

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): October 21, 2016

VistaGen Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

NEVADA
(State or other jurisdiction of incorporation)

000-54014
(Commission File Number)

20-5093315
(IRS Employer Identification Number)

343 Allerton Ave.
South San Francisco, California 94090
(Address of principal executive offices)

(650) 577-3600
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under 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))
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Item 7.01 Regulation FD Disclosure.

VistaGen Therapeutics, Inc. (the "*Company*") will begin using the corporate presentation materials, attached hereto as Exhibit 99.1, as early as October 24, 2016. The Company may continue to use these materials from time to time in conversations with investors and analysts.

In accordance with General Instruction B.2 for Form 8-K, the information in this Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "*Exchange Act*"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

See Exhibit Index.

Disclaimer.

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

Signatures

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

VistaGen Therapeutics, Inc.

Date: October 21, 2016

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Corporate presentation materials, dated October 2016.



VistaGen® Therapeutics

Developing Novel Medicines
for CNS Disorders

Corporate Presentation

Nasdaq: VTGN

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 Reports on Form 10-K filed with the Securities and Exchange Commission (SEC) on June 24, 2016, 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.



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VistaGen Overview

- **AV-101 (4-Cl-KYN), flagship clinical-stage oral CNS prodrug candidate**
 - New generation antidepressant with potential to displace atypical antipsychotics as primary adjunctive treatment for major depressive disorder (MDD); currently in Phase 2 development
 - Results from ongoing NIH-funded Phase 2a MDD study expected Q2 2017 and preparing to launch Phase 2b study for adjunctive treatment of MDD in Q1 2017
 - FDA Fast Track designation for adjunctive treatment of MDD anticipated in H1 2017
 - Safe and well-tolerated in Phase 1; drug-drug interaction and “Black Box” metabolic safety issues not anticipated
 - Multiple large CNS market opportunities, each with high clinical need
- **High-value peer M&A underscores potential upside opportunity**
- **Experienced CNS-focused team leading execution**



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Major Depressive Disorder: Substantial Market with Growing Unmet Need

350 Million People Worldwide Suffer From Depression¹



1 in 10 in U.S. Over Age 12 Takes an Antidepressant Medication²



Major Global Depression Markets are Expected to Grow at Staggering Rates³



U.S. Drug-Treated MDD Market Remains Substantially Underserved^{5,6}

11.2M US Drug Treated Patients with MDD

7.0M US Patients with Inadequate Response to Initial MDD Therapy
63% Treated with 2nd Line Therapy

Initial AV-101 Target Market

4.9M Drug Treated Patients with Treatment-Resistant MDD
44% Treatment Resistant after 2nd Line



1: World Health Organization; 2: U.S. National Institutes of Mental Health; 3: Unipolar Depression | Disease Landscape and Forecast | G7, January 11, 2016; 4: Rush AJ, et al. Am J Psychiatry. 2006; 163(11): 1905-1917 (STAR*D Study); 5: Decision Resources (PatientBase 2015)



Current Depression Medications

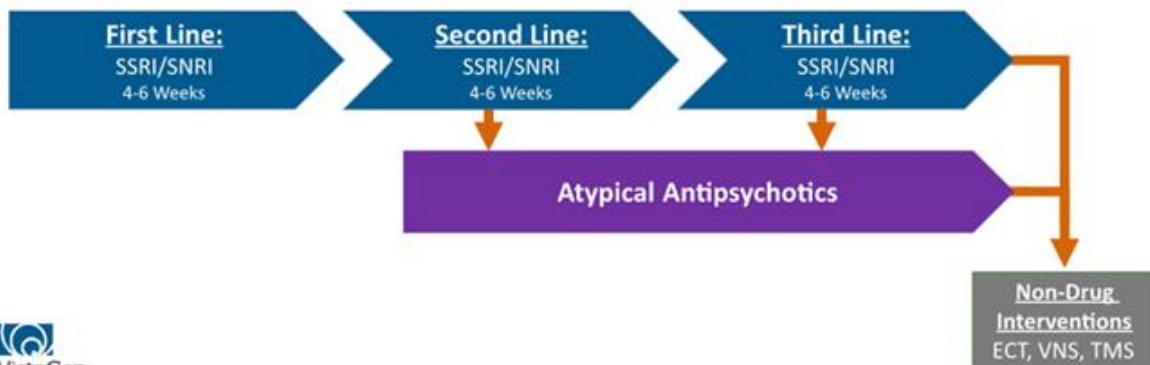
Standard Antidepressants (SSRIs and SNRIs)



Adjunctive Treatments (Atypical Antipsychotics)



Standard Algorithm for Treatment of Depression





Problems with Standard Antidepressants

- Often do not work**
 - Initial treatment effective in only 1 of 3 patients
- Slow to work**
 - Weeks to months to experience antidepressant benefits
- Side-effects**
 - Decreased libido, nausea, sleep disturbances

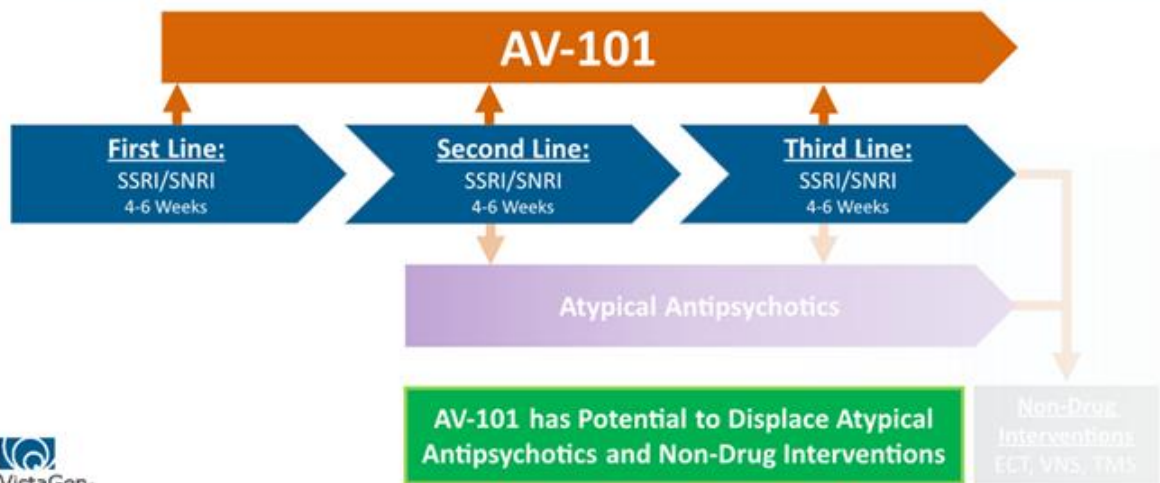


Problems with Atypical Antipsychotics as Adjunctive Treatment for MDD

- Limited efficacy**
 - Only 10-15% of patients respond
- Side-effects**
 - Weight gain and metabolic syndrome
 - Movement disorders and tardive dyskinesia
 - Sedation and cognitive impairment
- Safety concerns**
 - “Black Box” warning - mortality in elderly
 - Stroke
 - Convulsions



Where AV-101 Might Fit as an Adjunctive Therapy in the Depression Treatment Algorithm





Ketamine Hydrochloride

- FDA-approved anesthetic
- On WHO's Model List of Essential Medicines
- Administered IV or IM
- **NMDA receptor antagonist (ion channel blocker)**
- Schedule III Controlled Substance: risk of abuse
- Safety concerns include - anxiety, disorientation, hallucinations, hypertension and psychotic episodes
- Commonly known as a Club Drug - "Special K"



Ketamine: Potential Treatment for MDD

TIME 'Club Drug' Ketamine Provides Hope in Fight Against Depression

The New York Times Special K, a Hallucinogen, Raises Hopes and Concerns as a Treatment for Depression

THE WALL STREET JOURNAL Drugs to Lift Depression in Hours Rather Than Weeks

CBS NEWS New Class of Drugs Could Offer Depression Breakthrough



NIH Paradigm Shift in Treatment of Depression

Dr. Carlos Zarate Jr.



- Chief, Section on Neurobiology and Treatment of Mood Disorders at NIMH
- Principal Investigator, NIMH paradigm-shifting clinical studies of ketamine in MDD

NIH paradigm-shifting clinical study showed transformative antidepressant effects of ketamine in treatment resistant MDD patients, within 24 hours of a single IV infusion

"Recent data suggest that ketamine, given intravenously, might be the most important breakthrough in antidepressant treatment in decades."

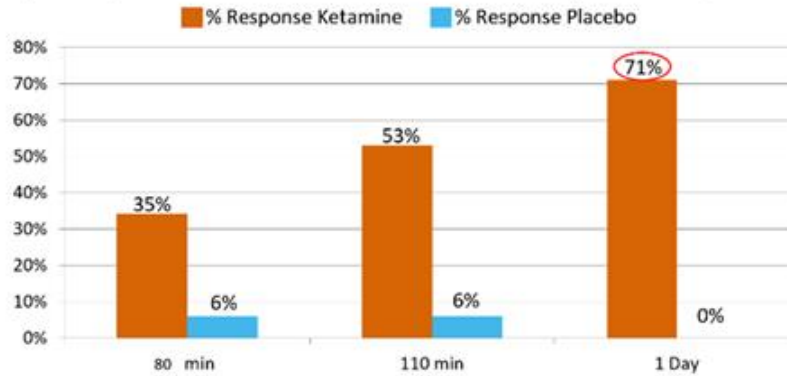
Thomas Insel, Former Director of NIMH



Rapid Antidepressant Effects of Ketamine in Dr. Zarate's NIH Study in MDD

Responder[†] Rates at 1 Day with Ketamine in Treatment-Resistant MDD

[†] Proportion of patients with treatment-resistant MDD with at least 50% improvement in depression rating



[†]Zarate, C. A., Jr., et al. (2006) "A randomized trial of an N-methyl-D-aspartate antagonist in treatment-resistant major depression." *Arch Gen Psychiatry* 63:856-864.

Also see:

- Murrough, J. W., et al. (2013) "Antidepressant efficacy of ketamine in treatment-resistant major depression: a two-site randomized controlled trial." *Am J Psychiatry* 170:1134-1142
- Zarate, C. A., Jr., et al. (2012) "Replication of ketamine's antidepressant efficacy in bipolar depression: a randomized controlled add-on trial." *Biol Psychiatry* 71:939-946.

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AV-101: A New Generation Oral Antidepressant

Ketamine-like Antidepressant Effects without Ketamine's Serious Side-Effects

- **New generation oral antidepressant prodrug candidate**, rapidly absorbed through the gut, actively transported into the brain, converted into its active metabolite, 7-Cl-KYNA, and binds to NMDAR Gly_B site
- **Similar to ketamine**: acts in the brain through the same glutamatergic AMPA-dependent pathway, rapidly inducing antidepressant effects
- **Safer than ketamine**: blocks the NMDAR through Gly_B site binding; ketamine blocks the ion channel of NMDARs, causing its negative side-effects
- **Safe and well-tolerated** in two NIH-funded Phase 1 safety studies; **no ketamine-like side-effects**
- **Drug-drug interaction and "Black Box" metabolic effects** related to atypical antipsychotics **not anticipated**

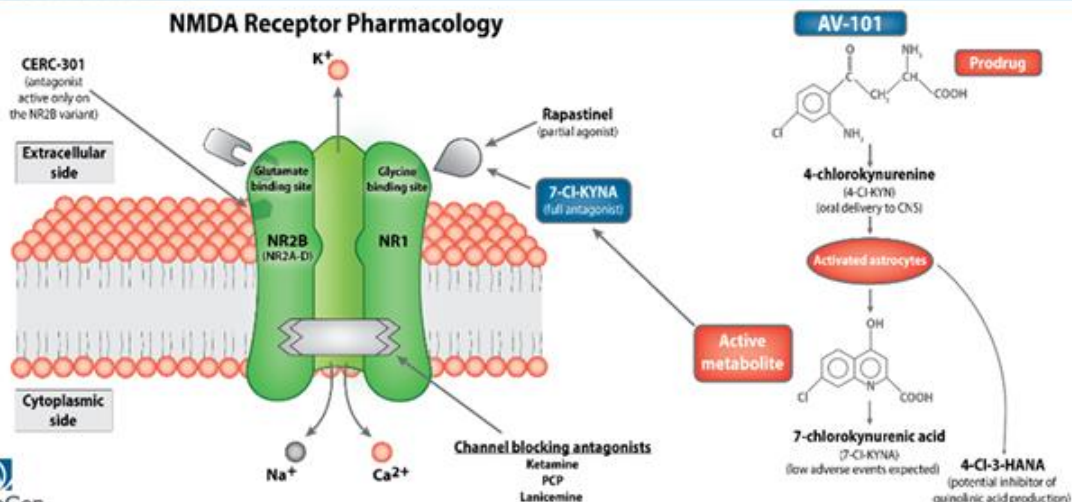


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AV-101 Indirectly Blocks NMDA Receptor Activity Through its Mechanism as a Glycine Antagonist

NMDA Receptor Pharmacology



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AV-101 Advantages Over NR2B Specific NMDA Receptor Antagonists

There are 9 different variants of the NMDAR ⁵

	Di-heteromeric NMDARs					Tri-heteromeric NMDARs			
	1/2A	1/2B	1/2C	1/2D	1/3A2	1/2A/2B	1/2A/2C	1/2B/2D	1/2B/3A
AV-101 Gly _B NMDA receptor antagonist regulates	+	+	+	+	+	+	+	+	+
NR2B specific NMDA receptor antagonist regulates	-	+	-	-	-	+	-	+	+

- In addition to neuronal cell-specific expression, within individual neurons, several NMDA receptor subtypes can be expressed⁵
- NR2B-selective compounds can only modulate 4 of the 9 NMDA receptor variants
- AV-101 decreases NMDA receptor function on all 9 NMDA receptor variants



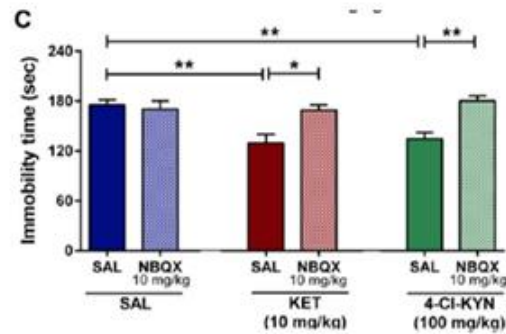
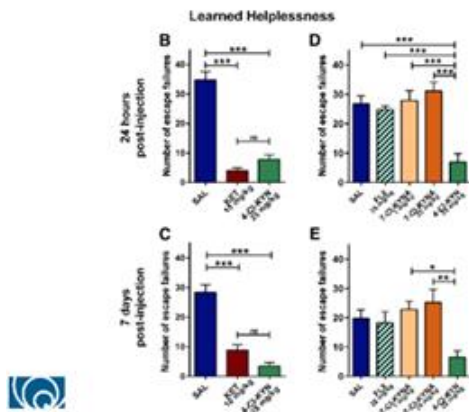
⁵ Paoletti, P., et al. (2013). "NMDA receptor subunit diversity: impact on receptor properties, synaptic plasticity and disease." *Nat Rev Neurosci* 14(6): 383.



AV-101 has Similar Efficacy to Ketamine in Published Preclinical Studies

A single dose of AV-101 demonstrated acute (24 h) and chronic (7 d) antidepressant effects similar to ketamine

NBQX (AMPA antagonist) blocks AV-101 effects which supports AMPA receptor activation as necessary for rapid-onset, NMDAR-mediated antidepressant effects



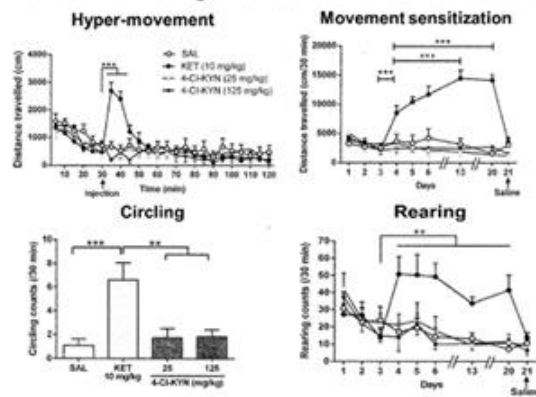
Zanos, P., et al. (2015). "The Prodrug 4-Chlorokynurene Causes Ketamine-Like Antidepressant Effects, but Not Side Effects, by NMDA/GlycineB-Site Inhibition." *J Pharmacol Exp Ther* 355(1): 76-85.



Compared to Ketamine, AV-101 Does Not Impair Rodent Behavior in Published Preclinical Studies

Benefits	AV-101	Ketamine
Forced-swim	Equivalent	Equivalent
Tail-suspension	Equivalent	Equivalent
Learned-helplessness	Equivalent	Equivalent
Novelty-suppressed feeding	Equivalent	Equivalent
Negative Behavioral Effects	AV-101	Ketamine
Abusive potential	no	yes
Hyper movement	no	yes
Movement sensitization	no	yes
Circling and rearing	no	yes
Sensory-motor gating	no	yes

AV-101 Had No Negative Behavioral Effects of Ketamine



Zanos, P., et al. (2015). "The Prodrug 4-Chlorokynurene Causes Ketamine-Like Antidepressant Effects, but Not Side Effects, by NMDA/GlycineB-Site Inhibition." *J Pharmacol Exp Ther* 355(1): 76-85.



- Received \$8.8 million from NIH for AV-101 preclinical development and two AV-101 Phase 1 clinical safety studies
- NIH Cooperative Research and Development Agreement (CRADA) signed in 2015
- NIH funding and conducting AV-101 Phase 2a study in MDD; results currently anticipated in Q2 2017

NIH and Dr. Zarate continue to drive paradigm shift away from standard antidepressants and towards a new generation of safer, ketamine-like, oral antidepressants



NIH-Funded AV-101 Phase 1a and Phase 1b Clinical Safety Studies

Phase 1a Study Design

- Randomized, double-blind, placebo-controlled
- Single oral dose with sequential dose-escalation
- Six single dose levels: 30, 120, 360, 720, 1,080 and 1,440 mg
- 36 subjects: 18 treatment and 18 placebo; 6 per cohort

Results

- Well-tolerated even at maximum dose; good bioavailability; no serious adverse events
- At higher doses, some subjects on AV-101 (and none on placebo) reported positive feelings of well-being similar to antidepressant effects reported with ketamine, without ketamine's side-effects

Phase 1b Study Design

- Randomized, double-blind, placebo-controlled
- Multiple oral dose (daily for 14 days), with sequential dose-escalation
- Three dose levels: 360, 1,080 and 1,440 mg
- 48 subjects: 36 treatment and 12 placebo; 16 per cohort

Results

- Well-tolerated even at maximum dose; good bioavailability; no serious adverse events
- Multiple subjects on AV-101 (and none on placebo) reported positive feelings of well-being similar to antidepressant effects reported with ketamine, without ketamine's side-effects



AV-101 Phase 1 Clinical Safety Studies: Reports of Feelings of Well-Being

Phase 1a			
Dose	# Subjects	# Subjects Expressing Well-Being	%
30	3	0	
120	3	0	
360	3	0	
730	3	0	
1080	3	0	
1440	3	2	
Total	18	2	11%
Placebo	18	0	0%
Phase 1b			
Dose	# Subjects	# Subjects Expressing Well-Being	%
360	12	1	
1080	12	1	
1440	12	1	
Total	36	3	8%
Placebo	12	0	0%

Combination of 1a & 1b			
Dose	# Subjects	# Subjects Expressing Well-Being	%
Highest Dose	15	3	20%
All Doses	54	5	9%
Placebo	30	0	0%

- Phase 1 safety studies - no direct measures of mood
- Feelings of well-being were voluntarily expressed by certain subjects on AV-101 during the interview process; no subjects on placebo expressed any similar feelings
- No comments expressed suggested any ketamine-like side-effects





NIH-Sponsored AV-101 Phase 2a Study in MDD

Primary Endpoint:
Safety and efficacy using standard Hamilton Rating Scale (HRS)

Secondary Endpoints:
Change from baseline in other widely-accepted measures of mood, depression and cognition

- Principal Investigator: Dr. Carlos Zarate, NIMH
- Double-blind, placebo-controlled, crossover design
- Single oral dose monotherapy for MDD, once per day for 14 days
- Target enrollment is 20 to 28 adult subjects
- Results currently anticipated in Q2 2017



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VistaGen's AV-101 Phase 2b Study in MDD Projected to Launch in Q1 2017

Primary Endpoint:
Efficacy demonstrated by a statistically significant decrease on the Montgomery-Asberg Depression Rating Scale (MADRS)

Secondary Endpoints:
Additional widely-accepted measures of mood, depression and cognition, including HAM-D-6, CGI-I

- Principal Investigator: Dr. Maurizio Fava, Harvard
- Projected enrollment: ca. 280 patients at 20 - 25 U.S. sites
- **Double-blind, placebo-controlled efficacy and safety study of AV-101 as adjunctive treatment for MDD patients with inadequate response to standard antidepressants**
- Novel Sequential Parallel Comparison Design (SPCD) to mitigate placebo effects
- Projected launch in Q1 2017; results currently anticipated in Q3 2018

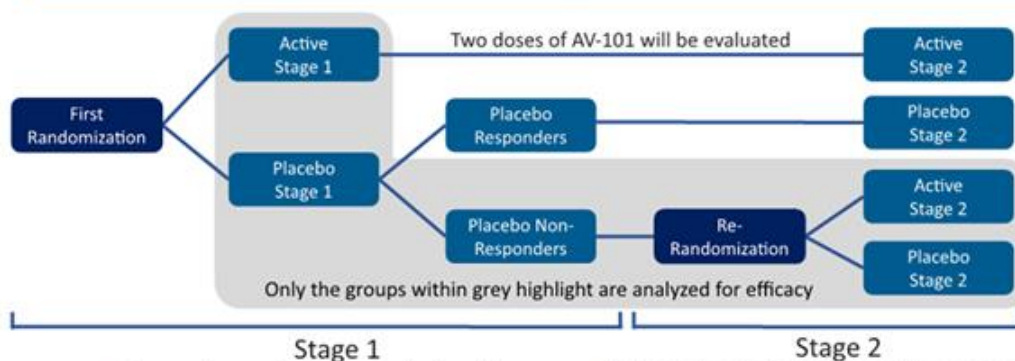


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AV-101 Phase 2b Study in MDD: Sequential Parallel Comparison Design (SPCD)

Clinical trial methodology to overcome the challenges of placebo effect in psychiatric clinical trials



Stage 1

Stage 2

- Compares drug vs. placebo in a standard parallel comparison design
- Drug vs. placebo differences are expected to be smaller, generating a large cohort of placebo non-responders

- Compares drug vs. placebo in a parallel comparison design involving only placebo non-responders
- **Placebo response is expected to be smaller**
- **Drug vs. placebo differences are expected to be greater**



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Preeminent CNS Clinical and Regulatory Advisors



Maurizio Fava, M.D.

- Professor of Psychiatry, Harvard Medical School; Director, Division of Clinical Research, Massachusetts General Hospital (MGH) Research Institute; Executive Director, MGH Clinical Trials Network and Institute

Thomas Laughren, M.D.

- Director (retired), FDA Division of Psychiatry Products, Office of New Drugs, Center for Drug Evaluation and Research (CDER)

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 at the 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



Leading CROs Supporting Phase 2b Execution



Leading full-service global CRO, with extensive CNS drug development, clinical trial design and execution, and regulatory services



Academic CRO within the Psychiatry Department at MGH, with high value expertise in CNS trial patient screening and recruitment



Global CRO providing experienced CMC and related regulatory services



High Value AV-101 CNS Expansion Opportunities

Potential to expand Phase 2 clinical development of AV-101 into multiple additional CNS indications, each representing a blockbuster opportunity

Neuropsychiatric Disorders

- Depression
- Bipolar disorder

Neurological Disorders

- Chronic neuropathic pain
- Epilepsy



Neurodegenerative Diseases

- Huntington's disease
- Parkinson's disease





Recent Pharma/Peer M&A Indicates Potential for Significant Upside

 <p>naurex INC A NEUROPHARMACEUTICAL COMPANY</p> <p>Rapastinel (GLYX-13)</p> <ul style="list-style-type: none"> Developed for treatment of MDD Similar to AV-101 (blocks NMDAR at Gly_B site), but is only administered IV 	 <ul style="list-style-type: none"> Allergan acquired Naurex in Sept 2015 after one Phase 2b study of rapastinel in MDD (ca. 360 patients) Allergan paid \$571 million in cash at closing; over \$1.1 billion of potential post-closing payments
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Business Development Strategy

Forbes "Allergan's acquisition of Naurex is a key positive for VistaGen as it is Naurex's closest competitor..."
- Gbola Amusa, Head of Healthcare Research, Chardan Capital Markets, NY¹

- Advance Phase 2 clinical development of AV-101 for adjunctive treatment of MDD and other CNS indications while exploring transformative partnering opportunities with Pharma and others focused on CNS markets



CNS-Related Value Indicators Suggest Significant Upside Potential

Recent Acquisitions			
Company	Acquirer	Product / Stage / Indication	Total Value
 naurex INC	 Allergan	Rapastinel (GLYX-13) / Phase 2b / Treatment of MDD	\$1.6 B
Selected Companies Focused on CNS Markets			
Company	Ticker	Development Stage	Market Cap*
 ACADIA [®] Pharmaceuticals	ACAD	Newly Approved Product	\$3.2 B
 Alkermes [®]	ALKS	Multiple Approved Products	\$6.7 B
 Intra-Cellular Therapies	ITCI	Phase 3	\$625 M
 SAGE THERAPEUTICS	SAGE	Phase 3	\$1.6 B



Capitalization - NASDAQ: VTGN

Closed \$10 Million Public Offering and Listed on NASDAQ in May 2016

Common Stock	8,269,463
Preferred Stock ⁽¹⁾	
Series A	750,000
Series B	1,160,240
Series C	2,318,012
Total Preferred Stock	4,228,252
Total Common and Preferred	12,497,715
Stock Plan Options	1,100,643
Common Stock Warrants ⁽²⁾	4,684,414
Total Options and Warrants	5,785,057
Total Common, Preferred, Options and Warrants	18,282,772

As of October 20, 2016

(1) Fixed conversion; no voting rights; shown on an as converted basis

(2) WALEP = \$6.44 per share



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Management Team

Shawn Singh - Chief Executive Officer

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

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

- 23 years of experience in senior biotechnology management, including as Chief Scientific Officer of Progenitor
- Progenitor; Lineberger Comprehensive Cancer Center

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

Jerrold Dotson, CPA - Chief Financial Officer, Secretary

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

Mark A. McPartland - Vice President, Corporate Development & Investor Relations

- 20 years of experience in business and corporate development, capital markets advisory, corporate communications and executive management consulting
- Combination of in-house, C-level biotech experience and multi-national independent investor relations and corporate communications agencies



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Board of Directors

Jon S. 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 - Director

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

Shawn Singh - CEO, Director

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

Ralph Snodgrass, Ph.D. - President, CSO, Director

- 23 years of experience in senior biotechnology management, including as Chief Scientific Officer of Progenitor
- Progenitor; Lineberger Comprehensive Cancer Center

Brian J. Underdown, Ph.D. - Director

- 30 years of leadership experience in the biopharmaceutical sector
- Key player in growth of 10 life science companies; former VP, Research, Pasteur Merieux Connaught (now Sanofi Pasteur); Venture Partner, Lumira Capital



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Near-Term Milestones Expected to Drive Value

	H1 2016	H2 2016	H1 2017	H2 2017	H1 2018	H2 2018
Listing on NASDAQ	✓					
FDA meeting re AV-101 Phase 2b study in MDD		★				
Commence AV-101 Phase 2b study in MDD			★			
AV-101 Fast Track designation for MDD			★			
Top line results from AV-101 Phase 2a study in MDD				★		
Top line results from AV-101 Phase 2b study in MDD						★



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VTGN: A Compelling Investment Opportunity

- ✓ Developing a new generation fast-acting oral antidepressant with strong safety and emerging efficacy profile addressing significant gap in global depression market
- ✓ Large, established global depression market with anticipated exponential growth
- ✓ Pipeline expansion opportunities in blockbuster neuropsychiatric, neurological and neurodegenerative indications
- ✓ Recent high-value peer M&A underscores opportunity for significant upside
- ✓ Highly experienced Management Team and CNS-focused Clinical and Regulatory Advisors leading execution



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VistaGen[®]
Therapeutics

Developing Novel Medicines
 for CNS Disorders

 Nasdaq : VTGN

www.vistagen.com

Updated as of 10/20/2016