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): June 14, 2021

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:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
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 \Box

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 \Box

Item 7.01 Regulation FD Disclosure.

On June 14, 2021, 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 9.01 Financial Statements and Exhibits.

(d) Exhibits Index

 Exhibit No.
 Description

 99.1
 VistaGen Therapeutics, Inc. Corporate Presentation, dated June 2021.

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.

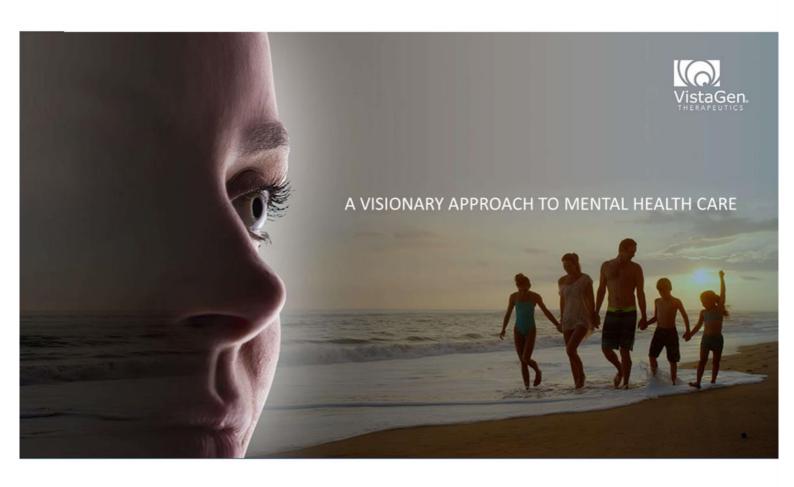
VistaGen Therapeutics, Inc.

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

Date: June 14, 2021

Exhibit No.	Description	
99.1	VistaGen Therapeutics Inc. Corporate Presentation, dated June 2021	





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 involve known and unknown risks that are difficult to predict and include all matters that are not historical facts. These forward-looking statements include information concerning the impact of the COVID-19 pandemic, our product candidates, development efforts, collaborations, intellectual property, financial condition, plans, development programs, prospects or future events and involve known or unknown risks that are difficult to predict. In some cases, you can identify forward-looking statements by the use of words such as "may," "could," "expect," "project," "outlook," "strategy," "intend," "plan," "seek," "anticipate," "believe," "estimate," "predict," "potential," "strive," "goal," "continue," "likely," "will," "would" and variations of these terms and similar expressions, or the negative of these terms or similar expressions. Such forward-looking statements are necessarily based upon estimates and assumptions that, while considered reasonable by us and our management, are inherently uncertain.

Our actual results or developments may differ materially from those projected or implied in these forward-looking statements. Factors that may cause such a difference include, without limitation, risks and uncertainties relating to the impact of the COVID-19 pandemic; market conditions; the impact of general economic, industry or political conditions in the United States or internationally; adverse healthcare reforms and changes of laws and regulations; manufacturing and marketing risks, including risks related to the COVID-19 pandemic, which may include, but are not limited to, unavailability of or delays in delivery of raw materials for manufacture of our CNS drug candidates and difficulty in initiating or conducting clinical trials; inadequate and/or untimely supply of one or more of our CNS drug candidates; and the risks more fully discussed in the section entitled "Risk Factors" in our most recent Annual Report on Form 10-K for the year ended March 31, 2020, and in our most recent Quarterly Report on Form 10-Q for the quarter ended December 31, 2020, as well as discussions of potential risks, uncertainties, and other important factors in our other filings with the U.S. Securities and Exchange Commission (SEC).

Our SEC filings are available on the SEC's website at www.sec.gov. Given these uncertainties, you should not place undue reliance on these forward-looking statements, which apply only as of the date of this presentation 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, other than as may be required by law. If we do update one or more forward-looking statements, no inference should be made that we will make additional updates with respect to those or other forward-looking statements.



COMPANY HIGHLIGHTS

- Three innovative CNS drug candidates advancing in clinical development
 - Unique mechanisms of action
 - · Therapeutic potential in multiple anxiety, depression and neurology markets
 - · Lead candidate in NDA-enabling Phase 3 development for acute treatment of anxiety in adults with Social Anxiety Disorder
 - · FDA Fast Track Designation in Social Anxiety Disorder, Major Depressive Disorder and Neuropathic Pain

Numerous catalysts anticipated 2021 – 2023

- Clinical: Multiple NDA-enabling Phase 3 trials and Phase 2 trials beginning in 2021/2022 with top line results in 2022 and 2023
- Regulatory: Potential for NDA submission in 1H 2023, Breakthrough Designation for SAD, and additional Fast Track Designations
- · Partnering: Exploring options to further expand ex-US development and commercial partnerships
- Solid Institutional Shareholder Base
- Strong Balance Sheet Cash/cash equivalents = \$104.3 million

1. As reported in the Company's Quarterly Report on form 10-Q for the fiscal third quarter ended 12/31/20, filed 2/11/21.





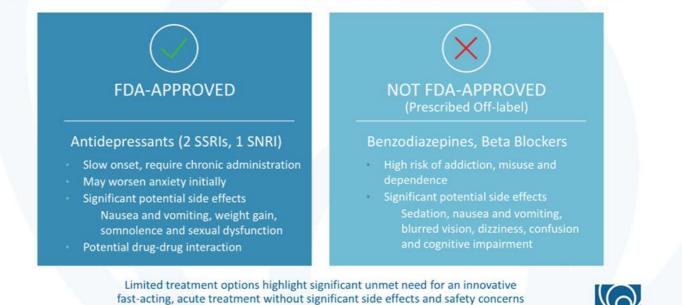
OUR CNS PIPELINE

			PHASE I	PHASE II	PHASE III
	Social Anxiety Disorder ¹	FDA Fast Track designation gra	inted		
DUID AD	Adjustment Disorder ²				
PH94B	Pre-procedural Anxiety (fMRI) ²				
Nasal Spray*	PTSD ³				
	Postpartum Anxiety ³				
	Panic Disorder ³				
	Major Depressive Disorder ⁴				
PH10	Treatment-resistant Depression ³				
Nasal Spray*	Postpartum Depression ³				
	Suicidal Ideation ³				
	LID Associated w/Parkinson's Therapy ⁵				
AV101*	Major Depressive Disorder ⁵	FDA Fast Track designation gra	inted		
(oral)	Neuropathic Pain ⁵	FDA Fast Track designation gra	inted		
with oral probenecid	Epilepsy ⁵				
	Suicidal Ideation ⁵				



CURRENT STANDARD OF CARE FOR SAD IS INADEQUATE

There is No FDA-Approved, Fast-Acting, Acute Treatment of Anxiety for Adults Suffering from SAD



/istaGen.

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THE "BENZO" EPIDEMIC

Recent FDA Boxed Warning Update on Benzodiazepines

NARNING

Benzodiazepines can be an important treatment option for treating disorders for which these drugs are indicated. However, even when taken at recommended dosages, **their use can lead to misuse**, **abuse**, **and addiction**.

FDA Drug Safety Communication | September 23, 2020

FDA U.S. FOOD & DRUG

"We are taking measures and requiring new labeling information to help health care professionals and patients better understand that while **benzodiazepines** have many treatment benefits, they also **carry with them an increased risk of abuse, misuse, addiction and dependence.**"

FDA Commissioner Stephen M. Hahn, M.D¹ | September 23, 2020

1. FDA News Release, FDA Requiring Labeling Changes for Benzodiazepines, September 23, 2020

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metring

PH94B FOR SOCIAL ANXIETY DISORDER

Acute Treatment of Anxiety for Adults with Social Anxiety Disorder

- Odorless pherine nasal spray
- Unique MOA
- Microgram-level dosing
- Designed to be fast-acting (within 15 minutes)
- Non-systemic and non-sedating
- Well-tolerated in all clinical studies to date
- Met primary endpoint in Phase 2 study public speaking challenge (p=0.002); NDA-enabling Phase 3 studies mirror Phase 2 study design
- FDA Fast Track designation
- Intended to treat patients on-demand, as-needed instead of currently-approved chronic antidepressants and off-label options

Potential to be the first FDA-approved fast-acting, acute treatment of anxiety for adults with Social Anxiety Disorder

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PH94B'S POTENTIAL MECHANISM OF ACTION

"Action from a Distance"

PH94B-induced anxiolytic effects appear consistent with the modulation of neural circuits involved in the pathogenesis of Social Anxiety Disorder

• Neurons in the limbic amygdala regulate fear and anxiety by modulating inhibitory neurotransmission in other brain regions

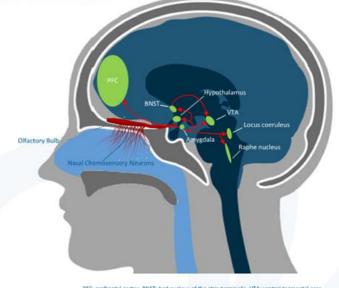
Microgram-level intranasal dose of PH94B (3.2 mcg) engages specific nasal chemosensory neurons (NCNs)

NCNs activate olfactory bulb neurons (OBNs) on the base of the brain

OBNs send neural connections specifically to neurons in the central limbic amygdala, resulting in downstream signaling and rapid anti-anxiety effects

Systemic uptake and distribution of PH94B is not required to produce rapid-onset anti-anxiety effects

Monti I, and Liebowitz MR (2020). Neural circuits of ansiolytic and antidepressant pheria /IstaGen Therapeutics — Copyright © 2021, All Rights Reserved.



PFC: prefrontal cortex, BNST: bed nucleus of the stria terminalis, VTA: ventral tegmental area



PH94B PHASE 2 SOCIAL ANXIETY DISORDER STUDY

Public Speaking and Social Interaction Challenges

- Phase 2B randomized, double-blind, placebo-controlled multi-center study (n=91)
- Public speaking and social interaction challenges
- Primary efficacy endpoint: Change in Subjective Units of Distress Scale (SUDS) scores from baseline compared to placebo
- Met primary efficacy endpoint (p=0.002 for public speaking challenge and p=0.009 for social interaction challenge)
- Very well-tolerated
- Conclusion: PH94B demonstrated potential to be a novel, fast-acting, well-tolerated acute treatment of anxiety in adults with social anxiety disorder

staGen

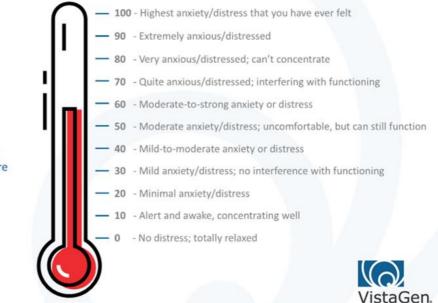
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SUBJECTIVE UNITS OF DISTRESS SCALE (SUDS)

Primary Efficacy Endpoint in Phase 2 and Phase 3

The SUDS measures the self-reported intensity of anxiety and/or distress in patients with SAD

- Patients are asked to rate their level of anxiety/distress on a scale of 0-100
- Physiological signs of distress such as sweating, shaking, increased heart rate or respiration, and gastrointestinal distress may be present at a score of 70, and are present at a score of 80

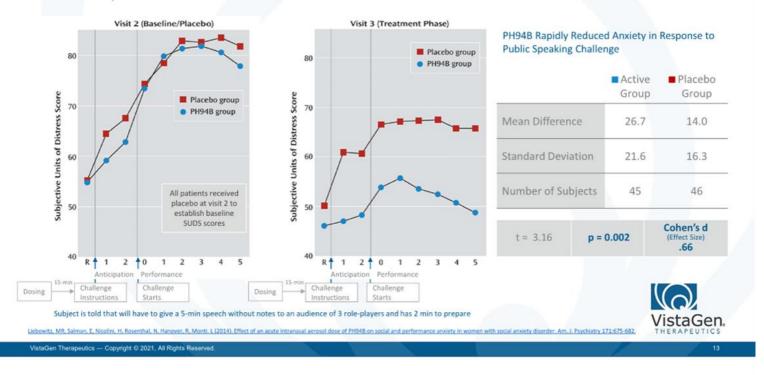


Oxford Clinical Psychology. © Oxford University Press, 2014

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PH94B PHASE 2 SAD STUDY – PUBLIC SPEAKING (n = 91)

Minute-by-Minute SUDS Scores



PH94B PALISADE PHASE 3 DEVELOPMENT PROGRAM

Acute Treatment of Anxiety for Adults with Social Anxiety Disorder

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

- Alignment with FDA that design of Phase 3 clinical studies to substantially mirror public speaking challenge in Phase 2 study.
- PALISADE-1 and PALISADE-2 Phase 3 studies are intended to enable a U.S. New Drug Application in 1H 2023.

PALISADE-1	PALISADE-2
Target enrollment: ca. 208	 Target enrollment: ca. 208
15 -18 sites in the US	15-18 sites in the US
Clinical/laboratory setting	 Clinical/laboratory setting
Public speaking challenge	Public speaking challenge
Visit 1 inclusion criteria is LSAS* score ≥70	■ Visit 1 inclusion criteria will be LSAS score ≥70
SUDS as primary efficacy endpoint as in Phase 2	SUDS as primary efficacy endpoint as in Phase 2
Initiated in mid-2021	Expected to begin in 2H 2021
Topline results expected mid-2022	Topline results expected in 2H 2022

*LSAS - Liebowitz Social Anxiety Scale VistaGen Therapeutics -- Copyright © 2021, All Rights Reserved

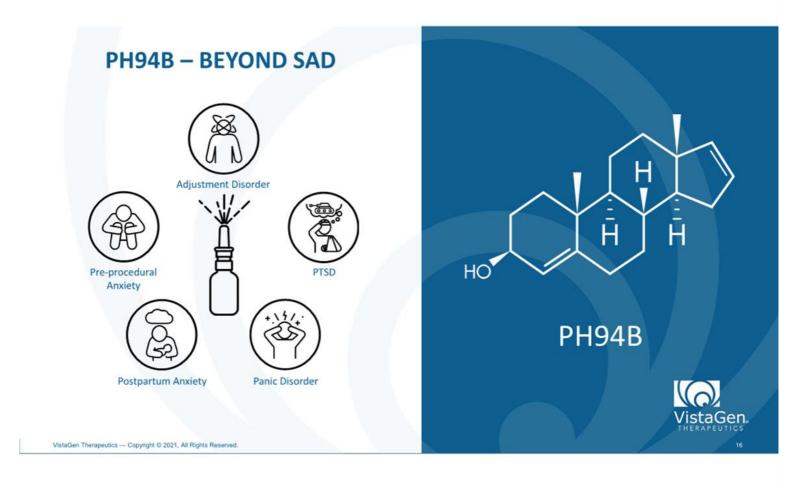


PH94B FOR ACUTE TREATMENT OF ANXIETY IN ADULTS WITH SAD

VistaGen's Initial Goal:

REPLACE ANTIDEPRESSANTS, BENZOS AND BETA BLOCKERS IN THE SAD TREATMENT PARADIGM WHICH HAS LACKED EFFECTIVENESS, SAFETY AND INNOVATION







MAJOR DEPRESSIVE DISORDER (MDD)



TIME



tional Institute of Mental Health, https://www.nimh.nih.gov/health/statistics/major-depression.shtml; 2. World Health Organization, https://www.who.int/nev

CURRENT STANDARD OF CARE FOR MDD IS INADEQUATE

ORAL ANTIDEPRESSANTS

• Often do not work; slow to work

- Initial ADT effective in 1 of 3 patients¹
- May take up to 6 weeks or more for antidepressant effects
- Significant potential side effects
 - Anxiety, sexual dysfunction, insomnia, dizziness, nausea and vomiting, headache, sweating

1. Rush AJ, et al. Am J. Psychiatry. 2006, 163(11): 1905-1917 (STAR*D Study)

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ORAL ATYPICAL ANTIPSYCHOTICS

- Often do not work
- Significant potential side effects
 - Weight gain, stomach pain, tiredness, dizziness, tardive dyskinesia, headache, nervousness, restlessness



PH10 FOR MAJOR DEPRESSIVE DISORDER

Potential Stand-alone Treatment for MDD

- Odorless pherine nasal spray
- Unique MOA
- Microgram-level dosing
- Designed for rapid-onset antidepressant effects without systemic uptake and distribution
- Successful exploratory Phase 2A clinical study
- Well-tolerated in all studies to date
- Preparing for U.S. Phase 2B clinical development
- Intended to be a stand-alone first or second line treatment option

Potential rapid-onset antidepressant effects without side effects and safety concerns of current oral antidepressants, adjunctive atypical antipsychotics and ketamine-based therapy

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PH10'S POTENTIAL MECHANISM OF ACTION

"Action from a Distance"

Designed to not require systemic uptake and distribution with the goal of producing rapid-onset antidepressant effects

- Microgram-level dose (6.4 mcg) designed to engage specific nasal chemosensory neurons (NCNs)
- NCNs activate olfactory bulb neurons (OBNs) on the base of the brain
- OBNs send neural connections to neurons in the central limbic amygdala, the brain center where mood is regulated
- Neurons in the amygdala stimulate release of excitatory neurotransmitters resulting in rapid-onset antidepressant effects





mygdala

Olfactory i

PH10 SHOWED ANTIDEPRESSANT EFFECTS IN MDD PATIENTS PUBLISHED EXPLORATORY PHASE 2A STUDY

- Phase 2A randomized, double-blind, placebo-controlled, parallel design POC clinical study (n=30)
- 3.2 mcg or 6.4 mcg of PH10 or placebo given intranasally 2 times per day, every day for 8 weeks
- Primary efficacy endpoint: Change in HAM-D-17 scores from baseline compared to placebo
- 6.4 mcg dose significantly reduced depressive symptoms as early as one week based on HAM-D-17 scores compared to placebo (p=0.022)
- Well-tolerated, no dissociative side effects or serious adverse events observed
- Results support advancement to Phase 2B clinical development

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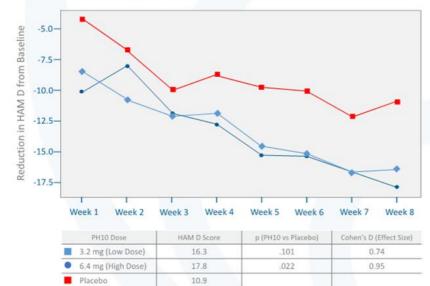
Rapid-onset antidepressant effects with PH10 observed in MDD patients with minimal side effects

Monti, L., Nicolini, H., Liebowitz, M., & Hanover, R. (2019). "A Placebo Controlled Trial of PH10: Test of a New Rapidly Acting Intranasally Administered Antidepressant." Br J Phar Med Res 4(6): 2157-2168



PH10 PHASE 2A MDD STUDY (n = 30)

Hamilton Depression (HAM D) Score Reduction From Baseline



6.4 microgram dose produced rapid-onset and sustained antidepressant effects in MDD patients with minimal side effects



Monti, L., Nicolini, H., Liebowitz, M., & Hanover, R. (2019), "A Placebo Controlled Trial of PH10: Test of a New Rapidly Acting Intranasally Administered Antidepressant." Br J Phar Med Res 4(6): 2157-2168

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PH10 U.S. PHASE 2B DEVELOPMENT PLAN

Major Depressive Disorder

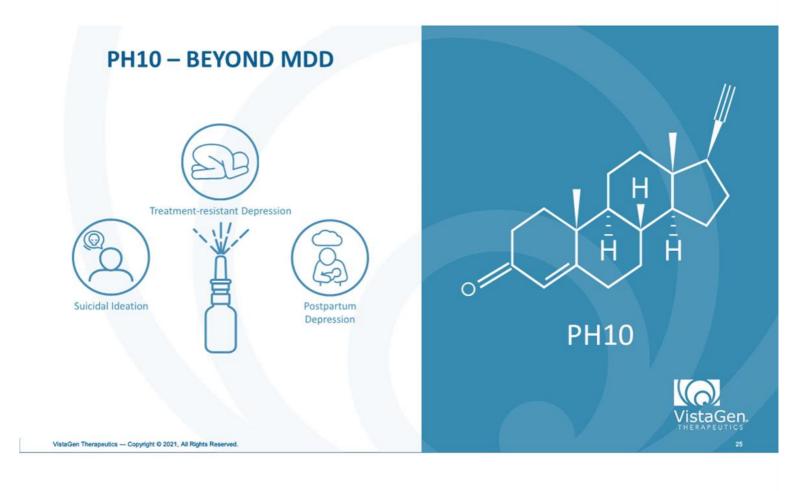
Principal Investigator: Dr. Maurizio Fava, Harvard University

- 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 (3.2 microgram (μg) or 6.4 μg) or placebo for 6 weeks
- Assessment of rapid-onset potential within less than one week, potentially hours to days
- Target launch 1H 2022
- Target enrollment, ca. 150 completed subjects

Primary Endpoint: Change in HAM-D-17 from baseline compared to placebo



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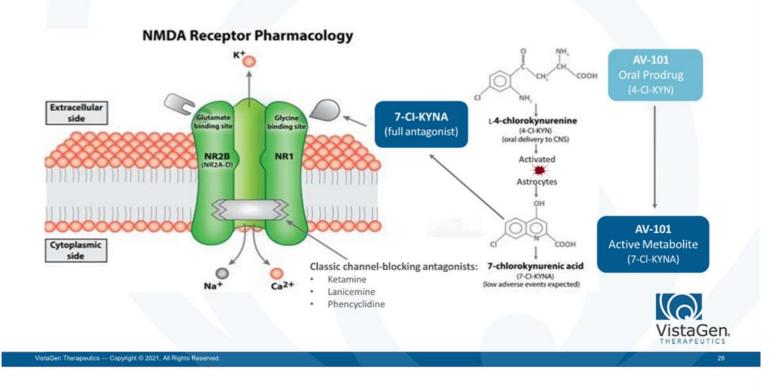
AV-101 FOR MDD AND OTHER CNS DISORDERS

Designed to Inhibit (but not block) NMDA Receptor Activity

- Oral prodrug of 7-Cl-KYNA, a potent and selective full antagonist at the glycine site of the NMDA receptor
- Well-tolerated in all clinical studies to date
- Two positive preclinical studies show increased brain concentrations of 7-CI-KYNA when administered in combination with FDA-approved probenecid
- Assessing multiple go forward opportunities in combination with probenecid
- FDA Fast Track designations for adjunctive treatment of MDD and treatment of neuropathic pain

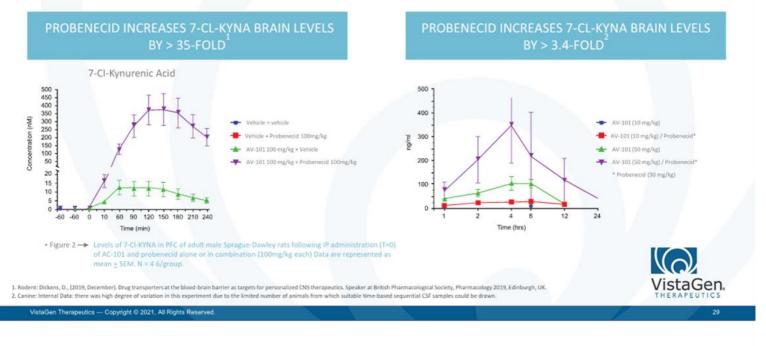


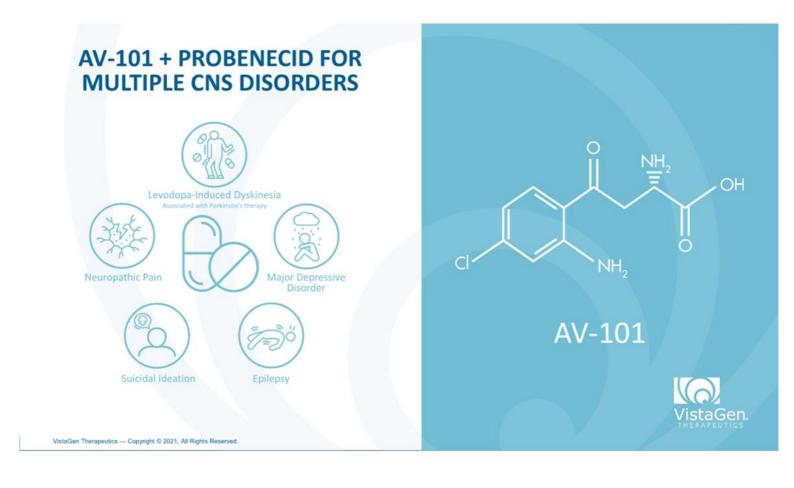
AV-101'S POTENTIAL MOA



AV-101 + PROBENECID

Recent Preclinical Data Demonstrate Substantial Increases in Rodent and Canine Brain Concentrations of 7-CI-KYNA







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DISTINGUISHED CLINICAL AND REGULATORY ADVISORS



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Thomas Laughren, M.D.





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





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

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