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 8, 2022

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 7.01 Regulation FD Disclosure.

On June 8, 2022, 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 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: June 8, 2022

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

Exhibit 99.1

VistaGen Therapeutics

A Visionary Approach to Mental Health Care

Corporate Presentation

June 2022

www.vistagen.com

Looking beyond the standard of care for anxiety, depression and other CNS disorders

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 to meet demand; entry of competitive products; and other technical and unexpected hurdles in the development, manufacture and commercialization 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, 2021, and in our most recent Quarterly Report on Form 10-Q for the quarter ended December 31, 2021, 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.

VistaGen

Our Vision: Radically Improve Mental Health Care - ***One Mind at a Time™***

Differentiated clinical-stage CNS drug candidates

Targeting large anxiety, depression and neurology markets

Numerous potential catalysts in 2022 and beyond

New MOAs bringing value to patients, physicians, and payers

Strong balance sheet and institutional shareholder base

Experienced leadership to execute through commercialization

VistaGen

Our Pipeline

PALISADE Phase 3 Program
Social Anxiety Disorder

- PALISADE-1
- PALISADE-2
- PALISADE-Long Term Safety
- PALISADE-Global
- PALISADE-Dose Response Study
- PALISADE Dosing Interval Study

Exploratory Phase 2A Program

- Adjustment Disorder with Anxiety
- Post Traumatic Stress Disorder (Biomarker)
- Procedural Anxiety (fMRI)

Major Depressive Disorder

- Phase 2B Study

Potential CNS Indications

- Phase 1B DDI Study

Ongoing Planned

The commencement of all potential studies is subject to U.S. FDA regulatory authorization.

PH94B vs. PH10 – Similar but Different

PH94B and PH10 are chemically distinct but physiologically similar.

Both bind to nasal chemosensory receptors, but each activates different nasal chemosensory neurons and interneurons resulting in different pharmacological effects.

PH94B	Properties	PH10
Nasal Chemosensory Cells	Primary target	Nasal Chemosensory Cells
Androstane	Chemical Molecule	Pregnane
Sympatholytic	Nervous System Effect	Sympathomimetic
Anti-anxiety	Pharmacological Effect	Anti-depressant

VistaGen

VistaGen Therapeutics

PH94B

for

Social Anxiety Disorder

www.vistagen.com

Looking beyond the standard of care for anxiety, depression and other CNS disorders

Social Anxiety Disorder is a debilitating mental health condition

*SAD is **more than just shyness**. It is a serious and **disabling** disorder characterized by …*

Debilitating emotional and physical symptoms

Emotional symptoms:

- Surges of intense and overwhelming anxiety and fear of embarrassment, judgment and humiliation
- Extreme self-consciousness
- Isolation leading to depression and addiction

Physical symptoms:

- Blushing / Sweating
- Trembling
- Nausea
- Fast Heartbeat / Chest Discomfort
- Shortness of Breath / Dizziness

In everyday social or performance situations

Meeting new people

Presenting at work or school

Public speaking

Interviewing for a job

Eating/drinking in front of others

Going to the doctor/dentist

Sources: ADAA Social Anxiety Brochure 2021; Social anxiety disorder - Symptoms and causes – www.mayoclinic.org

VistaGen

Social Anxiety Disorder impacts multiple facets of patient lives

Leading to occupational, social and academic impairment

- Leading **a limited, isolated & discouraging life**
- **Missing out** on moments with family & friends
- **Constant worry** about what others are thinking
- Unable to bring full self to work and **loss of opportunities**
- Daily changes in symptoms and **unpredictability** of triggers
- **Declining health** due to cumulative impact

"Making a phone call would send me into a hot sweat."

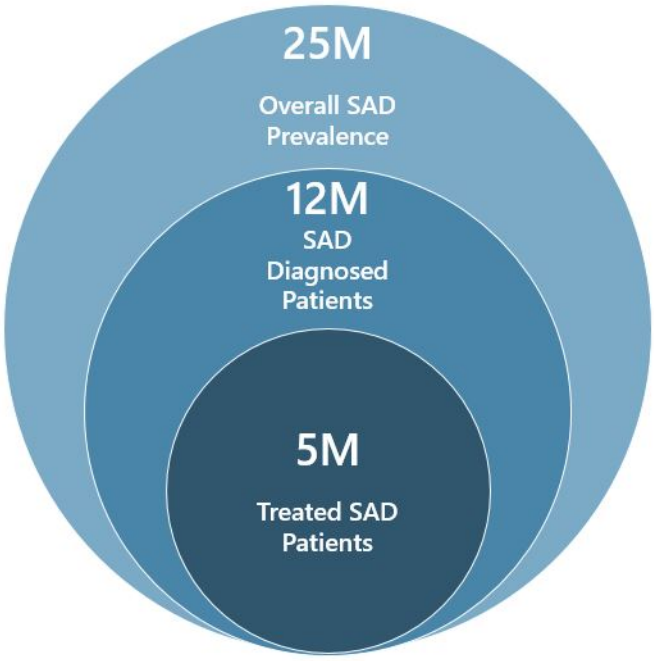
"...I do not like to tell others I'm avoiding them because of anxiety. I feel it may seem silly to others that do not struggle with it..."

"I feel like I'm missing most out on just living life being HAPPY and FREE. It would take for me to learn how to overcome SAD and how to control it ..."

Sources: Vistagen Proprietary Market Research October 2021

VistaGen

Social Anxiety Disorder affects ~10% of the US population, with only ~20% of patients helped by current pharmacotherapy



Future Patients

Patients suffering but unaware of SAD as a condition or not yet motivated to seek professional help

Underserved Patients

Patients unsatisfied with or unwilling to use current treatment options due to poor efficacy, unwanted side effects, and/or risk of addiction potential

Existing Patients

Patients cycling through treatments, often unsatisfied with their current treatment options but without satisfactory alternatives

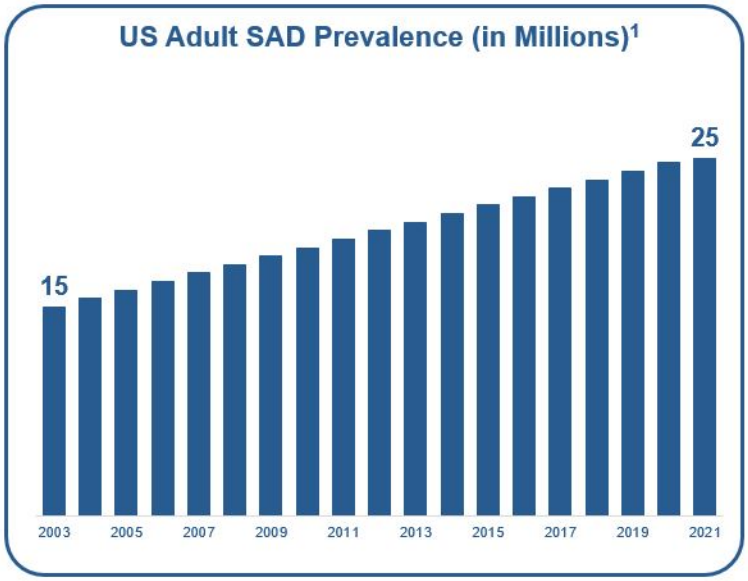
Sources: Kantar Health. Nov 2021. National Health and Wellness Survey (NHWS). 2021. [US]. Malvern, PA.

VistaGen

It has been ~2 decades since a new/novel therapy was approved for treatment of Social Anxiety Disorder

SAD is a highly prevalent condition which continues to affect increasing numbers of people in the US each year

SAD disease burden continues to grow but scientific innovation has been lacking



Sources: 1. NCS-R Survey, 2003; Kantar NHWS 2021, Internal Projections 2. Google Trends result May-2022

VistaGen

Current Standard of Care for Social Anxiety Disorder is Inadequate

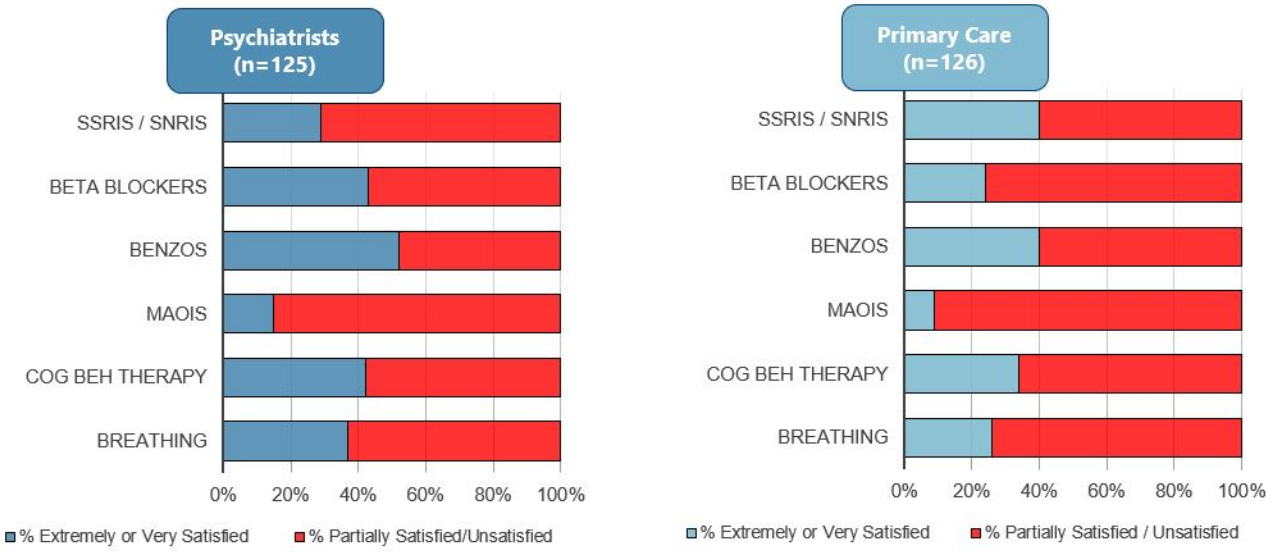
Treatments For Social Anxiety Order							
Drug	**Fast Acting**	**No Systemic Absorption**	**No Long-Term Side Effects** (Sexual dysfunction etc.)	**Non-Sedating**	**No Cognitive/ Motor Impairment**	**No Withdrawal Syndrome**	**No Abuse Potential**
FDA Approved (SSRIs/SNRIs: sertraline, paroxetine, venlafaxine)	⊖	⊖	⊖	✓	✓	⊖	✓
Off-Label* (benzodiazepines)	✓	⊖	⊖	⊖	⊖	⊖	⊖
Preferred Novel SAD Therapy	✓	✓	✓	✓	✓	✓	✓

* Beta blockers are sometimes used in subjects with performance anxiety for reducing physical symptoms such as rapid heart rate, however they do not address psychic anxiety. They are also contraindicated in patients with depression and asthma and can cause physical side effects such as dry mouth, fatigue, nausea, cold extremities, dizziness, or fainting

VistaGen

Physician satisfaction with current therapies is modest, leaving significant opportunity for new, differentiated therapies

Satisfaction with current treatments for ACUTE episodes of SAD from a large online survey



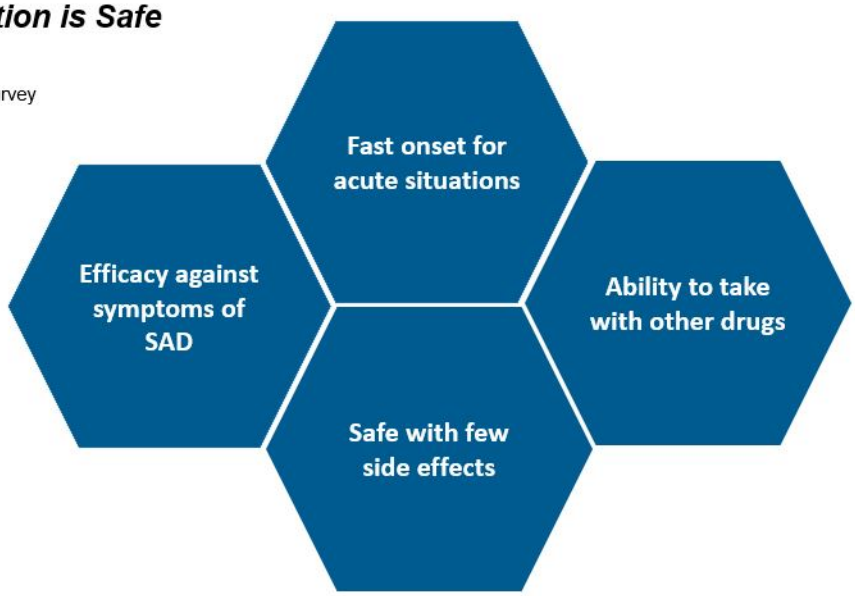
VistaGen

Sources: VistaGen Proprietary Market Research, Online Survey, Jan 2022

SAD patients desire new treatment options to fill unmet needs

The Ideal SAD Medication is Safe & Works Quickly

– patient survey



Sources: Vistagen Proprietary Market Research October 2021

VistaGen

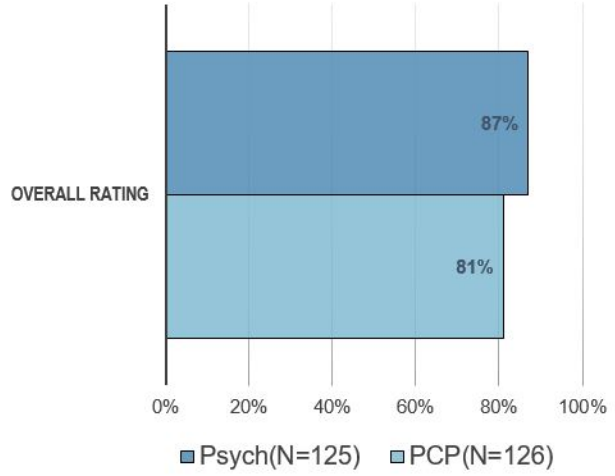
PH94B has potential to be 1st FDA-approved fast-acting, acute treatment of SAD

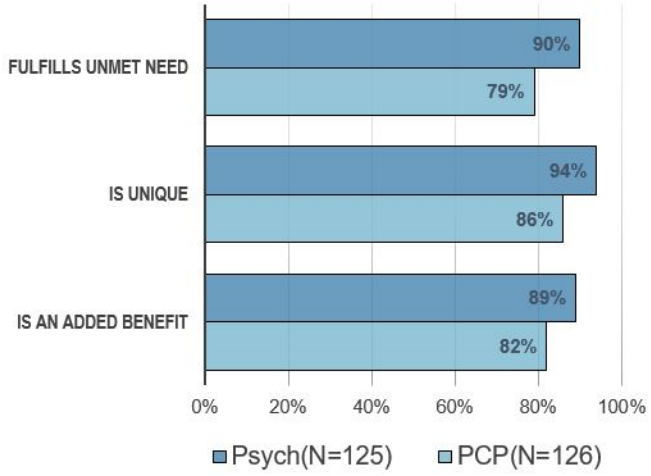
- Odorless & Tasteless
- Differentiated MoA Specific for SAD
- Used on as-needed basis
- Designed to be fast-acting (within 15 mins)
- Designed to be non-systemic, non-sedating
- Designed to be non-addictive
- Well-tolerated in all clinical studies to date
- FDA Fast Track designation

PH94B is a novel synthetic neuroactive steroid nasal spray

PH94B is rated highly by physicians and recognized as a potentially valuable and differentiated approach to treating acute episodes of SAD

Physician assessment of a blinded PH94B product profile from a large online survey of 251 respondents





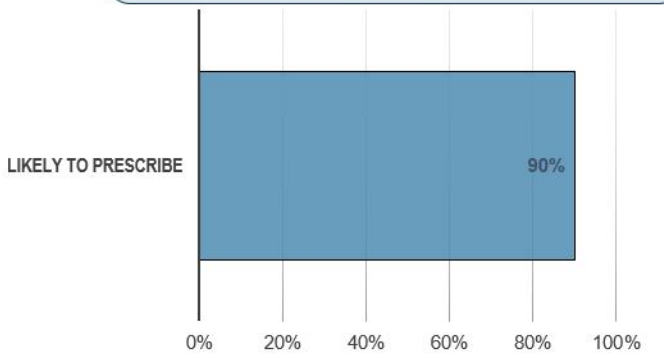
VistaGen

Sources: Vistagen Proprietary Market Research, Online Survey, Jan 2022 (n=251); top 2-box of 5-pt scale, based on the profile of a product consistent with our investigational compound PH94B

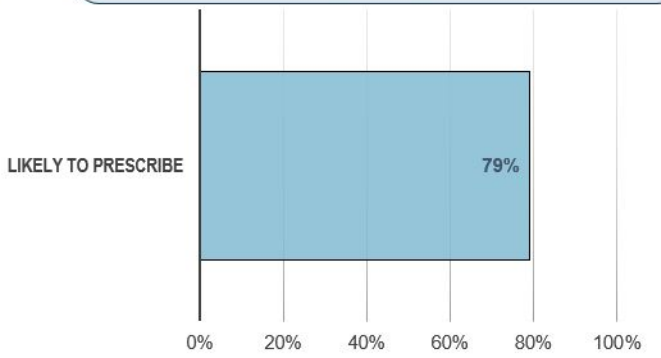
Physicians indicate very high intent to prescribe PH94B for SAD

After reviewing a blinded PH94B product profile . . .

90% of Psychiatrists indicated they would likely prescribe PH94B (N=125)



79% of Primary Care Physicians indicated they would likely prescribe PH94B (N=126)

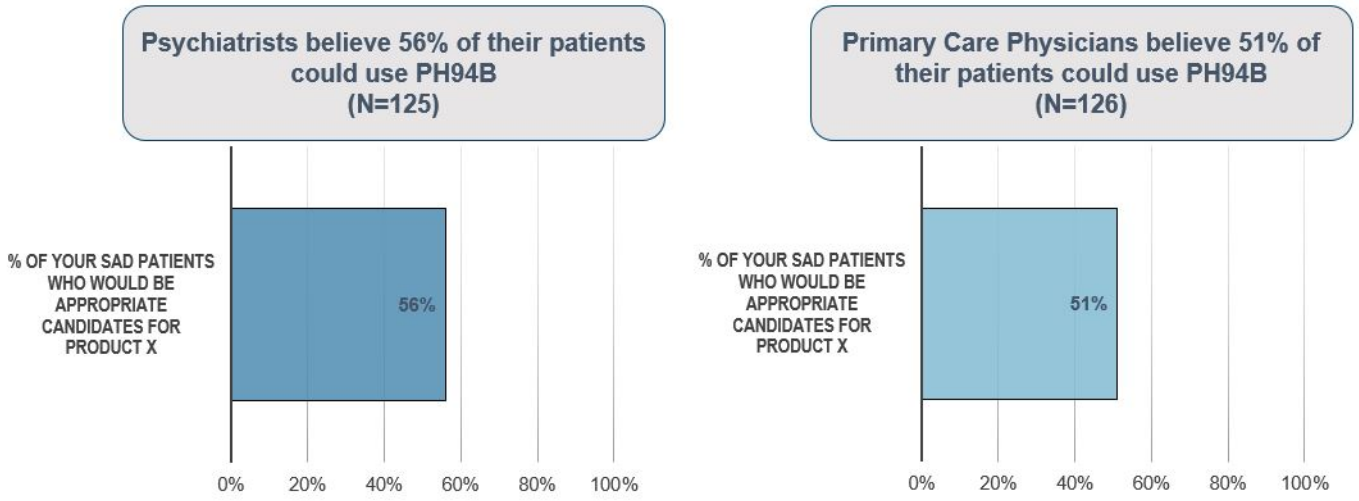


VistaGen

Sources: Vistagen Proprietary Market Research, Online Survey, Jan 2022 (n=251); top 2-box of 5-pt scale, based on the profile of a product consistent with our investigational compound PH94B.

Physicians believe that PH94B would be appropriate for the majority of their SAD patients

After reviewing a blinded PH94B product profile . . .

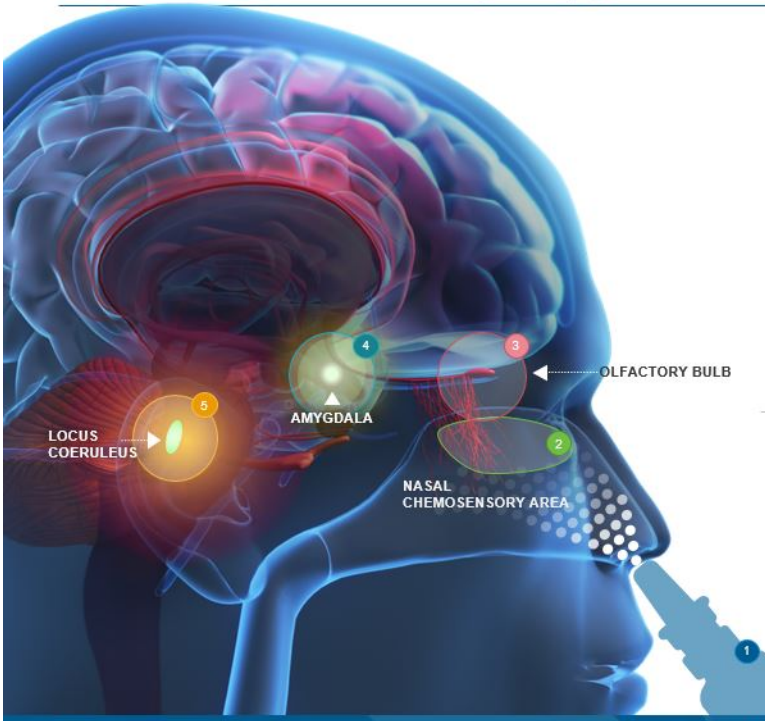


VistaGen

Sources: Vistagen Proprietary Market Research, Online Survey, Jan 2022 (n=251); top 2-box of 5-pt scale, based on the profile of a product consistent with our investigational compound PH94B

PH94B

Novel MOA via olfactory-amygdala circuit



1. Microgram-level intranasal dose of PH94B (3.2 mcg) is administered
2. PH94B engages peripheral receptors in nasal chemosensory neurons (NCNs)
3. Once stimulated with PH94B, NCNs then trigger subsets of interneurons in the olfactory bulbs (OB)
4. Neurons in the OB then stimulate inhibitory GABAergic neurons in the limbic amygdala, the main fear and anxiety center of the brain
5. The stimulation of the limbic amygdala DECREASES the activity of the sympathetic nervous system which facilitates fear extinction activity of the limbic-hypothalamic system as well as in other parts of the brain

Monti L, and Liebowitz MR (2020). Neural circuits of anxiolytic and antidepressant *pherine* molecules.
CNS Spectrums https://doi.org/10.1017/S109285292000190X

VistaGen

PH94B

Positive Phase 1 Data

Sympatholytic effects observed in healthy volunteers after PH94B administration

Design: Three similarly designed Phase 1 studies in healthy volunteers

Target Enrollment: N = 64, 32 male & 32 female

Dose administered: 0.2 µg to 0.4 µg locally and topically using an experimental nasal spray device

Results: PH94B transiently reduced all the physiologic biomarkers (Respiratory rate, heart rate and electrodermal activity) in all three studies

Implications: Data suggest that PH94B has the potential for anxiolytic activity via modulation of CNS mechanisms

[1] Multifunctional Miniprobe ®; L. Monti US Patent 5,303,703

Physiologic biomarkers showed transiently reduced autonomic nervous system activity after intranasal administration of PH94B in normal healthy volunteers

VistaGen

PH94B

Highly Significant Phase 2 Data in Social Anxiety Disorder

- Phase 2B randomized, double-blind, placebo-controlled multi-center study (n=91)
- Study uniquely designed to assess the efficacy of a fast-acting drug for social anxiety disorder in an acute anxiety setting
- Stressors included both public speaking and social interaction challenges

Primary efficacy endpoints:

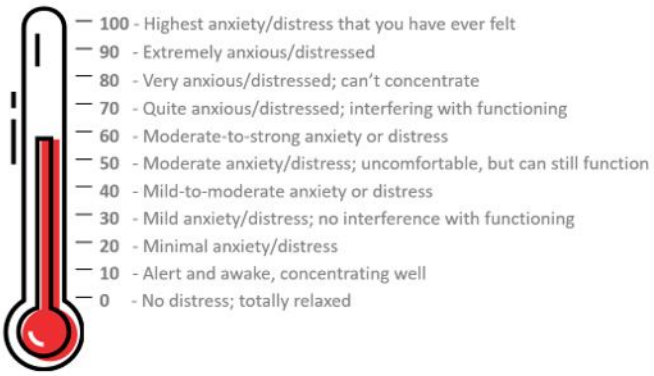
- ✓ Change in Subjective Units of Distress Scale (SUDS) scores from baseline vs. placebo
- ✓ Met primary efficacy endpoints
  - ✓ p=0.002 for public speaking challenge
  - ✓ p=0.009 for social interaction challenge
- ✓ Very well-tolerated

PH94B demonstrated potential to be a novel, fast-acting, well-tolerated acute treatment of anxiety in adults with SAD

Subjective Units of Distress Scale (SUDS) is the ideal scale to measure acute anxiety in the moment of a stressful event

The SUDS scale measures the patient's self-reported intensity of anxiety and/or distress at a point in time

- Patients are asked to rate their current level of anxiety/distress on a scale of 0-100



The SUDS scale is the primary endpoint for PH94B Phase 2 and Phase 3 trials

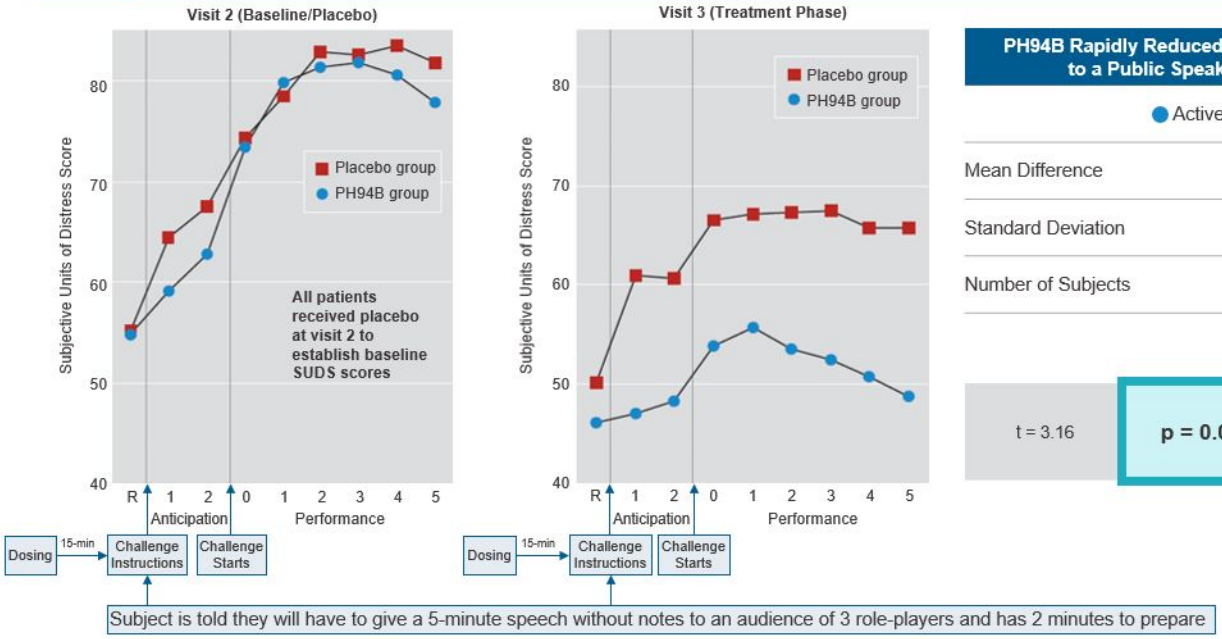
- SUDS has become the standard for acute measurement of anxiety, now leveraged in several ongoing clinical trials
- SUDS captures patient-reported rather than investigator-reported outcomes
- LSAS is used as inclusion criteria given its focus on the past two weeks, and is used to diagnose and measure the severity of SAD over longer periods of time

VistaGen

PH94B

Phase 2 SAD Study — Public Speaking Challenge (n = 91)

Minute-by-Minute SUDS Scores



PH94B Rapidly Reduced Anxiety in Response to a Public Speaking Challenge

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

t = 3.16 | **p = 0.002** | **Cohen's d** (Effect Size) **0.66**

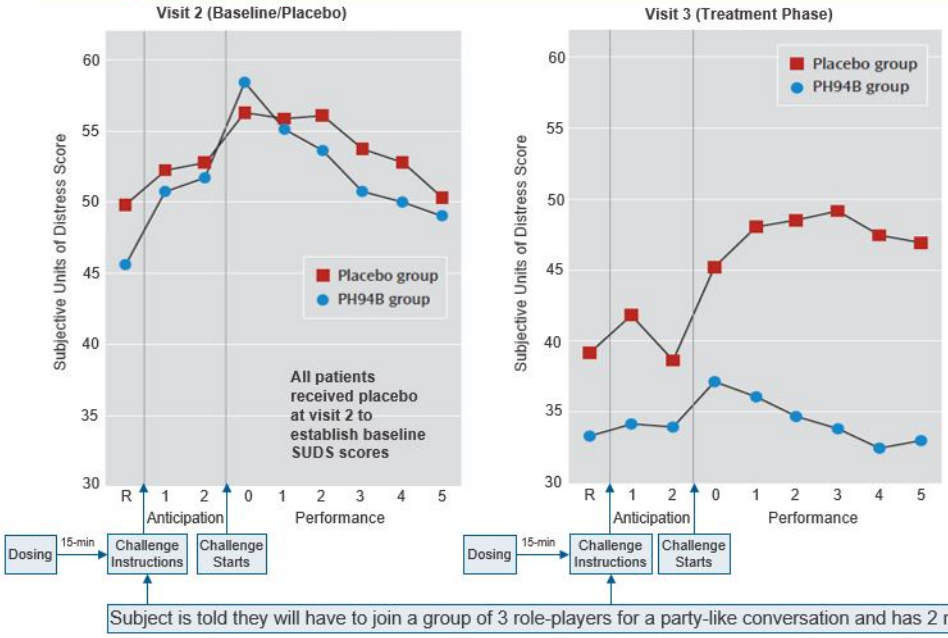
VistaGen

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

Phase 2 SAD Study — Social Interaction Challenge (n = 91)

Minute-by-Minute SUDS Scores



Subject is told they will have to join a group of 3 role-players for a party-like conversation and has 2 minutes to prepare

PH94B Rapidly Reduced Anxiety in Response to a Social Interaction Challenge

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

t = 2.67 | **p = 0.009** | **Cohen's d** (Effect Size) **0.56**

Social Interaction Challenge dosing occurs ≈60 minutes post Public Speaking Challenge dosing

VistaGen

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

PALISADE-1 and PALISADE-2 Phase 3 SAD Studies

Acute Treatment of Anxiety for Adults with Social Anxiety Disorder

Principal Investigator: Dr. Michael Liebowitz, Columbia University

Objectives: Evaluate efficacy, safety, and tolerability of PH94B for the acute treatment of anxiety in adults with social anxiety disorder

Study design: U.S. randomized, multi-center, double-blind, placebo-controlled clinical trials

Primary Endpoint: Change in SUDS scores from baseline vs. placebo

Target enrollment: N = 208

PALISADE-1: Initiated mid-2021; topline results expected mid-2022

PALISADE-2: Initiated Q3 2021; topline results expected 2H 2022

If successful, intended to support PH94B US NDA submission for acute treatment of anxiety in adults with SAD

VistaGen

PH94B – Potential Opportunities Beyond Social Anxiety Disorder

Adjustment Disorder	Prevalence: **~18M**	Current treatment paradigm lacks major studies to support pharmacotherapy. A need exists for evidence based clinical interventions for adjustment disorder
Post Traumatic Stress Disorder	Prevalence: **~9M**	A minority of PTSD patients (< 30%) achieve full remission, leaving unmet need for new effective and preventive medications
Procedural Anxiety	Prevalence: **~9M**	Current treatment options come with safety issues & variable efficacy and are not ideal for many patients and procedural situations
Post-partum Anxiety	Prevalence: **~0.6M**	Drugs are prescribed that are approved for the general population, but none are ideal for the needs of new mothers.
Panic Disorder	Prevalence: **~7M**	Treatments lack consistent symptom control, with bother-some side effects and risk of abuse. Options do not provide acute symptomatic relief

The efficacy of PH94B for these indications is theoretical. VistaGen has not conducted clinical trials that could demonstrate efficacy of our investigational product for such potential uses.

Sources: 1. Mauro et al. 2009, 2. Reismnan et al. 2016, 3. Antonin et al. 2021, 4. Carske et al. 2005, 5. Julia et al. 2019.

VistaGen

VistaGen Therapeutics

PH10

for

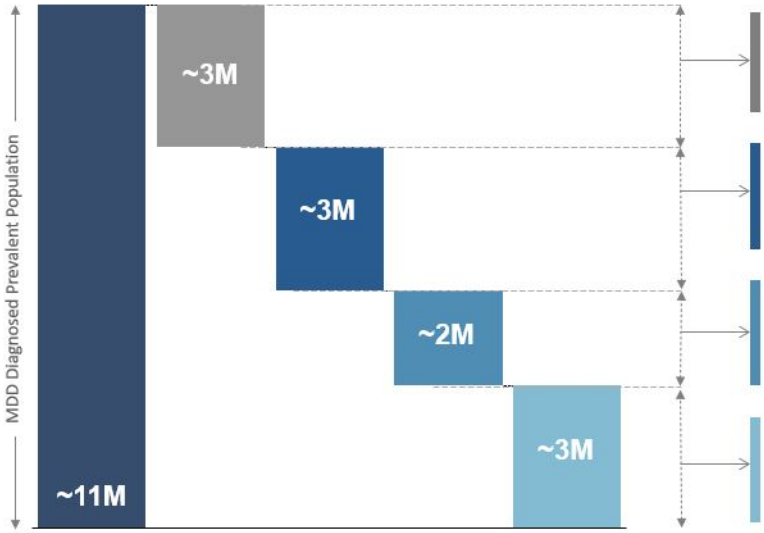
Major Depressive Disorder

www.vistagen.com

Looking beyond the standard of care for anxiety, depression and other CNS disorders

Significant Unmet Need in Major Depressive Disorder (MDD)

21 million US Adults had at least one major depressive episode in 2020



Untreated Pts: A large percentage of patients remain untreated as a result of lack of options and discontinuations due to severe side effects

First Line Treated Pts: Only 1 in 3 patients respond to first anti-depressant. May take **4 to 6 weeks or more for antidepressant effects**. **Significant potential side effects** such as Anxiety, sexual dysfunction, insomnia, dizziness and nausea

Second Line Treated Pts: Augmentation with anti-psychotics may have limited efficacy and be associated with significant potential side effects, including weight gain, stomach pain, tiredness, dizziness, tardive dyskinesia, headache, restlessness

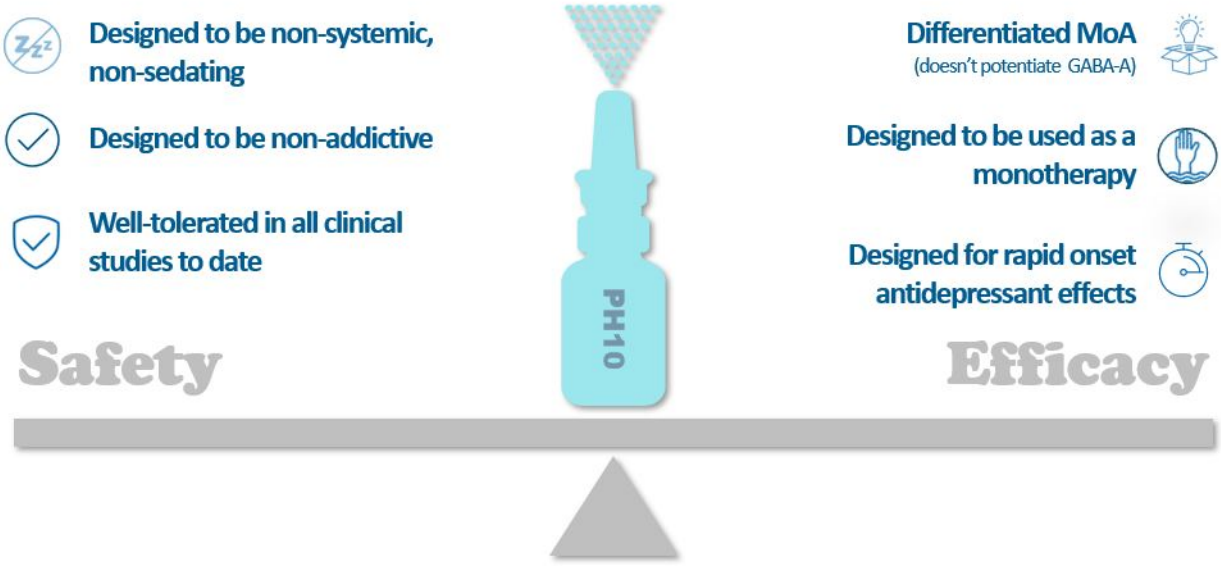
Third Line plus Pts: Large unmet need for patients resistant to second line treatment options. **Lack of safe and efficacious options for Treatment Resistant & Refractory MDD**

VistaGen

1. Substance Abuse and Mental Health Services Administration. (2020). Key substance use and mental health indicators in the United States: Results from the 2019 National Survey on Drug Use and Health
2. World Health Organization, https://www.who.int/news-room/fact-sheets/detail/depression; 3. Rush AJ, et al. Am J. Psychiatry. 2006; 163(11): 1905-1917 (STAR*D Study)

PH10 is a potential stand-alone treatment for Major Depressive Disorder

PH10 is an odorless & tasteless novel synthetic neuroactive steroid nasal spray

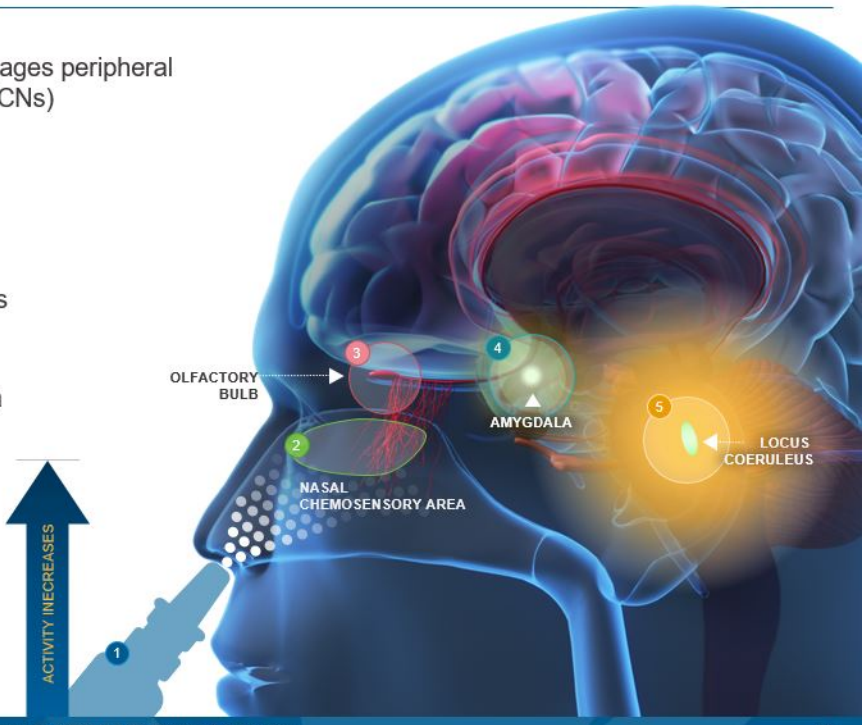


VistaGen

PH10

Novel MOA via olfactory-amygdala circuit

1. Microgram-level intranasal dose of PH10 engages peripheral receptors in nasal chemosensory neurons (NCNs)
2. Chemosensory receptors in nose
3. Trigger subsets of neurons in the olfactory bulbs
4. Which stimulate neurons in the limbic amygdala
5. Which INCREASES activity of limbic-hypothalamic sympathetic nervous system and increases the release of catecholamines



VistaGen

Monti L, and Liebowitz MR (2020). Neural circuits of anxiolytic and antidepressant *phenine* molecules. *CNS Spectrums* https://doi.org/10.1017/S109285292000190X

PH10
Antidepressant Effects in Exploratory Phase 2A Study

Study design: Phase 2A randomized, double-blind, placebo-controlled, parallel design POC clinical study

Dose administered: 3.2 mcg or 6.4 mcg of PH10 or placebo given intranasally 2 times per day, every day for 8 weeks

Target enrollment: N = 30

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

Results: 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)

Safety: Well-tolerated, no dissociative side effects or serious adverse events observed

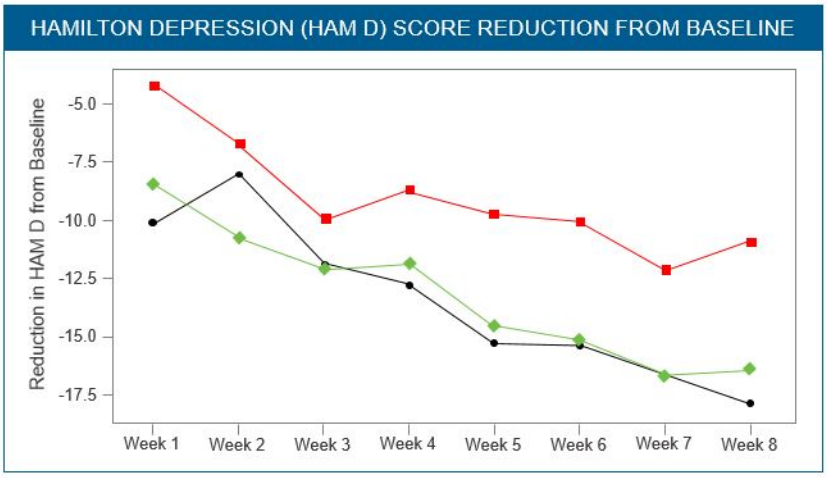
Implications: Supports advancement to Phase 2B clinical development

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.

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

VistaGen

PH10
Phase 2A MDD Study (n = 30)



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

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

VistaGen

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 - Potential Opportunities Beyond Major Depressive Disorder

Treatment Resistant Depression	Prevalence: **~7M**	Treatment lacks consistent symptom control, bother-some side effects and tolerance, and risk of abuse. Options do not provide acute symptomatic relief
Post Partum Depression	Prevalence: **~0.5M**	Concern of PPD treatments is high among patients; non-systemic options are needed especially for breastfeeding mothers
Suicidal Ideation	Prevalence: **~12M**	Suicidal Ideation is undertreated and lacks awareness outside of comorbid diagnosis. Overall HCPs lack understanding of suicidal antecedent validators and skills for suicide risk assessments

The efficacy of PH10 for these indications is theoretical. VistaGen has not conducted clinical trials that could demonstrate efficacy of our investigational product for such potential uses.

Sources: 1. Results from the 2019 National Survey on Drug Use and Health; 2. Zhdanava M, et al., J Clin Psychiatry. 2021;82(2):20m13699; 3. Wang, Zet al, Transl Psychiatry 11, 543 (2021); 4. Cox EQ, et al. J Clin Psychiatry. 2016;77(9):1189 1200; 5. Piscopo K, et al, 2016 6. Bommersbach TJ, et al, JAMA Psychiatry. 2022;79(3):219–231.

VistaGen

VistaGen Therapeutics

AV-101

for
Multiple CNS Disorders

www.vistagen.com

Looking beyond the standard of care for anxiety, depression and other CNS disorders

AV-101

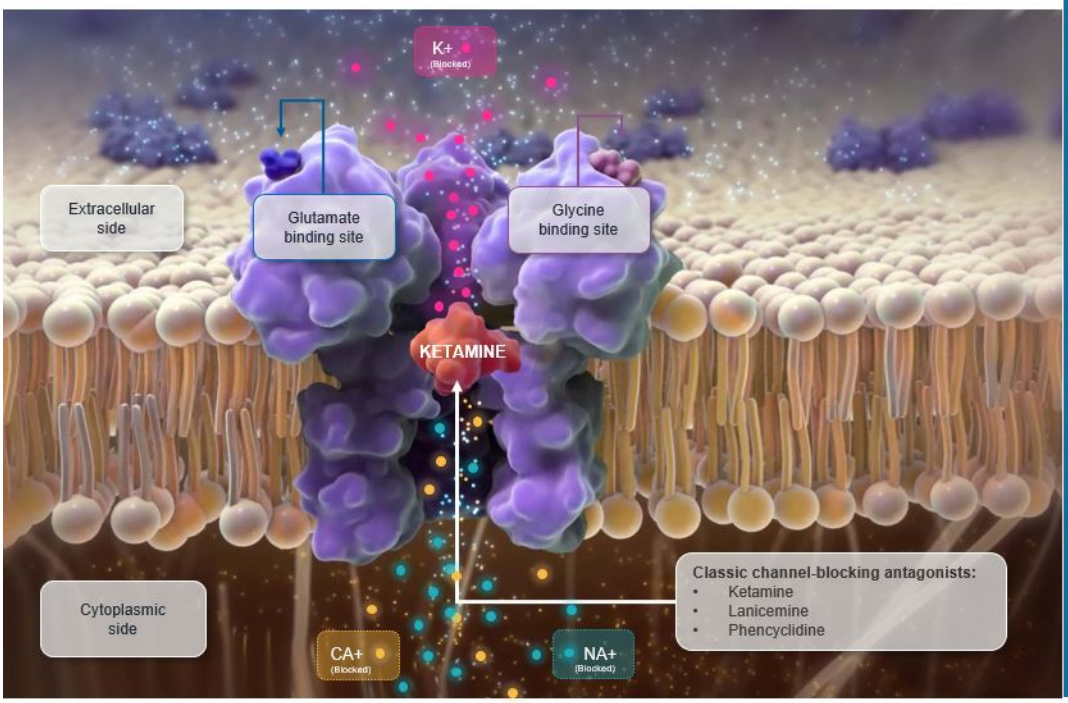
For Multiple CNS Disorders

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-Cl-KYNA when administered in combination with FDA-approved probenecid
- Assessing go forward opportunities in a DDI study in combination with probenecid
- FDA Fast Track designations for adjunctive treatment of MDD and treatment of neuropathic pain

VistaGen

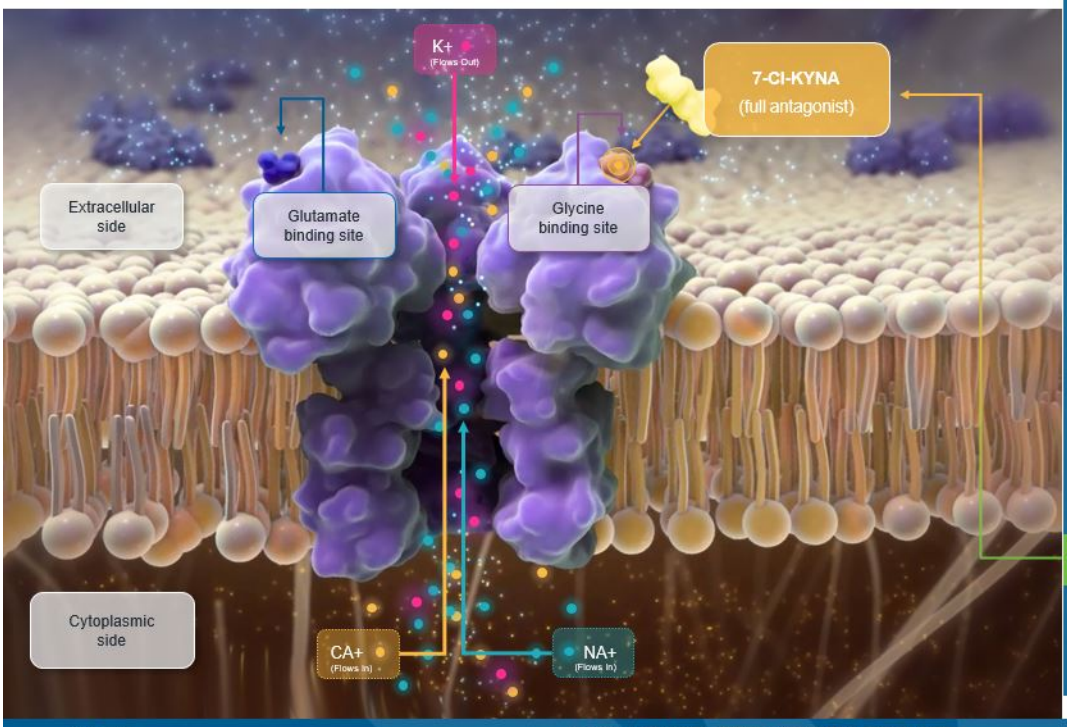
Ketamine Therapy



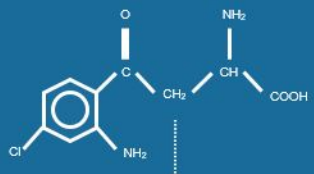
Ketamine completely blocks the ion channel of NMDAR, causing undesirable safety concerns

VistaGen

AV-101's Potential MOA

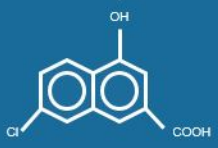


AV-101 - Oral Prodrug (4-Cl-KYN)



L-4-chlorokynurenine (4-Cl-KYN) (oral delivery to CNS)

Activated Astrocytes



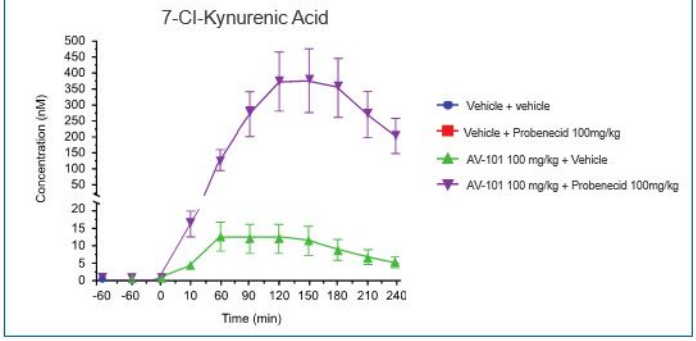
AV-101 - Active Metabolite (7-Cl-KYNA)

VistaGen

AV-101 + Probenecid

Recent Preclinical Data Demonstrate Substantial Increases in Brain Concentrations of 7-Cl-KYNA

PROBENECID INCREASES 7-CL-KYNA BRAIN LEVELS BY > 35-FOLD[1]



PROBENECID INCREASES 7-CL-KYNA BRAIN LEVELS BY > 3.4-FOLD[2]

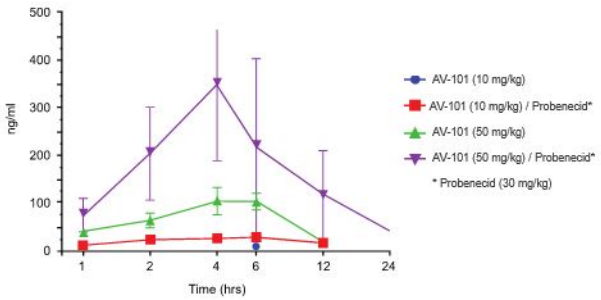


Figure 2 → Levels of 7-Cl-KYNA in PFC of adult male Sprague-Dawley rats following IP administration (T=0) of AV-101 and probenecid alone or in combination (100mg/kg each) Data are represented as mean ± SEM. N = 4 6/group.

1. Rodent: Dickens, D., (2019, December). Drug transporters at the blood-brain barrier as targets for personalized CNS therapeutics. Speaker at British Pharmacological Society, Pharmacology 2019, Edinburgh, UK.
2. Canine: Internal Data: there was high degree of variation in this experiment due to the limited number of animals from which suitable time-based sequential CSF samples could be drawn.

VistaGen

Dynamic Leaders Driving Innovative Treatments for Mental Health

Positioning VistaGen for Near-Term Success

Shawn K. Singh
Chief Executive Officer

30 years of experience with bio-pharmaceutical companies, health care venture capital and a profitable CRO

Ralph Snodgrass, Ph.D.
President, Chief Scientific Officer

25 years of experience in senior biotechnology management

Mark A. Smith, M.D., Ph.D.
Chief Medical Officer

25 years of large Pharma CNS drug development experience

Ann Cunningham, MBA
Chief Commercial Officer

25 years of experience in sales, marketing and global life cycle product management

Jerrold D. Dotson, CPA
Chief Financial Officer

25 years of experience in senior management finance and administration

Reid Adler, J.D.
Chief Legal Officer

35 years of experience with innovation management in life sciences

AstraZeneca · CALYPTE BIOMEDICAL CORPORATION · DUPONT · CATO RESEARCH · CATO BIOVENTURES · Lilly · NIH National Institute of Mental Health

Otsuka · PROGENITOR LIFE SCIENCES · SciClone PHARMACEUTICALS · Shire · teva · UNC LINEBERGER COMPREHENSIVE CANCER CENTER

VistaGen

Distinguished Clinical and Regulatory Advisors

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

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)

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

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

Mark Wallace, M.D.

Professor of Clinical Anesthesiology, Chair of the Division of Pain Medicine, Medical Director and Director at the University of California, San Diego

VistaGen

Healthy minds create healthy communities, and we are innovating to change the trajectory of global mental health care…

One Mind at a Time™