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): January 29, 2018

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 (see General Instruction A.2. below):

☐ 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))

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 7.01 Regulation FD Disclosure

Issuance of Letter to Stockholders

On January 29, 2018, Shawn Singh, Chief Executive Officer and Director of VistaGen Therapeutics, Inc. (the "*Company*"), sent a letter to the Company's stockholders highlighting the Company's recent milestones and discussing the impending launch of the Company's Phase 2 clinical study of its lead product candidate, AV-101, for the adjunctive treatment of Major Depressive Disorder. A copy of the press release announcing Mr. Singh's issuance of the letter is attached hereto as Exhibit 99.1, and a copy of Mr. Singh's letter is attached hereto as Exhibit 99.2.

Use of New Corporate Presentation

On January 29, 2018, the Company utilized a new corporate presentation (the "*Corporate Presentation*") for business purposes. A copy of the Corporate Presentation is attached hereto as Exhibit 99.3.

The information in this Current Report on Form 8-K, including the information set forth in Exhibits 99.1, 99.2 and 99.3 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 any exhibit 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.

In addition, this Current Report on Form 8-K and the exhibit(s) attached hereto 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.

Item 9.01 Financial Statements and Exhibits.

See Exhibit Index.

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: January 30, 2018

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release issued by VistaGen Therapeutics, Inc., dated January 29, 2018
99.2	Letter to Shareholders, dated January 29, 2018
99.3	Corporate Presentation, dated January 29, 2018

VistaGen Therapeutics Issues Letter to Stockholders as Company Prepares to Initiate AV-101 Phase 2 Study for Major Depressive Disorder

South San Francisco, CA (January 29, 2018) – VistaGen Therapeutics, Inc. (NASDAQ: VTGN), a clinical-stage biopharmaceutical company focused on developing new generation medicines for depression and other central nervous system (CNS) disorders, today issued a letter to stockholders as the Company prepares to initiate its Phase 2 study of AV-101 for Major Depressive Disorder (MDD).

The full version of the letter to stockholders may be accessed using the following link, or by visiting the Investor Relations section of the Company's website, www.vistagen.com.

https://d1io3yog0oux5.cloudfront.net/vistagen/files/docs/shareholder-letter.pdf

In the letter to stockholders, Shawn Singh, Chief Executive Officer, highlights the Company's recent milestones and discusses the impending launch of the Company's Phase 2 clinical study of AV-101 for MDD. VistaGen's AV-101 is an oral new generation antidepressant with a mechanism of action that is fundamentally differentiated from all standard, FDA-approved antidepressants.

"In early-2017, I had the privilege of "Ringing the Bell" at The Nasdaq Stock Market's headquarters in Times Square on behalf of our company. That exciting and unique corporate event proved to be a symbolic prologue to the productive year for VistaGen that followed. The milestones we accomplished in 2017 have strongly positioned us to advance our AV-101 Phase 2 program to new levels throughout this year and next," commented Mr. Singh in the letter to stockholders. "Following a productive meeting with the U.S. Food and Drug Administration (FDA) in the fall of 2017, we achieved two key regulatory milestones before year end. First, in October 2017, the FDA authorized us to proceed, under our Investigational New Drug (IND) application, with our U.S. multi-center Phase 2 clinical study of AV-101 as an oral new generation adjunctive treatment for MDD patients with an inadequate response to standard, FDA-approved antidepressants. In addition, in December 2017, the FDA granted us Fast Track Designation for development of AV-101 for treatment of MDD, providing us the opportunity for frequent FDA interactions regarding the most appropriate and efficient development pathway to bring AV-101 to MDD patients. 2017 culminated with the closing of an underwritten public offering that generated gross proceeds of $15 million, enabling us to commence and advance through our Phase 2 study in 2018. I want to thank, again, our underwriters and our new and existing investors for supporting our vision."

Recent Accomplishments:

- Received "green light" from the FDA to launch AV-101 Phase 2 MDD adjunctive treatment study pursuant to our IND.
- Received Fast Track Designation from the FDA for development of AV-101 as an adjunctive treatment for MDD. Fast Track Designation is designed to facilitate the development and review of new treatments for serious conditions, such as MDD, with unmet medical need.
- Continued to strengthen our intellectual property portfolio as the European Patent Office (EPO) granted a patent related to methods of treating depression with AV-101 and certain other neurological indications, and the U.S. Patent and Trademark Office (USPTO) issued U.S. Patent No. 9,834,801 related to certain methods of production for AV-101.
- AV-101 was featured on the cover of *The Journal of Pain* in October 2017, a peer-reviewed publication of nonclinical studies of the effects of AV-101 in well-established nonclinical models of pain. This article is available at the following link: http://dx.doi.org/10.1016/j.jpain.2017.03.014).
- Closed underwritten public offering that generated gross proceeds of $15 million. Proceeds from the offering enable us to continue research and development, primarily related to our Phase 2 clinical study of AV-101 for MDD.

Mr. Singh continued, “As a result of receiving a “green light” from the FDA, we anticipate launching our AV-101 Phase 2 MDD adjunctive treatment study during the current quarter, with topline data expected to be available during the first half of 2019. In addition, we expect one of our principal collaborators, the U.S. National Institute of Mental Health, to complete its Phase 2 monotherapy study of AV-101 in treatment-resistant MDD patients during 2018. This Phase 2 study is being conducted by Dr. Carlos Zarate Jr., Chief, Section on the Neurobiology and Treatment of Mood Disorders and Chief of the Experimental Therapeutics and Pathophysiology Branch at the NIMH. AV-101 caught the attention of Dr. Zarate, widely considered a pioneer in ketamine research for MDD, and his team after head-to-head preclinical studies of AV-101 vs. ketamine, ultimately resulting in a Cooperative Research and Development Agreement between VistaGen and the U.S. National Institutes of Health, whereby the NIMH is fully funding and conducting the NIMH Phase 2 monotherapy MDD study of AV-101.”

Anticipated Milestones over next 12 to 18 Months:

- **First Quarter of 2018:**
  - Launch our Phase 2 clinical study of AV-101 for MDD with Dr. Maurizio Fava of Harvard University as Principal Investigator; a 180-patient, U.S. multi-center, double-blind, placebo controlled efficacy and safety study evaluating AV-101 as an adjunctive treatment in MDD patients with an inadequate response to standard, FDA-approved antidepressants.
- **Second Half of 2018:**
  - NIMH AV-101 Phase 2 MDD monotherapy study topline results.
  - Completion of our AV-101 Phase 2 MDD adjunctive treatment study.
- **First Half of 2019:**
  - Launch of AV-101 Phase 2 studies in neuropathic pain and Parkinson’s disease levodopa-induced dyskinesia.
  - AV-101 Phase 2 MDD adjunctive treatment study topline results.

VistaGen kicked off 2018 by hosting meetings with current investors, prospective institutional investors and potential strategic partners during the 36th Annual J.P. Morgan Healthcare Conference and 10th Annual Biotech Showcase in San Francisco. Additionally, Mr. Singh participated on a panel with distinguished scientists and clinicians focused on the neuroscience of depression and addiction during the Healthcare Innovation Forum held at the University of California, San Francisco (UCSF) Medical Center in San Francisco.

Mr. Singh concluded, “Reflecting on a productive week in San Francisco, it is apparent to us that a paradigm shift towards a new generation of faster-acting antidepressants, particularly those targeting NMDA and AMPA receptors, is emerging. Throughout 2018, we will remain focused on our core mission - to develop new generation medicines for depression and other CNS disorders affecting millions of people worldwide who do not currently have adequate treatment alternatives. Personally, and professionally, I am motivated and passionate about our mission. I maintain the highest confidence in our strategy and our team, and I anticipate that 2018 will yield even more exciting achievements intended to deliver both life-changing benefits to CNS patients and extraordinary value to our stockholders.”

About VistaGen
VistaGen Therapeutics, Inc. (NASDAQ: VTGN), is a clinical-stage biopharmaceutical company focused on developing new generation medicines for depression and other CNS disorders. VistaGen's lead CNS product candidate, AV-101, is in Phase 2 development, initially as a new generation oral antidepressant drug candidate for MDD AV-101's mechanism of action is fundamentally different from all FDA-approved antidepressants and atypical antipsychotics used adjunctively to treat MDD, with potential to drive a paradigm shift towards a new generation of safer and faster-acting antidepressants. AV-101 is currently being evaluated by the U.S. National Institute of Mental Health (NIMH) in a small Phase 2 monotherapy study in MDD being fully funded by the NIMH and conducted by Dr. Carlos Zarate Jr., Chief, Section on the Neurobiology and Treatment of Mood Disorders and Chief of Experimental Therapeutics and Pathophysiology Branch at the NIMH. VistaGen is preparing to launch a 180-patient Phase 2 study of AV-101 as an adjunctive treatment for MDD patients with an inadequate response to standard, FDA-approved antidepressants. Dr. Maurizio Fava of Harvard University is the Principal Investigator of the VistaGen's AV-101 MDD Phase 2 adjunctive treatment study. AV-101 may also have the potential to treat multiple CNS disorders and neurodegenerative diseases in addition to MDD, including neuropathic pain, epilepsy, Huntington's disease, Parkinson's disease levodopa-induced dyskinesia (PD LID) and other CNS diseases and disorders where modulation of the NMDA receptors, activation of AMPA pathways and/or key active metabolites of AV-101 may achieve therapeutic benefit.

For more information, please visit www.vistagen.com and connect with VistaGen on:
Twitter
LinkedIn
Facebook

Forward-Looking Statements
The statements in this press release that are not historical facts may constitute forward-looking statements that are based on current expectations and are subject to risks and uncertainties that could cause actual future results to differ materially from those expressed or implied by such statements. Those risks and uncertainties include, but are not limited to, risks related to the successful launch, continuation and results of the NIMH's Phase 2 (MDD monotherapy) and/or the Company's planned Phase 2 (MDD adjunctive treatment) clinical studies of AV-101, allowance of patent applications and continued protection of its intellectual property, and the availability of substantial additional capital to support its operations, including the AV-101 Phase 2 clinical development activities described above. These and other risks and uncertainties are identified and described in more detail in VistaGen's filings with the Securities and Exchange Commission (SEC). These filings are available on the SEC's website at www.sec.gov. VistaGen undertakes no obligation to publicly update or revise any forward-looking statements.

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January 29, 2018

Dear Fellow Stockholders:

In early-2017, I had the privilege of "Ringing the Bell" at The Nasdaq Stock Market's headquarters in Times Square on behalf of our company. That exciting and unique corporate event proved to be a symbolic prologue to the productive year for VistaGen that followed. The milestones we accomplished in 2017 have strongly positioned us to advance our AV-101 Phase 2 program to new levels throughout this year and next.

Regulatory and Clinical Development

We refer to AV-101 as a "new generation" antidepressant because its mechanism of action (the way it works in the brain) is fundamentally different from all FDA-approved antidepressants, as well as all FDA-approved atypical antipsychotics often used together with standard antidepressants. Investment, innovation, industry expertise and a lot of hard work by our focused and passionate teams, teams committed to making a game-changing impact in the treatment of multiple diseases and disorders involving the central nervous system (CNS), have advanced us to the threshold of launching our potentially transformative Phase 2 study of AV-101 for treatment of Major Depressive Disorder (MDD). Our primary goal is to develop and ultimately receive regulatory approval to commercialize AV-101 worldwide for multiple CNS diseases and disorders. Our initial regulatory and commercial strategies to accomplish that goal are focused on developing AV-101 as an oral, safe, and faster-acting new generation treatment alternative for millions of MDD patients with inadequate therapeutic results from standard antidepressants, displacing atypical antipsychotics in the current MDD drug treatment paradigm. It is a potentially game-changing goal indeed, and our teams are well-suited for the challenge.

Following a productive meeting with the U.S. Food and Drug Administration (FDA) in the Fall of 2017, we achieved two key regulatory milestones before year end. First, in October 2017, the FDA authorized us to proceed, under our Investigational New Drug (IND) application, with our U.S. multi-center Phase 2 clinical study of AV-101 as an oral new generation adjunctive treatment for MDD. This study will focus on treatment of MDD patients with an inadequate response to standard, FDA-approved antidepressants. In addition, in December 2017, the FDA granted us Fast Track Designation for development of AV-101 for treatment of MDD, providing us the opportunity for frequent FDA interactions regarding the most appropriate and efficient development pathway to bring AV-101 to MDD patients.
As a result of receiving a "green light" from the FDA, we anticipate launching our AV-101 Phase 2 MDD adjunctive treatment study during the current quarter, with topline data expected to be available during the first half of 2019.

During 2018, we expect one of our principal collaborators, the U.S. National Institute of Mental Health (NIMH), to complete its Phase 2 monotherapy study of AV-101 in treatment-resistant MDD patients. This Phase 2 study is being conducted by Dr. Carlos Zarate Jr., Chief, Section on the Neurobiology and Treatment of Mood Disorders and Chief of the Experimental Therapeutics and Pathophysiology Branch at the NIMH. AV-101 caught the attention of Dr. Zarate, widely considered a pioneer in ketamine research for MDD, and his team after head-to-head preclinical studies of AV-101 vs. ketamine, ultimately resulting in a Cooperative Research and Development Agreement (CRADA) between VistaGen and the U.S. National Institutes of Health (NIH), whereby the NIMH is fully funding and conducting the NIMH Phase 2 monotherapy MDD study of AV-101.

Manufacturing and Patents

In connection with our AV-101 Phase 2 program, as well as potential Phase 3 development and commercialization, we, together with our contract manufacturing organization, developed a novel process for the production of AV-101 drug substance. We believe our new proprietary AV-101 production process will significantly improve manufacturing efficiency.

We strengthened our intellectual property around AV-101 in 2017. In Europe, the European Patent Office (EPO) granted our patent related to methods of treating depression with AV-101 and certain other neurological indications. Additionally, the U.S. Patent and Trademark Office (USPTO) granted a patent related to certain methods of production of AV-101. These issued patents, together with the potential issuance of additional AV-101 patent applications currently under review in the US, European Union and other key pharmaceutical markets, provide VistaGen with added long-term intellectual property protection for AV-101 and enhance its commercial potential.

Additional Highlights

AV-101 for Neuropathic Pain and Parkinson's Disease Levodopa-induced Dyskinesia (PD LID)

In addition to MDD, we believe AV-101 may also have the potential to treat multiple CNS disorders and neurodegenerative diseases, including neuropathic pain, PD LID and other CNS diseases and disorders where modulation of NMDA receptors, activation of AMPA pathways and/or key active metabolites of AV-101 may achieve therapeutic benefit. In October 2017, a peer-reviewed publication of nonclinical studies of the effects of AV-101 in four well-established nonclinical models of pain was featured on the cover of *The Journal of Pain* (http://dx.doi.org/10.1016/j.jpain.2017.03.014). In these studies, AV-101 was found to have robust anti-nociceptive effects, similar to gabapentin, but with a better side effect profile in several pre-clinical models of hyperalgesia and allodynia, with results suggesting AV-101's potential for treating multiple pain states. We believe the positive results published in these studies, taken together with successful AV-101 Phase 1a and 1b clinical safety studies and the epidemic abuse of prescription opioid pain medicines, support further investment in Phase 2 clinical studies to assess efficacy and safety of AV-101 as a new non-opioid treatment alternative for patients suffering from neuropathic pain. We are also excited about the opportunity to explore AV-101's potential to reduce dyskinesia associated standard levodopa, or L-DOPA, therapy for Parkinson's disease, based on results from non-clinical studies. Without diverting our priority focus on MDD, we plan to expand our AV-101 Phase 2 clinical program during the next year to include these important CNS indications with significant unmet need.

Capital Markets

2017 culminated with the closing of an underwritten public offering that generated gross proceeds of $15 million. This financing enables us to commence and advance our Phase 2 study in 2018. I want to thank, again, our underwriters and our new and existing investors for supporting our vision.

2018 J.P. Morgan Healthcare Conference and University of California, San Francisco Panel Discussion

Earlier this month, our team kicked off 2018 by hosting numerous meetings with current investors, prospective institutional investors and potential strategic partners during the 36th Annual J.P. Morgan Healthcare Conference and 10th Annual Biotech Showcase in San Francisco. Additionally, I was honored to participate on a panel with distinguished scientists and clinicians focused on the neuroscience of depression and addiction during the Healthcare Innovation Forum held at the University of California, San Francisco (UCSF) Medical Center in San Francisco. Our in-depth panel discussions were not only encouraging and motivating, but also eye-opening regarding potential advances in neuropsychiatry on the horizon at UCSF.

Reflecting on a productive week in San Francisco, it is apparent that a paradigm shift towards a new generation of faster-acting antidepressants, particularly those targeting NMDA and AMPA receptors, is emerging. The positive effects on depression and pain through the IV administration of ketamine is well documented, and significant investment has been made by big Pharma to explore its benefits. For example, Janssen Research & Development, one of the Janssen Pharmaceutical Companies of Johnson & Johnson, has made a significant investment in esketamine, an intranasally-administered NMDA receptor antagonist currently in Phase 3 development with a mechanism of action similar to ketamine treatment currently administered by injection. If approved by the FDA, esketamine would be one of the first new approaches to treat patients with MDD in the last 50 years. Similar to ketamine and esketamine, AV-101 targets the NMDA and AMPA receptors, however AV-101 is oral and it inhibits the NMDA receptor activity rather than blocking it, thereby producing ketamine-like antidepressant effects without safety concerns associated with ketamine.

I am as eager and passionate as I have ever been to see what transpires from our AV-101 Phase 2 program, especially our impending Phase 2 adjunctive treatment study in MDD patients with an inadequate response to standard antidepressants. Throughout 2018, we will remain focused on our core mission - to develop new generation medicines for depression and other CNS disorders affecting millions of people worldwide who do not currently have adequate treatment alternatives. I maintain the highest confidence in our strategy and our teams, and I anticipate that 2018 will yield even more exciting achievements intended to deliver both life-changing benefits to CNS patients and extraordinary value to our stockholders.

Very truly yours,

Shawn Singh,
Chief Executive Officer and Director
VistaGen Therapeutics, Inc.

DEVELOPING NEW GENERATION MEDICINES FOR DEPRESSION AND OTHER CNS DISORDERS

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, 2017, filed with the Securities and Exchange Commission (SEC) on June 29, 2017, 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.

www.vistagen.com

VistaGen Overview

NASDAQ: VTGN

VistaGen® Therapeutics

Clinical-stage, CNS-focused, emphasis on depression, pain and Parkinson's disease levodopa-induced dyskinesia (PD LID)

AV-101, oral new generation antidepressant; new non-opioid alternative for neuropathic pain

Phase 2 in depression ongoing in 2018; Phase 2 in pain and PD LID in 2019

Potentially transformative clinical catalysts in 2018 and 2019

Strong long term support from NIH

Experienced teams leading execution

www.vistagen.com

VistaGen® Therapeutics

Major Depressive Disorder (MDD)

SUBSTANTIAL MARKET WITH GROWING UNMET NEED

OVER
300 MILLION
PEOPLE WORLDWIDE SUFFER FROM DEPRESSION[1]

1 in 10 in U.S. Over Age 12 Takes an Antidepressant[2]

Global Depression Market is Expected to Grow[3]

U.S. Drug-Treated MDD Market is Substantially Underserved[4,5]

11.6M
U.S. Drug-Treated Patients with MDD

INITIAL AV-101 TARGET MARKET

7.3M
U.S. Patients with Inadequate Response to Initial MDD Therapy
63% Treated with 2nd Line Therapy

5.1M
U.S. Patients with Inadequate Response to MDD Therapy
44% Treatment-Resistant after 2nd Line Therapy

1: World Health Organization; 2: U.S. National Institutes of Mental Health; 3: Zion Research: Depression Drug Market: April 2016, 4: Rush AJ, et al. Am J. Psychiatry. 2006, 163(11): 1905-1917 (STAR*D Study), 5: Decision Resources 2016

VistaGen® Therapeutics

Current FDA-Approved Drug Treatments for MDD

PROBLEMS WITH CURRENT ANTIDEPRESSANTS AND ADJUNCTIVE ATYPICAL ANTIPSYCHOTICS

PROZAC® fluoxetine hydrochloride | zoloft® (sertraline HCl) | Cymbalta® duloxetine HCl

Current Antidepressants

- **Often do not work**
  - Initial treatment effective in only 1 of 3 patients
- **Slow to work**
  - May take 4 to 6 weeks or more to achieve antidepressant effects
- **Side-effects**
  - Anxiety, decreased libido, nausea, sleep, disturbances, weight gain and more

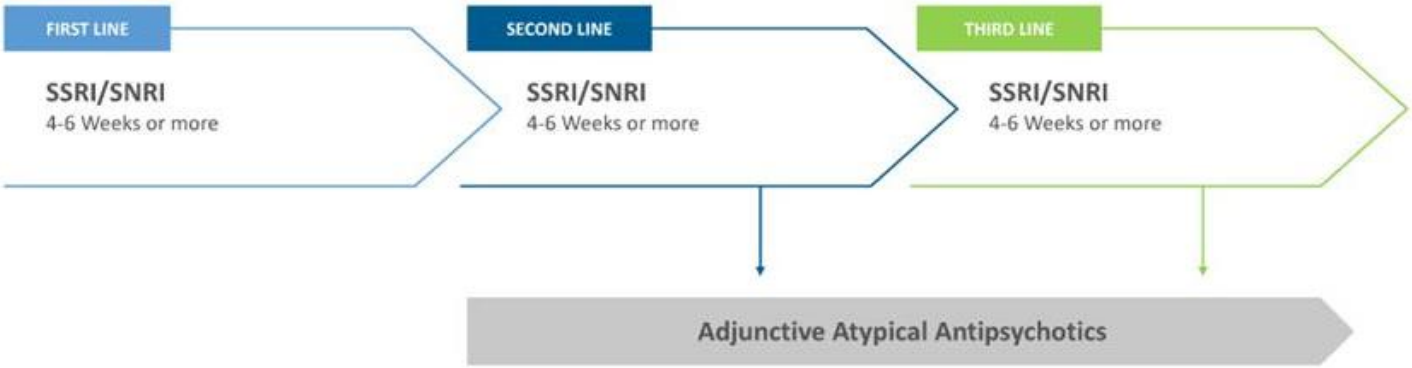
ABILIFY® (aripiprazole) | REXULTI® brexpiprazole tablets | Seroquel®

Current Adjunctive Atypical Antipsychotics

- **Limited efficacy**
  - Only 10 to 20% of MDD patients respond
- **Side effects**
  - Weight gain, metabolic syndrome, tardive dyskinesia, sedation, cognitive impairment
- **Safety concerns**
  - "Black Box" warnings - mortality in elderly, cardiovascular complications, convulsions, stroke

Current MDD Drug Treatment Paradigm

VistaGen® Therapeutics



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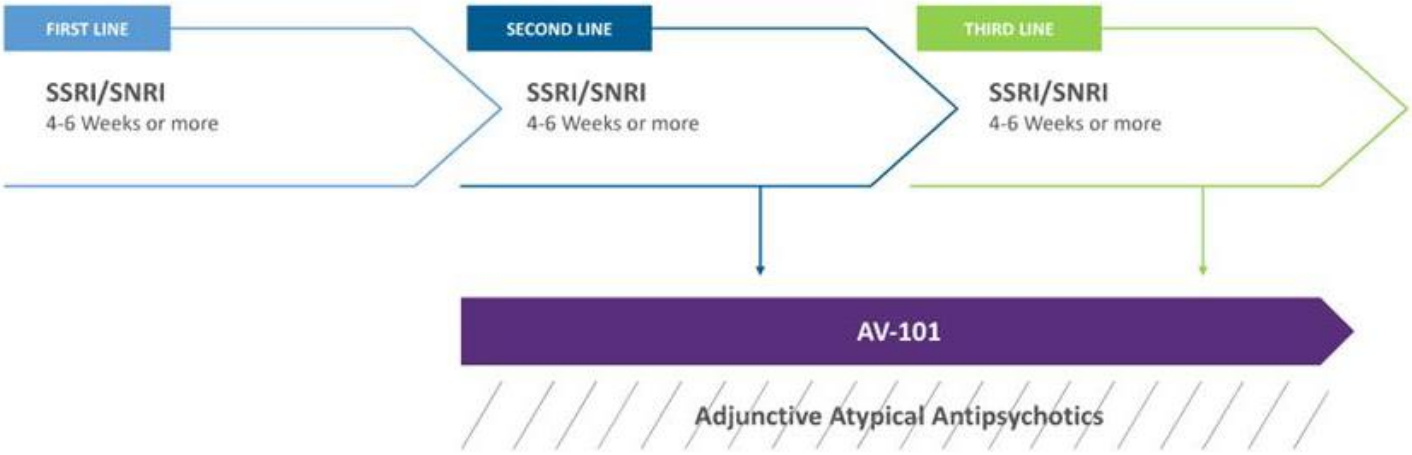
VistaGen® Therapeutics

Initial Target in Current MDD Drug Treatment Paradigm

AV-101'S INITIAL FIT, AS A NEW GENERATION ADJUNCTIVE THERAPY



Initial Objective - Displace Adjunctive Atypical Antipsychotics in the MDD Drug Treatment Paradigm

VistaGen® Therapeutics

Ketamine is Driving a Paradigm Shift in the Treatment of MDD

1: http://www.nimh.nih.gov/about/director/2014/ketamine.shtml

VistaGen® Therapeutics

The Ketamine Story

A PARADIGM SHIFT TOWARDS NEW GENERATION ANTIDEPRESSANTS

FDA-approved anesthetic

Currently, only available by injection

Popular Club Drug: "Special K"

NUMEROUS SAFETY CONCERNS: confusion, dissociation, hallucinations, dizziness, increased blood pressure and heart rate, abuse potential

- **MOA is fundamentally different from all FDA-approved antidepressants and adjunctive atypical antipsychotics**
- Clinical studies at the NIMH and academic research centers in treatment-resistant MDD patients had game-changing results

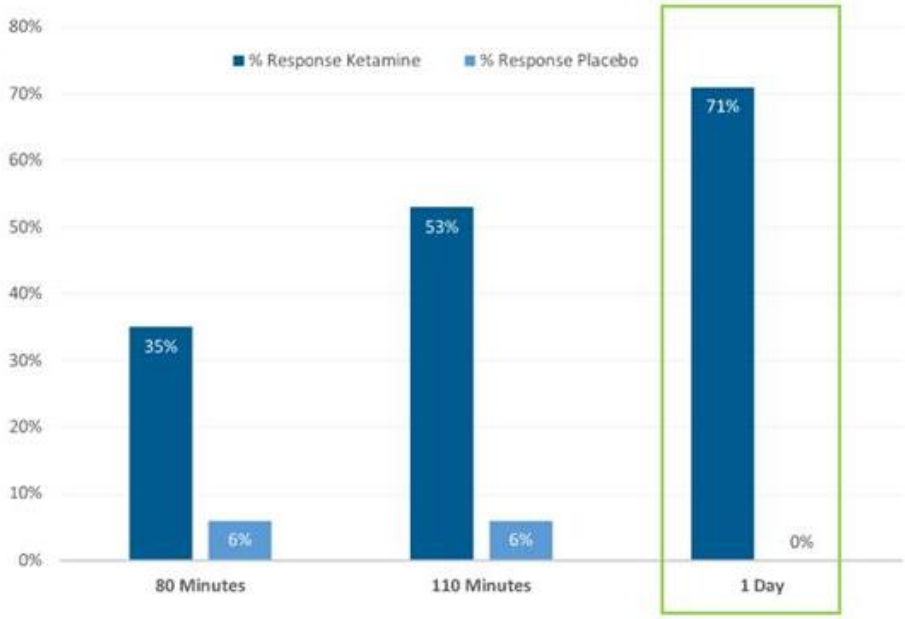
NIMH's Breakthrough Ketamine Study in Treatment-resistant MDD

VistaGen® Therapeutics

ANTIDEPRESSANT EFFECTS WITHIN 1 DAY OF A SINGLE TREATMENT

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



[1]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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Ketamine offers new hope for MDD patients, but is it a long-term solution?

VistaGen Therapeutics

"Club Drug Ketamine **Provides Hope** in Fight Against Depression"

TIME

"Drugs to Lift Depression **in Hours** Rather Than Weeks"

THE WALL STREET JOURNAL.

VistaGen® Therapeutics

AV-101 (4-Chlorokynurenine)

POTENTIAL KETAMINE-LIKE NEW GENERATION TREATMENT FOR MDD

ORAL

- Prodrug, rapidly absorbed through the gut, actively transported into the brain, converted into it active metabolite, which binds to NMDA receptors

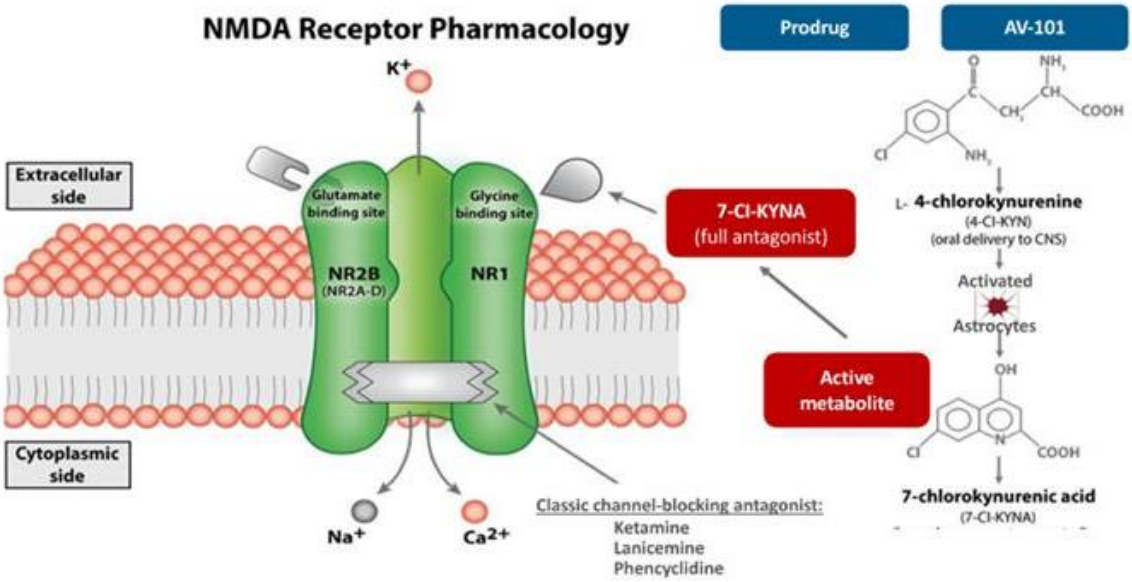
FAST-ACTING, KETAMINE-LIKE ANTIDEPRESSANT EFFECTS, WITHOUT KETAMINE'S SAFETY CONCERNS

- Inhibits NMDAR activity through Gly_B site binding; ketamine blocks the ion channel of NMDAR and induces psychotomimetic side effects
- Like ketamine, AV-101 demonstrates fast-acting antidepressant effects in rodent models via upregulation of AMPA receptors
- Well-tolerated in two NIH-funded Phase 1 safety studies
- Currently in Phase 2 clinical development
- Drug-drug interaction and "Black Box" metabolic effects not anticipated

VistaGen® Therapeutics

AV-101's Mechanism of Action

AV-101'S ACTIVE METABOLITE (7-Cl-KYNA) INHIBITS NMDA RECEPTOR ACTIVITY



AV-101 vs. Ketamine

PRECLINICAL EVIDENCE OF KETAMINE-LIKE ANTIDEPRESSANT EFFECTS WITHOUT KETAMINE-LIKE SAFETY CONCERNS

The Journal of Pharmacology and Experimental Therapeutics

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

Panos Zanos, Sean C. Piantadosi, Hui-Qiu Wu, Heather J. Pribut, Matthew J. Dell, Adem Can, H. Ralph Snodgrass, Carlos A. Zarate, Jr., Robert Schwarcz, and Todd D. Gould

VistaGen® Therapeutics

AV-101 vs. Ketamine in Published Preclinical Studies

Benefits	AV-101	Ketamine
Forced-swim	EQUIVALENT	
Tail-suspension	EQUIVALENT	
Learned-helplessness	EQUIVALENT	
Novelty-suppressed feeding	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

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

NIH Support for AV-101

VALUABLE LONG-TERM RELATIONSHIP AND SUPPORT FOR AV-101 DEVELOPMENT

Direct funding for AV-101 Preclinical and Phase 1

$8.8 million in direct non-dilutive cash awards for support of AV-101 preclinical development and first-in-human Phase 1 clinical safety studies

Clinical and financial support for AV-101 Phase 2

Fully funding, and Dr. Carlos Zarate, Jr. as Principal Investigator is conducting, a small (n=~20) Phase 2 MDD monotherapy clinical study in treatment-resistant MDD patients

NIH National Institute of Mental Health

NIH and Dr. Zarate continue to drive the paradigm shift to new generation antidepressants

NIH-Sponsored AV-101 Phase 1 Safety Studies

NO KETAMINE-LIKE SAFETY CONCERNS

AV-101 Phase 1a Study

- Randomized, double-blind, placebo-controlled
- Single oral dose with sequential dose-escalation
- Six single dose levels: 30, 120, 360, 720, 1,080, 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 (none on placebo) reported positive feelings of well-being similar to antidepressant effects reported with ketamine, without ketamine's side-effects

AV-101 Phase 1b Study

- Randomized, double-blind, placebo-controlled
- Multiple oral dose (daily/14 days), 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 (none on placebo) reported positive feelings of well-being similar to antidepressant effects reported with ketamine, without ketamine's side-effects

NIMH-Sponsored AV-101 Phase 2 Monotherapy Study

MDD ORAL MONOTHERAPY

Principal Investigator:

Dr. Carlos Zarate, Jr., NIMH

- Single site: NIMH
- Double-blind, placebo-controlled, crossover design
- Single oral dose monotherapy, in treatment-resistant MDD patients, once per day for 14 days
- Target enrollment: ca. 20 adult subjects

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

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

NIMH completion expected

www.vistagen.com

AV-101 Phase 2 Adjunctive Treatment Study

NEW GENERATION ORAL ADJUNCTIVE TREATMENT FOR INADEQUATE SSRI/SNRI MONOTHERAPY

Principal Investigator:

Dr. Maurizio Fava, Harvard University

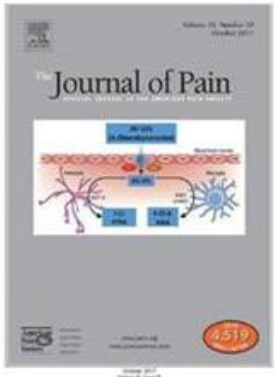
- Projected enrollment: ~180 patients
- Double-blind, placebo-controlled, 2-Stage Sequential Parallel Comparison Design (SPCD)
- **Objective:** assess efficacy and safety of AV-101 + standard antidepressants in MDD patients with an inadequate response to standard antidepressants
- Single oral dose, once per day for 14 days
- Projected launch and completion in 2018

Primary Endpoint:
Efficacy demonstrated by a decrease on the Montgomery-Asberg Depression Rating Scale

Secondary Endpoints:
Additional widely-accepted measures of mood, depression and cognition

www.vistagen.com

AV-101 for Neuropathic Pain



VistaGen® Therapeutics

UNMET MEDICAL NEED

At least 5% of U.S. population suffers from severe neuropathic pain; most treated with addictive opioids or marginally effective antidepressants and anticonvulsants

RATIONALE

NMDA receptor antagonists such as ketamine can improve neuropathic pain, but their risk/benefit ratio is too problematic to permit chronic, widespread use

EVIDENCE FOR AV-101

In recently published preclinical studies, AV-101 reduced neuropathic pain in four well-established models of pain with similar efficacy to gabapentin, but with a superior side effect profile[1]

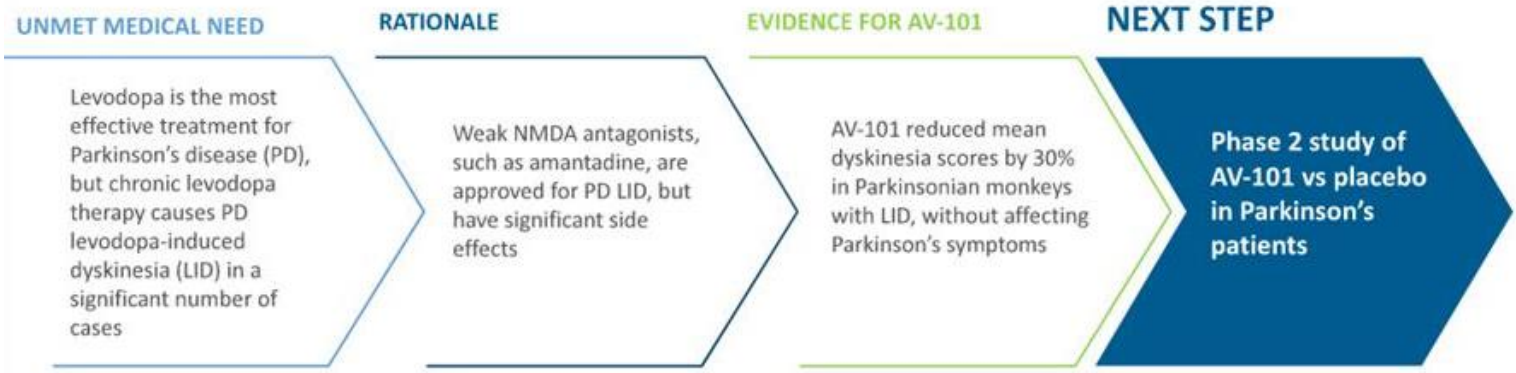
NEXT STEP

Phase 2 study of AV-101 vs placebo in patients with neuropathic pain

1. Yaksh, T.L., et al. (2017). "Characterization of the Effects of L-4-Chlorokynurenine on Nociception in Rodents." The Journal of Pain 18: 1184-1196.

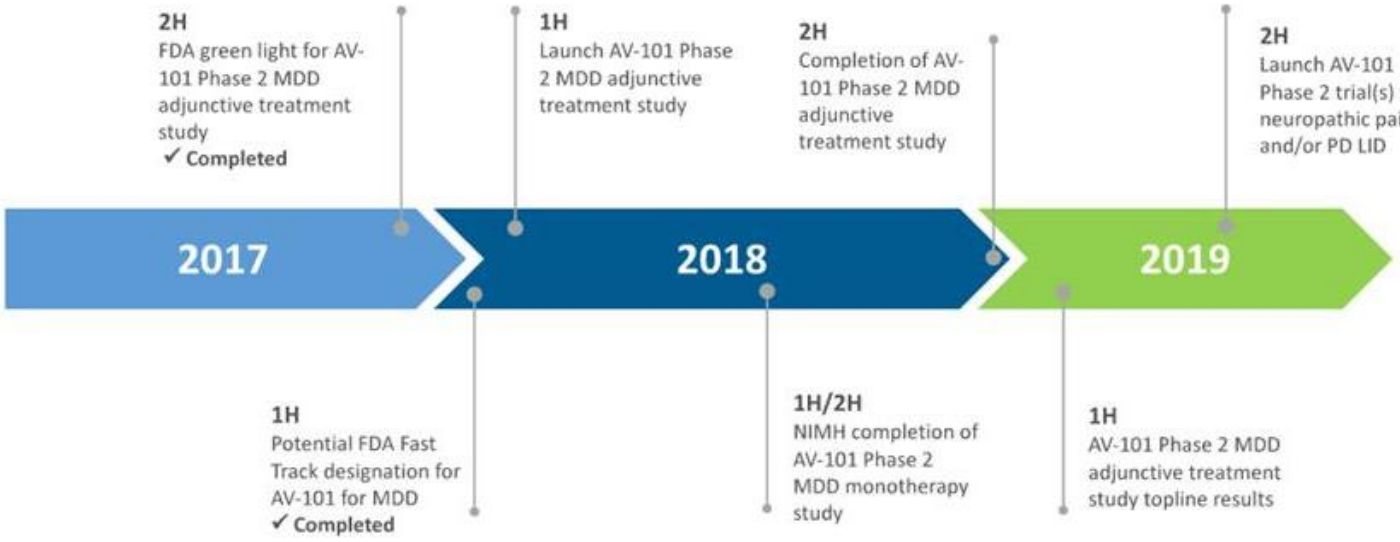
VistaGen® Therapeutics

AV-101 for Parkinson's disease levodopa-induced dyskinesia



Short Time Horizon to Potential Clinical Catalysts

VistaGen® Therapeutics



VistaGen Therapeutics

High-Value Peer/Pharma M&A Underscores Upside Potential

naurex INC
A NEUROPHARMACEUTICAL COMPANY

Rapastinel

- New generation antidepressant candidate
- Similar MOA to AV-101 (NMDAR/AMPA)
- Ketamine-like antidepressant effects, without ketamine's side effects
- **IV only**

Allergan

Acquired by Allergan after Phase 2

- **$571 million** in cash at closing
- **$1.0+ billion in** potential milestone payments

Preeminent CNS 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

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)

Sanjay Mathew, M.D.

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

Gerard Sanacora, Ph.D., M.D.

Professor of Psychiatry, Yale School of Medicine; Director, Yale Depression Research Program; Scientific Director, Yale-New Haven Hospital Interventional Psychiatry Service

Mark Wallace, M.D.

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

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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VistaGen Highlights

NASDAQ: VTGN

VistaGen® Therapeutics

Clinical-stage, focused on depression, pain and PD LID

AV-101, oral new generation antidepressant; oral non-opioid alternative for neuropathic pain

Phase 2 for MDD in 2018; planning Phase 2 for pain and PD LID in 2019

Potentially transformative catalysts in 2018 and 2019

Strong support from NIH

Experienced team

DEVELOPING NEW GENERATION MEDICINES FOR DEPRESSION AND OTHER CNS DISORDERS