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): $\underline{October\ 13,2020}$

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	r any of the following provisions:		
☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 23 ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.1 ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchang ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchang	14a -12) ge Act (17 CFR 240.14d -2(b))			
ecurities registered pursuant to Section 12(b) of the Act:				
<u>Title of each class</u> Common Stock, par value \$0.001 per share	Trading Symbol(s) VTGN	Name of each exchange on which registered Nasdaq Capital Market		
ndicate by check mark whether the registrant is an emerging growth company as $(40.12b-2)$	defined in Rule 405 of the Securities Act of 1933	3 (17 CFR 230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (1	17 CF	
		Emerging Growth Comp	pany [
f an emerging growth company, indicate by check mark if the registrant has elected ection 13(a) of the Exchange Act \Box	d not to use the extended transition period for con	mplying with any new or revised financial accounting standards provided purs	suant	

Item 3.01 Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing.

On October 13, 2020, VistaGen Therapeutics, Inc. (the "Company") received a letter (the "Extension Notice") from the Listing Qualifications Staff of The Nasdaq Stock Market, LLC ("Nasdaq") notifying the Company that Nasdaq has granted the Company a 180-day extension, until April 12, 2021 (the "Extension Period"), to regain compliance with the requirement for the Company's common stock ("Common Stock") to maintain a minimum bid price of \$1.00 per share for continued listing on the Nasdaq Capital Market, as set forth in Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement").

The Extension Notice has no immediate effect on the continued listing status of the Company's Common Stock on the Nasdaq Capital Market.

The Company's listing remains fully effective.

As previously disclosed in the Company's Current Report on Form 8-K, filed on January 31, 2020, the Company received notice from Nasdaq that the Company was not in compliance with the Minimum Bid Price Requirement for a period of 30 consecutive business days (the "Initial Notice"). As provided in the Initial Notice, the Company had a 180-day period, until July 29, 2020, to regain compliance with the Minimum Bid Price Requirement, which period was extended by Nasdaq until October 12, 2020 as a result of the impact on the global market caused by the COVID-19 pandemic. The Company did not regain compliance with the Minimum Bid Price Requirement before October 12, 2020, and instead advised Nasdaq of its intent to cure the deficiency within the Extension Period.

The Company will continue to monitor the closing bid price of its Common Stock and seek to regain compliance with the Minimum Bid Price Requirement within the Extension Period. If the Company does not regain compliance with the Minimum Bid Price Requirement within the Extension Period, Nasdaq will provide written notification to the Company that its Common Stock will be subject to delisting, at which time the Company may appeal Nasdaq's delisting determination to a Nasdaq Hearing Panel (the "Panel"). There can be no assurance that, if the Company does need to appeal a Nasdaq delisting determination to the Panel, that such appeal would be successful.

Item 7.01 Regulation FD Disclosure.

On October 13, 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 99.1.

The information in this Item 7.01 of this Current Report on Form 8-K, including the information set forth in Exhibit 99.1, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), nor shall Exhibit 99.1 filed herewith be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

See Exhibit Index

Disclaimer.

This Current Report on Form 8-K may contain, among other things, certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, without limitation, (i) statements with respect to the Company's plans, objectives, expectations and intentions; and (ii) other statements identified by words such as "may", "could", "would", should", "believes", "expects", "anticipates", "estimates", "intends", "plans" or similar expressions. These statements are based upon the current beliefs and expectations of the Company's management and are subject to significant risks and uncertainties.

Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

VistaGen Therapeutics, Inc.

Date: October 13, 2020

By: <u>/s/ Shawn K. Singh</u> Shawn K. Singh, J.D. Chief Executive Officer

EXHIBIT INDEX

Exhibit No. Description
99.1 VistaGen Therapeutics, Inc. Corporate Presentation, dated October 2020.

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

vw.VistaGer

Nasdaq : VTGN

Corporate Presentation



Forward-looking Statements



This presentation contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements concern our product candidates, 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.

Mental Health Crisis

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



Forbes

"The Pandemic Has Caused An Increase In Anxiety, Stress, Depression And Suicides"



TIME STORE

THE AGE OF

CNN Health

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







"COVID-19 pandemic causes mental health crisis in Americas, says WHO official"

Social Media is Damaging Mental Health



"How 'Keeping Up With The Joneses' On Social Media is Damaging Everyone's Mental Health"

"Lots of Time on Social Media Linked to Anxiety, Depression in Teens" "Why Instagram is the Worst Social Media for Mental Health"



Forbes





"A Rise in Depression Among Teens and Young Adults Could be Linked to Social Media Use"



"How Removing 'Likes' from Instagram Could Affect Our Mental Health"



"Benzo" Epidemic

VistaGen® Therapeutics

"Benzodiazepines: Primary Care's New Drug Problem"

Psychiatry Advisor



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



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



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

FORTUNE





Boxed Warning Update on Benzodiazepines

"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

"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.D.¹

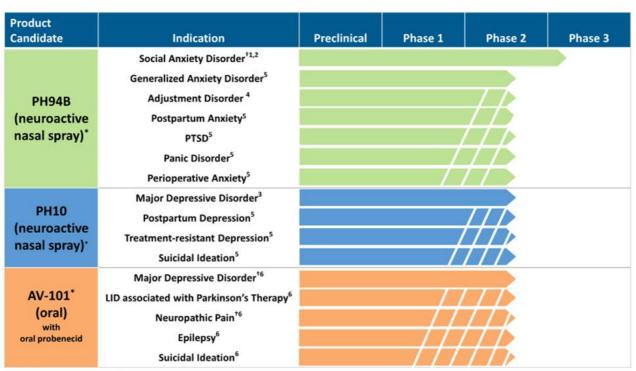
September 23, 2020

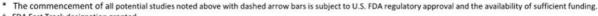
1. FDA News Release, FDA Requiring Labeling Changes for Benzodiazepines, September 23, 2020

VistaGen is committed to developing and commercializing new generation medicines that go beyond the standard of care for anxiety, depression and other CNS disorders.



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





[†] FDA Fast Track designation granted

- 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

VistaGen®

Therapeutics

^{1.} Successful Phase 2 program completed; preparing for pivotal Phase 3 clinical development

VistaGen®

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

More than Just Shyness



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

Affects as many as

20 million¹

Americans



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



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

Current Standard of Care for SAD is Inadequate





Not FDA-Approved

* Prescribed Off-label *

Antidepressants (2 SSRIs, 1 SNRI)

- ★ Slow onset, chronic administration
- ★ May worsen anxiety initially
- ★ Significant potential side effects
 - Nausea and vomiting, weight gain, sleepiness, sexual problems
- ➤ Potential drug-drug interaction

Benzodiazepines, Beta Blockers

- * Addiction risk
- ★ Significant potential side effects
 - Nausea and vomiting, blurred vision, dizziness, sedation, confusion, and cognitive impairment

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



PH94B Neuroactive Nasal Spray for Treatment of Anxiety Disorders

ww.VistaGen



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

PH94B

Acute Treatment of Anxiety for Adults with Social Anxiety Disorder

- Odorless, synthetic neuroactive nasal spray
- Fast-acting (within 15 minutes)
- Non-systemic
- Exceptional safety in all clinical studies to date
- Highly statistically significant Phase 2 study (p=0.002)
- FDA consensus on Phase 3 studies to mirror Phase 2
- FDA Fast Track designation granted

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



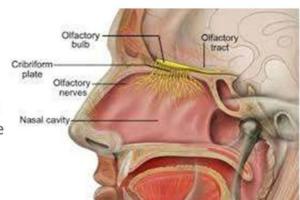


PH94B's Mechanism of Action

"Action from a Distance"

/istaGen®

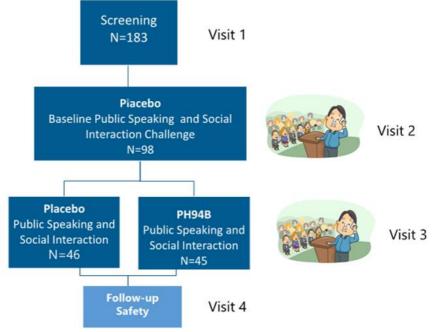
- Microgram level intranasal dose (3.2 mcg) engages specific nasal chemosensory neurons (NCNs)
- NCNs activate olfactory bulb neurons (OBNs) on the base of the brain
- OBNs send neural connections specifically to neurons in the central limbic amygdala, the brain center where fear and anxiety are regulated
- Neurons in the limbic amygdala modulate inhibitory neurotransmitters, resulting in rapid anti-anxiety effects
- Systemic uptake and distribution not required to produce rapid-onset anti-anxiety effects



PH94B Phase 2 SAD Study

Public Speaking

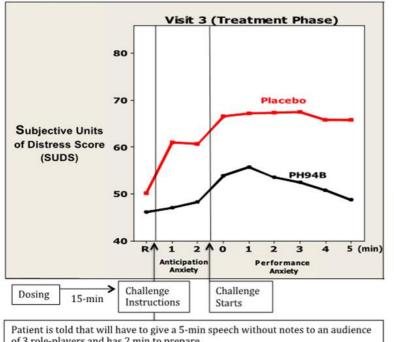




Liebowitz, MR, Salman, E, Nicolini, H, Rosenthal, N, Hanover, R, Monti. L (2014). Effect of an acute intranasal aerosol dose of PH948 on social and performance anxiety in women with social anxiety disorder. Am. J. Psychiatry 171:675-682

PH94B Phase 2 SAD 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

		Cohen's d
t = 3.16	p = 0.002	(Effect Size)
		.66

of 3 role-players and has 2 min to prepare

VistaGen_®

PH94B North American Pivotal Phase 3 SAD Study Summary:

Acute Treatment of Anxiety for Adults with Social Anxiety Disorder

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

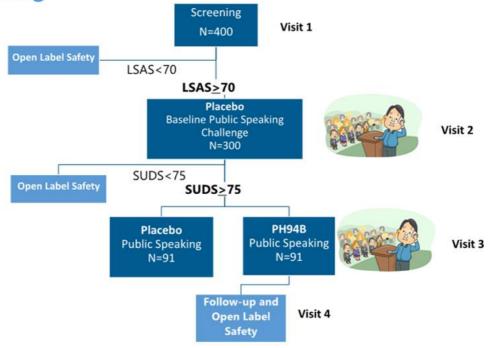
- FDA consensus that design of pivotal Phase 3 public speaking clinical studies will mirror highly statistically significant (p=0.002) Phase 2 public speaking study
 - Single, laboratory-simulated, anxiety-provoking public speaking challenge
 - Single dose, 3.2 μg
 - Primary efficacy endpoint assessed using Subjective Units of Distress Scale (SUDS)
- 15 sites in North America
- Target enrollment (completed subjects), 182¹

1. Planned PH94B Global Pivotal Phase 3 SAD Study will involve 240 completed subjects

PH94B North American Pivotal Phase 3 SAD Study:



Public Speaking



PH94B for Acute Treatment of SAD in the U.S.





*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 18

EverInsight/CBC Group Collaboration

Development and Commercialization of PH94B in Key Asian Markets

• Obligations:

- EverInsight (funded by CBC Group) will be responsible for development 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





Adjustment Disorder



- Emotional or behavioral reaction considered excessive or out of proportion to a stressful event or major life change that occurred within previous 3 months
- · Significantly impairs functioning
- COVID-19 pandemic and civil unrest have created many anxiety-provoking stressors
- Current medicine, especially benzos, have major side effects and safety concerns









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, 25-30

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

PH94B Potential Beyond SAD Adjustment Disorder Post-**Traumatic** Postpartum Stress **Anxiety** Disorder Preoperative Generalized Anxiety **Pre-testing** (MRI) Disorder **Anxiety Panic** Disorder





Major Depressive Disorder (MDD) in the U.S.

Pre-Pandemic

17.3 million adults in the U.S. had at least one major depressive episode¹



Globally, 264 million people of all ages suffer from depression²

During the Pandemic

"Depression Has Skyrocketed During the COVID-19 Pandemic, Study Says"





National Institute of Mantal Health https://www.nimh.nih.gov/health/statistics/maior-depression.shtml-2. World Health Organization. https://www.who.int/news-room/fact-sheets/detail/depression.



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 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 Neuroactive Nasal Spray for Treatment of Depression Disorders

ww.vistagei



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

PH10

Stand-alone Treatment for Adults with Major Depressive Disorder

- Odorless synthetic neuroactive nasal spray
- Non-systemic
- Successful Phase 2A in MDD completed
- Potential rapid-onset antidepressant effects
- Exceptional safety in all studies to date
- Preparing for Phase 2B clinical development

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



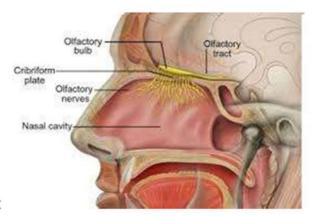


PH10's Mechanism of Action

"Action from a Distance"

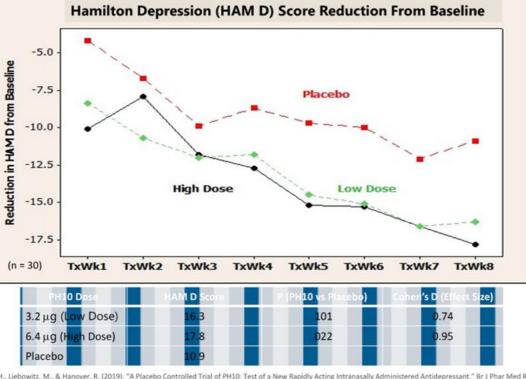


- Microgram level dose (6.4 mcg) engages specific nasal chemosensory neurons (NCNs)
- NCNs activate olfactory bulb neurons (OBNs) on the base of the brain
- OBNs send neural connections to neurons in the central limbic amygdala, the brain center where mood is regulated
- Neurons in the amygdala stimulate release of excitatory neurotransmitters resulting in rapid-onset antidepressant effects
- Systemic uptake and distribution not required to produce rapid-onset antidepressant effects



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





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

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 μg or 6.4 μg) or placebo for 4 weeks
- · Rapid-onset potential within less than one week, potentially hours to days
- Target enrollment, 150 (completed subjects)

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

PH10



Potential Beyond MDD





AV-101 for Treatment of Depression and Neurological Disorders

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

AV-101 (4-CI- KYN)

- Oral prodrug of 7-Cl-KYNA, a potent and selective NMDAR glycine site antagonist
- Exceptional safety in all studies to date
- Two positive preclinical studies show increased brain concentrations of 7-Cl-KYNA when administered in combination with FDA-approved probenecid
- Assessing multiple go forward opportunities
- FDA Fast Track designations in MDD and pain







AV-101's Mechanism of Action



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

NMDA Receptor Pharmacology AV-101 **Oral Prodrug** (4-CI-KYN) Extracellular 7-CI-KYNA L-4-chlorokynurenine (4-CI-KYN) (oral delivery to CNS) side (full antagonist) NR2B (NR2A-D) NR1 Activated Astrocytes AV-101 Cytoplasmic side **Active Metabolite** (7-CI-KYNA) Classic channel-blocking antagonists: 7-chlorokynurenic acid Ca²⁺ (7-CI-KYNA) (low adverse events expected) Ketamine Lanicemine

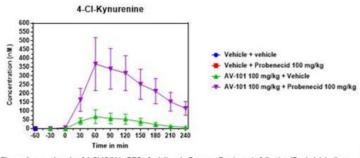
Phencyclidine

AV-101 and Probenecid



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

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



• Figure-1 → Levels-of-4-CI-K/N-in-PFC-of-adult-male-Sprague-Dav/ley-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

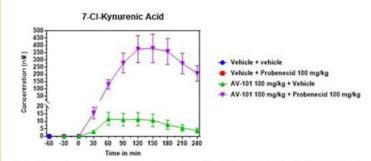
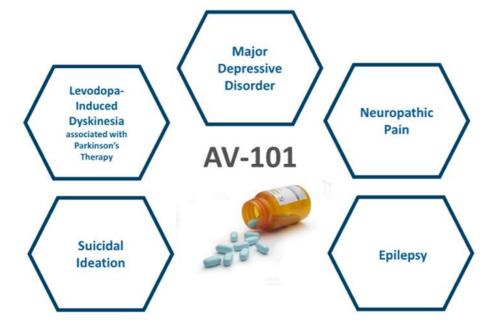


 Figure-2 → Levels-of-7-CI-KYNA-in-PFC of-adult-male Sprague-Dawley-rats-following-IP-administration-(T=0)-of-AV-101-and-probenecid-alone-or-in-combination-(100-mg/kg,-each). ← Data-are-represented as mean ± SEM. N = 4-8/group.¶

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/Probenecid for Multiple CNS Disorders





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



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



MN

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

Experienced Team Leading Execution



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

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

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



Jerrold D. Dotson, CPA

Chief Financial Officer, Secretary

- 20 years of experience in senior management finance and administration
- Calypte Biomedical; Discovery Foods; California & Hawaiian Sugar; Clorox

Mark A. Smith, M.D., Ph.D.

Chief Medical Officer

- 20 years of large Pharma CNS drug development experience
- Teva Pharmaceuticals; Shire Pharmaceuticals; AstraZeneca Pharmaceuticals; DuPont Pharmaceutical Company; U.S. National Institute of Mental Health



Mark A. McPartland

Vice President, Corporate Development

- 20 years of experience in corporate development, capital markets and management consulting
- Stellar Biotechnologies; MZ Group; Hayden Communications; Alliance Advisors



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Multiple Shots on Goal

- > PH94B for Anxiety Disorders
- > PH10 for Depression Disorders
- > AV-101 for Depression and Neurological Disorders



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





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