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): August 13, 2020

VistaGen Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

NEVADA	**000-54014**	**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))

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 ☐

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 2.02 Results of Operations and Financial Condition.

On August 13, 2020, VistaGen Therapeutics, Inc. (the "*Company*") issued a press release to announce the Company's financial results for its fiscal year 2021 first quarter ended June 30, 2020. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1.

Item 7.01. Regulation FD Disclosure.

On August 14, 2020, the Company began utilizing a new corporate presentation. A copy of the updated corporate presentation is attached to this Current Report on Form 8-K as Exhibit 99.2.

Disclaimer.

The information in this Current Report on Form 8-K, including the information set forth in Exhibits 99.1 and 99.2, are 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 Exhibits 99.1 and 99.2 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	Press Release issued by VistaGen Therapeutics, Inc., dated August 13, 2020
99.2	VistaGen Therapeutics, Inc. Corporate Presentation, dated August 2020

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: August 14, 2020

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

Exhibit 99.1

VistaGen Therapeutics Reports Fiscal 2021 First Quarter Financial Results and Highlights CNS Pipeline and Business Progress

Company Received Over $17.5 Million Net Proceeds from PH94B Upfront License Payment and Public Offering of Common Stock Subsequent to Quarter-end

Positive Meeting with the FDA Sets Key Aspects of Pivotal PH94B Phase 3 Study

SOUTH SAN FRANCISCO, Calif., August 13, 2020 -- (BUSINESS WIRE)—VistaGen Therapeutics, Inc. (Nasdaq: VTGN), a biopharmaceutical company developing new generation medicines for anxiety, depression and other central nervous system (CNS) disorders, today reported financial results for its fiscal 2021 first quarter ended June 30, 2020.

"We accomplished several meaningful milestones thus far this fiscal year that positively impact our clinical development programs, including our PH94B Phase 3 program in social anxiety disorder. We reached consensus with the FDA on the key aspects of the design of our pivotal Phase 3 clinical studies of PH94B for acute treatment of anxiety in adults with social anxiety disorder. This design is similar to the design of the highly statistically significant Phase 2 study of PH94B in social anxiety disorder," said Shawn Singh, Chief Executive Officer of VistaGen. "Additionally, we received the $5 million upfront license payment from our partnering arrangement with EverInsight Therapeutics for Phase 3 development and commercialization of PH94B in key markets in Asia. We also completed a successful public offering of our common stock, resulting in gross proceeds to us of $14.29 million. These accomplishments significantly strengthen our go-forward development plans. We believe now more than ever; the global society needs new, safe, fast-acting treatments for anxiety and depression andwe remain committed to achieving that goal."

Financial Highlights During and Subsequent to the Fiscal 2021 First Quarter:

- VistaGen received a $5 million non-dilutive upfront license payment from EverInsight Therapeutics, the Company's strategic partner for Phase 3 development and commercialization of PH94B for anxiety-related disorders in multiple key markets in Asia.
- VistaGen completed an underwritten public offering of common stock resulting in gross proceeds of $14.29 million to the Company, before underwriting discounts and commissions and offering expenses.

CNS Pipeline Highlights:

- VistaGen reached consensus with the FDA on key aspects regarding the Company's initial pivotal Phase 3 study of PH94B for acute treatment of anxiety in adults with social anxiety disorder (SAD) that, among other details, may provide significant time- and cost-efficiencies for its Phase 3 program.
    - As in the highly statistically significant (p=0.002) Phase 2 study of PH94B in SAD, VistaGen's Phase 3 study will involve a single laboratory-simulated anxiety-provoking public speaking challenge.
    - The Phase 3 study will be a randomized, double-blind, placebo-controlled, parallel comparison study conducted at approximately 12 to 15 sites in North America.
    - The Subjective Units of Distress Scale (SUDS) will be used to assess the primary efficacy endpoint in the study.
    - Dr. Michael Liebowitz, Professor of Clinical Psychiatry at Columbia University, director of the Medical Research Network in New York City, and creator of the Liebowitz Social Anxiety Scale (LSAS), will be the Principal Investigator of the study.
    - Target enrollment (completed patients) will be approximately 182 adult patients with SAD.
- Through the FDA's Coronavirus Treatment Acceleration Program (CTAP), VistaGen submitted its preliminary protocol and development plan for an exploratory, open-label Phase 2A study of PH94B for acute treatment of adjustment disorder with anxiety (AjDA), including, but not limited to, anxiety-provoking stressors related to the diverse impact of the COVID-19 pandemic (e.g., fear and anxiety regarding health and safety, economic loss, unemployment, social isolation, distance-learning, etc.) and civil unrest.
    - The Company is currently working closely with the FDA on plans for the Phase 2A study in AjDA, which, when study preparations are completed, will be conducted in New York City by Dr. Michael Liebowitz.

Financial Results for the Fiscal Quarter Ended June 30, 2020:

Net loss: Net loss attributable to common stockholders for the fiscal quarter ended June 30, 2020 decreased to approximately $3.5 million compared to $6.5 million for the fiscal quarter ended June 30, 2019.

Research and development (R&D) expense: R&D expense decreased to approximately $1.7 million from $4.3 million for the quarters ended June 30, 2020 and 2019, respectively, primarily due to the completion of our Phase 2 study of AV-101 in major depressive disorder in the fourth calendar quarter of 2019. Expenses related to that study and other AV-101 related nonclinical activities decreased by $2.5 million in the quarter ended June 30, 2020 compared to expense in the quarter ended June 30, 2019. Noncash research and development expenses, primarily stock-based compensation, and depreciation in both periods, accounted for approximately $249,000 and $416,000 in the quarters ended June 30, 2020 and 2019, respectively.

General and administrative (G&A) expense: G&A expense decreased to approximately $1.4 million from approximately $1.9 million for the quarters ended June 30, 2020 and 2019, respectively. Noncash G&A expense, $466,000 in the quarter ended June 30, 2020, decreased from $772,000 in the quarter ended June 30, 2019, primarily due to decreases in stock-based compensation and the noncash components of investor and public relations expense attributable to the amortization of the fair value of common stock or warrants granted to service providers.

Cash Position: At June 30, 2020, VistaGen had cash and cash equivalents of $1.5 million, compared to $1.4 million at March 31, 2020. After June 30, 2020, the Company received net proceeds totaling approximately $17.5 million from (i) the $5.0 million gross non-dilutive upfront license fee payment from EverInsight Therapeutics, Inc. pursuant our PH94B strategic collaboration agreement for development and commercialization of PH94B in key markets in Asia, and (ii) the gross proceeds of approximately $14.29 million from the sale of shares of common stock in the underwritten public offering.

As of August 13, 2020, there were 77,998,057 shares of common stock outstanding.

About PH94B
PH94B is a rapid-onset (within approximately 15 minutes) synthetic neurosteroid nasal spray with therapeutic potential across a broad range of anxiety-related disorders. Easily self-administered in microgram-level doses, PH94B does not require systemic uptake and distribution to produce its rapid-onset anti-anxiety effects.

VistaGen is preparing for Phase 3 clinical development of PH94B as a potential new generation fast-acting, non-sedating, non-addictive acute treatment of anxiety in adults with social anxiety disorder (SAD). The FDA has granted Fast Track designation for development of PH94B for this indication, believed to be the first such designation by the FDA for a drug candidate for SAD.

With its rapid-onset pharmacology, lack of systemic exposure and excellent safety profile in earlier studies, PH94B has potential as a novel treatment for multiple additional anxiety-related disorders. VistaGen is also preparing for exploratory Phase 2A development of PH94B for acute treatment of adjustment disorder. View more background information on SAD and a video on PH94B's mechanism of action.

About PH10
PH10 is an investigational synthetic neurosteroid with therapeutic potential in a wide range of neuropsychiatric indications involving depression and suicidal ideation. VistaGen is initially developing PH10 as a potential fast-acting, non-sedating, non-addictive new generation stand-alone treatment of major depressive disorder (MDD). Following successfully completed Phase 2A development for MDD, VistaGen is now preparing for Phase 2B clinical development of PH10 for MDD.

About AV-101
AV-101 (4-Cl-KYN) targets the NMDAR (N-methyl-D-aspartate receptor), an ionotropic glutamate receptor in the brain. Abnormal NMDAR function is associated with numerous CNS diseases and disorders. AV-101 is an oral prodrug of 7-chlorokynurenic acid (7-Cl-KYNA), which is a potent and selective full antagonist of the glycine co-agonist site of the NMDAR that inhibits the function of the NMDAR. Unlike ketamine and other NMDAR antagonists, 7-Cl-KYNA is not an ion channel blocker. In all studies to date, AV-101 has exhibited no dissociative or hallucinogenic psychological side effects or safety concerns similar to those that may be caused by amantadine, esketamine and ketamine. With its exceptionally few side effects and excellent safety profile, AV-101 has potential to be an oral new generation treatment for multiple CNS indications. 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 VistaGen Therapeutics, Inc.
VistaGen Therapeutics is a clinical-stage biopharmaceutical company developing new generation medicines for anxiety, depression and certain CNS disorders where current treatments are believed by VistaGen to be inadequate, resulting in high unmet need. Each of VistaGen's three drug candidates has a differentiated mechanism of action, an exceptional safety profile, and therapeutic potential in several large global CNS markets. For more information, please visit www.vistagen.com and connect with VistaGen on Twitter, LinkedIn and Facebook.

Forward Looking Statements
Various statements in this release are "forward-looking statements" concerning VistaGen's future expectations, plans and prospects, including the potential for successful Phase 3 development of PH94B for acute treatment of anxiety in adults with social anxiety disorder and Phase 2A development for acute treatment of adjustment disorder, as well as ongoing clinical development of PH10 for the potential treatment of MDD and AV-101 as a potential treatment in multiple CNS indications. These forward-looking statements are neither promises nor guarantees of future performance, and are subject to a variety of risks and uncertainties which could cause actual results to differ materially from those contemplated in these forward-looking statements, including the risks that: development and approval of PH94B, PH10 or AV-101 may not be achieved in any market; the FDA may decide that the results of any of the Company's clinical development programs, including its PH94B Phase 3 clinical program for acute treatment of anxiety in adult patients with SAD or any other anxiety-related disorder, are not sufficient for regulatory approval; development of PH94B, PH10 and/or AV-101 may not be successful in any indication; success in nonclinical studies or in earlier-stage clinical trials may not be repeated or observed in future studies which may not support further development or be sufficient to gain regulatory approval to market PH94B, PH10 and/or AV-101; adverse events may be encountered at any stage of development that negatively impact further development. Other risks and uncertainties include, but are not limited to, issues related to: adverse healthcare reforms and changes of laws and regulations; general industry and market conditions; manufacturing and marketing risks, which may include, but are not limited to, unavailability of or delays in delivery of raw materials for manufacture of PH94B, PH10 and/or AV-101; inadequate and/or untimely supply of PH94B, PH10 and/or AV-101 to meet demand; entry of competitive products; and other technical and unexpected hurdles in the development, manufacture and commercialization of PH94B, PH10 and/or AV-101, as well as those risks more fully discussed in the section entitled "Risk Factors" in VistaGen's most recent Annual Report on Form 10-K for the year ended March 31, 2020, and subsequent quarterly reports on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in the company's other filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent the Company's views only as of today and should not be relied upon as representing its views as of any subsequent date. The Company explicitly disclaims any obligation to update any forward-looking statements.

VistaGen Company Contact
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VistaGen Therapeutics Inc.
Phone: +1 (650) 577-3600
Email: IR@vistagen.com

Tables Follow

VISTAGEN THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(Amounts in dollars, except share amounts)
(Unaudited)

	June 30, 2020	March 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,545,900	$ 1,355,100
Prepaid expenses and other current assets	633,000	225,100
Total current assets	2,178,900	1,580,200
Property and equipment, net	184,200	209,600
Right of use asset - operating lease	3,492,100	3,579,600
Deferred offering costs	263,900	355,100
Security deposits and other assets	47,800	47,800
Total assets	$ 6,166,900	$ 5,772,300
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 1,307,300	$ 1,836,600
Accrued expenses	607,800	561,500
Current notes payable, including accrued interest	428,900	56,500
Operating lease obligation - current portion	325,700	313,400
Financing lease obligation - current portion	3,400	3,300
Total current liabilities	2,673,100	2,771,300
Non-current liabilities:		
Non-current portion of notes payable	124,700	-
Accrued dividends on Series B Preferred Stock	5,347,600	5,011,800
Operating lease obligation - non-current portion	3,631,100	3,715,600
Financing lease obligation - non-current portion	2,100	3,000
Total non-current liabilities	9,105,500	8,730,400
Total liabilities	11,778,600	11,501,700
Commitments and contingencies (Note 10)		
Stockholders' equity (deficit):		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at June 30, 2020 and March 31, 2020:		
Series A Preferred, 500,000 shares authorized, issued and outstanding at June 30, 2020 and March 31, 2020	500	500
Series B Preferred; 4,000,000 shares authorized at June 30, 2020 and March 31, 2020; 1,160,240 shares issued and outstanding at June 30, 2020 and March 31, 2020	1,200	1,200
Series C Preferred; 3,000,000 shares authorized at June 30, 2020 and March 31, 2020; 2,318,012 shares issued and outstanding at June 30, 2020 and March 31, 2020	2,300	2,300
Common stock, $0.001 par value; 175,000,000 shares authorized at June 30, 2020 and March 31, 2020; 55,937,472 and 49,348,707 shares issued and outstanding at June 30, 2020 and March 31, 2020, respectively	55,900	49,300
Additional paid-in capital	203,330,700	200,092,800
Treasury stock, at cost, 135,665 shares of common stock held at June 30, 2020 and March 31, 2020	(3,968,100)	(3,968,100)
Accumulated deficit	(205,034,200)	(201,907,400)
Total stockholders' deficit	(5,611,700)	(5,729,400)
Total liabilities and stockholders' deficit	$ 6,166,900	$ 5,772,300

VISTAGEN THERAPEUTICS
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Amounts in Dollars, except share amounts)
(Unaudited)

	Three Months Ended June 30,	
	2020	**2019**
Operating expenses:		
Research and development	$ 1,731,200	$ 4,313,900
General and administrative	1,390,600	1,910,100
Total operating expenses	3,121,800	6,224,000
Loss from operations	(3,121,800)	(6,224,000)
Other income (expenses), net:		
Interest income (expense), net	(3,200)	16,500
Other income	600	-
Loss before income taxes	(3,124,400)	(6,207,500)
Income taxes	(2,400)	(2,400)
Net loss and comprehensive loss	$ (3,126,800)	$ (6,209,900)
Accrued dividends on Series B Preferred stock	(335,800)	(302,500)
Net loss attributable to common stockholders	$ (3,462,600)	$ (6,512,400)
Basic and diluted net loss attributable to common stockholders per common share	$ (0.07)	$ (0.15)
Weighted average shares used in computing basic and diluted net loss attributable to common stockholders per common share	51,321,355	42,622,965

Exhibit 99.2

Nasdaq: VTGN

Summer 2020

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

Forward-looking Statements

VistaGen® Therapeutics

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, development efforts, collaborations, intellectual property, financial condition, plans and development programs. These statements involve risks, uncertainties and assumptions, and are based on the current estimates and assumptions of the management of VistaGen Therapeutics, (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, 2020, filed with the Securities and Exchange Commission (SEC) on June 29, 2020, as well as any updates to those risk factors filed with the SEC from time to time in our current and periodic reports on Forms 8-K and 10-Q, respectively. 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

A Growing Mental Health Pandemic

The Washington Post

"A third of Americans now show signs of clinical anxiety or depression, Census Bureau finds amid coronavirus pandemic"

CNN Health

"The coronavirus pandemic is causing a mental health crisis, the UN warns"

TIME

THE AGE OF ANXIETY

Beyond Stress • Lessons and Treatments • You Are Not Alone

U.S.News & WORLD REPORT

"Lots of Time on Social Media Linked to Anxiety, Depression in Teens"

"In a Pandemic-Stressed America, Protests Add to Mental Strain"

VistaGen Therapeutics

U.S.News & WORLD REPORT

"The Coronavirus Pandemic May Be Causing an Anxiety Pandemic"

CNBC make it

www.vistagen.com

A Growing "Benzo Epidemic"

VistaGen Therapeutics

"Anti-anxiety medication prescriptions up 34 percent since coronavirus"

TIME

PsychiatryAdvisor

"Benzodiazepines: Primary Care's New Drug Problem"

"It's not just opioids: What doctors want you to know about benzos"

CNN health

"Use of Opioids, Benzodiazepines at Same Time is Skyrocketing."

FORTUNE

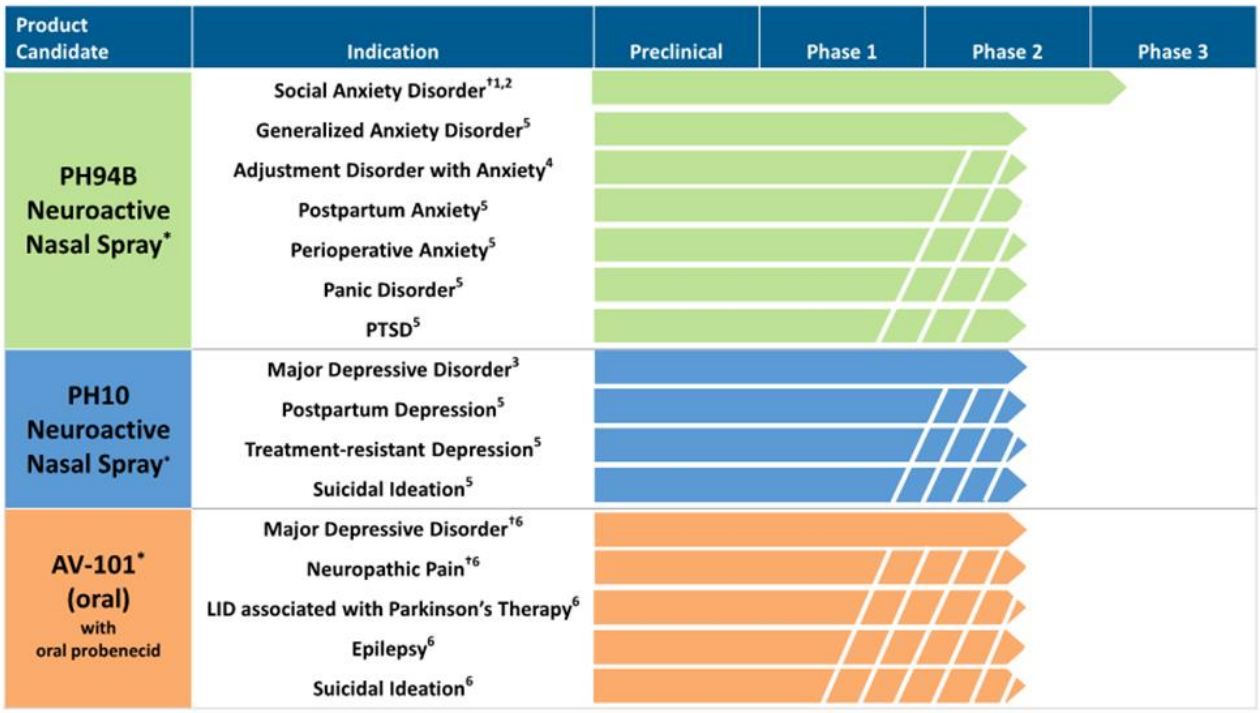
VistaGen is committed to developing and commercializing innovative medicine for treatment of anxiety, depression and neurology disorders we believe are not adequately addressed by current therapies.

www.vistagen.com

Nasdaq: VTGN

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

Our CNS Pipeline



VistaGen® Therapeutics

* The commencement of all potential studies noted above with dashed arrow bars is subject to U.S. FDA regulatory approval and the availability of sufficient funding.
† FDA Fast Track designation granted

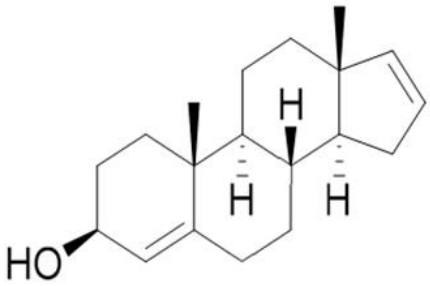
1. Successful Phase 2 program completed; preparing for pivotal Phase 3 clinical development
2. EverInsight Therapeutics has exclusive rights to develop and commercialize in certain markets in Asia
3. Successful Phase 2A program completed; preparing for Phase 2B program
4. Preparing for open-label Phase 2A program
5. Assessing for potential Phase 2A program
6. Assessing for Phase 1B to support potential Phase 2A

PH94B neuroactive nasal spray

(3β)-androsta-4,16-dien-3-ol

VistaGen® Therapeutics

- Social Anxiety Disorder
- Adjustment Disorder
- Postpartum Anxiety
- PTSD
- Generalized Anxiety Disorder
- Preoperative/Pre-testing Anxiety
- Panic Disorder

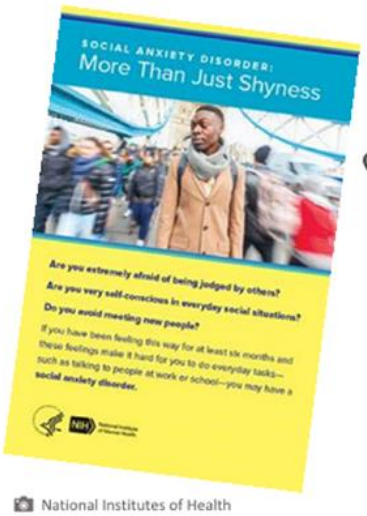


LOOKING BEYOND CURRENT TREATMENTS FOR CNS DISEASES AND DISORDERS WITH HIGH UNMET NEED

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

VistaGen® Therapeutics

More than Just Shyness



National Institutes of Health

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

Affects as many as

20 million[1]

Americans

Anxiety and fear in everyday social and performance situations

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

[1]Harvard 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

VistaGen Therapeutics

FDA APPROVED

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

Antidepressants

- 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, as needed treatment for SAD

PH94B: Acute Treatment of Anxiety for Adults with Social Anxiety Disorder

VistaGen® Therapeutics

- Odorless, synthetic neurosteroid nasal spray
- Successful Phase 2 completed
- Recent FDA consensus on pivotal Phase 3 study
- Rapid-onset (10-15 minutes)
- Exceptional safety
- FDA Fast Track designation, first ever granted for SAD

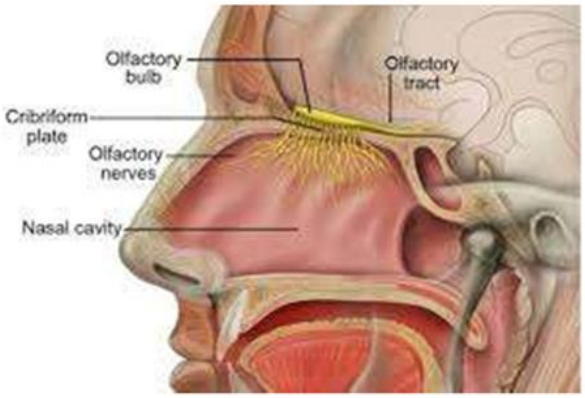
Potential to be the first FDA-approved rapid-onset acute treatment of anxiety for adults with SAD

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

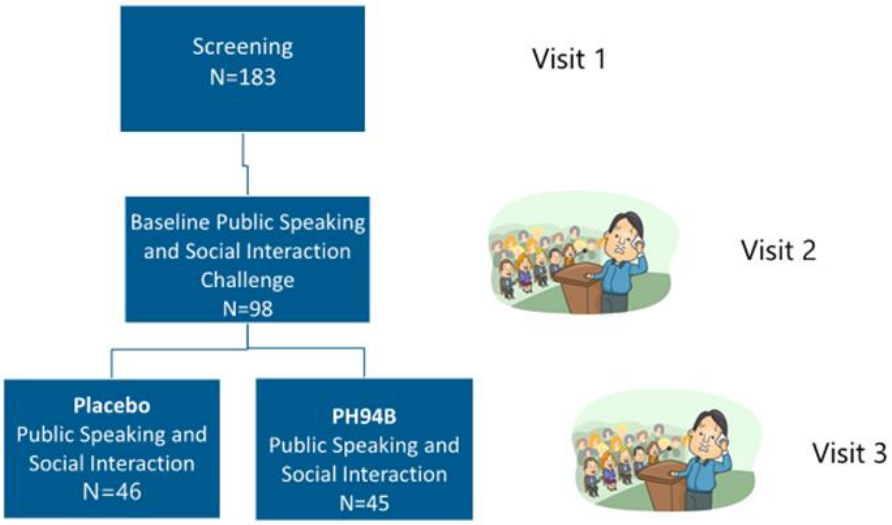
PH94B Mechanism of Action

VistaGen® Therapeutics

- Microgram level dose (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 to neurons in the central limbic amygdala, the brain center where fear and anxiety are regulated
- Neurons in the limbic amygdala modulate inhibitory/excitatory neurotransmitters, resulting in rapid anti-anxiety effects
- **Systemic uptake and distribution of 3.2 mcg dose not required to produce rapid-onset anti-anxiety effects**

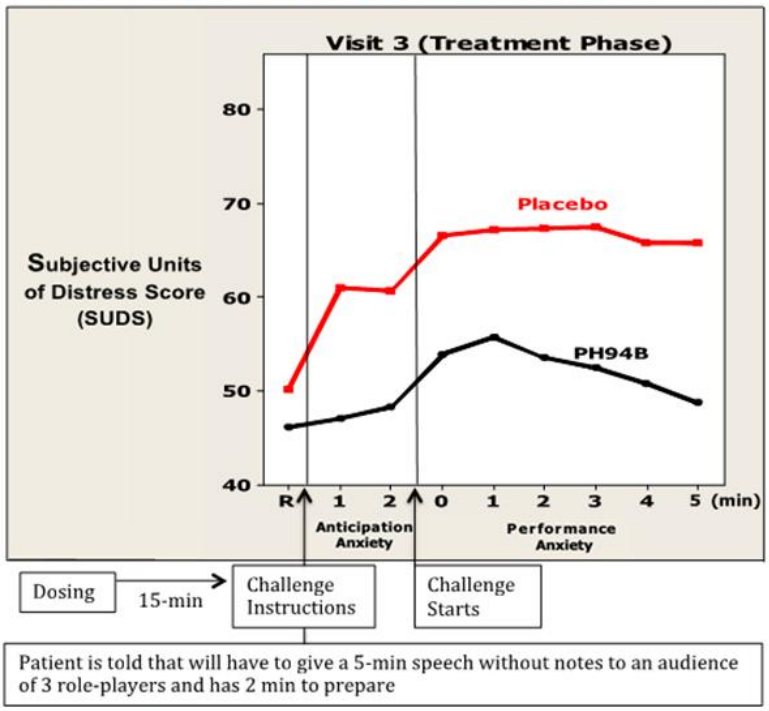


Completed PH94B Phase 2 Study - Public Speaking Challenge



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

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) .66

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.

PH94B Initial Pivotal Phase 3 Study: Acute Treatment of Anxiety for Adults with Social Anxiety Disorder

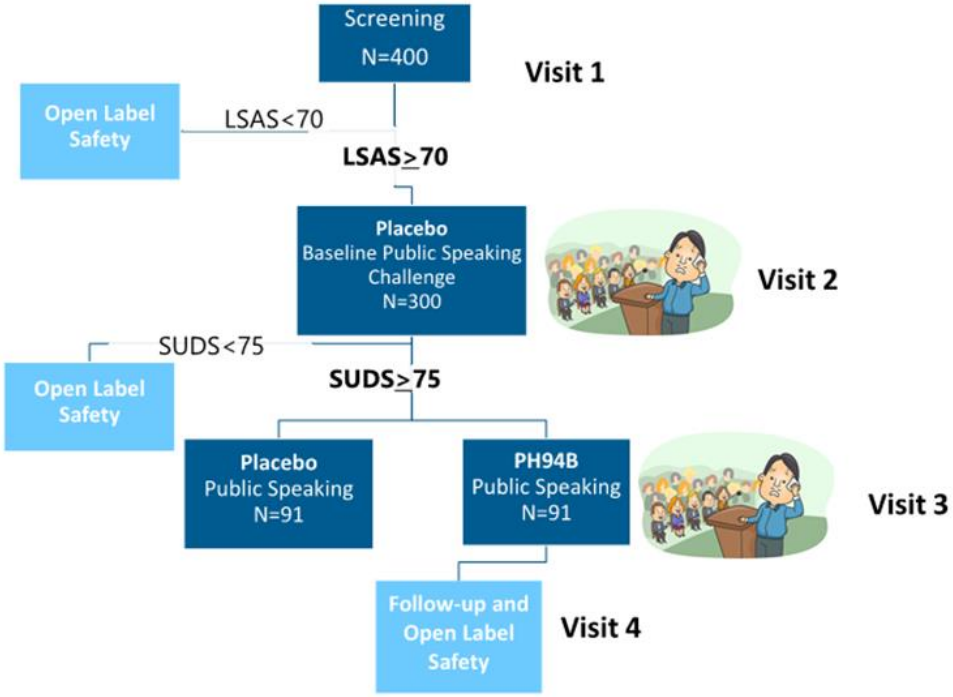
VistaGen Therapeutics

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

- Recent FDA agreement will substantially reduce cost (50%), time and variability
- Design same as highly statistically significant (p=0.002) Phase 2 public speaking study
  - Assessing a single, identical, laboratory-simulated, anxiety-provoking public speaking challenge to all subjects
  - Single dose of PH94B (3.2 μg) or placebo administered after randomization
  - Primary efficacy endpoint assessed using Subjective Units of Distress Scale (SUDS)
- 12-15 sites in North America
- Target enrollment (completed subjects), 182

PH94B Initial Pivotal Phase 3 Study - Public Speaking Challenge

VistaGen Therapeutics



PH94B Commercial Opportunity – U.S. SAD Market

VistaGen Therapeutics

SUBSTANTIAL UNMET NEED

There are few novel anti-anxiety medications in late-stage clinical development. PH94B promotion, SAD disease education and U.S. DTC advertising efforts will drive physician urgency to diagnose and treat.

UNIQUE MOA

Most clinicians are cautiously optimistic that PH94B is not habit-forming due to its novel, differentiated MOA, non-systemic administration and lack of benzodiazepine-like side effects.

STRONG INTENT TO PRESCRIBE

Motivated by safety/tolerability, efficacy and convenient on-demand use, most clinicians intend to offer PH94B to a majority of their patients with SAD. Most patients are interested in trying PH94B and would be motivated to discuss with an HCP after seeing an advertisement.

EASE OF USE

Patients and clinicians will likely prefer PH94B's acute, on-demand rapid-onset activity, much like a rescue inhaler for an acute asthma attack, and its exceptional side effects profile vs. antidepressants, benzodiazepines and beta blockers.

*Includes pediatric SAD indication, peak year sales; but excludes all other anxiety-related disorders; market research and commercial assessment prepared by i3 Strategy, Winter 2019

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EverInsight/CBC Group Collaboration June 2020

Phase 3 Development and Commercialization of PH94B for Acute Treatment of Anxiety in Adults with SAD in Key Asian Markets

- Obligations:
  - EverInsight (currently funded by CBC Group) will be responsible for Phase 3 clinical development, regulatory submissions and commercialization of PH94B in the Territory
- Territory:
  - Greater China
  - South Korea
  - Southeast Asia
- Financial terms:
  - $5 million upfront payment (received August 2020)
  - Potential milestone payments up to $172 million
  - Royalties on commercial sales

VistaGen Therapeutics

Adjustment Disorder with Anxiety

- Emotional or behavioral reaction considered excessive or out of proportion to a stressful event or major life change occurring within 3 months of the anxiety-provoking stressor
- Significantly impairs social, occupational and/or other important areas of functioning
- Diverse impact of the COVID-19 pandemic and recent civil unrest have created fear, anxiety and uncertainty about health and safety, economic loss, unemployment, and new educational, occupational and social norms
- Current anti-anxiety medicines, especially benzodiazepines, have significant limitations and problematic side effects and safety concerns

VistaGen Therapeutics

PH94B Phase 2 Program for Adjustment Disorder

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

Treatment of Adjustment Disorder with Anxiety

PART A

- Exploratory, open-label, single-site Phase 2A study in New York City
- Target enrollment, 30

POTENTIAL PART B

- Randomized, double-blind, placebo-controlled, multi-center U.S. Phase 2B study
- Potential target enrollment, 150

PART A exploratory Phase 2A open-label study protocol submitted to FDA under Coronavirus Treatment Acceleration Program (CTAP); protocol development discussions ongoing with FDA Division of Psychiatry Products

Additional Anxiety-related Indications

VistaGen Therapeutics

Postpartum Anxiety

Generalized Anxiety Disorder

Panic Disorder

PH94B

Preoperative & Pre-testing (MRI) Anxiety

Post-Traumatic Stress Disorder

Potential Next Step: Exploratory Phase 2A studies

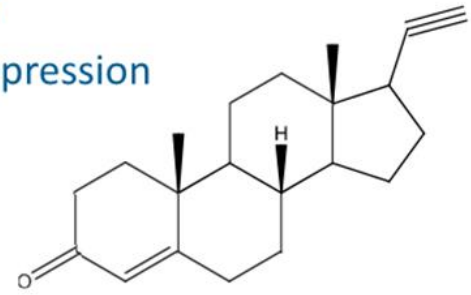
PH10 neuroactive nasal spray

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

VistaGen® Therapeutics

Novel, safe, fast-acting therapy for:

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



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

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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 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

FDA-Approved Oral MDD Treatments Fall Short

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

Oral 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

PH10 for MDD

VistaGen® Therapeutics

- Odorless synthetic neurosteroid nasal spray
- Successful Phase 2A completed
- Potential rapid-onset antidepressant effects
- Exceptional safety
- Preparing for Phase 2B

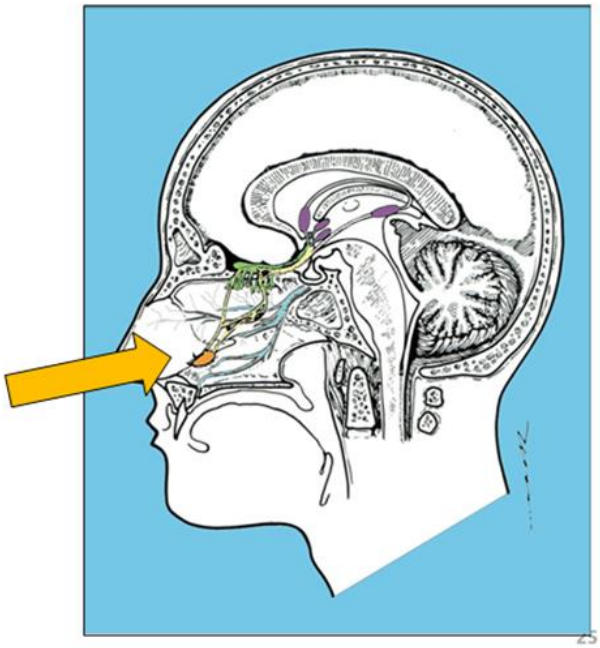
Potential stand-alone rapid-onset antidepressant without side effects and safety concerns of ketamine-based therapy

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

PH10 Mechanism of Action

VistaGen® Therapeutics

- Microgram level dose (6.4 mcg) engages 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 limbic amygdala stimulate release of excitatory neurotransmitters (glutamate, norepinephrine) resulting in rapid-onset antidepressant effects
- **Systemic uptake and distribution not required to produce rapid-onset antidepressant effects**



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PH10 Published Phase 2A MDD Monotherapy Study (n = 30)

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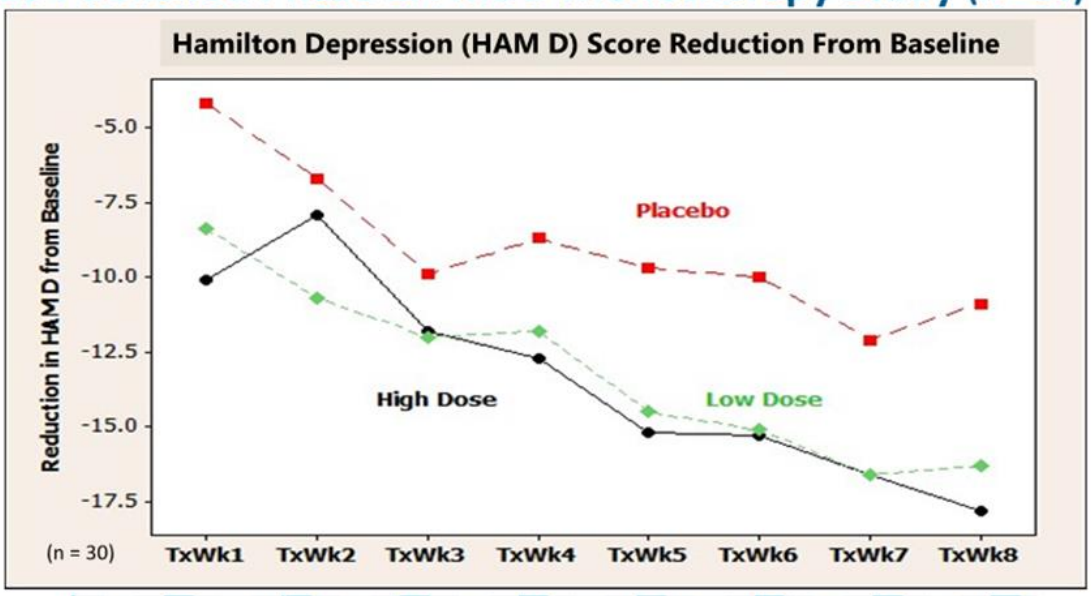


PH10 Dose	HAM D Score	P (PH10 vs Placebo)	Cohen's D (Effect Size)
3.2 µg (Low Dose)	16.3	.101	0.74
6.4 µg (High Dose)	17.8	.022	0.95
Placebo	10.9		

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

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 U.S. Phase 2B Development Plan for MDD

VistaGen Therapeutics

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 μg or 6.4 μg) or placebo for 4 weeks
- Rapid-onset potential within less than one week, potentially hours to days
- Target enrollment, n= ca. 150 patients

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

Additional Indications

VistaGen Therapeutics

Suicidal Ideation

Postpartum Depression

PH10

Treatment-Resistant Depression

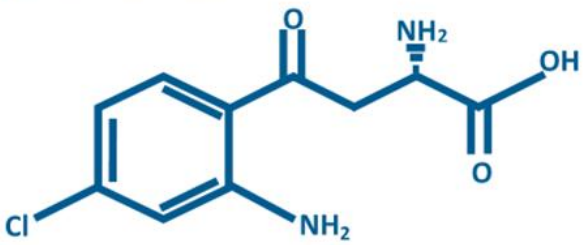
Potential Next Steps: Exploratory Phase 2A studies

AV-101

L-4-chlorokynurenine

VistaGen® Therapeutics

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



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

AV-101

VistaGen® Therapeutics

- Oral NMDAR glycine site antagonist
- Prodrug of 7-Cl-KYNA
- Exceptional safety
- FDA Fast Track designations in MDD and pain
- Go forward plan with adjunctive probenecid

Nasdaq: VTGN

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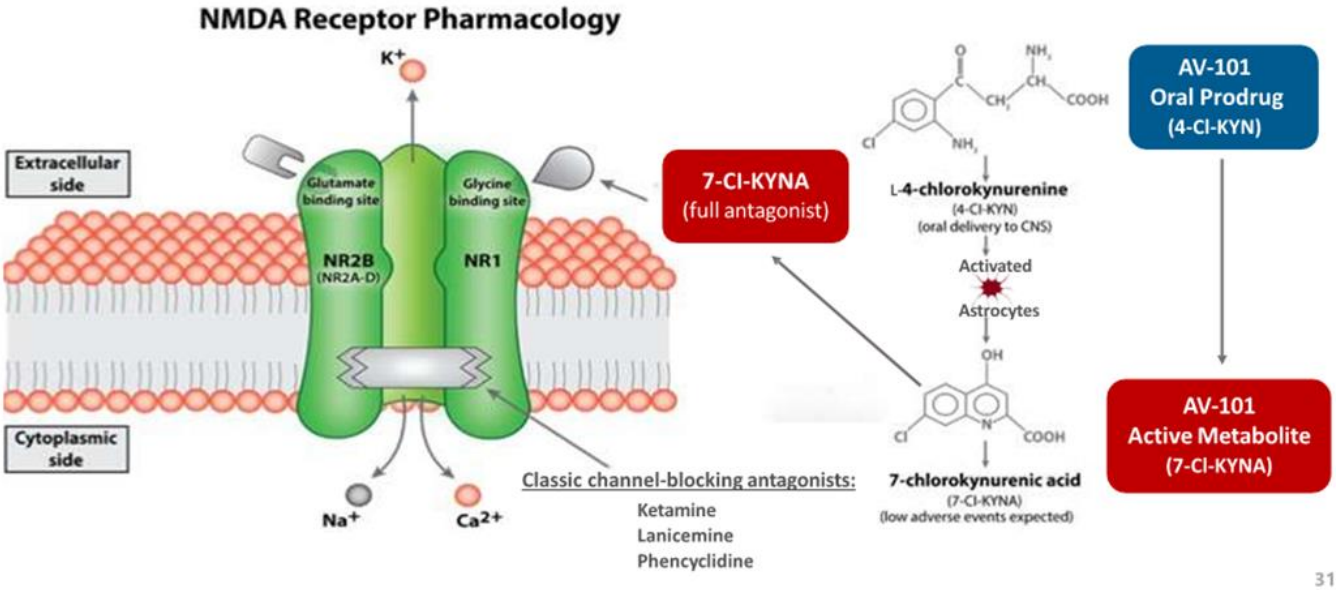
AV-101's Mechanism of Action

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



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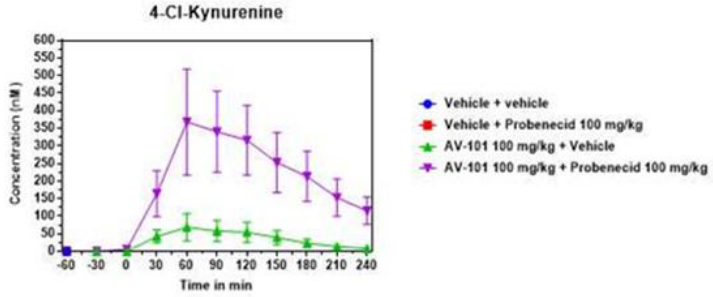
AV-101 and Adjunctive Probenecid

Recent preclinical data demonstrate substantial increases in rodent brain concentrations of both AV-101 (4-Cl-KYN) and 7-Cl-KYNA

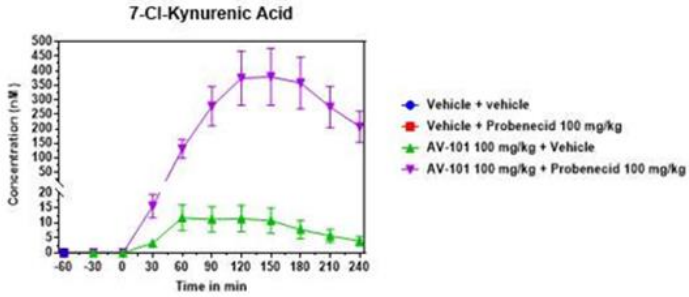
VistaGen® Therapeutics

Probenecid increases AV-101 (4-Cl-KYN) brain levels by ~ 7-fold



• Figure 1 → Levels of 4-Cl-KYN in PFC of adult male Sprague-Dawley rats following IP administration (T=0) of AV-101 and probenecid alone or in combination (100 mg/kg, each).
Data are represented as mean ± SEM. N = 4-6/group.

Probenecid increases 7-Cl-KYNA brain levels by > 35-fold



• Figure 2 → Levels of 7-Cl-KYNA in PFC of adult male Sprague-Dawley rats following IP administration (T=0) of AV-101 and probenecid alone or in combination (100 mg/kg, each).
Data are represented as mean ± SEM. N = 4-6/group.

Dickens, D., (2019, December). Drug transporters at the blood-brain barrier as targets for personalised CNS therapeutics. Speaker at British Pharmacological Society, Pharmacology 2019, Edinburgh, UK,

AV-101 with Adjunctive Probenecid for Multiple CNS Indications

VistaGen Therapeutics

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

AV-101

Next Step: Acute Canine Preclinical (PK) Study

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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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

3 Differentiated, Clinical-Stage CNS Drug Candidates

VistaGen® Therapeutics

- Novel mechanisms of action
- Rapid-onset potential
- Exceptional safety
- Multiple accessible global markets

VistaGen® Therapeutics

LOOKING BEYOND CURRENT TREATMENTS FOR ANXIETY, DEPRESSION AND OTHER CNS DISEASES AND DISORDERS WITH HIGH UNMET NEED

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