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 12, 2021

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 12, 2021, VistaGen Therapeutics, Inc. (the "*Company*") issued a press release to announce the Company's financial results for its fiscal year 2022 first quarter ended June 30, 2021. 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 12, 2021, the Company began utilizing a new corporate presentation, a copy of which is attached to this Current Report on Form 8-K as Exhibit 99.2.

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 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	Press Release issued by VistaGen Therapeutics, Inc., dated August 12, 2021
99.2	VistaGen Therapeutics, Inc. Corporate Presentation, dated August 2021.

Signatures

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

VistaGen Therapeutics, Inc.

Date: August 12, 2021

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

VistaGen Therapeutics Reports Fiscal Year 2022 First Quarter Financial Results and Provides Corporate Update

PALISADE Phase 3 Program to evaluate PH94B for rapid-onset acute treatment of anxiety in adults with social anxiety disorder (SAD) progressing on plan

Additional potential NDA-enabling clinical studies expected to initiate in 2021

SOUTH SAN FRANCISCO, Calif., August 12, 2021 – VistaGen Therapeutics, Inc. (NASDAQ: VTGN), a biopharmaceutical company committed to developing and commercializing a new generation of medicines with the potential to go beyond the current standard of care for anxiety, depression and other central nervous system (CNS) disorders, today reported financial results for its fiscal year 2022 first quarter ended June 30, 2021 and provided a corporate update.

"The strong momentum we generated in fiscal 2021 leading up to the launch of our PALISADE Phase 3 Program for PH94B as a potential rapid-onset acute treatment of anxiety in adults with social anxiety disorder continued throughout the first quarter of fiscal 2022. The initiation of PALISADE-1 was a major milestone in the program. That study is proceeding as planned, with topline data anticipated in mid-2022. We remain on track to initiate PALISADE-2, which will be a counterpart of PALISADE-1, later this year, together with several other planned clinical studies we believe will be supportive of a potential U.S. New Drug Application for PH94B if our PALISADE Phase 3 Program is successful. We have also made progress in our Phase 2A clinical development program for PH94B, which is focused on additional anxiety disorders beyond SAD. We recently received from the U.S. Food and Drug Administration notice that we may proceed with our proposed exploratory Phase 2A clinical study of PH94B for treatment of adjustment disorder with anxiety. We expect to initiate that study in the U.S. before year end," said Shawn Singh, Chief Executive Officer of VistaGen.

"Our core mission is to improve mental health and well-being for individuals around the world. As we continue to advance on that goal and into the next phases of our corporate development, we have enhanced diversity and collective expertise on our Board and across all key internal functions. We are well-positioned to drive our clinical-stage programs through multiple development and regulatory milestones, as well as appropriately-timed pre-commercial activities, and, if our PALISADE Phase 3 Program is successful, PH94B commercial launch operations in the U.S.," continued Singh.

Recent Corporate Highlights

- Initiated PALISADE Phase 3 Program for PH94B with PALISADE-1, a U.S., multi-center, randomized, double-blind, placebo-controlled Phase 3 clinical study to evaluate the efficacy, safety and tolerability of PH94B for the acute treatment of anxiety in adults with SAD. Topline results from PALISADE-1 are anticipated in mid-2022.
- Received notice from the U.S. Food and Drug Administration (FDA) that we may proceed with our exploratory Phase 2A clinical study of PH94B in adults experiencing adjustment disorder with anxiety (AjDA).
- Appointed Mary L. Rotunno, J.D. to our Board of Directors, adding significant healthcare industry expertise as a leader and strategist as we advance late-stage development of our CNS product candidates for anxiety and depression disorders.
- Appointed Maggie FitzPatrick to our Board of Directors, bringing extensive leadership in healthcare consumer-focused engagement, marketing and public relations. Ms. FitzPatrick has driven marketing communications initiatives for some of the world's largest and most successful companies, including Johnson & Johnson and Cigna.
- Included in the Russell 2000® Index, one of the most cited performance benchmarks for small-cap companies, increasing overall awareness and exposure for VistaGen within the investment community.

CNS Pipeline Updates

PH94B Nasal Spray

In May, VistaGen initiated its PALISADE Phase 3 Program with PALISADE-1, a U.S., multi-center, randomized, double-blind, placebo-controlled Phase 3 clinical study to evaluate the efficacy, safety and tolerability of PH94B for the acute treatment of anxiety in adults with SAD. The Company expects to initiate PALISADE-2, a replicate of PALISADE-1, in the second half of calendar 2021. If successful, these clinical studies are designed to be among the studies necessary to support a potential PH94B U.S. New Drug Application (NDA) to the FDA. PH94B has been granted Fast Track designation status by the FDA for development as an acute treatment of anxiety in adults with SAD.

Recently, the Company received a notice from the FDA allowing commencement of its exploratory Phase 2A clinical study of PH94B in adults experiencing AjDA. The study is expected to start by the end of 2021. In addition to studies of PH94B in SAD and AjDA, the Company is also preparing for exploratory Phase 2A clinical studies of PH94B in adults experiencing other anxiety disorders, including postpartum anxiety, post-traumatic stress disorder and pre-procedural anxiety.

PH10 Nasal Spray

Exploratory Phase 2A clinical development of PH10 as a potential rapid-onset treatment of major depressive disorder (MDD) has been completed. VistaGen is preparing to initiate a U.S. Phase 2B multi-center, randomized, double-blind, placebo-controlled study to evaluate the efficacy, safety and tolerability of PH10 as a potential rapid-onset, stand-alone treatment for MDD in mid-2022. PH10 also has potential as a novel treatment for treatment-resistant depression, postpartum depression and suicidal ideation.

AV-101

VistaGen is currently preparing to initiate a Phase 1B clinical study to evaluate AV-101 in combination with probenecid during the second half of calendar 2021. The FDA has granted Fast Track designation for development of AV-101 as a potential adjunctive treatment for MDD and as a non-opioid treatment for neuropathic pain. AV-101 also has the potential to be developed as a treatment for levodopa-induced dyskinesia, suicidal ideation, epilepsy and other neurological disorders involving the NMDA (N-methyl-D-aspartate) receptor.

Fiscal Year 2022 First Quarter Financial Results

Revenue: The Company recognized $0.4 million in sublicense revenue from its $5 million upfront payment pursuant to its PH94B development and commercialization agreement with EverInsight Therapeutics (now AffaMed Therapeutics) during the quarter ended June 30, 2021, compared to none in the quarter ended June 30, 2020.

Research and development (R&D) expense: Research and development expense increased by $3.9 million, from $1.7 million to $5.6 million for the quarters ended June 30, 2020 and 2021, respectively. The increase in R&D expense is primarily related to the commencement of our PALISADE Phase 3 Program for PH94B in SAD with PALISADE-1, as well as other clinical and nonclinical developmental and manufacturing activities for both PH94B and PH10, which accounted for increased expenses of approximately $2.7 million during the quarter ended June 30, 2021 in comparison to the same quarter in the prior year. Salaries and benefits expense for the quarter ended June 30, 2021 increased by approximately $1.0 million versus the comparable prior-year quarter, primarily due to the hiring of additional senior management and other personnel focused on clinical operations, outsourced manufacturing activities and regulatory affairs.

General and administrative (G&A) expense: General and administrative expense increased to approximately $2.5 million for the quarter ended June 30, 2021 compared to approximately $1.4 million for the quarter ended June 30, 2020. Salaries and benefits expense for the quarter ended June 30, 2021 increased by approximately $0.6 million versus the comparable prior-year quarter, primarily due to the hiring of additional senior management and other administrative personnel.

Net loss: Net loss for the quarters ended June 30, 2021 and 2020 was approximately $7.7 million and $3.1 million, respectively.

Cash Position: At June 30, 2021, the Company had cash and cash equivalents of approximately $97.8 million.

As of August 11, 2021, the Company had 192,903,896 shares of common stock outstanding.

Conference Call

VistaGen will host a conference call and live audio webcast this afternoon at 2:00 p.m. Pacific Time to provide a corporate update and discuss its financial results for its fiscal year 2022 first quarter ended June 30, 2021.

U.S. Dial-in (Toll Free): 1-800-935-5014
International Dial-in Number (Toll): 1-212-231-2920
Conference ID: 21996610
Webcast Link: **http://public.viavid.com/index.php?id=146257**

A telephone playback of the conference call will be available after approximately 5:00 p.m. Pacific Time on August 12, 2020. To listen to the replay, call toll free 1-844-512-2921 within the United States or 1-412-317-6671 when calling internationally (toll). Please use the replay PIN number 21996610.

About VistaGen
VistaGen Therapeutics is a biopharmaceutical company committed to developing and commercializing innovative medicines with the potential to go beyond the current standard of care for anxiety, depression, and other CNS disorders. Each of VistaGen's drug candidates has a differentiated potential mechanism of action, has been well-tolerated in all clinical studies to date and has therapeutic potential in multiple CNS indications. For more information, please visit www.VistaGen.com and connect with VistaGen on Twitter, LinkedIn, and Facebook.

Forward Looking Statements

This press release contains certain forward-looking statements within the meaning of the federal securities laws. These forward-looking statements involve known and unknown risks that are difficult to predict and include all matters that are not historical facts. 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 delays in launching and/or conducting our planned clinical trials, including delays due to the impact of the ongoing COVID-19 pandemic; fluctuating costs of materials and other resources required to conduct our planned clinical and non-clinical trials; 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, 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 due to the ongoing COVID-19 pandemic or otherwise; 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 fiscal year ended March 31, 2021 and in our most recent Quarterly Report on Form 10-Q for the quarter ended June 30, 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. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this press release and should not be relied upon as representing our views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements, 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.

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

	June 30, 2021	March 31, 2021

ASSETS

Current assets:		
Cash and cash equivalents	$ 97,776,900	$ 103,108,300
Receivable from collaboration partner	44,000	40,600
Prepaid expenses and other current assets	1,871,400	835,100
Deferred contract acquisition costs - current portion	133,500	133,500
Total current assets	99,825,800	104,117,500
Property and equipment, net	482,800	367,400
Right of use asset - operating lease	3,125,300	3,219,600
Deferred offering costs	224,700	294,900
Deferred contract acquisition costs - non-current portion	200,800	234,100
Security deposits and other assets	47,800	47,800
Total assets	$ 103,907,200	$ 108,281,300

LIABILITIES AND STOCKHOLDERS EQUITY

Current liabilities:		
Accounts payable	$ 2,316,200	$ 838,300
Accrued expenses	2,150,000	1,562,700
Deferred revenue - current portion	1,420,200	1,420,200
Operating lease obligation - current portion	378,400	364,800
Financing lease obligation - current portion	2,200	3,000
Total current liabilities	6,267,000	4,189,000
Non-current liabilities:		
Accrued dividends on Series B Preferred Stock	6,634,500	6,272,700
Deferred revenue - non-current portion	2,136,200	2,490,300
Operating lease obligation - non-current portion	3,252,700	3,350,800
Total non-current liabilities	12,023,400	12,113,800
Total liabilities	18,290,400	16,302,800
Commitments and contingencies		
Stockholders equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at June 30, 2021 and March 31, 2021:		
Series A Preferred, 500,000 shares authorized, issued and outstanding at June 30, 2021 and March 31, 2021	500	500
Series B Preferred; 4,000,000 shares authorized at June 30, 2021 and March 31, 2021; 1,131,669 shares issued and outstanding at June 30, 2021 and March 31, 2021	1,100	1,100
Series C Preferred; 3,000,000 shares authorized at June 30, 2021 and March 31, 2021; 2,318,012 shares issued and outstanding at June 30, 2021 and March 31, 2021	2,300	2,300
Series D Preferred; 2,000,000 shares authorized at June 30, 2021 and March 31, 2021; no shares and 402,149 shares issued and outstanding at June 30, 2021 and March 31, 2021, respectively	-	400
Common stock, $0.001 par value; 325,000,000 shares authorized at June 30, 2021 and March 31, 2021; 191,632,008 and 180,751,234 shares issued at June 30, 2021 and March 31, 2021, respectively	191,600	180,800
Additional paid-in capital	316,975,600	315,603,100
Treasury stock, at cost, 135,665 shares of common stock held at June 30, 2021 and March 31, 2021	(3,968,100)	(3,968,100)
Accumulated deficit	(227,586,200)	(219,841,600)
Total stockholders equity	85,616,800	91,978,500
Total liabilities and stockholders equity	$ 103,907,200	$ 108,281,300

VistaGen® Therapeutics

VISTAGEN THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS
(Amounts in Dollars, except share amounts)
(Unaudited)

	Three Months Ended June 30,	
	2021	**2020**
Sublicense revenue	$ 354,100	$ -
Total revenues	354,100	-
Operating expenses:		
Research and development	5,603,600	1,731,200
General and administrative	2,496,700	1,390,600
Total operating expenses	8,100,300	3,121,800
Loss from operations	(7,746,200)	(3,121,800)
Other income (expenses), net:		
Interest income (expense), net	5,100	(3,200)
Other income	-	600
Loss before income taxes	(7,741,100)	(3,124,400)
Income taxes	(3,400)	(2,400)
Net loss and comprehensive loss	(7,744,500)	(3,126,800)
Accrued dividends on Series B Preferred stock	(361,800)	(335,800)
Net loss attributable to common stockholders	$ (8,106,300)	$ (3,462,600)
Basic and diluted net loss attributable to common stockholders per common share	$ (0.04)	$ (0.07)
Weighted average shares used in computing basic and diluted net loss attributable to common stockholders per common share	189,924,158	51,321,355

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, 2020, as well as discussions of potential risks, uncertainties, and other important factors in our other filings with the U.S. Securities and Exchange Commission (SEC).

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

VistaGen
THERAPEUTICS

COMPANY HIGHLIGHTS

- **Three innovative CNS drug candidates advancing in clinical development**
  - Unique mechanisms of action
  - Therapeutic potential in multiple anxiety, depression and neurology markets
  - Lead candidate in NDA-enabling Phase 3 development for acute treatment of anxiety in adults with Social Anxiety Disorder
  - FDA Fast Track Designation in Social Anxiety Disorder, Major Depressive Disorder and Neuropathic Pain
- **Numerous catalysts anticipated 2021 – 2023**
  - **Clinical**: Multiple NDA-enabling Phase 3 trials and Phase 2 trials beginning in 2021/2022 with top line results in 2022 and 2023
  - **Regulatory**: Potential for NDA submission in 1H 2023, Breakthrough Designation for SAD, and additional Fast Track Designations
  - **Partnering**: Exploring options to further expand ex-US development and commercial partnerships
- **Solid Institutional Shareholder Base**
- **Strong Balance Sheet**

VistaGen THERAPEUTICS

OUR CNS PIPELINE

PRODUCT CANDIDATE	POTENTIAL INDICATIONS	PRECLINICAL	PHASE I	PHASE II	PHASE III
PH94B Nasal Spray	Social Anxiety Disorder[1]	FDA Fast Track designation granted			
	Adjustment Disorder[2]				
	Pre-procedural Anxiety (fMRI)[2]				
	PTSD[3]				
	Postpartum Anxiety[3]				
	Panic Disorder[4]				
PH10 Nasal Spray	Major Depressive Disorder[5]				
	Treatment-resistant Depression[4]				
	Postpartum Depression[4]				
	Suicidal Ideation[4]				
AV101 (oral) with oral probenecid	LID Associated w/Parkinson's Therapy[6]				
	Major Depressive Disorder[6]	FDA Fast Track designation granted			
	Neuropathic Pain[6]	FDA Fast Track designation granted			
	Epilepsy[6]				
	Suicidal Ideation[6]				

1. PALISADE-1 Phase 3 trial initiated in Q2 2021; PALISADE-2 Phase 3 trial planned to begin in 2H 2021
2. Preparing for exploratory Phase 2A clinical development in 2H 2021
3. Preparing for exploratory Phase 2A clinical development in 1H 2022
4. Assessing for potential exploratory Phase 2A clinical development
5. Successful Phase 2A clinical development completed; preparing for Phase 2B clinical trial in 1H 2022
6. Preparing for Phase 1B clinical development in 2H 2021; assessing for potential exploratory Phase 2A clinical development in 2022

VistaGen THERAPEUTICS

SOCIAL ANXIETY DISORDER
(Social Phobia)

ONE OF THE MOST PREVALENT MENTAL HEALTH CONDITIONS IN THE U.S.

EFFECTING AS MANY AS

23.7 MILLION[1] AMERICANS

"More than Just Shyness" - Substantially Impacts Daily Living

1. Kantar National Health and Wellness Survey (NHWS), 2020

- 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

VistaGen THERAPEUTICS

CURRENT STANDARD OF CARE FOR SAD IS INADEQUATE

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

FDA-APPROVED

Antidepressants (2 SSRIs, 1 SNRI)

- Slow onset, require chronic administration
- May worsen anxiety initially
- Significant potential side effects
  - Nausea and vomiting, weight gain, somnolence and sexual dysfunction
- Potential drug-drug interaction

NOT FDA-APPROVED
(Prescribed Off-label)

Benzodiazepines, Beta Blockers

- High risk of addiction, misuse and dependence
- Significant potential side effects
  - Sedation, nausea and vomiting, blurred vision, dizziness, confusion and cognitive impairment

Limited treatment options highlight significant unmet need for an innovative fast-acting, acute treatment without significant side effects and safety concerns

VistaGen THERAPEUTICS

THE "BENZO" EPIDEMIC

Recent FDA Boxed Warning Update on Benzodiazepines

WARNING

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

FDA Drug Safety Communication | September 23, 2020

FDA U.S. FOOD & DRUG ADMINISTRATION

"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

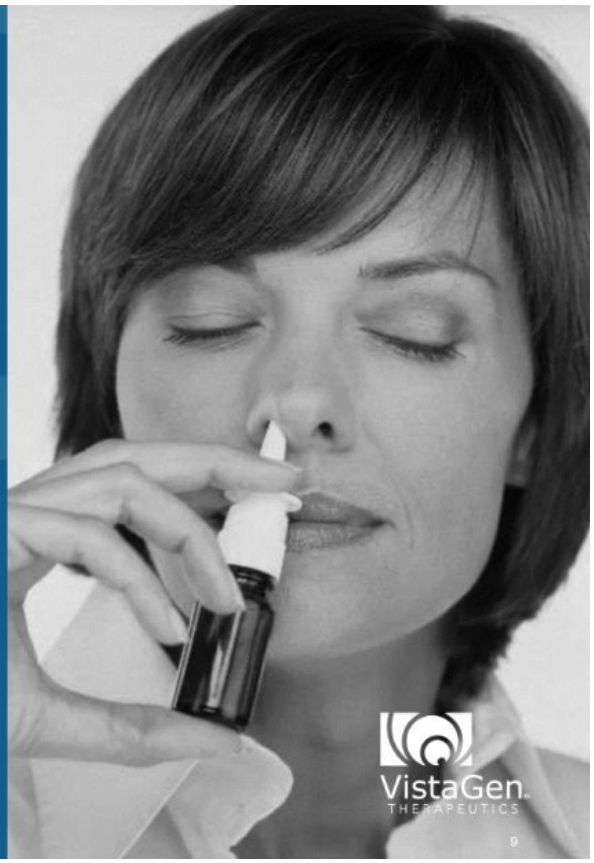
1. FDA News Release, FDA Requiring Labeling Changes for Benzodiazepines, September 23, 2020

PH94B FOR SOCIAL ANXIETY DISORDER

Acute Treatment of Anxiety for Adults with Social Anxiety Disorder

- Odorless pherine nasal spray
- Unique MOA
- Microgram-level dosing
- Designed to be fast-acting (within 15 minutes)
- Non-systemic and non-sedating
- Well-tolerated in all clinical studies to date
- Met primary endpoint in Phase 2 study public speaking challenge (p=0.002);
- Potential NDA-enabling Phase 3 studies mirror Phase 2 study design
- FDA Fast Track designation

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

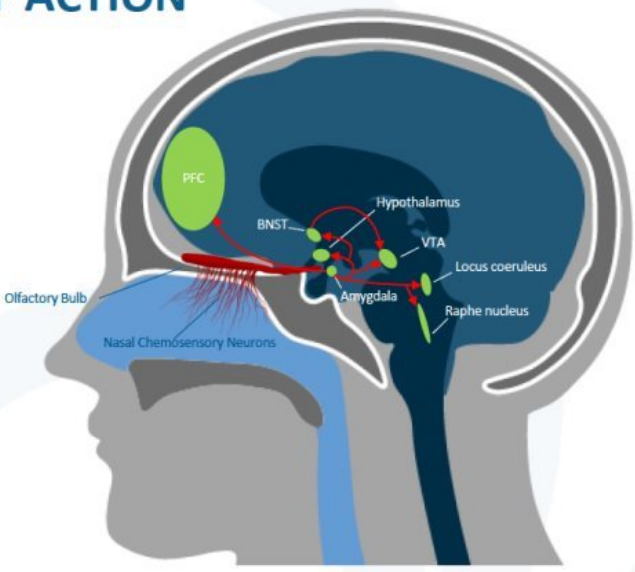


PH94B'S POTENTIAL MECHANISM OF ACTION

"Action from a Distance"

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

- Neurons in the limbic amygdala regulate fear and anxiety by modulating inhibitory neurotransmission in other brain regions
- Microgram-level intranasal dose of PH94B (3.2 mcg) engages specific peripheral **nasal chemosensory neurons (NCNs)**
- NCNs activate **olfactory bulb neurons (OBNs)** on the base of the brain
- OBNs send neural connections specifically to neurons in the central limbic amygdala, resulting in downstream signaling and rapid anti-anxiety effects
- **Systemic uptake and distribution of PH94B is not required to produce rapid-onset anti-anxiety effects**



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

VistaGen
THERAPEUTICS

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

PH94B PHASE 2 SOCIAL ANXIETY DISORDER STUDY

Public Speaking and Social Interaction Challenges

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

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

SUBJECTIVE UNITS OF DISTRESS SCALE (SUDS)

Primary Efficacy Endpoint in Phase 2 and Phase 3

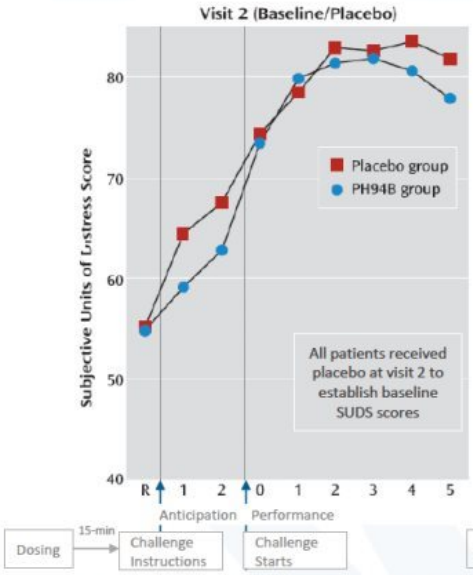
The SUDS measures the self-reported intensity of anxiety and/or distress in patients with SAD

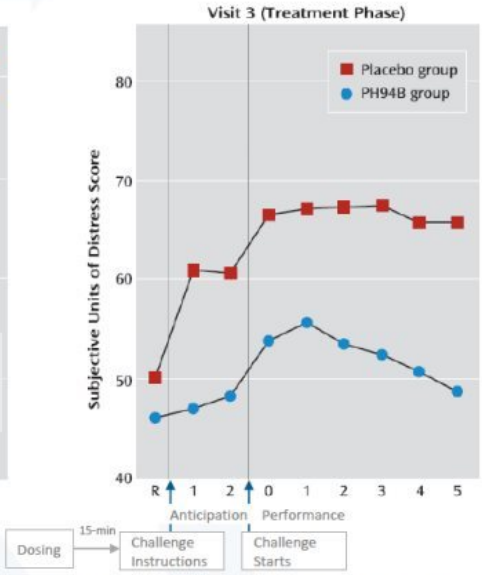
- Patients are asked to rate their level of anxiety/distress on a scale of 0-100
- Physiological signs of distress such as sweating, shaking, increased heart rate or respiration, and gastrointestinal distress may be present at a score of 70, and are present at a score of 80

Oxford Clinical Psychology. © Oxford University Press, 2014

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

Minute-by-Minute SUDS Scores





Subject is told that will have to give a 5-min speech without notes to an audience of 3 role-players and has 2 min to prepare

PH94B Rapidly Reduced Anxiety in Response to 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) .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.

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PH94B PALISADE PHASE 3 PROGRAM

Acute Treatment of Anxiety for Adults with Social Anxiety Disorder

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

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

PALISADE-1

- Target enrollment: ca. 208
- 15 sites in the U.S.
- Clinical/laboratory setting
- Public speaking challenge
- Visit 1 inclusion criteria is LSAS* score ≥70
- SUDS as primary efficacy endpoint as in Phase 2
- Initiated in mid-2021
- Topline results expected mid-2022

PALISADE-2

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

*LSAS – Liebowitz Social Anxiety Scale

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PH94B FOR ACUTE TREATMENT OF ANXIETY IN ADULTS WITH SAD

VistaGen's Initial Goal:

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

SUBSTANTIAL UNMET NEED FOR ACUTE TREATMENT

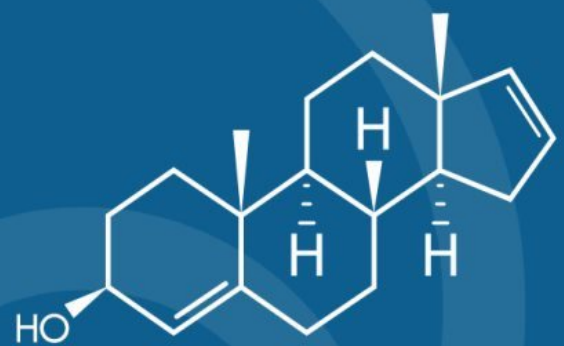
DIFFERENTIATED SAFETY v BENZOS

RAPID-ONSET MOA

STRONG INTENT TO PRESCRIBE

VistaGen THERAPEUTICS

PH94B – BEYOND SAD



PH94B

VistaGen THERAPEUTICS

MAJOR DEPRESSIVE DISORDER (MDD)

PRE – PANDEMIC

IN THE US

19.4 MILLION

Adults had at Least One Major Depressive Episode[1]

GLOBALLY

264 MILLION

People of All Ages Suffer from Depression[2]

DURING THE PANDEMIC

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

TIME

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

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CURRENT STANDARD OF CARE FOR MDD IS INADEQUATE

ORAL ANTIDEPRESSANTS

- **Often do not work; slow to work**
  - Initial ADT effective in 1 of 3 patients[1]
  - May take up to 6 weeks or more for antidepressant effects
- **Significant potential side effects**
  - Anxiety, sexual dysfunction, insomnia, dizziness, nausea and vomiting, headache, sweating

ORAL ATYPICAL ANTIPSYCHOTICS

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

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

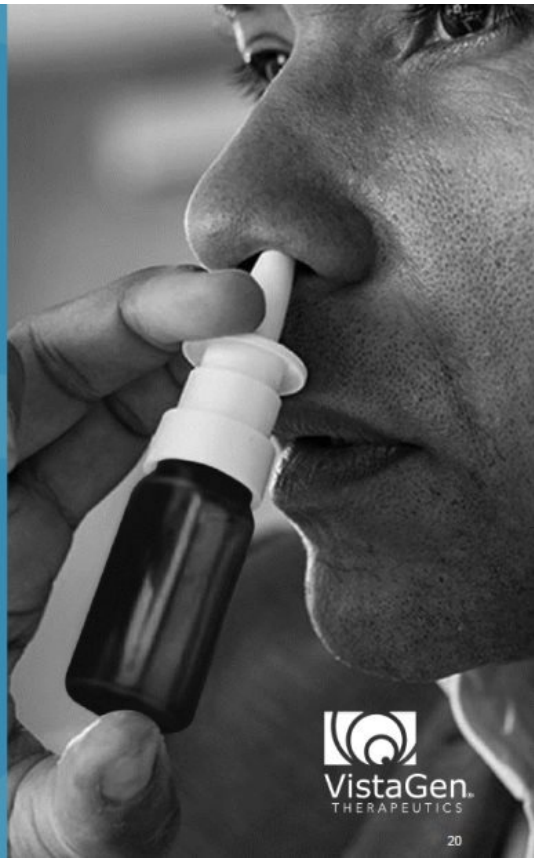
VistaGen THERAPEUTICS

PH10 FOR MAJOR DEPRESSIVE DISORDER

Potential Stand-alone Treatment for MDD

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

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

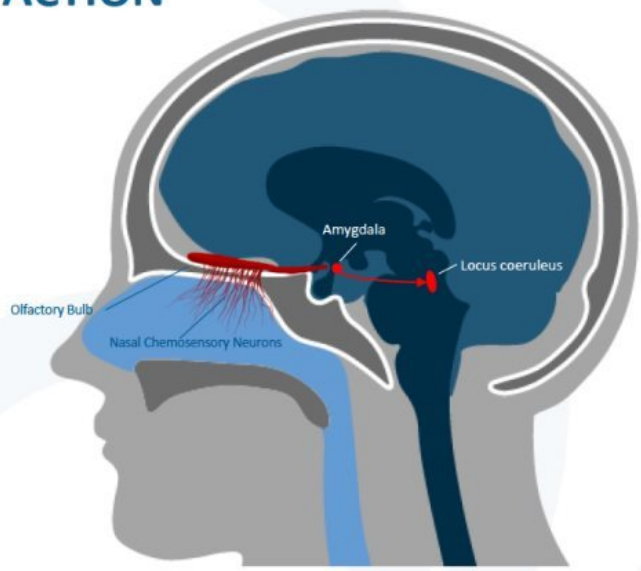


PH10'S POTENTIAL MECHANISM OF ACTION

"Action from a Distance"

Innovative Mechanism of Action, differentiated from all known antidepressants

- Microgram-level dose (6.4 mcg) designed to engage specific peripheral **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
- **Designed to not require systemic uptake and distribution with the goal of producing rapid-onset antidepressant effects**



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

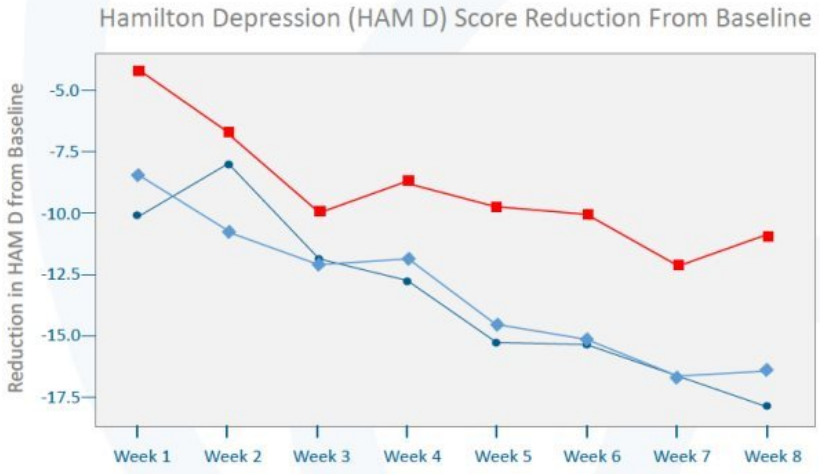
PH10 SHOWED ANTIDEPRESSANT EFFECTS IN MDD PATIENTS PUBLISHED EXPLORATORY PHASE 2A STUDY

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

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

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

PH10 PHASE 2A MDD STUDY (n = 30)



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

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

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PH10 U.S. PHASE 2B DEVELOPMENT PLAN

Major Depressive Disorder

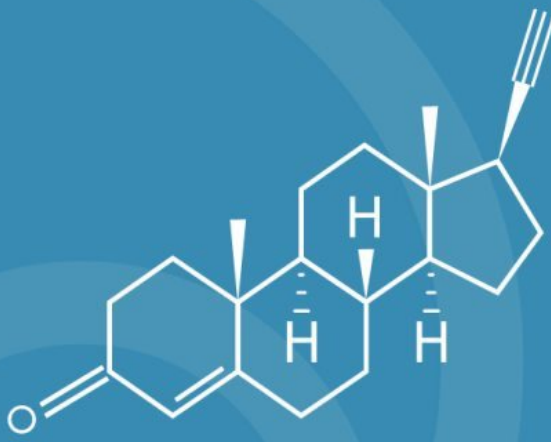
Principal Investigator: Dr. Maurizio Fava, Harvard University

- U.S. multi-center, randomized, double-blind, placebo-controlled, monotherapy clinical trial
- MDD patients with zero or 1 prior failure on a standard oral antidepressant
- Twice a day administration of PH10 (3.2 microgram (µg) or 6.4 µg) or placebo for 6 weeks
- Assessment of rapid-onset potential within less than one week, potentially hours to days
- Target launch mid-2022
- Target enrollment, ca. 150 completed subjects

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

VistaGen THERAPEUTICS

PH10 – BEYOND MDD



PH10

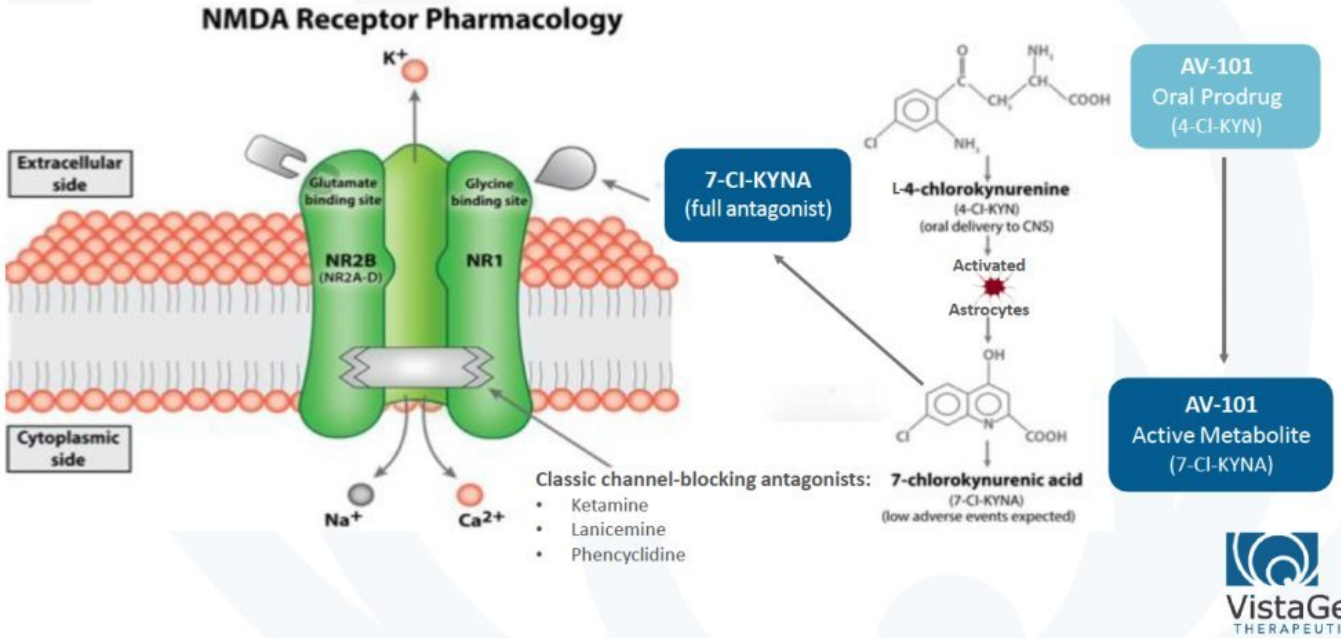
VistaGen THERAPEUTICS

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 multiple go forward opportunities in combination with probenecid
- FDA Fast Track designations for adjunctive treatment of MDD and treatment of neuropathic pain

AV-101'S POTENTIAL MOA

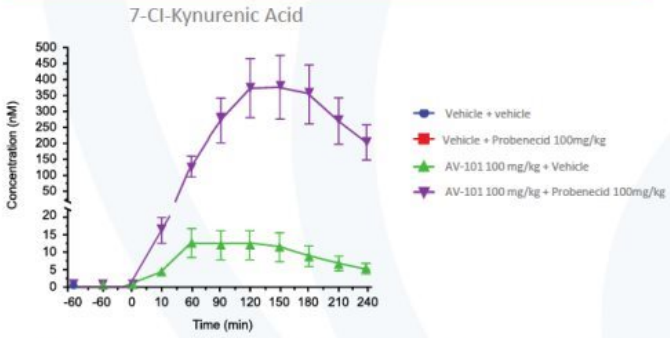


VistaGen THERAPEUTICS

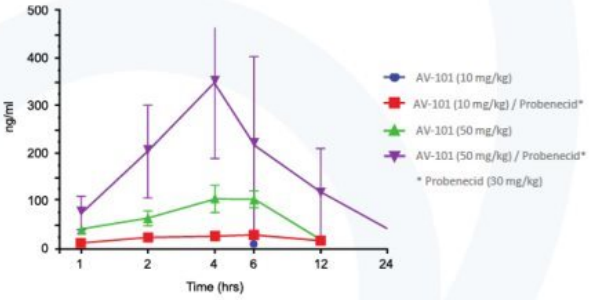
AV-101 + PROBENECID

Recent Preclinical Data Demonstrate Substantial Increases in Rodent and Canine 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 AC-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.

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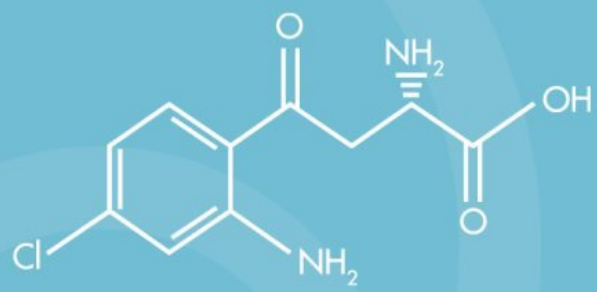
AV-101 + PROBENECID FOR MULTIPLE CNS DISORDERS



AV-101

VistaGen THERAPEUTICS

EXPERIENCED TEAM LEADING EXECUTION

Positioning VistaGen for Near-Term Success

Shawn K. Singh
Chief Executive Officer

30 years of experience with biopharmaceutical companies, health care venture capital and a profitable CRO

- Artemis Neuroscience
- SciClone Pharmaceuticals
- Cato BioVentures
- Cato Research
- Morrison & Foerster

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

25 years of experience in senior biotechnology management

- Progenitor
- Linberger Comprehensive Cancer Center

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

25 years of large Pharma CNS drug development experience

- Teva Pharmaceutical
- Shire Pharmaceuticals
- AstraZeneca Pharmaceutical
- DuPont Pharmaceutical Company
- U.S. National Institute of Mental Health

Ann Cunningham, MBA
Chief Commercial Officer

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

- I³ Strategy Partners
- Teva Pharmaceutical Industries
- Otsuka America Pharmaceutical
- Eli Lilly

Jerrold D. Dotson, CPA
Chief Financial Officer

25 years of experience in senior management finance and administration

- Calypte Biomedical
- Discovery Foods
- California & Hawaii Sugar
- Clorox

Jaakko Lappalainen, MD, Ph.D.
Senior Vice President, Global Clinical Development & Pharmacovigilance

Mark Ginski, Ph.D.
Senior Vice President, Head of CMC

Jo Cato, III, Ph.D.
Senior Vice President, Development Operations

Louis Monti, MD, Ph.D.
Vice President, Translational Medicine

Erik Berglund, MD, Ph.D., RAC
Vice President, Global Regulatory Affairs

Rita Hanover, Ph.D., RAC
Vice President, Biostatistics and Clinical Analytics

Ellis Wilson, Jr. EMBA
Vice President, Global Clinical Operations

Mark McPartland
Vice President, Corporate Development

Mark Flather
Vice President, Investor Relations

VistaGen THERAPEUTICS

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HARVARD UNIVERSITY

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Director (retired), U.S. Food and Drug Administration (FDA) Division of Psychiatry Products, Office of New Drugs, Center for Drug Evaluation and Research (CDER)

FDA

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

COLUMBIA UNIVERSITY DEPARTMENT OF PSYCHIATRY

MRN

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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

Yale University

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

UC San Diego SCHOOL OF MEDICINE

VistaGen THERAPEUTICS

INVESTMENT HIGHLIGHTS

VistaGen Therapeutics (NASDAQ: VTGN)

- Multiple differentiated clinical-stage CNS drug candidates
- Increasing clinical development momentum
- Numerous potential catalysts 2021 – 2023
- Exploring additional ex-US partnership opportunities
- Strong Balance Sheet and Institutional Shareholder Base
- Experienced leadership team to execute through commercialization

VistaGen THERAPEUTICS

VistaGen THERAPEUTICS

NASDAQ: VTGN

IR@vistagen.com
