
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): **September 14, 2018**

VistaGen Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

NEVADA
(State or other jurisdiction of incorporation)

001-37761
(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 5.07 Submission of Matters to a Vote of Security Holders.

On September 14, 2018, VistaGen Therapeutics, Inc. (the “Company”) held its 2018 Annual Meeting of Stockholders (the “Annual Meeting”). The matters voted upon at the Annual Meeting and the results of the voting are set forth below.

Proposal No. 1- Election of Directors

Director Nominees	For	Withheld
Jon S. Saxe	4,915,906	97,194
Shawn K. Singh	4,899,517	113,583
H. Ralph Snodgrass	4,885,209	127,891
Brian J. Underdown	4,876,074	137,026
Jerry B. Gin	4,852,173	160,927

The Company’s Directors are elected by the affirmative vote of a plurality of the votes cast. Accordingly, the Company’s stockholders elected each of the nominees named above to serve on the Company’s Board of Directors until the 2019 Annual Meeting of Stockholders, or until their successors are elected and qualified.

Proposal No. 2- Ratification of Appointment of Auditors

For	Against	Abstain
15,901,502	902,448	208,892

The vote required to approve this proposal was the affirmative vote of a majority of the votes cast on the proposal. Accordingly, stockholders ratified the appointment of OUM & Co, LLP as the Company’s registered independent public accounting firm for the fiscal year ending March 31, 2019.

For more information about the foregoing proposals, please review the Company’s definitive proxy statement, filed with the Securities and Exchange Commission on July 27, 2018.

Item 7.01 Regulation FD Disclosure.

On September 14, 2018, the Company utilized a new corporate presentation at the Annual Meeting (the “Corporate Presentation”). A copy of the Corporate Presentation is attached hereto as Exhibit 99.1.

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

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 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: September 18, 2018

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

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
99.1	Corporate Presentation, dated September 2018



DEVELOPING NEW GENERATION MEDICINES FOR DEPRESSION AND OTHER CNS DISORDERS

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www.vistagen.com

Overview

NASDAQ: VTGN



Focused on CNS diseases and disorders with high unmet need



AV-101, in Phase 2, with potential to be the first oral new generation NMDA receptor modulator for at home treatment of Major Depressive Disorder



PH94B, entering Phase 3, with potential to be the first acute (as-needed) treatment of Social Anxiety Disorder



VistaStem, with potential for regenerative medicine and drug rescue

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Pipeline



Product Candidate	Indication	Preclinical	Phase 1	Phase 2	Phase 3
AV-101	Major Depressive Disorder (Inadequate Response to SSRIs/SNRIs)	VTGN ELEVATE Study			
	Major Depressive Disorder (Treatment-resistant)	U.S. National Institute of Mental Health Study			
	Suicidal Ideation	Baylor/VA First-Step Study			
	Neuropathic Pain	VTGN Phase 2 IND authorized			
	Parkinson's Disease Levodopa-Induced Dyskinesia	VTGN Phase 2 IND in process			
	Epilepsy*				
	Huntington's Disease*				
PH94B	Social Anxiety Disorder (PRN treatment)				

*Next steps TBD

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AV-101

Major Depressive Disorder

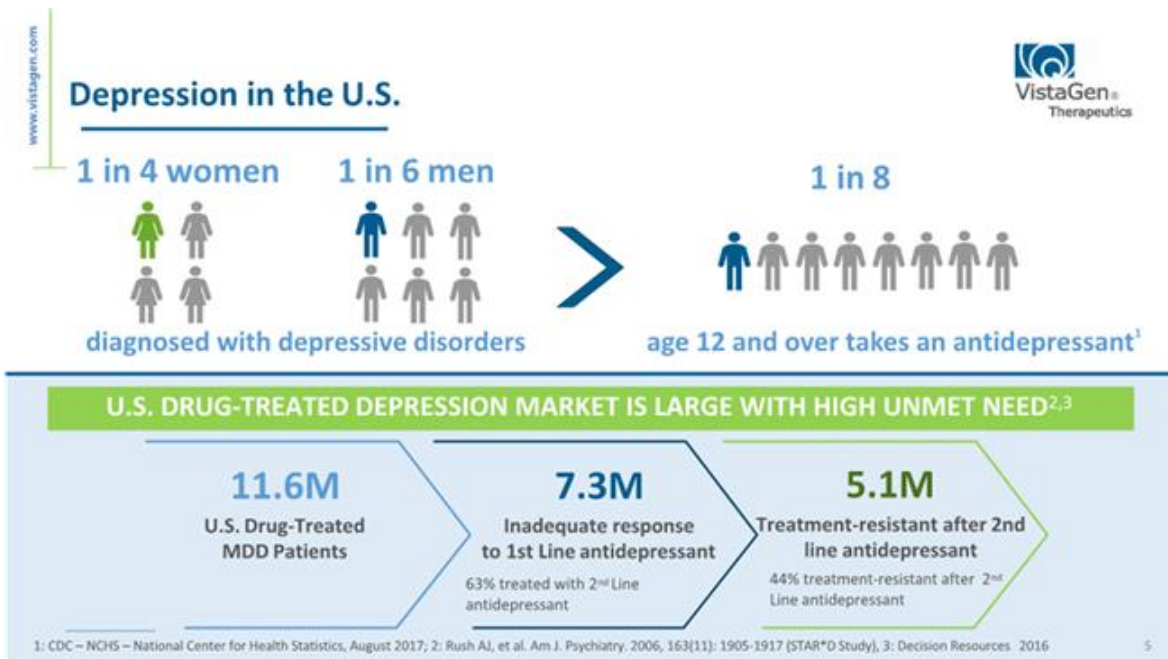
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Nasdaq: VTGN

DEVELOPING NEW GENERATION MEDICINES FOR DEPRESSION AND OTHER CNS DISORDERS

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Current Depression Drugs Fall Short for Millions of Patients

Current Antidepressants

PROZAC (fluoxetine hydrochloride), zoloft (sertraline HCl), Cymbalta* (duloxetine HCl)

Current Adjunctive Antipsychotics

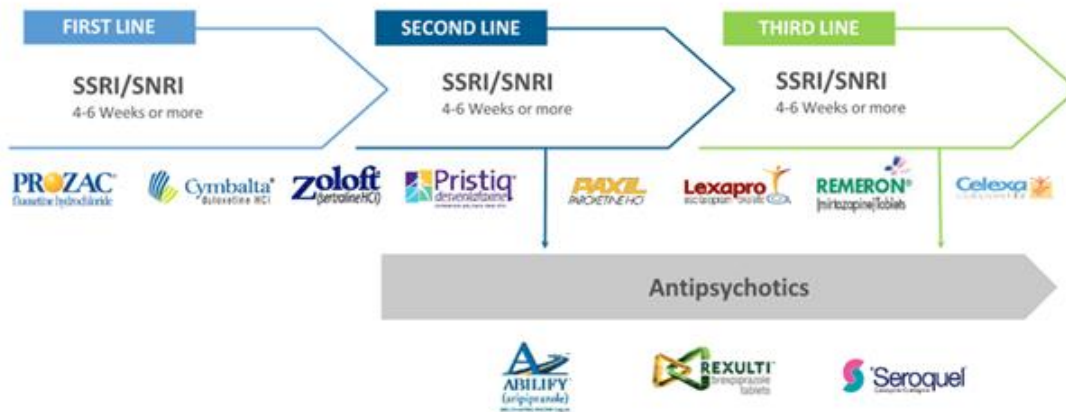
ABILIFY (aripiprazole), REXULTI (brexpiprazole tablets), Seroquel

- Often do not work
 - First antidepressant effective in only 1 of 3 patients
- Slow to work
 - May take 4 to 6 weeks for antidepressant effects
- Numerous side effects
 - Anxiety, sexual dysfunction, insomnia, fatigue

- Often do not work
 - Only 10 to 20% of patients respond
- Safety concerns
 - “Black Box” warnings
- Numerous side effects
 - Weight gain, akathisia, tardive dyskinesia

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Current Depression Drug Treatment Paradigm

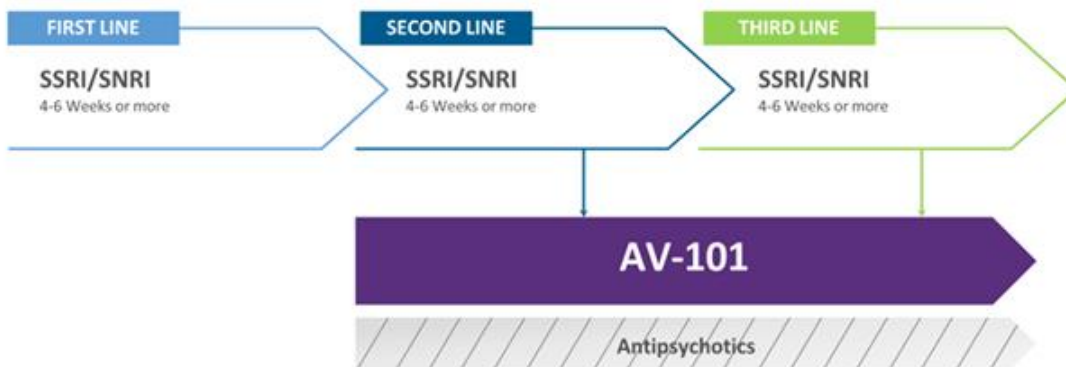


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First Goal for AV-101

REPLACE ANTIPSYCHOTICS IN THE DEPRESSION DRUG TREATMENT PARADIGM



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The Ketamine Story: Breakthrough Shift in Depression Treatment Paradigm



FUNDAMENTALLY DIFFERENT MOA

- FDA-approved anesthetic
- NMDAR antagonist
- Works on a different neurotransmitter than current drugs
- IV only (intra-nasal spray in Phase 3)
- Must be given in a medical setting

FASTER-ACTING THAN ALL CURRENT DRUGS

"[K]etamine, given intravenously, might be the most important breakthrough in antidepressant treatment in decades."

Thomas Insel

Former Director, U.S. National Institute of Mental Health¹

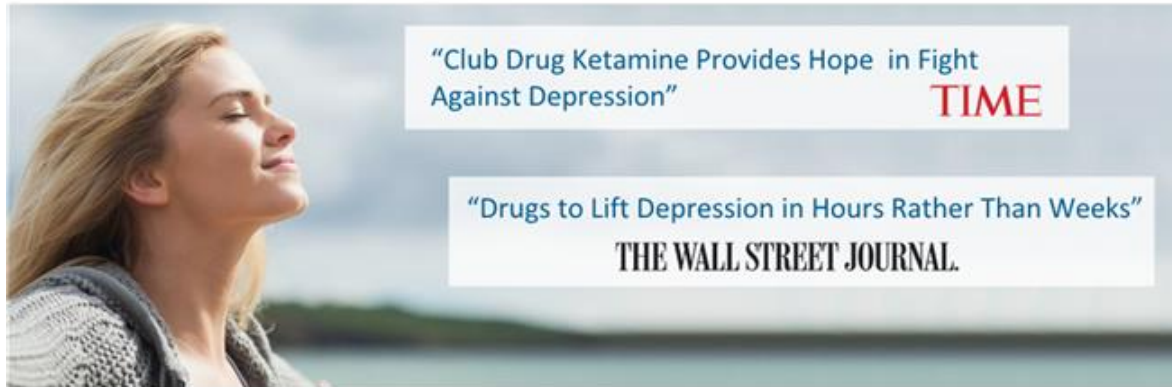
SIDE EFFECTS & SAFETY CONCERNS

- DEA Schedule III Drug
- Risk of Abuse
- Dissociation
- Hallucinations
- Confusion
- Dizziness
- Increased BP

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

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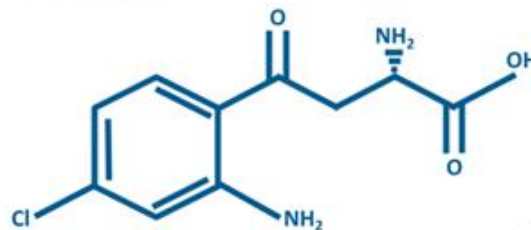
AV-101 A New Generation Antidepressant Candidate



- ✓ Oral NMDA receptor GlyB antagonist
- ✓ Ketamine-like antidepressant effects
- ✓ No ketamine-like side effects
- ✓ Different from all FDA-approved antidepressants



- Very well-tolerated in NIH-funded safety studies
- Three clinical studies currently underway
- Potential for transformative results in 2019



AV-101's Mechanism of Action

Classic NMDA Receptor Channel-Blocking Antagonists
Ketamine, PCP, Lanicemine



Ketamine blocks the ion channel of the NMDA receptor

AV-101's Active Metabolite (7-Cl-KYNA)
(full antagonist)



AV-101 does not block NMDA receptor activity, it inhibits it

AV-101 vs. Ketamine in Published Preclinical Studies



"Our results highlight the potential of 4-Cl-KYN as a next-generation, rapid-acting antidepressant medication, with a safer side-effect profile than ketamine¹."

Rapid-acting Antidepressant Effects

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

Negative Side 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

1. 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. ¹³

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NIMH Phase 2 Clinical Study AV-101 for Major Depressive Disorder



Principal Investigator: **Dr. Carlos Zarate, Jr., National Institute of Mental Health**

- NIH-funded
- Monotherapy for treatment-resistant depression
- Oral dose, once per day for 14 days
- Target enrollment = ca. 20 adults
- Completion anticipated 2H 2018; topline results anticipated 1H 2019

Primary Endpoint:

Safety and efficacy using standard Hamilton Rating Scale (HRS)

Secondary Endpoints:

Change from baseline in widely-accepted measures of mood, depression and cognition

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ELEVATE Phase 2 Clinical Study AV-101 for Major Depressive Disorder

Principal Investigator: **Dr. Maurizio Fava, Harvard Medical School**

- VistaGen-funded
- Adjunctive therapy for inadequate response to current antidepressants
- Oral dose, once per day for 14 days
- Target enrollment = ca. 180 patients
- Completion and topline results anticipated 1H 2019

Primary Endpoint:

50% Decrease on Montgomery-Asberg Depression Rating Scale (MADRS)

Secondary Endpoints:

Additional widely-accepted measures of mood, depression and cognition

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Additional Goals for AV-101 in Depression

1. Prevent relapse following ketamine therapy
2. Stand alone, first line oral therapy



NEXT STEPS



Phase 2 studies of AV-101 following ketamine therapy and as a stand alone, at-home first-line therapy

AV-101

Additional Opportunities

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Nasdaq: VTGN

DEVELOPING NEW GENERATION MEDICINES FOR DEPRESSION AND OTHER CNS DISORDERS

Baylor/VA Phase 1 Clinical Study

AV-101 for Suicidal Ideation



U.S. Department
of Veterans Affairs

Baylor
College of
Medicine

Principal Investigator: Dr. Marijn Lijffijt, Baylor College of Medicine

- First-step study to test anti-suicidal effects of AV-101 in healthy volunteer U.S. Military Veterans
- Completion anticipated end of 2H 2018; topline results anticipated 1H 2019
- Proposed next step is a Phase 2 study in U.S. Military Veterans in 2H 2019

Primary Objectives:

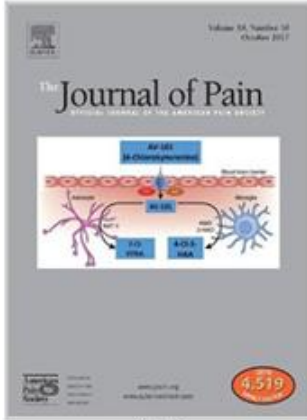
Define neurophysiological markers and further evaluate safety and tolerability

Secondary Objectives:

Assess clinical chemistry measurements and change in blood plasma concentration of QA and KA

AV-101 for Neuropathic Pain

New Oral, Non-opioid, Non-addictive, Non-sedating Treatment Option



Preclinical data, together with successful Phase 1 safety studies, support a Phase 2a clinical study to assess AV-101's potential as a new generation neuropathic pain treatment alternative to gabapentin and pregabalin.

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-Chlorokynuremine on Nociception in Rodents." The Journal of Pain 18: 1184-1196

AV-101 for Parkinson's Dyskinesia

New Option to Reduce Dyskinesia Associated with L-DOPA Therapy



Levodopa-induced dyskinesia occurs in 80% of patients with PD after 5-10 years



Preclinical data in monkey models, together with successful Phase 1 safety studies, support a Phase 2a clinical study to assess AV-101's potential as a new generation PD LID treatment alternative to amantadine

NEXT STEP

Phase 2 study of AV-101 vs placebo in Parkinson's patients

PH94B

Social Anxiety Disorder

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DEVELOPING NEW GENERATION MEDICINES FOR DEPRESSION AND OTHER CNS DISORDERS

Social Anxiety Disorder (SAD)

Social Phobia - more than just shyness

Social anxiety disorder (SAD) is an intense, irrational, and persistent fear of being scrutinized or negatively evaluated by other people

SAD has a considerable impact on patients' lives, with lost opportunities, increased depression, alcoholism etc.

Physical symptoms: sweating, racing heart, blushing, trembling, dizziness

12%

of U.S. population may experience SAD sometime in their lives

8%

of U.S. population suffer from SAD in a given year



SAD often starts in adolescence

SAD can be "situational" such as performing in front of an audience, or "generalized," a much more debilitating condition that can provoke anxiety in almost every situation

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Current Pharmacological Treatments for SAD

FDA-approved

- Antidepressants
 - SSRIs such as paroxetine and sertraline and SNRIs such as venlafaxine
 - ✗ Take weeks to months to work and may worsen anxiety initially
 - ✗ Many patients are reluctant to take long-term, daily SSRIs or SNRIs with significant side effects for a disorder that may be situational

Off-label

- Benzodiazepines such as alprazolam (Xanax)
 - ✗ Addiction
 - ✗ Tolerance
 - ✗ Sedation
 - ✗ Cognitive impairment
- Beta blockers such as propranolol
 - May relieve physical symptoms such as racing heart etc.

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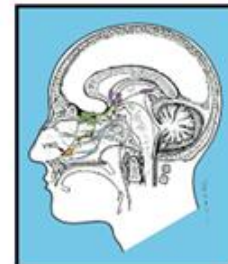
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PH94B

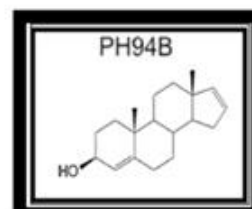
A Novel, Rapid-Acting, On-Demand Treatment for SAD



- ✓ Nasal spray
- ✓ As-needed (PRN) administration
- ✓ Works in minutes
- ✓ Non-sedating
- ✓ Non-addictive



- Very well-tolerated in Phase 1 and Phase 2 clinical studies
- No systemic exposure
- No toxicity
- Phase 3-ready



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VistaStem

Regenerative Medicine and Drug Rescue

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Nasdaq: VTGN

DEVELOPING NEW GENERATION MEDICINES FOR DEPRESSION AND OTHER CNS DISORDERS

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VistaStem Therapeutics

Stem cell technology for regenerative medicine and drug rescue



- Wholly-owned subsidiary
- Participant in FDA's Comprehensive *in vitro* Proarrhythmia Assay (CiPA) initiative focused on next generation, stem cell-based predictive cardiac toxicology screening for drug development and drug rescue
- Exclusive license of cardiac stem cell technology to BlueRock Therapeutics for development and commercialization of regenerative medicine and cellular therapies to treat heart disease
- Potential for additional regenerative medicine collaborations regarding blood, chondrocyte and liver cells

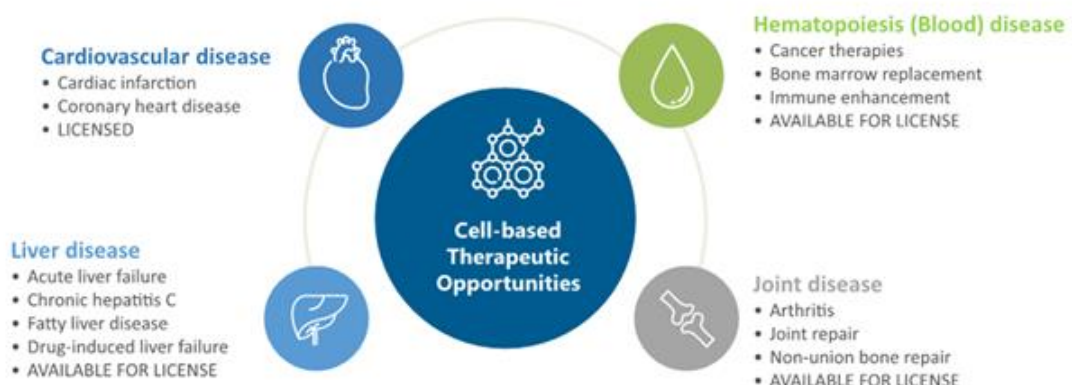


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Regenerative Medicine Opportunities



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VistaGen Summary

NASDAQ: VTGN



Clinical stage, focused on multiple CNS markets with high unmet need



AV-101 and PH94B have potential to drive paradigm shifts in treatment of depression, pain, suicidal ideation and social anxiety disorder



VistaStem, potential for novel regenerative medicine and drug rescue



Multiple clinical and corporate catalysts within 12 to 18 months

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DEVELOPING NEW GENERATION MEDICINES FOR DEPRESSION AND OTHER CNS DISORDERS

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