UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) of the SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): August 13, 2019

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

NEVADA	**001-37761**	**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) ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act ☐

Item 2.02 Results of Operations and Financial Condition.

On August 13, 2019, VistaGen Therapeutics, Inc. (the "*Company*") issued a press release to announce the Company's financial results for its fiscal year 2020 first quarter ended June 30, 2019. 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.

See Item 8.01.

Item 8.01 Other Items.

On August 15, 2019, the Company announced that it has achieved completion of target patient enrollment of 180 patients in the Company's Phase 2 ELEVATE clinical trial. ELEVATE is a multi-center, double-blind, placebo-controlled clinical study to evaluate the efficacy and safety of AV-101, the Company's novel, oral NMDA (N-methyl-D-aspartate) receptor glycine site antagonist, as an adjunctive treatment (together with an FDA-approved oral antidepressant) for major depressive disorder in adult patients with an inadequate therapeutic response to their current antidepressants. The Company expects to report topline results from the ELEVATE study before the year end 2019. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.2.

On August 15, 2019, 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 99.3.

The information in this Current Report on Form 8-K, including the information set forth in Exhibits 99.1 and 99.3, 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 Exhibits 99.1 and 99.3 filed herewith be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits Index

Exhibit No.	Description
99.1	Press Release issued by VistaGen Therapeutics, Inc., dated August 13, 2019.
99.2	Press Release issued by VistaGen Therapeutics, Inc., dated August 15, 2019.
99.3	VistaGen Therapeutics, Inc. Corporate Presentation, dated August 2019.

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 16, 2019

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

EXHIBIT INDEX

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VistaGen Therapeutics Reports Fiscal 2020 First Quarter Financial Results

SOUTH SAN FRANCISCO, Calif., August 13, 2019 - VistaGen Therapeutics (NASDAQ: VTGN), a clinical-stage biopharmaceutical company developing new generation medicines for central nervous system (CNS) diseases and disorders with high unmet need, today announced financial results for its fiscal year 2020 first quarter ended June 30, 2019.

"The next few months are potentially transformative for VistaGen, as we look forward to several clinical and regulatory milestones before year-end," stated Shawn Singh, Chief Executive Officer of VistaGen. "We have three differentiated clinical-stage drug candidates, each of which has an exceptional safety profile in studies to date and significant therapeutic and commercial potential in multiple large and growing CNS markets where current treatments are inadequate to meet the needs of millions of patients. Our team is focused on driving continued progress across our pipeline, and we are confident in our efforts to achieve our core goals – to deliver both safe and effective new generation treatments in neuropsychiatry and neurology for patients and extraordinary value to our loyal shareholders."

Financial Results for the Fiscal Quarter Ended June 30, 2019:

Net loss attributable to common stockholders for the fiscal quarter ended June 30, 2019 was approximately $6.2 million, including approximately $1.2 million of noncash charges, compared to $4.2 million for the fiscal quarter ended June 30, 2018, primarily attributable to increased research and development activities relating to the Company's CNS drug development programs.

Research and development expense totaled $4.3 million for the fiscal quarter ended June 30, 2019, compared with $2.7 million for the fiscal quarter ended June 30, 2018. The increase in research and development expense is primarily related to the continued progress of ELEVATE, the Company's Phase 2 clinical study evaluating efficacy and safety of AV-101, its novel oral NMDA (N-methyl-D-aspartate) receptor glycine site antagonist, as an add-on treatment (together with an FDA-approved oral antidepressant) for adults with major depressive disorder (MDD), several preclinical studies, including studies supporting AV-101's potential for treating neuropathic pain (NP) and levodopa-induced dyskinesia (LID) in patients with Parkinson's disease, and manufacturing activities involving AV-101 and the Company's two novel, clinical-stage neuroactive nasal spray candidates, PH94B for social anxiety disorder (SAD) and PH10 for MDD.

General and administrative expense was approximately $1.9 million in the fiscal quarter ended June 30, 2019, compared to approximately $1.5 million in the fiscal quarter ended June 30, 2018. The increase was primarily attributable to noncash stock compensation expense.

At June 30, 2019, VistaGen had cash and cash equivalents of $8.3 million, compared to $13.1 million at March 31, 2019.

As of August 13, 2019, there were 42,622,965 shares of common stock outstanding.

About VistaGen

VistaGen Therapeutics is a clinical-stage biopharmaceutical company developing new generation medicines for CNS diseases and disorders where current treatments are inadequate, resulting in high unmet need. VistaGen's pipeline includes three differentiated, clinical-stage CNS drug candidates, AV-101, PH10 and PH94B, each with an exceptional safety profile in all clinical studies to date and therapeutic potential in multiple large and growing CNS markets. For more information, please visit www.vistagen.com and connect with VistaGen on Twitter, LinkedIn and Facebook.

Forward-Looking Statements

This release contains various statements concerning VistaGen's future expectations, plans and prospects, including without limitation, our expectations regarding development and commercialization of our three drug candidates: (i) AV-101 for MDD, NP, LID and suicidal ideation; (ii) PH94B for SAD; and (iii) PH10 for MDD. In addition, statements concerning the Company's future expectations may include statements regarding intellectual property and commercial protection of our drug candidates. Each of these statements constitute forward-looking statements for the purposes of the safe harbor provisions under the Private Securities Litigation Reform Act of 1995. These forward-looking statements are neither promises nor guarantees of future performance and are subject to a variety of risks and uncertainties, many of which are beyond our control, and may cause actual results to differ materially from those contemplated in these forward-looking statements. Those risks include the following: (i) we may encounter unexpected adverse events in patients during our clinical development of any product candidate that cause us to discontinue further development; (ii) we may not be able to successfully demonstrate the safety and efficacy of our product candidates at each stage of clinical development; (iii) success in preclinical studies or in early-stage clinical trials may not be repeated or observed in ongoing or future studies, and ongoing or future preclinical and clinical results may not support further development of, or be sufficient to gain regulatory approval to market AV-101, PH94B, and/or PH10; (iv) decisions or actions of regulatory agencies may negatively affect the progress of, and our ability to proceed with, further clinical studies or to obtain marketing approval for our drug candidates; (v) we may not be able to obtain or maintain adequate intellectual property protection and other forms of marketing and data exclusivity for our product candidates; (vi) we may not have access to or be able to secure substantial additional capital to support our operations, including our ongoing clinical development activities; and (vii) we may encounter technical and other unexpected hurdles in the manufacturing and development of any of our product candidates. Certain other risks are more fully discussed in the section entitled "Risk Factors" in our most recent annual report on Form 10-K, as well as discussions of potential risks, uncertainties, and other important factors in our other filings with the Securities and Exchange Commission (SEC). Our SEC filings are available on the SEC's website at www.sec.gov. In addition, any forward-looking statements represent our views only as of the issuance of this 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.

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VISTAGEN THERAPEUTICS, INC.
Consolidated Balance Sheets
(Amounts in dollars, except share amounts)

	June 30, 2019 (Unaudited)	March 31, 2019 (Note 2)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 8,297,100	$ 13,100,300
Receivable from supplier	-	300,000
Prepaid expenses and other current assets	482,600	250,900
Total current assets	8,779,700	13,651,200
Property and equipment, net	286,500	312,700
Right of use asset - operating lease	3,833,300	-
Security deposits and other assets	47,800	47,800
Total assets	$ 12,947,300	$ 14,011,700
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 933,900	$ 1,055,000
Accrued expenses	1,847,000	1,685,600
Current notes payable	246,400	57,300
Operating lease oligation	278,100	-
Financing lease obligation	3,000	3,000
Total current liabilities	3,308,400	2,800,900
Non-current liabilities:		
Accrued dividends on Series B Preferred Stock	4,050,700	3,748,200
Deferred rent liability	-	381,100
Operating lease obligation	3,956,900	-
Financing lease obligation	5,500	6,300
Total non-current liabilities	8,013,100	4,135,600
Total liabilities	11,321,500	6,936,500
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at June 30, 2019 and March 31, 2019		
Series A Preferred, 500,000 shares authorized, issued and outstanding at June 30, 2019 and March 31, 2019	500	500
Series B Preferred; 4,000,000 shares authorized at June 30, 2019 and March 31, 2019;		
1,160,240 shares issued and outstanding at June 30, 2019 and March 31, 2019	1,200	1,200
Series C Preferred; 3,000,000 shares authorized at June 30, 2019 and March 31, 2019;		
2,318,012 shares issued and outstanding at June 30, 2019 and March 31, 2019	2,300	2,300
Common stock, $0.001 par value; 100,000,000 shares authorized at June 30, 2019 and March 31, 2019;		
42,758,630 shares issued and outstanding at June 30, 2019 and March 31, 2019	42,800	42,800
Additional paid-in capital	192,890,400	192,129,900
Treasury stock, at cost, 135,665 shares of common stock held at June 30, 2019 and March 31, 2019	(3,968,100)	(3,968,100)
Accumulated deficit	(187,343,300)	(181,133,400)
Total stockholders' equity	1,625,800	7,075,200
Total liabilities and stockholders' equity	$ 12,947,300	$ 14,011,700

VISTAGEN THERAPEUTICS, INC.
STATEMENTS OF OPERATIONS
(Amounts in dollars, except share amounts)
(Unaudited)

	Three Months Ended June 30,	
	2019	**2018**
Operating expenses:		
Research and development	$ 4,313,900	$ 2,743,700
General and administrative	1,910,100	1,466,300
Total operating expenses	6,224,000	4,210,000
Loss from operations	(6,224,000)	(4,210,000)
Other income (expenses), net:		
Interest income (expense), net	16,500	(2,100)
Loss before income taxes	(6,207,500)	(4,212,100)
Income taxes	(2,400)	(2,400)
Net loss and comprehensive loss	$ (6,209,900)	$ (4,214,500)
Accrued dividend on Series B Preferred stock	(302,500)	(273,500)
Net loss attributable to common stockholders	$ (6,512,400)	$ (4,488,000)
Basic and diluted net loss attributable to common stockholders per common share	$ (0.15)	$ (0.20)
Weighted average shares used in computing basic and diluted net loss attributable to common stockholders per common share	42,622,965	22,987,066

VistaGen Therapeutics Achieves Target Patient Enrollment in the ELEVATE Study of AV-101 as an Adjunctive Treatment for Major Depressive Disorder

Company on Track to Report Topline Data Before Year End

SOUTH SAN FRANCISCO, Calif., August 15, 2019 – VistaGen Therapeutics (NASDAQ: VTGN), a clinical-stage biopharmaceutical company developing new generation medicines for central nervous system (CNS) diseases and disorders with high unmet need, announced today that the Company has achieved completion of target patient enrollment (n = 180) in its Phase 2 ELEVATE clinical trial. ELEVATE is a multi-center, double-blind, placebo-controlled clinical study to evaluate the efficacy and safety of AV-101, VistaGen's novel, oral NMDA (N-methyl-D-aspartate) receptor glycine site antagonist, as an adjunctive treatment (together with an FDA-approved oral antidepressant (AD)) for major depressive disorder (MDD) in adult patients with an inadequate therapeutic response to their current AD.

VistaGen expects to report topline results from the Phase 2 ELEVATE study before the year end 2019.

"We are very encouraged to reach this important milestone in our Phase 2 development program for AV-101 in MDD. Achieving target patient enrollment puts us one step closer to redefining the standard of care for a large and growing number of individuals who are unable to reduce their symptoms of depression with their current antidepressant alone," said Shawn Singh, Chief Executive Officer, VistaGen. "We look forward to completing the ELEVATE study in the near term and reporting topline data by year end."

About AV-101

AV-101 (4-Cl-KYN) belongs to a new generation of investigational medicines in neuropsychiatry and neurology known as NMDA (N-methyl-D-aspartate) glutamate receptor modulators. The NMDA receptor is a pivotal receptor in the brain and abnormal NMDA function is associated with multiple CNS diseases and disorders, including chronic neuropathic pain, epilepsy, MDD, levodopa-induced dyskinesia (LID) and many others. AV-101 is an oral prodrug of 7-Cl-KYNA which binds uniquely at the glycine site of the NMDA receptor. With its exceptional safety profile in all studies to date, AV-101 has potential to be a new at-home treatment for multiple large market CNS indications where current treatments are inadequate to meet high unmet patient needs. VistaGen is currently focused on potential development of AV-101 for MDD, neuropathic pain, suicidal ideation and dyskinesia associated with levodopa treatment for Parkinson's disease. The FDA has granted Fast Track designation for development of AV-101 as both a potential adjunctive treatment for MDD and as a non-opioid treatment for neuropathic pain.

About ELEVATE
Among VistaGen's objectives for AV-101 in MDD is to replace atypical antipsychotics in the current MDD drug treatment paradigm and redefine the standard of care for individuals who are unable to reduce their symptoms of depression with their current antidepressant alone. The ELEVATE study is an ongoing U.S. multi-center, randomized, double-blind, placebo-controlled Phase 2 clinical study to evaluate the efficacy and safety of adjunctive use of AV-101 in adult MDD patients who have an inadequate response to standard FDA-approved antidepressant therapy, either a selective serotonin reuptake inhibitor (SSRI), a serotonin norepinephrine reuptake inhibitor (SNRI), or bupropion. The primary endpoint of the study is the change from baseline on the Montgomery-Åsberg Depression Rating Scale (MADRS-10) total score.

About Major Depressive Disorder (MDD)
MDD is a serious neurobiologically-based mood disorder, affecting approximately 16 million adults in the U.S., according to the NIMH. Individuals diagnosed with MDD exhibit depressive symptoms, such as a depressed mood or a loss of interest or pleasure in daily activities, for more than a two-week period, as well as impaired social, occupational, educational or other important functioning which has a negative impact on their quality of life. Globally, MDD affects nearly 300 million people of all ages and is the leading cause of disability worldwide.

About VistaGen
VistaGen Therapeutics is a clinical-stage biopharmaceutical company developing new generation medicines for CNS diseases and disorders where current treatments are inadequate, resulting in high unmet need. VistaGen's pipeline includes three differentiated, clinical-stage CNS drug candidates, AV-101, PH10 and PH94B, each with an exceptional safety profile in all clinical studies to date and therapeutic potential in multiple large and growing CNS markets. For more information, please visit www.vistagen.com and connect with VistaGen on Twitter, LinkedIn and Facebook.

Forward-Looking Statements
This release contains various statements concerning VistaGen's future expectations, plans and prospects, including without limitation, our expectations regarding development and commercialization of our three drug candidates, (i) AV-101 for MDD, and specifically the completion of our ELEVATE study, NP, LID and suicidal ideation; (ii) PH94B for SAD; and (iii) PH10 for MDD. In addition, statements concerning the Company's future expectations may include statements regarding intellectual property and commercial protection of our drug candidates. Each of these statements constitute forward-looking statements for the purposes of the safe harbor provisions under the Private Securities Litigation Reform Act of 1995. These forward-looking statements are neither promises nor guarantees of future performance and are subject to a variety of risks and uncertainties, many of which are beyond our control, and may cause actual results to differ materially from those contemplated in these forward-looking statements. Among these risks is the possibility that (i) we may encounter unexpected adverse events in patients during our clinical development of any product candidate, including in AV-101 during the ELEVATE study, that cause us to discontinue further development, (ii) we may not be able to successfully demonstrate the safety and efficacy of our product candidates at each stage of clinical development, including for AV-101 during the ELEVATE study, (iii) success in preclinical studies or in early-stage clinical trials may not be repeated or observed in ongoing or future studies, and ongoing or future preclinical and clinical results may not support further development of, or be sufficient to gain regulatory approval to market AV-101, (iv) decisions or actions of regulatory agencies may negatively affect the progress of, and our ability to proceed with, the ELEVATE study or other further clinical studies or to obtain marketing approval for our drug candidates, (v) we may not be able to obtain or maintain adequate intellectual property protection and other forms of marketing and data exclusivity for our product candidates, (vi) we may not have access to or be able to secure substantial additional capital to support our operations, including our ongoing clinical development activities, and (vii) we may encounter technical and other unexpected hurdles in the manufacturing and development of any of our product candidates. Certain other risks are more fully discussed in the section entitled "Risk Factors" in our most recent annual report on Form 10-K and subsequent quarterly reports on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in our other filings with the Securities and Exchange Commission (SEC). Our SEC filings are available on the SEC's website at www.sec.gov. In addition, any forward-looking statements represent our views only as of the issuance of this 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.

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Exhibit 99.3

VistaGen® Therapeutics

www.vistagen.com

Nasdaq: VTGN

August 2019

www.vistagen.com

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, our development efforts, our collaborations, our intellectual property, our financial condition, our plans and our development programs. These statements involve risks, uncertainties and assumptions, and are based on the current estimates and assumptions of the management of VistaGen Therapeutics, Inc. (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, 2019, filed with the Securities and Exchange Commission (SEC) on June 25, 2019, as well as any updates to those risk factors filed with the SEC from time to time in our periodic and current reports on Forms 8-K and 10-Q. 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.


Looking Beyond Current Treatments for
CNS Diseases and Disorders with High Unmet Need
VistaGen is developing differentiated new generation medications for large and growing mental health and neurology markets where current treatments are inadequate to meet the needs of millions of patients worldwide.
VistaGen®
Therapeutics

www.vistagen.com

Looking beyond current therapies for CNS disorders with high unmet need

VistaGen Therapeutics

- New generation MOAs
- 3 differentiated clinical-stage product candidates
- Fast-acting, exceptional safety
- Multiple large and growing CNS markets
- Potentially transformative milestones in 2H 2019

Our Pipeline

VistaGen® Therapeutics

Product Candidate	Indication	Preclinical	Phase 1	Phase 2	Phase 3
PH94B*	Social Anxiety Disorder[1]				
	Generalized Anxiety Disorder[2]				
	PTSD, Postpartum Anxiety, Panic[3]				
AV-101*	Major Depressive Disorder†[4] (inadequate response to ADT)				
	Major Depressive Disorder[3] (ketamine therapy relapse prevention)				
	Neuropathic Pain†[5]				
	Parkinson's LID[5]				
	Suicidal Ideation[3,6]				
	Epilepsy[3]				
PH10*	Major Depressive Disorder[2] (stand-alone treatment)				

* All potential future studies are subject to securing sufficient internal and/or collaborative third-party funding
† FDA Fast Track designation

1. Preparing for initial pivotal Phase 3 study in 2020
2. Assessing/preparing for Phase 2b study in 2020/2021
3. Assessing for potential Phase 2a study in 2020/2021
4. Phase 2 study ongoing – the ELEVATE study
5. Planning for potential Phase 2a study in 2020
6. Baylor/VA 1st-step Phase 1b study ongoing

PH94B neuroactive nasal spray

VistaGen® Therapeutics

Pherine, synthetic neuroactive steroid
(3β)-androsta-4,16-dien-3-ol

Novel, safe, fast-acting, on-demand therapy for:

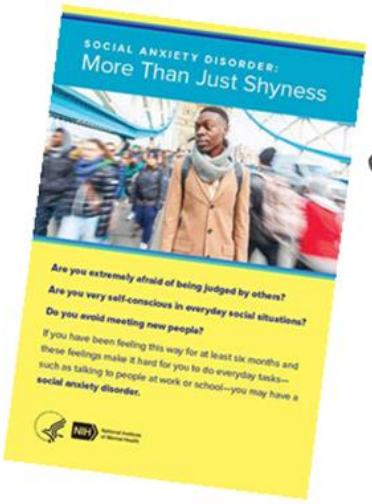
- Social Anxiety Disorder
- Generalized Anxiety Disorder
- Postpartum Anxiety
- Panic Disorder
- Post-Traumatic Stress Disorder

Nasdaq: VTGN

VistaGen Therapeutics

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 million[1]

Americans

Anxiety/fear in everyday social and performance situations

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

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

Current SAD Drug Treatments Fall Short

VistaGen Therapeutics

FDA APPROVED

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

Antidepressants (2 SSRIs, 1 SNRI)

- Slow onset, chronic administration
- May worsen anxiety initially
- Significant side effects
- Potential drug-drug interaction

Benzodiazepines & Beta Blockers

- Addiction risk
- Sedation
- Cognitive impairment
- Cardiac concerns

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

PH94B for SAD

VistaGen® Therapeutics

Novel, safe, fast-acting, on-demand therapy

- Fundamentally differentiated from all current treatments
- Successful Phase 2 completed
- Fast-acting efficacy (10-15 minutes), exceptional safety
- Microgram dose, no systemic exposure
- Well-tolerated, non-sedating, non-addictive

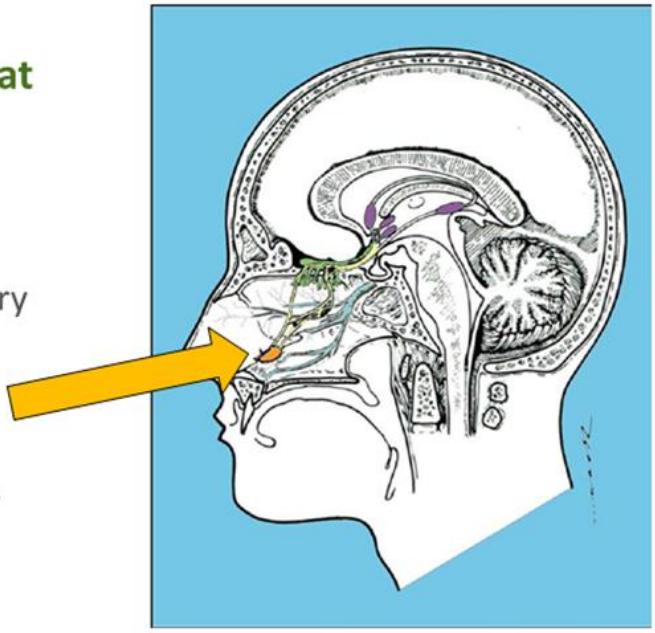
Potential to be first FDA-approved fast-acting, treatment for SAD

Nasdaq: VTGN

VistaGen Therapeutics

Mechanism of Action

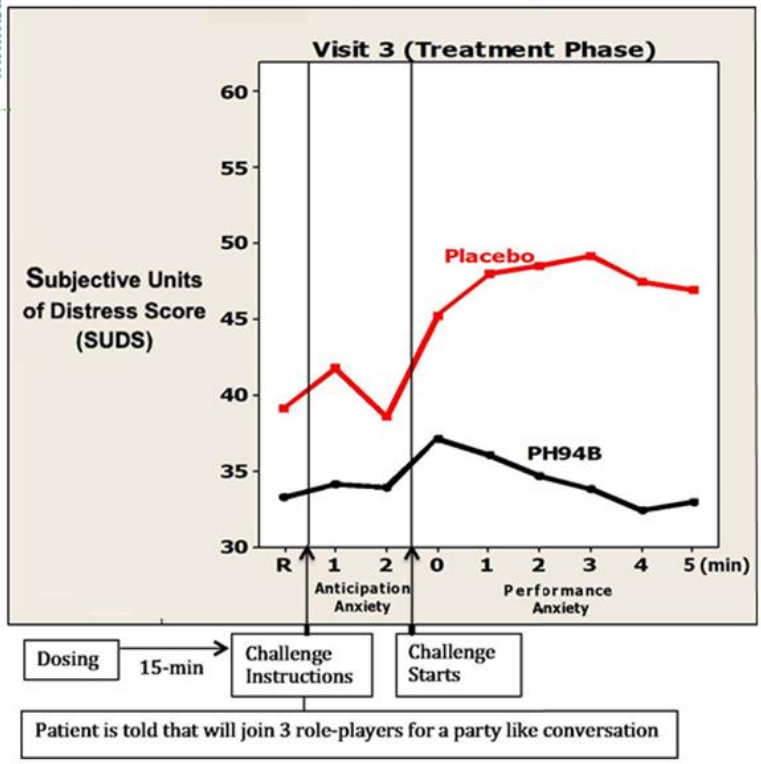
- **Activates nasal chemosensory neurons that trigger neural circuits in the brain that suppress fear and anxiety**
  - Engages nasal chemosensory neurons that trigger a subset of neurons in the main olfactory bulbs (OB)
  - OB neurons stimulate inhibitory GABAergic neurons in the limbic amygdala, decreasing release of norepinephrine, and facilitating fear extinction and activity of the limbic-hypothalamic parasympathetic system



www.vistagen.com

PH94B Phase 2 Study – Social Interaction (n = 91)

VistaGen Therapeutics



PH94B Rapidly Reduced Anxiety in Response to Social Interaction Challenge

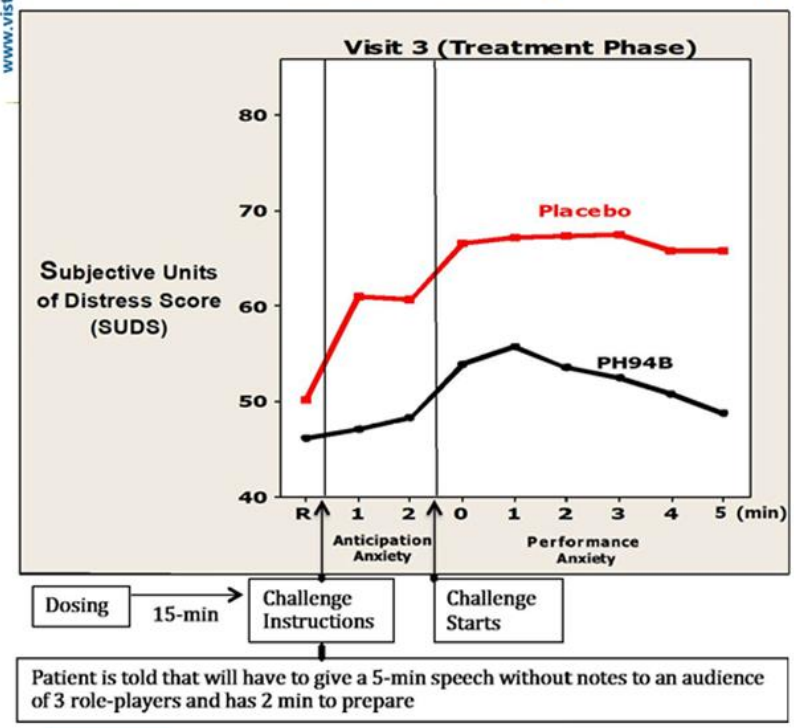
Active Group:	Placebo Group:
Mean Difference = 18.3	Mean Difference = 6.6
Standard Deviation = 17.4	Standard Deviation = 23.6
Number of Subjects = 45	Number of Subjects = 46

t = 2.67	p = 0.009	Cohen's d (Effect size) .56

www.vistagen.com

PH94B Phase 2 Study – Public Speaking (n = 91)

VistaGen Therapeutics



PH94B Rapidly Reduced Anxiety in Response to Public Speaking Challenge

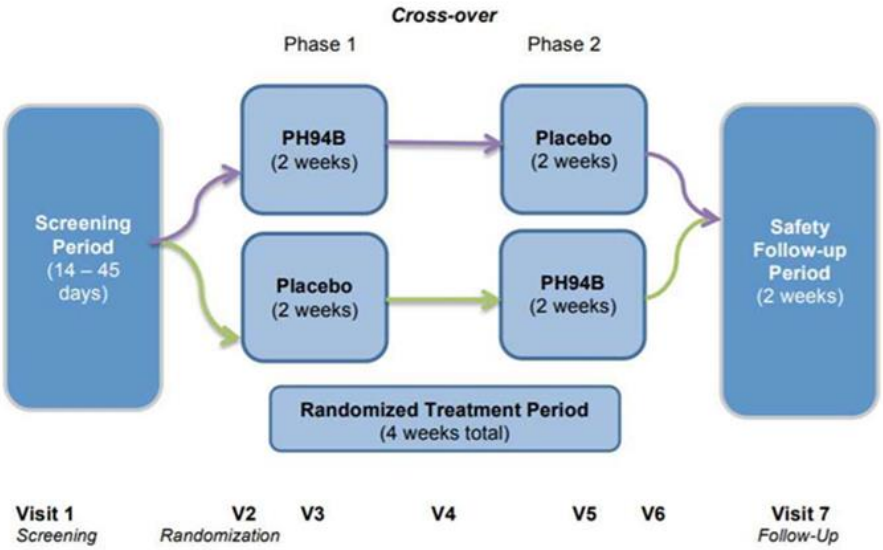
Active Group:	Placebo Group:
Mean Difference = 26.7	Mean Difference = 14.0
Standard Deviation = 21.6	Standard Deviation = 16.3
Number of Subjects = 45	Number of subjects = 46

t = 3.16	p = 0.002	Cohen's d (Effect Size) .72

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.

VistaGen Therapeutics

PH94B Pilot Phase 3 Crossover Study (n = 22)

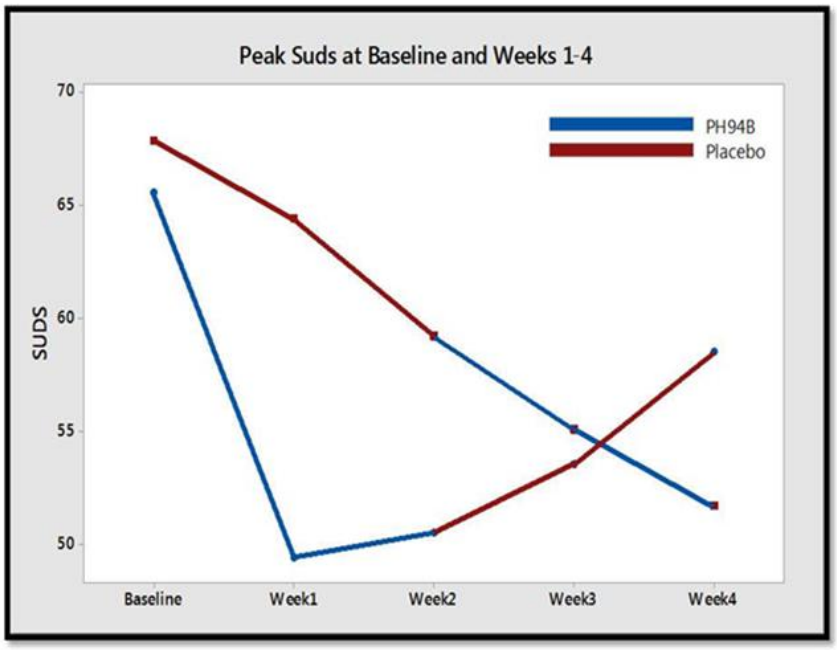


Adult subjects were randomized on a 1:1 basis to PH94B or placebo for two weeks, and then crossed over to the opposite treatment for an additional two weeks.

Liebowitz, M.R., Hanover, R., Draine, A., Careri, J., Monti, L., Smith, M., Moran, M., & Burnetta, D. (2019). Effect of As-Needed Use of Intranasal PH94B on Social and Performance Anxiety in Individuals with Social Anxiety Disorder. 2019 Anxiety and Depression Association of America (ADAA) Annual Conference Poster Session.

PH94B Pilot Phase 3 Crossover Study

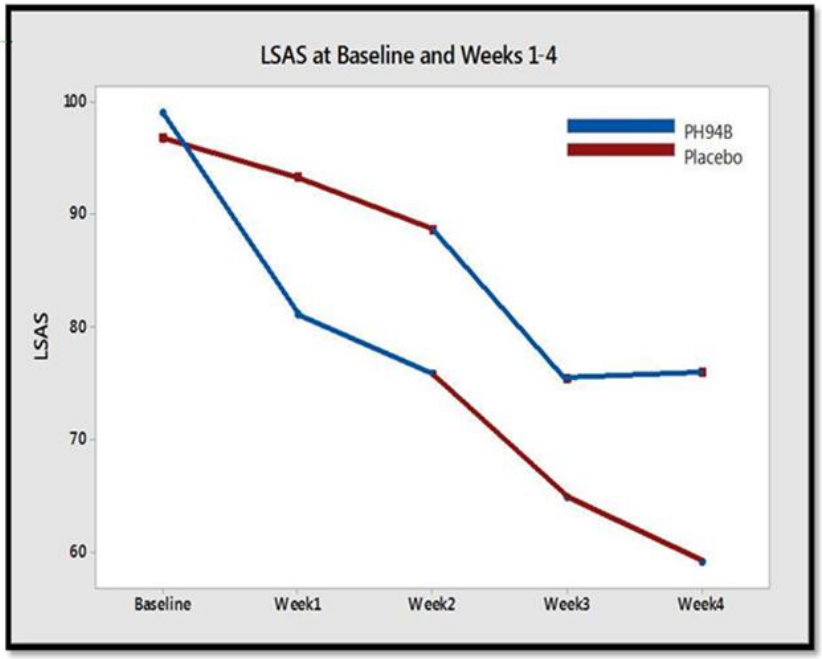
VistaGen Therapeutics



- Early suggestions of drug/placebo differences were seen in Week 1 and 2 SUDS scores: average change in SUDS at week 1 was 16.1 for PH94B versus 3.4 for placebo (t=1.86, p=.078, ES .79), and at week 2, the average change was 15.9 for PH94B and 6.9 for placebo (t= 1.35, p=0.192, ES .576)
- Peak SUDS score for the PH94B group increased when crossed over to placebo, though not back to the baseline level, due to increased confidence from PH94B treatment prior to crossover

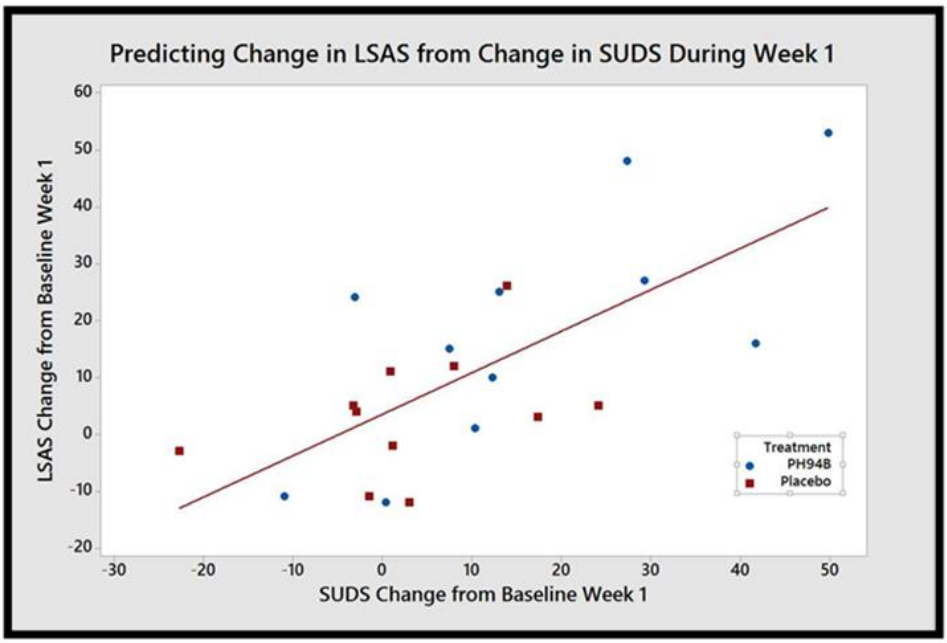
PH94B Pilot Phase 3 Crossover Study

VistaGen Therapeutics



- In the sample as a whole, drop in LSAS scores after treatment did not differ between groups because subjects receiving PH94B before receiving placebo continued to improve when crossed over to placebo
- After the first 2 weeks of treatment, subjects who received PH94B dropped an average of 23.2 points on the LSAS, while those who received placebo dropped only 8.2 points, showing a trend difference (t=1.9, p=.07) with a large effect size of .812
- Similar trend differences on total LSAS scores were seen after 1 week of treatment, where the PH94B group showed a 17.8 point drop compared to a 3.5 point drop with placebo (t=2.02, p=.057, ES .86)

PH94B Pilot Phase 3 Crossover Study



Changes in total LSAS scores were closely associated with change in SUDS peak anxiety scores at Week 1 (R-sq (adj) 45.2%) and at Week 2 (R-sq (adj) 34.95%). Looking at LSAS subscales, the strongest associations for SUDS peak anxiety scores were with the LSAS avoidance subscale at Week 1 (R-sq (adj) 58.78%) and Week 2 (R-sq (adj) 42.74%), and LSAS performance at Week 1 (R-sq (adj) 50.33%)

Planned Pivotal Phase 3 Development Plan for SAD

First Phase 3 Study

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

- Randomized, double-blind, placebo-controlled, monotherapy study
- 3.2 μg of PH94B or placebo for 4 Weeks
- Multi-center, ca. 15 sites in North America
- Target enrollment, ca. 200 patients (100 PH94B and 100 placebo)
- Target launch, 2H 2020
- Target completion, 2H 2021

Primary Endpoint: Change in LSAS from baseline compared to placebo

AV-101

VistaGen® Therapeutics

Synthetic NMDA receptor GlyB antagonist
L-4-chlorokynurenine; 7-chlorokynurenic acid

Novel oral prodrug therapy for:

- Major Depressive Disorder
- Suicidal Ideation
- Neuropathic Pain
- Levodopa-Induced Dyskinesia
- Epilepsy

Nasdaq: VTGN

www.vistagen.com

VistaGen Therapeutics

Major Depressive Disorder in the U.S.

1 in 4 women **1 in 6 men**

diagnosed with depressive disorders

1 in 8

age 12 and over takes an antidepressant[1]

LARGE ADDRESSABLE MARKET WITH HIGH UNMET NEED[2,3]

11.6M
Drug-treated patients with Major Depressive Disorder

7.3M
Inadequate response to 1st antidepressant

5.1M
Treatment-resistant after 2nd antidepressant

1. CDC – NCHS – National Center for Health Statistics, August 2017; 2. Rush AJ, et al. Am J. Psychiatry. 2006, 163(11): 1905-1917 (STAR*D Study); 3. Decision Resources 2016.

VistaGen Therapeutics

FDA-Approved MDD Treatments Fall Short

Current Oral Antidepressants

- **Often do not work; slow to work**
  - Initial ADT effective in 1 of 3 patients
  - May take 4 to 6 weeks or more for antidepressant effects
- **Significant side effects**
  - Anxiety, sexual dysfunction, insomnia

Atypical Antipsychotics

- **Often do not work**
  - Only ca. 20% of patients respond to augmentation
- **Significant side effects**
  - Weight gain, akathisia, insomnia, dizziness, tardive dyskinesia

VistaGen Therapeutics

Ketamine Therapy for Treatment-Resistant Depression

Intravenous ketamine

"Ketamine offers lifeline for people with severe depression, suicidal thoughts"

CNN

Intranasal ketamine

The New York Times

"Fast-Acting Depression Drug, Newly Approved, Could Help Millions"

CNBC

"J&J's new ketamine-like depression drug Spravato off to 'very, very strong start,' company says"

Ketamine therapy offers new hope to millions, but are they long-term solutions?

VistaGen Therapeutics

> **"In the clinical trials, the most common side effects of SPRAVATO™ when used along with an antidepressant taken by mouth included: dissociation, dizziness, nausea, sedation, spinning sensation, reduced sense of touch and sensation, anxiety, lack of energy, increased blood pressure, vomiting, and feeling drunk."[1]**
>
> **Janssen Pharmaceuticals, Inc.**
> Press Release, March 5, 2019

- **Side Effects?**
- **Safety Concerns?**
- **High Cost?**
- **Inconvenience?**
- **Compliance?**
- **Durability?**

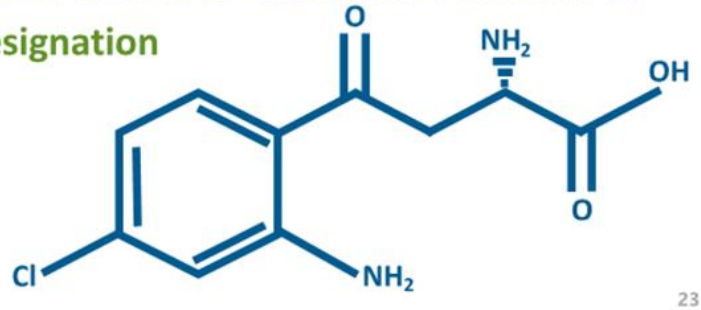
1. Johnson & Johnson Press Release. Janssen Announces U.S. FDA Approval of SPRAVATO™ (esketamine) CIII Nasal Spray for Adults with Treatment-Resistant Depression (TRD) Who Have Cycled Through Multiple Treatments Without Relief. Available at: https://www.jnj.com/janssen-announces-u-s-fda-approval-of-spravatotm-esketamine-ciii-nasal-spray-for-adults-with-treatment-resistant-depression-trd-who-have-cycled-through-multiple-treatments-without-relief

AV-101 for MDD: Transformative Potential

Rapid-onset Potential, Exceptional Safety

VistaGen Therapeutics

- Oral prodrug of 7-Cl-KYNA
- NMDA receptor glycine site antagonist (a full antagonist)
- Rapid-onset antidepressant effects and neurogenesis in preclinical studies
- Well-tolerated in all clinical studies to date
- No psychological side effects or treatment-related SAEs
- FDA Fast Track designation



ELEVATE Phase 2 study ongoing

Top line results 2H 2019

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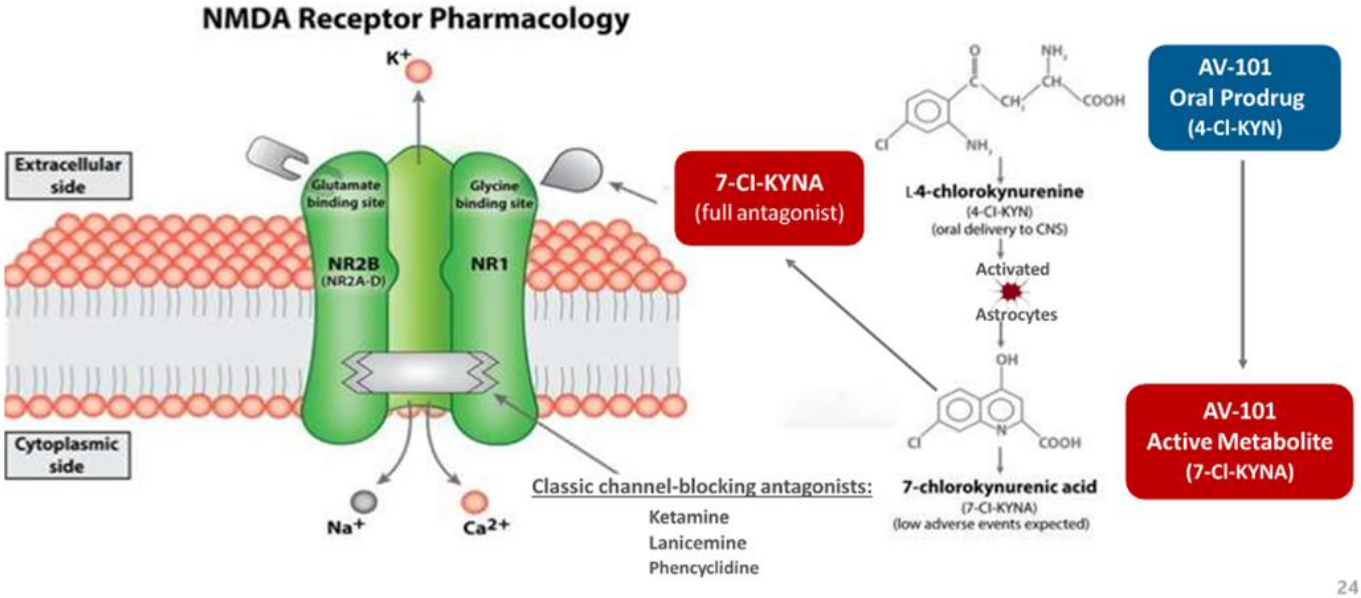
VistaGen Therapeutics

AV-101's Mechanism of Action

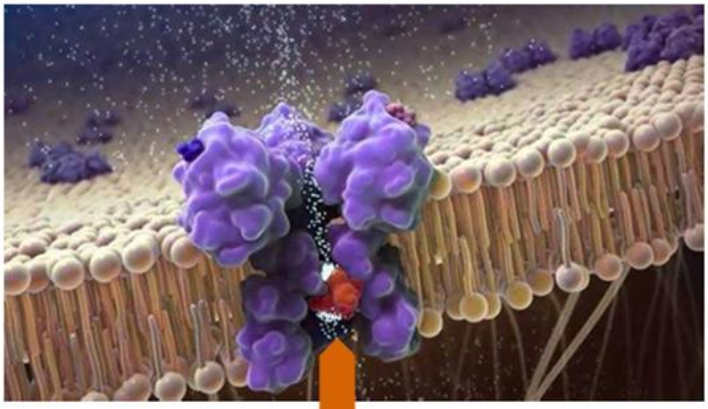
Inhibits NMDA Receptor Activity



AV-101's Mechanism of Action

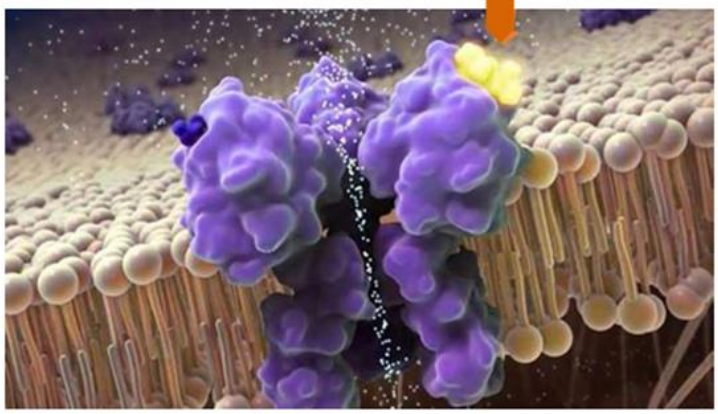
Inhibits NMDA Receptor Activity

VistaGen Therapeutics



Ketamine completely blocks the ion channel of the NMDA receptor

AV-101's active metabolite (7-Cl-KYNA) does not block NMDA receptor activity; it inhibits it



AV-101 vs. Ketamine in Published Preclinical Studies

VistaGen Therapeutics

"The Prodrug 4-Chlorokynurenine Causes Ketamine-Like Antidepressant Effects, but Not Side Effects, by NMDA/GlycineB-Site Inhibition."

Zanos, P., et al. (2015). *J Pharmacol Exp Ther* 355(1): 76-85.

Antidepressant-like Effects	AV-101	Ketamine
Forced-swim	COMPARABLE	
Tail-suspension	COMPARABLE	
Learned-helplessness	COMPARABLE	
Novelty-suppressed feeding	COMPARABLE	
Side Effects	**AV-101**	**Ketamine**
Psychotomimetic and rewarding	No	Yes
Hyper movement	No	Yes
Movement sensitization	No	Yes
Circling and rearing	No	Yes
Sensory-motor gating	No	Yes

Phase 1 trials demonstrate that AV-101 is very well tolerated and orally bioavailable

VistaGen Therapeutics

- Plasma half-life is about 2 hr
- Dosed up to 1440 mg daily for 2 weeks
- Adverse events were placebo-like except for some feelings of euphoria or "well-being" especially at the higher doses
- **No ketamine-like psychosis**
- No QT prolongation
- No abnormalities in clinical chemistry or hematology

Contents lists available at ScienceDirect

Scandinavian Journal of Pain

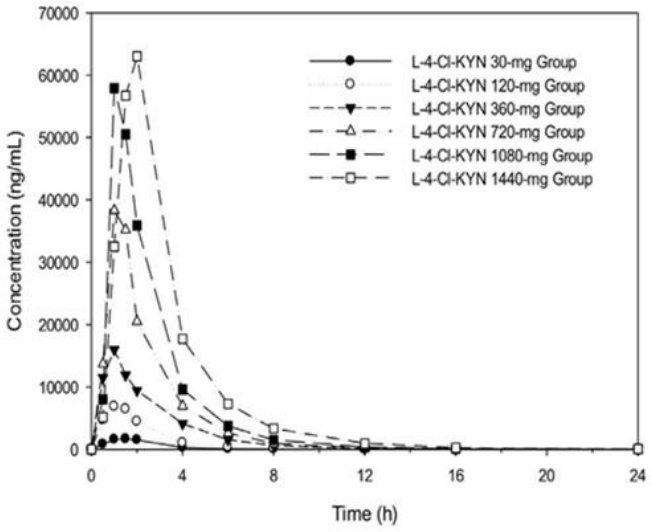
journal homepage: www.ScandinavianJournalPain.com

Clinical pain research

Randomized, double-blind, placebo-controlled, dose-escalation study: Investigation of the safety, pharmacokinetics, and antihyperalgesic activity of L-4-chlorokynurenine in healthy volunteers

Mark Wallace[a,*], Alexander White[b], Kathy A. Grako[c], Randal Lane[c], Allen (Jo) Cato[c], H. Ralph Snodgrass[d]

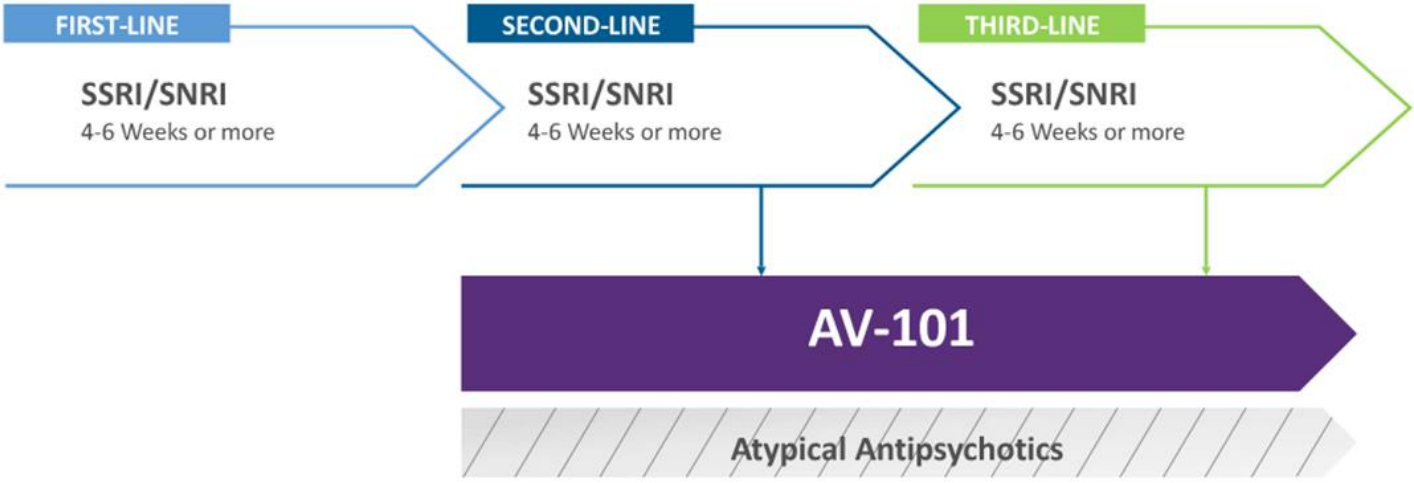
Plasma levels of AV-101 in normal volunteers following single oral dosing



Initial Objective for AV-101 in MDD

VistaGen Therapeutics

Displace atypical antipsychotics in current MDD treatment paradigm



ELEVATE: Ongoing Phase 2 Clinical Study

Investigating AV-101 as a potential add-on oral treatment for MDD

VistaGen Therapeutics

Principal Investigator: Dr. Maurizio Fava, Harvard Medical School

- Multi-center U.S. study
- Evaluation of AV-101 as add-on MDD treatment for patients with inadequate response to current SSRI / SNRI therapy
- Oral dose (1440 mg) 1x/day 14 days
- Target enrollment, ca. 180 patients
- Top line results 2H 2019

Primary Endpoint: Change in MADRS-10 from baseline compared to placebo

PH10 neuroactive nasal spray

VistaGen® Therapeutics

Pherine, synthetic neuroactive steroid
Pregn-4-en-20-yne-3-one

Novel, safe, fast-acting therapy for
Major Depressive Disorder

Nasdaq: VTGN

PH10 Neuroactive Nasal Spray

Rapid-Onset, Exceptional Safety

VistaGen Therapeutics

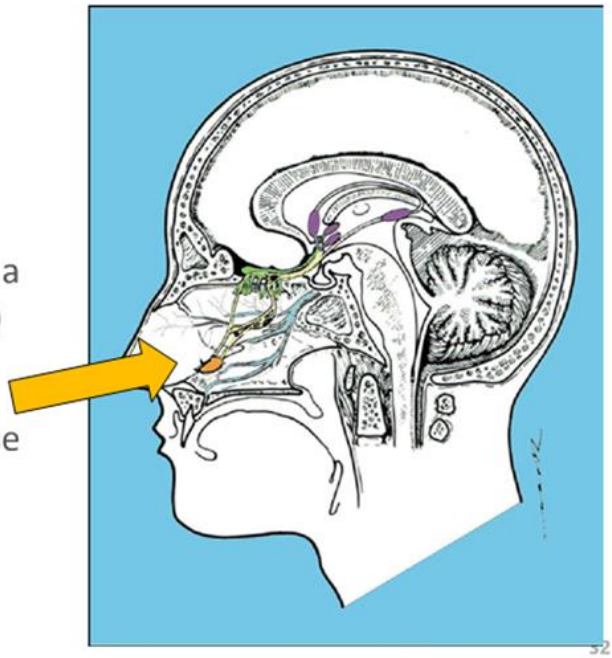
- Fundamentally differentiated from all current depression therapies
- Successful Phase 2a completed
- Rapid-onset antidepressant efficacy demonstrated in Phase 2a
- Microgram dose, no systemic exposure
- Well-tolerated, minimal side effects
- Stand-alone potential
- Preparing for Phase 2B in 2H 2020

Potential for fast-acting, esketamine-like antidepressant effects, without its psychological side effects and safety concerns

Mechanism of Action

VistaGen Therapeutics

- **Activates nasal chemosensory neurons that trigger neural circuits in the brain leading to antidepressant effects**
  - Engages nasal chemosensory neurons that trigger a subset of neurons in the main olfactory bulbs (OB)
  - OB neurons stimulate neurons in the limbic amygdala that release norepinephrine and increase activity of the limbic-hypothalamic sympathetic nervous system



VistaGen Therapeutics

PH10 Phase 1 Safety and Tolerability Study

PH10 found to be safe to use in clinical studies

Study Design

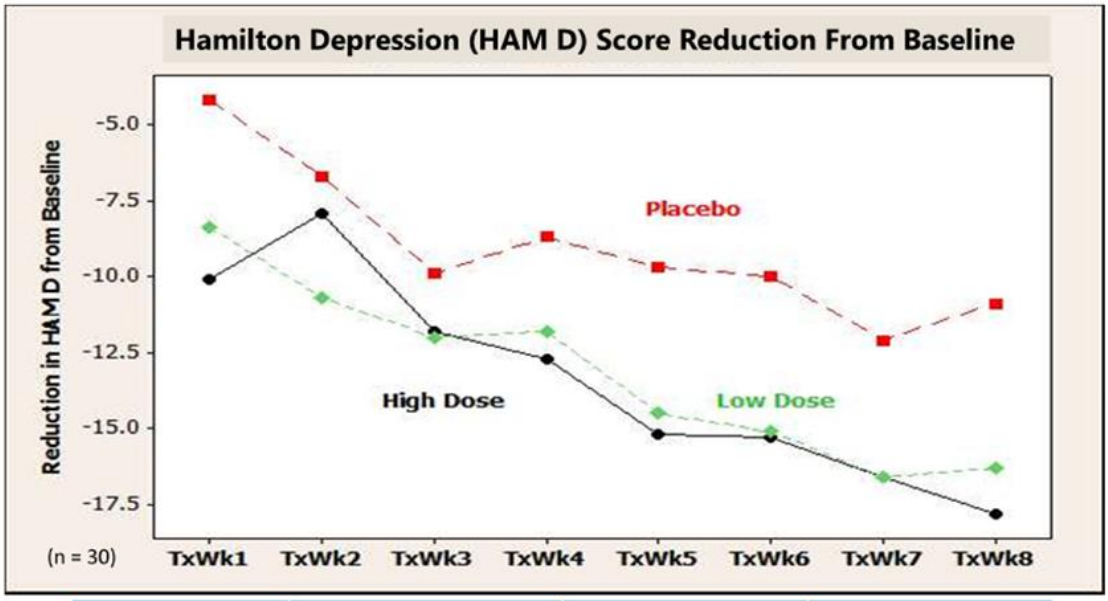
- Open, prospective, multiple flexible doses, controlled with placebo in 12 healthy volunteers
- Dose range: 0.8 µg to 6.4 µg
- Self-administered intranasally in escalating doses

Conclusions

- Different escalating doses of PH10 administered to Group A (0.8 µg to 2.4 µg) and Group B (3.2 µg to 6.4 µg) were well tolerated and did not produce local (nasal) or general severe adverse effects (SAEs) that were different from the effect of administration of placebo nasal spray
- No significant findings on clinical laboratory markers, vital signs, neuropsychological assessments, cognitive brain mapping or evoked (cognitive) potentials
- Most frequent AE's: increased appetite, dizziness, and somnolence of mild intensity

PH10 Phase 2a MDD Study – Monotherapy (n = 22)

VistaGen Therapeutics



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

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

Planned Phase 2b Development Plan for MDD

VistaGen Therapeutics

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

- 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 (1.6, 3.2 or 6.4 μg) or placebo for 4 Weeks
- Target enrollment, ca. 200 patients
- Target start, 2H 2020
- Target completion, 1H 2022

Primary Endpoint: Change in MADRS from baseline compared to placebo

AV-101 for Suicidal Ideation

U.S. Department of Veterans Affairs

Baylor College of Medicine

VistaGen Therapeutics

Baylor / VA Phase 1b Clinical Study

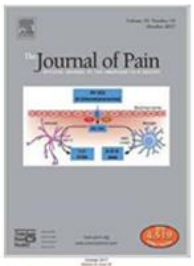
- Sponsored by U.S. Department of Veteran's Affairs (VA)
- Ongoing at Baylor University
- First-step target engagement study
- Double-blind, placebo-controlled, crossover design
- Two single doses of AV-101 (720 mg and 1440 mg) and placebo over three weeks
- Target enrollment, 12 healthy U.S. Military Veterans
- Top line results, end of Q4 2019

Primary Objective: Target engagement relevant to NMDA antagonism and suicidal ideation

VistaGen Therapeutics

AV-101 for Neuropathic Pain

- FDA Fast Track designation
- Potential oral non-opioid treatment option
- Non-addictive and non-sedating in published preclinical studies



"[W]e've undertaken … steps to advance the development of non-addictive treatments for pain."[1]

Scott Gottlieb, M.D., former FDA Commissioner

Potential Next Step: Phase 2a study

AV-101 for Parkinson's LID

- Potential FDA Fast Track designation
- Parkinson's disease (PD) levodopa-induced dyskinesia (LID)
- AV-101 maintained antiparkinsonian benefits of levodopa without causing serious side effects associated with current oral amantadine-based therapy for LID in preclinical data
- Potential to replace oral amantadine for PD LID

Potential Next Step: Phase 2a study

1. FDA Commissioner Scott Gottlieb, M.D., https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm618831.htm

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Distinguished Clinical and Regulatory Advisors

VistaGen Therapeutics

Maurizio Fava, M.D.
Professor of Psychiatry, Harvard Medical School; Director, Division of Clinical Research, Massachusetts General Hospital (MGH) Research Institute; Executive Director, MGH Clinical Trials Network and Institute

Sanjay Mathew, M.D.
Associate Professor of Psychiatry and Behavioral Sciences, Marjorie Bintliff Johnson and Raleigh White Johnson; Jr. Chair for Research in Psychiatry and Menninger Department of Psychiatry & Behavioral Sciences, Baylor College of Medicine

Michael Liebowitz, M.D.
Professor of Clinical Psychiatry, Columbia University; Managing Director and Founder, The Medical Research Network, LLC; Director (retired), Anxiety Disorders Clinic at the New York State Psychiatric Institute

Gerard Sanacora, Ph.D., M.D.
Professor of Psychiatry, Yale School of Medicine; Director, Yale Depression Research Program; Scientific Director, Yale-New Haven Hospital Interventional Psychiatry Service

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

Mark Wallace, M.D.
Professor of Clinical Anesthesiology, Chair of the Division of Pain Medicine, Medical Director and Director at the University of California, San Diego

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Experienced Team Leading Execution

VistaGen Therapeutics

Shawn K. Singh
Chief Executive Officer
- 25 years of experience with biopharmaceutical companies, a healthcare venture capital firm and a profitable CRO
- Artemis Neuroscience; SciClone Pharmaceuticals; Cato BioVentures; Cato Research: Morrison & Foerster

Ralph Snodgrass, Ph.D.
President, Chief Scientific Officer
- 23 years of experience in senior biotechnology management
- Progenitor; Lineberger Comprehensive Cancer Center

Jerrold D. Dotson, CPA
Chief Financial Officer, Secretary
- 20 years of experience in senior management finance and administration
- Calypte Biomedical; Discovery Foods; California & Hawaiian Sugar; Clorox

Mark A. Smith, M.D., Ph.D.
Chief Medical Officer
- 20 years of large Pharma CNS drug development experience
- Teva Pharmaceuticals; Shire Pharmaceuticals; AstraZeneca Pharmaceuticals; DuPont Pharmaceutical Company; U.S. National Institute of Mental Health

Mark A. McPartland
Vice President, Corporate Development
- 20 years of experience in corporate development, capital markets and management consulting
- Stellar Biotechnologies; MZ Group; Hayden Communications: Alliance Advisors

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Board of Directors

VistaGen Therapeutics

Jon Saxe Chairman

- 35 years of biopharmaceutical experience, director of multiple public and private healthcare companies
- Former President and Director, PDL BioPharma; CEO, Synergen (acquired by Amgen for $262M); VP, Licensing and Corporate Development, Head of Patent Law, Hoffmann-La Roche

Jerry Gin, Ph.D., MBA

- 45 years of healthcare industry experience; Co-Founder of Oculex (acquired by Allergan for $230M)
- Co-Founder, President and CEO of Nuvora

Ann Cunningham, MBA

- 20 years of experience including commercial and leadership roles at multiple global companies in the pharmaceutical industry
- Teva Pharmaceuticals; Otsuka America Pharmaceutical; Eli Lilly and Company

Shawn Singh, JD, CEO

- 25 years of experience with biopharmaceutical companies, a venture capital firm and a profitable CRO
- Artemis Neuroscience; SciClone Pharmaceuticals; Cato BioVentures; Cato Research

Brian Underdown, Ph.D.

- 30 years of leadership experience in biopharmaceutical sector; key player in growth of 10 Life Science companies
- Former VP, Research, Pasteur Merieux Connaught (now Sanofi Pasteur); Venture Partner, Lumira Capital

Ralph Snodgrass, Ph.D. President, CSO

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

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Looking beyond current therapies for CNS disorders with high unmet need

VistaGen Therapeutics

- New generation MOAs
- 3 differentiated clinical-stage product candidates
- Fast-acting, exceptional safety
- Multiple large and growing CNS markets
- Potentially transformative milestones in 2H 2019

VistaGen®
Therapeutics

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

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