beta Blockers

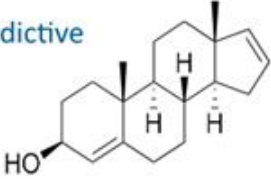
- ✗ Addiction risk
- ✗ Significant potential side effects
 - ❖ Nausea and vomiting
 - ❖ Blurred vision
 - ❖ Dizziness
 - ❖ Sedation
 - ❖ Confusion and cognitive impairment



There is no FDA-approved, fast-acting treatment for SAD

PH94B for SAD

- Fundamentally different from all current SAD therapies
- Successful Phase 2 completed; Phase 3 in 2020
- Fast-acting efficacy (10-15 minutes), exceptional safety
- Microgram dose, non-systemic
- Well-tolerated, non-sedating, non-addictive

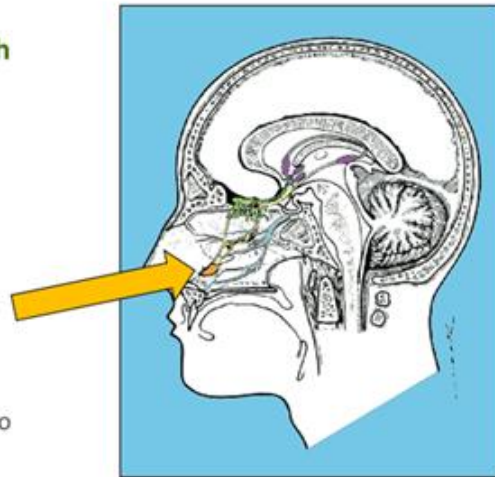
Potential to be first FDA-approved fast-acting treatment for SAD



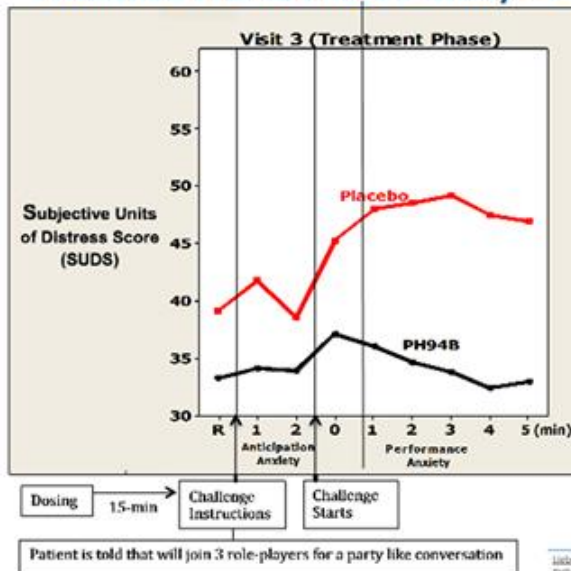
PH94B Mechanism of Action

- Engages nasal chemosensory receptors, which activate neural circuits in the brain that suppress fear and anxiety
 - Engages nasal chemosensory receptors, which activate olfactory bulb neurons that project to the limbic amygdala
 - Modulates activity of the limbic-hypothalamic autonomic nervous system, which is involved in the pathophysiology of SAD and multiple other anxiety and mood disorders
 - Does not require systemic uptake and distribution to produce its pharmacological effects



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



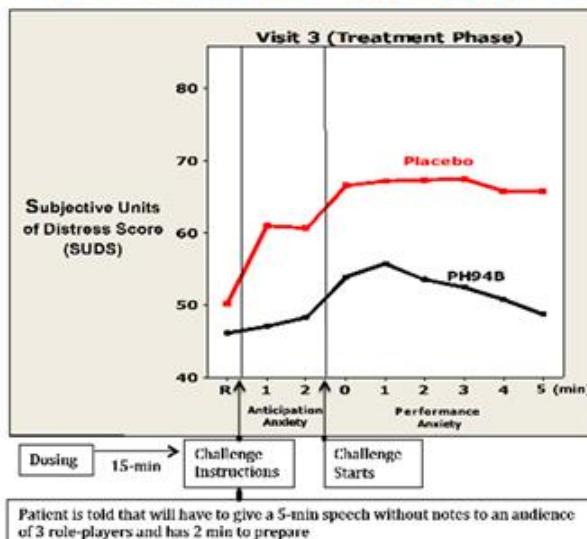
PH94B Rapidly Reduced Anxiety in Response to Social Interaction Challenge

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

Litwack, M.R., Salzman, F., Nicolini, H., Rosenblatt, 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.

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



PH94B Rapidly Reduced Anxiety in Response to Public Speaking Challenge

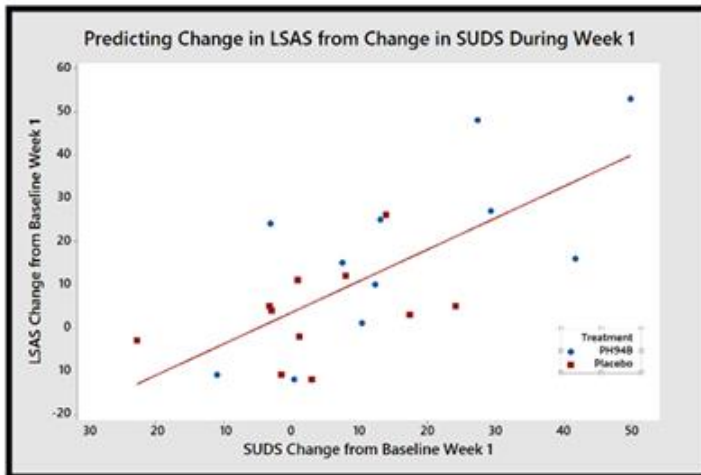
Active Group:	Placebo Group:
Mean Difference = 26.7	Mean Difference = 14.0
Standard Deviation = 21.6	Standard Deviation = 16.3
Number of Subjects = 45	Number of subjects = 46

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

Litwack, M.R., Salzman, F., Nicolini, H., Rosenblatt, 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 Pilot Phase 3 Crossover Study



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%)

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PH94B Phase 3 Development Plan for SAD Initial Phase 3 Study

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

- Randomized, double-blind, placebo-controlled, monotherapy study
- 3.2 µg of PH94B or placebo for 4 weeks
- Multi-center, ca. 15 sites in North America
- Target enrollment, ca. 200 patients (100 PH94B and 100 placebo)
- Target launch, 2H 2020
- Target completion, 2H 2021

Primary Endpoint: Change in LSAS from baseline compared to placebo

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AV-101

L-4-chlorokynurenine

Novel oral NMDA receptor GlyB antagonist for:

- Major Depressive Disorder
- Suicidal Ideation
- Neuropathic Pain
- Levodopa-Induced Dyskinesia associated with Parkinson's Therapy
- Epilepsy



VistaGen[®]
Therapeutics



Major Depressive Disorder in the U.S.

1 in 4 women



1 in 6 men



diagnosed with depressive disorders



1 in 8



age 12 and over takes an antidepressant¹

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. Ruth AJ, et al. Am J Psychiatry. 2006; 163(11): 1905-1917 (STAR*D Study); 3. Decision Resources 2016.

FDA-Approved MDD Treatments Fall Short

Current Oral 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 potential side effects
 - Anxiety, sexual dysfunction, insomnia, dizziness, nausea and vomiting, headache, sweating

Atypical Antipsychotics

- Often do not work
 - Only ca. 20% of patients respond to augmentation
- Significant potential side effects
 - Weight gain, stomach pain, tiredness, dizziness, tardive dyskinesia, headache, nervousness, restlessness

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Ketamine Therapy for Treatment-Resistant Depression

Intravenous ketamine



“Ketamine offers lifeline for people with severe depression, suicidal thoughts”



Intranasal ketamine



“J&J’s new ketamine-like depression drug Spravato off to ‘very, very strong start,’ company says”

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

“In the clinical trials, the most common side effects of SPRAVATO™ when used along with an antidepressant taken by mouth included: dissociation, dizziness, nausea, sedation, spinning sensation, reduced sense of touch and sensation, anxiety, lack of energy, increased blood pressure, vomiting, and feeling drunk.”¹

Janssen Pharmaceuticals, Inc.
Press Release, March 5, 2019

- Side Effects?**
- Safety Concerns?**
- High Cost?**
- Inconvenience?**
- Compliance?**
- Durability?**

1. Johnson & Johnson Press Release. Janssen Announces U.S. FDA Approval of SPRAVATO™ (esketamine) CII Nasal Spray for Adults with Treatment-Resistant Depression (TRD) Who Have Cycled Through Multiple Treatments Without Relief. Available at: <https://www.jnj.com/janssen-announces-u-s-fda-approval-of-spravato-2-esketamine-cii-nasal-spray-for-adults-with-treatment-resistant-depression-trd-who-have-cycled-through-multiple-treatments-without-relief>

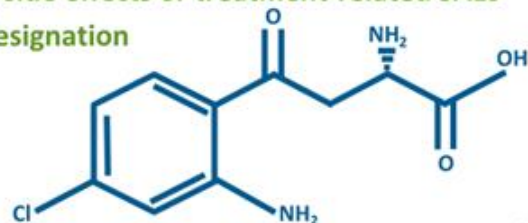
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AV-101 for MDD: Transformative Potential Rapid-onset Potential, Exceptional Safety



- 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
- FDA Fast Track designation

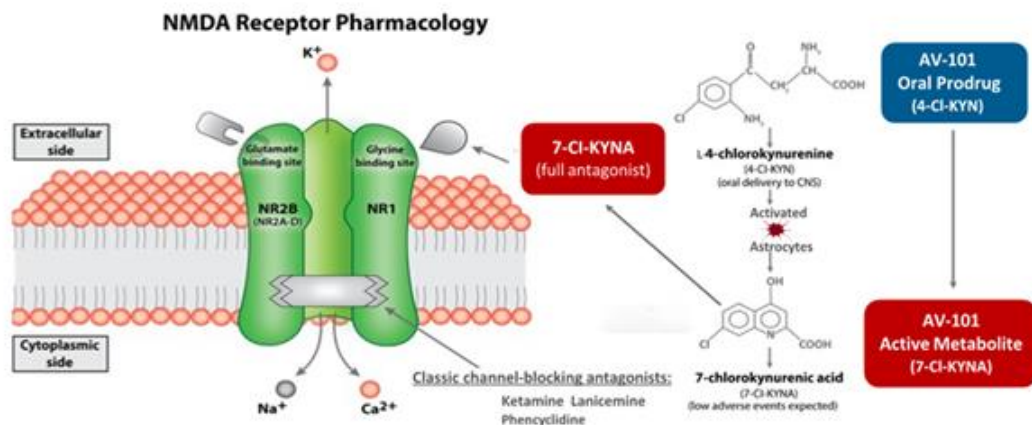
ELEVATE Phase 2 study completed
Top line results 2H 2019



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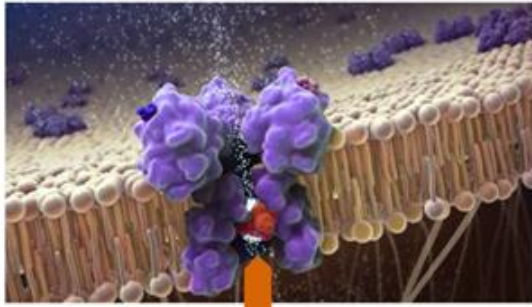
AV-101's Mechanism of Action

4-Cl-KYN (prodrug) → 7-Cl-KYNA (active metabolite)



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AV-101 Inhibits NMDA Receptor Activity



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

Ketamine-Like Antidepressant Effects, without Ketamine's Side Effects



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

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

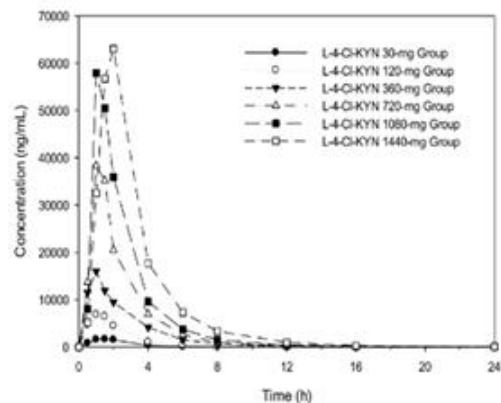
AV-101 Published Phase 1 Clinical Trials AV-101 is Very Well Tolerated and Orally Bioavailable

- Plasma half-life is about 2 hr
- Dosed up to 1440 mg daily for 2 weeks
- Adverse events were placebo-like except for some feelings of euphoria or "well-being" especially at the higher doses
- **No ketamine-like psychosis**
- No QT prolongation
- No abnormalities in clinical chemistry or hematology



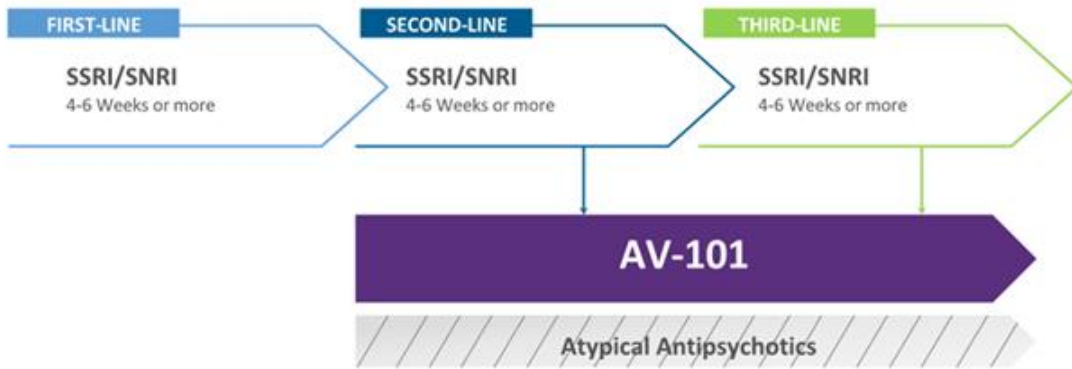
Clinical pain research
Randomized, double-blind, placebo-controlled, dose-escalation study: Investigation of the safety, pharmacokinetics, and antihyperalgesic activity of L-4-chlorokynurenine in healthy volunteers
Mark Wallace^{1,2}, Alexander White¹, Kathy A. Grako¹, Randal Lane¹, Allen (Jo) Cato¹, H. Ralph Swadlow¹

Plasma levels of AV-101 in normal volunteers following single oral dosing



Initial Objective for AV-101 in MDD

Displace atypical antipsychotics in current MDD treatment paradigm



AV-101 for MDD – The ELEVATE Study

Phase 2 Clinical Study of AV-101 as an Adjunctive Treatment for MDD

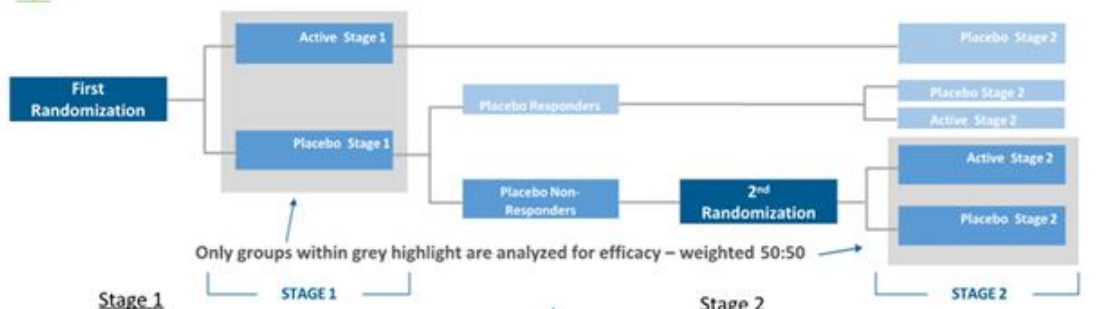
Principal Investigator: **Dr. Maurizio Fava, Harvard Medical School**

- Multi-center U.S. Phase 2 clinical study
- Evaluation of efficacy and safety of AV-101 as an adjunctive treatment for adult MDD patients with an inadequate response to their current SSRI / SNRI therapy
- SSRI/SNRI + AV-101 or placebo, 1x/day for 14 days
- Sequential Parallel Comparison Design (SPCD)
- Target enrollment (n=180) achieved August 2019; study completed
- Top line results, 2H 2019

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

AV-101 for MDD – The ELEVATE Study

Sequential Parallel Comparison Design (SPCD)



- Compares drug vs. placebo in a standard parallel design
- 3:1 ratio of placebo: drug generates a large cohort of placebo non-responders

- Compares drug vs. placebo only in placebo non-responders
- Drug vs. placebo differences are expected to be greater

CLINICAL TRIAL METHODOLOGY DESIGNED TO OVERCOME
CHALLENGE OF PLACEBO EFFECTS IN NEUROPSYCHIATRIC STUDIES

PH10 neuroactive nasal spray

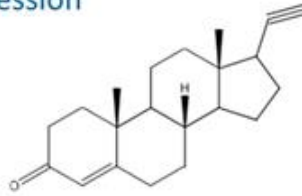
Pregn-4-en-20-yne-3-one



VistaGen®
Therapeutics

Novel, safe, fast-acting therapy for:

- Major Depressive Disorder
- Treatment-Resistant Depression
- Peripartum Depression
- Suicidal Ideation



Nasdaq: VTGN

www.vistagen.com

PH10 Neuroactive Nasal Spray

Rapid-Onset, Exceptional Safety



- Fundamentally different from all current depression therapies
- Successful Phase 2a completed
- Rapid-onset antidepressant efficacy demonstrated in Phase 2a
- Microgram dose, non-systemic
- Well-tolerated, minimal side effects
- Stand-alone and adjunctive potential
- Preparing for Phase 2b

Potential at-home therapy with fast-acting, esketamine-like antidepressant effects, without potential psychological side effects and safety concerns associated with ketamine therapy

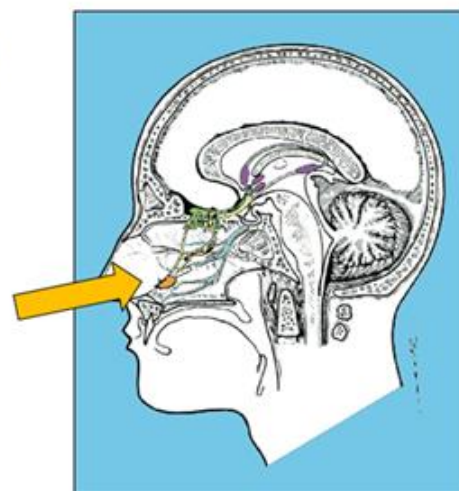
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www.vistagen.com

PH10 Mechanism of Action



- Engages nasal chemosensory receptors, which activate neural circuits in the brain leading to antidepressant effects
 - Engages nasal chemosensory receptors, which activate olfactory bulb neurons that project to the limbic amygdala
 - OB neurons stimulate neurons in the limbic amygdala that release norepinephrine and increase activity of the limbic-hypothalamic sympathetic nervous system
 - Does not require systemic uptake and distribution to produce its pharmacological effects



PH10 Phase 1 Safety and Tolerability Study

PH10 found to be safe to use in clinical studies

Study Design

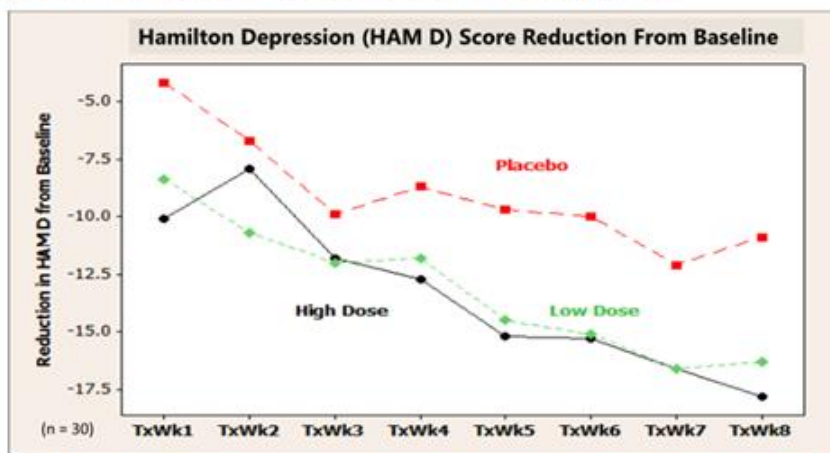
- Open, prospective, multiple flexible doses, controlled with placebo in 12 healthy volunteers
- Dose range: 0.8 µg to 6.4 µg
- Self-administered intranasally in escalating doses

Conclusions

- Different escalating doses of PH10 administered to Group A (0.8 µg to 2.4 µg) and Group B (3.2 µg to 6.4 µg) were well tolerated and did not produce local (nasal) or general severe adverse effects (SAEs) that were different from the effect of administration of placebo nasal spray
- No significant findings on clinical laboratory markers, vital signs, neuropsychological assessments, cognitive brain mapping or evoked (cognitive) potentials
- Most frequent AE's: increased appetite, dizziness, and somnolence of mild intensity

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PH10 Phase 2a MDD Monotherapy Study (n = 22)



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

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		

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PH10 Phase 2b Development Plan for MDD

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 /1H 2021

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

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AV-101 for Suicidal Ideation



U.S. Department
of Veterans Affairs



Baylor / VA Phase 1b Clinical Study (ongoing)

- Sponsored by U.S. Department of Veteran's Affairs (VA)
- 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, ca. 12 healthy U.S. Military Veterans
- Top line results, end of Q4 2019

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

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AV-101 for Neuropathic Pain in Preclinical Studies



- Significant dose-response with similar efficacy in a rat model of a mononeuropathy as compared to gabapentin (Neurontin) and pregabalin (Lyrica)
- Robust analgesic effects, similar to gabapentin and pregabalin, but fewer side effects as measured in the rotarod assay
- Potential oral non-opioid treatment option
- Non-addictive and non-sedating
- FDA Fast Track designation



Potential Next Step: Phase 2a study

1. FDA Commissioner Scott Gottlieb, M.D., <https://www.fda.gov/news-events/press-announcements/ucm638811.htm>

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AV-101 for Levodopa-induced Dyskinesia Associated with Parkinson's Therapy in Preclinical Studies



- Antidyskinetic effects in the MPTP primate model similar to those generally observed with amantadine therapy, but without adverse effects experienced with amantadine
- Significantly ($p = 0.01$) reduced LID without affecting the timing, extent, or duration of the anti-Parkinsonian therapeutic benefits of levodopa
- Potential to replace oral amantadine for LID associated with Parkinson's therapy
- Potential FDA Fast Track designation



Potential Next Step: Phase 2a study

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Distinguished Clinical and Regulatory Advisors

<p>HARVARD UNIVERSITY</p>	<p>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</p>		<p>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</p>
<p>COLUMBIA UNIVERSITY DEPARTMENT OF PSYCHIATRY</p>	<p>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</p>		<p>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</p>
	<p>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)</p>		<p>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</p>

Experienced Team Leading Execution

<p>Ralph Snodgrass, Ph.D. President, Chief Scientific Officer</p> <ul style="list-style-type: none"> • 23 years of experience in senior biotechnology management • Progenitor; Lineberger Comprehensive Cancer Center 		<p>Shawn K. Singh Chief Executive Officer</p> <ul style="list-style-type: none"> • 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
<p>Mark A. Smith, M.D., Ph.D. Chief Medical Officer</p> <ul style="list-style-type: none"> • 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 		<p>Jerrold D. Dotson, CPA Chief Financial Officer, Secretary</p> <ul style="list-style-type: none"> • 20 years of experience in senior management finance and administration • Calypso Biomedical; Discovery Foods; California & Hawaiian Sugar; Clorox
		<p>Mark A. McPartland Vice President, Corporate Development</p> <ul style="list-style-type: none"> • 20 years of experience in corporate development, capital markets and management consulting • Stellar Biotechnologies; MZ Group; Hayden Communications; Alliance Advisors

Board of Directors

<p>Jerry Gin, Ph.D., MBA</p> <ul style="list-style-type: none"> • 45 years of healthcare industry experience; Co-Founder of Oculex (acquired by Allergan for \$230M) • Co-Founder, President and CEO of Nuvoira 	<p>Jon Saxe Chairman</p> <ul style="list-style-type: none"> • 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
<p>Shawn Singh, JD, CEO</p> <ul style="list-style-type: none"> • 25 years of experience with biopharmaceutical companies, a venture capital firm and a profitable CRO • Artemis Neuroscience; SciClone Pharmaceuticals; Cato BioVentures; Cato Research 	<p>Ann Cunningham, MBA</p> <ul style="list-style-type: none"> • 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
<p>Ralph Snodgrass, Ph.D. President, CSO</p> <ul style="list-style-type: none"> • 23 years of experience in senior biotechnology management • Progenitor; Lineberger Comprehensive Cancer Center 	<p>Brian Underdown, Ph.D.</p> <ul style="list-style-type: none"> • 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

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

New generation MOAs

3 differentiated clinical-stage product candidates

Fast-acting, exceptional safety

Multiple large and growing CNS markets

Potentially transformative milestones in 2H 2019



VistaGen[®]
Therapeutics

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

 Nasdaq:VTGN



VistaGen Therapeutics Announces Last Patient Completes Dosing in the ELEVATE Phase 2 Study of AV-101 for Major Depressive Disorder

Company on Track to Report Top Line Results Before Year End

SOUTH SAN FRANCISCO, Calif., October 08, 2019 – VistaGen Therapeutics (NASDAQ: VTGN), a clinical-stage biopharmaceutical company developing new generation medicines for central nervous system (CNS) diseases and disorders with high unmet need, announced today that the last patient has completed dosing in the ELEVATE Phase 2 clinical study of AV-101, the Company's novel, oral NMDA (N-methyl-D-aspartate) receptor glycine site antagonist, as an adjunctive (add-on) treatment with an FDA-approved oral antidepressant for major depressive disorder (MDD). The Company remains on track to report top line results of the ELEVATE study before the end of 2019.

About AV-101

AV-101 (4-Cl-KYN) belongs to a new generation of investigational medicines in neuropsychiatry and neurology known as NMDA glutamate receptor modulators. The NMDA receptor is a pivotal receptor in the brain and abnormal NMDA function is associated with numerous CNS diseases and disorders. AV-101 is an oral prodrug of 7-Cl-KYNA, a potent and selective full antagonist of the glycine coagonist site of the NMDA receptor. With its exceptional safety profile in all studies to date, AV-101 has potential to be a new at-home treatment for multiple large market CNS indications where current treatments are inadequate to satisfy high unmet patient needs. VistaGen is currently focused on AV-101's potential to treat depression, dyskinesia associated with levodopa therapy for Parkinson's disease, epilepsy, neuropathic pain and suicidal ideation. The FDA has granted Fast Track designation for development of AV-101 as a potential adjunctive treatment for MDD and as a non-opioid treatment for neuropathic pain.

About the ELEVATE Study

Among VistaGen's key objectives for AV-101 in MDD is to replace atypical antipsychotics in the current MDD drug treatment paradigm and redefine the standard of care for individuals who are unable to reduce their symptoms of depression with their current oral antidepressant alone. The ELEVATE study is VistaGen's U.S. multi-center, randomized, double-blind, placebo-controlled 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 oral antidepressant therapy. VistaGen achieved target enrollment (n = 180) in the ELEVATE study in August 2019. The primary endpoint of the ELEVATE study is the change from baseline on the Montgomery-Åsberg Depression Rating Scale (MADRS-10) total score.

About Major Depressive Disorder (MDD)

MDD is a serious neurobiologically-based mood disorder, affecting approximately 17.3 million adults in the U.S., or 7.1% of the U.S. adult population, according to the U.S. National Institute of Mental Health. 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 according to the World Health Organization.

About VistaGen

VistaGen Therapeutics is a clinical-stage biopharmaceutical company developing new generation medicines for CNS diseases and disorders where current treatments are inadequate, resulting in high unmet need. VistaGen's pipeline includes three differentiated, clinical-stage CNS drug candidates, AV-101, PH10 and PH94B, each with an exceptional safety profile in all clinical studies to date and therapeutic potential in multiple large and growing CNS markets. 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 three drug candidates, (i) AV-101 for depression, dyskinesia associated with levodopa therapy for Parkinson's disease, epilepsy, neuropathic pain and suicidal ideation ; (ii) PH94B for social anxiety disorder, generalized anxiety disorder, peripartum anxiety, preoperative anxiety, panic disorder and post-traumatic stress disorder; and (iii) PH10 for MDD, peripartum depression and suicidal ideation. In addition, statements concerning the Company's future expectations may include statements regarding intellectual property and commercial protection of our drug candidates. Each of these statements 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, including for AV-101 during the ELEVATE study, (iii) success in preclinical studies or in early-stage clinical trials may not be repeated or observed in ongoing or future studies, and ongoing or future preclinical and clinical results may not support further development of, or be sufficient to gain regulatory approval to market AV-101, (iv) decisions or actions of regulatory agencies may negatively affect the progress of, and our ability to proceed with, 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 required 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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