VistaGen Therapeutics, Inc.
Form 10-Q
February 12, 2019

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

Form 10-Q
(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended December 31, 2018
or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to .

Commission File Number: 001-37761

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

Nevada	20-5093315
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

343 Allerton Avenue
South San Francisco, CA 94080
(Address of principal executive offices including zip code)

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer	[ ]	Accelerated filer	[ ]
Non-Accelerated filer	[ ]	Smaller reporting company	[X]
		Emerging growth company	[ ]

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of February 11, 2019, 31,120,465 shares of the registrant’s common stock, $0.001 par value, were issued and outstanding.

VistaGen Therapeutics, Inc.
Quarterly Report on Form 10-Q
for the Quarter Ended December 31, 2018

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PART I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (Unaudited)

VISTAGEN THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(Amounts in Dollars, except share amounts)

	December 31, 2018 (Unaudited)	March 31, 2018 (Note 2)
ASSETS		
Current assets:		
Cash and cash equivalents	$6,285,300	$10,378,300
Prepaid expenses and other current assets	853,800	644,800
Total current assets	7,139,100	11,023,100
Property and equipment, net	334,900	207,400
Security deposits and other assets	47,800	47,800
Total assets	$7,521,800	$11,278,300
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$1,086,700	$1,195,700
Accrued expenses	827,100	206,300
Current notes payable	49,100	53,900
Capital lease obligations	2,900	2,600
Total current liabilities	1,965,800	1,458,500
Non-current liabilities:		
Accrued dividends on Series B Preferred Stock	3,456,300	2,608,300
Deferred rent liability	399,800	285,600
Capital lease obligations	7,100	9,300
Total non-current liabilities	3,863,200	2,903,200
Total liabilities	5,829,000	4,361,700

Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at December 31, 2018 and March 31, 2018:		
Series A Preferred, 500,000 shares authorized, issued and outstanding at December 31, 2018 and March 31, 2018	500	500
Series B Preferred; 4,000,000 shares authorized at December 31, 2018 and March 31, 2018; 1,160,240 shares issued and outstanding at December 31, 2018 and March 31, 2018	1,200	1,200
Series C Preferred; 3,000,000 shares authorized at December 31, 2018 and March 31, 2018; 2,318,012 shares issued and outstanding at December 31, 2018 and March 31, 2018	2,300	2,300
Common stock, $0.001 par value; 100,000,000 shares authorized at December 31, 2018 and March 31, 2018; 31,204,380 and 23,068,280 shares issued and outstanding at December 31, 2018 and March 31, 2018, respectively	31,200	23,100
Additional paid-in capital	181,035,800	167,401,400
Treasury stock, at cost, 135,665 shares of common stock held at December 31, 2018 and March 31, 2018	(3,968,100)	(3,968,100)
Accumulated deficit	(175,410,100)	(156,543,800)
Total stockholders' equity	1,692,800	6,916,600
Total liabilities and stockholders' equity	$7,521,800	$11,278,300

See accompanying notes to Condensed Consolidated Financial Statements.

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VISTAGEN THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)
(Amounts in dollars, except share amounts)

	Three Months Ended December 31,		Nine Months Ended December 31,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	$5,335,500	$1,601,800	$13,340,300	$5,124,600
General and administrative	1,856,800	1,266,000	5,494,100	4,997,400
Total operating expenses	7,192,300	2,867,800	18,834,400	10,122,000
Loss from operations	(7,192,300)	(2,867,800)	(18,834,400)	(10,122,000)
Other expenses, net:				
Interest expense, net	(1,800)	(2,000)	(6,800)	(7,700)
Loss on extinguishment of accounts payable	(22,700)	(135,000)	(22,700)	(135,000)
Loss before income taxes	(7,216,800)	(3,004,800)	(18,863,900)	(10,264,700)
Income taxes	-	-	(2,400)	(2,400)
Net loss and comprehensive loss	(7,216,800)	(3,004,800)	(18,866,300)	(10,267,100)
Accrued dividend on Series B Preferred stock	(290,900)	(263,000)	(848,000)	(766,600)
Deemed dividend from trigger of down round provision feature	-	(199,200)	-	(199,200)
Net loss attributable to common stockholders	$(7,507,700)	$(3,467,000)	$(19,714,300)	$(11,232,900)
Basic and diluted net loss attributable to common stockholders per common share	$(0.24)	$(0.25)	$(0.75)	$(1.03)
Weighted average shares used in computing basic and diluted net loss attributable to common stockholders per common share	30,696,312	13,895,642	26,418,440	10,947,556

See accompanying notes to Condensed Consolidated Financial Statements.

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VISTAGEN THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(Amounts in Dollars)

	Nine Months Ended December 31,	
	2018	2017
Cash flows from operating activities:		
Net loss	$(18,866,300)	$(10,267,100)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	64,800	65,300
Stock-based compensation	2,519,700	1,386,900
Expense related to modification of warrants	25,800	292,700
Fair value of common stock granted for services	277,600	1,554,800
Fair value of common stock issued for product licenses and option	4,250,000	-
Fair value of warrants granted for services	79,800	-
Loss on extinguishment of accounts payable	22,700	135,000
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	34,600	259,600
Accounts payable and accrued expenses	511,800	(41,800)
Deferred rent	109,200	159,900
Net cash used in operating activities	(10,970,300)	(6,454,700)
Cash flows from property and investing activities:		
Purchases of equipment	-	(1,600)
Construction of tenant improvements	(169,800)	-
Net cash used in investing activities	(169,800)	(1,600)
Cash flows from financing activities:		
Net proceeds from issuance of common stock and warrants, including Units	6,608,700	16,721,900
Proceeds from exercise of warrants	605,700	-
Repayment of capital lease obligations	(2,000)	(1,700)
Repayment of notes payable	(165,300)	(153,400)
Net cash provided by financing activities	7,047,100	16,566,800
Net (decrease) increase in cash and cash equivalents	(4,093,000)	10,110,500
Cash and cash equivalents at beginning of period	10,378,300	2,921,300
Cash and cash equivalents at end of period	$6,285,300	$13,031,800

Supplemental disclosure of noncash activities:		
Insurance premiums settled by issuing note payable	$160,500	$142,400
Accrued dividends on Series B Preferred	$848,000	$766,600
Deemed dividend from trigger of down round provision feature	$-	$199,200
Settlement of accounts payable by issuance of common stock	$40,000	$450,000

See accompanying notes to Condensed Consolidated Financial Statements.

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VISTAGEN THERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

Note 1. Description of Business

Overview

VistaGen Therapeutics. Inc., a Nevada corporation (which may be referred to as VistaGen, the Company, we, our, or us), is a clinical-stage biopharmaceutical company focused on developing new generation medicines for multiple central nervous system (CNS) diseases and disorders with high unmet need. We believe each of our CNS pipeline candidates, AV-101, PH10 and PH94B, has the potential to be administered at home and provide rapid-onset therapeutic benefits without psychological or other side effects and safety concerns associated with many current and potential new generation medications for CNS diseases and disorders, such as major depressive disorder (MDD) and social anxiety disorder (SAD), affecting millions of individuals in the United States and foreign markets. Each drug candidate in our pipeline is either currently in or has successfully completed Phase 2 clinical development. AV-101, our oral NMDA receptor glycine B antagonist, is in Phase 2 development, initially as an adjunctive treatment of MDD. The FDA has granted Fast Track designation for development of AV-101 as both a potential adjunctive treatment of MDD and as a non-opioid treatment for neuropathic pain. PH10, our potentially first-in-class, rapid-onset neuroactive steroid nasal spray for MDD, has completed an initial successful exploratory Phase 2 clinical study and is now being prepared for a multi-dose follow-on Phase 2 clinical study in MDD. PH94B, our potentially first-in-class, rapid-onset neuroactive steroid nasal spray for as-needed (PRN) treatment of SAD, has completed a successful Phase 2 clinical program, a successful pilot Phase 3 study and is now being prepared for pivotal Phase 3 clinical development, with potential to be the first FDA-approved PRN treatment of SAD.

AV-101

AV-101, an investigational prodrug candidate in Phase 2 clinical development, is an orally bioavailable NMDAR GlyB (N-methyl-D-aspartate receptor glycine B) antagonist in development as a potential new treatment for multiple CNS indications with high unmet need, including MDD, neuropathic pain (NP), levodopa-induced dyskinesia associated with Parkinson’s disease therapy (PD LID) and suicidal ideation (SI). In two NIH-funded AV-101 Phase 1 clinical safety studies, AV-101 was well tolerated in healthy subjects at all doses tested, in both single-ascending and multiple-ascending dose studies, without causing any observed psychological or sedative side effects. The United States Food and Drug Administration (FDA) has granted Fast Track designation for development of AV-101 as a potential new treatment for adjunctive treatment of MDD and for treatment of NP.

Major Depressive Disorder

Major depressive disorder is a serious biologically-based mood disorder, affecting approximately 16 million adults in the United States according to the U.S. National Institute of Mental Health (the NIMH). The CDC estimates that one in four women and one in six men in the United States have been diagnosed with MDD. 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. According to the U.S. Centers for Disease Control and Prevention (CDC), about one in eight Americans aged 12 and over takes an FDA-approved antidepressant, and there are an estimated 11.6 million drug-treated patients suffering from MDD. While current FDA-approved antidepressants are widely used, the STAR*D study, the largest clinical trial conducted in depression to date, found that approximately two-thirds of patients with MDD do not respond to their initial antidepressant treatment, of which approximately 5.1

million patients remain resistant to treatment following the second antidepressant treatment. According to the NIMH, inadequate response to current antidepressants is among the key reasons MDD is a leading public health concern in the United States, creating a significant unmet medical need for new agents with fundamentally different mechanisms of action.

We believe oral AV-101 has potential for multiple applications in global depression markets if successfully developed and approved. Given its excellent tolerability profile, we believe AV-101 has potential as a new generation monotherapy and as an adjunctive therapy to both (i) augment current antidepressants approved by the FDA for patients with MDD who have an inadequate response to standard antidepressants (SSRIs and SNRIs) and (ii) prevent relapse of MDD following successful intravenous or intranasal treatment with ketamine hydrochloride (ketamine), a member of a class of drugs that block NMDA receptor activity. Ketamine is an FDA-approved, rapid-acting general anesthetic currently administered only by intravenous or intramuscular injection. The off-label use of ketamine in treatment-resistant depression (TRD), defined as those patients who have failed at least two prior treatment attempts involving current antidepressants, has been studied in numerous clinical trials conducted by depression experts at Yale University and other academic institutions, as well as at the NIMH, including by Dr. Carlos Zarate, Jr., the NIMH's Chief of Experimental Therapeutics & Pathophysiology Branch and of the Section on Neurobiology and Treatment of Mood and Anxiety Disorders. In randomized, placebo-controlled, double blind clinical trials reported by Dr. Zarate and others at the NIMH, a single sub-anesthetic dose of ketamine (0.5 mg/kg over 40 minutes) produced robust and rapid (within twenty-four hours) antidepressant effects in MDD patients who had not responded to at least two prior treatment attempts involving standard antidepressants. These results were in sharp contrast to the very slow-onset activity of SSRIs and SNRIs, which usually require many weeks or more of chronic usage to achieve similar antidepressant effects. We believe AV-101 may have potential to deliver rapid-onset antidepressant effects similar to ketamine, but without causing psychological, sedative or other side effects and safety concerns associated with ketamine, and as an oral therapy conveniently administered at home rather than in a medical setting or involving the required the use of needles.

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AV-101 is currently in Phase 2 clinical development in the United States for MDD. ELEVATE is our ongoing Phase 2 multi-center, multi-dose, double blind, placebo-controlled clinical study to evaluate the efficacy and safety of AV-101 as a new generation adjunctive treatment of MDD in adult patients with an inadequate therapeutic response to current FDA-approved antidepressants (the ELEVATE Study). Dr. Maurizio Fava, Professor of Psychiatry at Harvard Medical School and Director, Division of Clinical Research, Massachusetts General Hospital (MGH) Research Institute, is the Principal Investigator of the ELEVATE Study assisting our internal team, which is led by Mark Smith, MD, PhD, our Chief Medical Officer. Dr. Fava was the co-Principal Investigator with Dr. A. John Rush of the STAR*D study, the findings of which were published in journals such as the New England Journal of Medicine (NEJM) and the Journal of the American Medical Association (JAMA).

AV-101 is also the subject of a small randomized, double-blind, placebo-controlled cross-over Phase 2 clinical study being conducted and funded by the NIMH, pursuant to our Cooperative Research and Development Agreement (CRADA) with the NIMH (the NIMH Study). Dr. Carlos Zarate, Jr., Chief of the NIMH's Experimental Therapeutics & Pathophysiology Branch and its Section on Neurobiology and Treatment of Mood and Anxiety Disorders, is acting as the Principal Investigator for the NIMH Study. This trial is focused on the pharmacodynamic and potential therapeutic effects in such patients using standard measurements of clinical responses and measurement of responses of a number of biomarkers associated with engagement of the NMDA receptor thought to be associated with clinical response. Dr. Zarate and the NIMH were among the first in the U.S. to conduct clinical studies in MDD patients with inadequate responses to multiple current FDA-approved antidepressants that demonstrated the robust, fast-acting antidepressant effects of ketamine within twenty-four hours of a single sub-anesthetic dose administered by IV injection.

The FDA has granted Fast Track designation for development of AV-101 as a potential new adjunctive treatment of MDD.

Suicidal Ideation

According to the World Health Organization (WHO), every year approximately 800,000 people worldwide take their own life and many more attempt suicide. The CDC views suicide as a major public health concern in the United States, as rates of suicide have been increasing for both men and women and across all age groups. Suicide is the 10th leading cause of death in the U.S. and is one of just three leading causes that are on the rise. According to experts in the field of suicidal ideation (SI), characterized as suicidal thoughts and behavior, the number of Americans who die by suicide is, since 2010, higher than those who die in motor vehicle accidents. People of all genders, ages, and ethnicities can be at risk for suicide. Suicidal ideation is complex and there is no single cause. The NIMH attributes many different factors contribute to someone making a suicide attempt, including, but not limited to, depression, other mental health disorders or substance abuse disorder. Additionally, according to reports released by the United States Department of Veterans Affairs (VA), the U.S. Military Veteran population is at significantly higher risk for suicide than the general population.

We are collaborating with Baylor College of Medicine (Baylor) and the VA on a small Phase 1b clinical trial of AV-101 involving healthy volunteer U.S. Military Veterans from either Operation Enduring Freedom, Operation Iraqi Freedom or Operation New Dawn (the Baylor Study). The Baylor Study is a randomized, double-blind, placebo-controlled cross-over study designed as a target engagement study as the first-step in our plans to test potential anti-suicidal effects of AV-101 in U.S. Military Veterans. Dr. Marijn Lijffijt of Baylor is the Principal Investigator of the Baylor Study. VistaGen and the VA entered into a Material Transfer Cooperative Research and Development Agreement (MT CRADA) regarding clinical trial material for the Baylor Study. Government funding from the VA is being provided for substantially all other study costs.

Neuropathic Pain

Neuropathic pain (NP), a complex, chronic pain state affecting millions of Americans, results from problems with signals from nerves. The American Chronic Pain Association has identified various causes of NP, including tissue injury, nerve damage or disease, diabetes, infection, toxins, certain types of drugs, such as antivirals and chemotherapeutic agents, certain cancers, and even chronic alcohol intake. With NP, damaged, dysfunctional or injured nerve fibers send incorrect signals to other pain centers and impact nerve function both at the site of injury and areas around the injury. Unfortunately, many NP treatments on the market today have side effects, including anxiety, depression, dizziness, cognitive impairment and/or sedation.

The effects of AV-101 as a potential new treatment for NP were assessed in published peer-reviewed preclinical studies involving four well-established models of pain. In these studies, AV-101 was observed to have robust, dose-dependent anti-nociceptive effects, as measured by dose-dependent reversal of NP in the Chung (nerve ligation), formalin and carrageenan thermal models in rats, and was well-tolerated. The publication, titled: “Characterization of the effects of L-4-chlorokynurenine on nociception in rodents,” by lead author, Tony L. Yaksh, Ph.D., Professor in Anesthesiology at the University of California, San Diego, was published in The Journal of Pain in April 2017 (J Pain. 18:1184-1196, 2017)). Gabapentin, an FDA-approved anticonvulsant, has been associated with sedation and mild cognitive impairment in third party literature. Other commonly prescribed medications for NP include drugs targeting opioid receptors in the brain. Unfortunately, misuse of such drugs can lead to a significantly increased risk of addiction, and, we believe, their therapeutic utility for neuropathic pain is unclear. We are planning to advance AV-101 into an exploratory Phase 2a clinical study, subject to securing sufficient capital, to assess its potential as a new oral non-opioid treatment to reduce debilitating NP, as well as its potential to avoid sedative side effects and cognitive impairment that have been observed in third party literature to be associated with other NP treatments, and to reduce the risk of addiction associated with pain medications targeting opioid receptors.

The FDA has granted Fast Track designation for development of AV-101 as a potential new, non-opioid treatment of NP.

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Parkinson’s Disease Levodopa-Induced Dyskinesia

Parkinson's disease (PD) is a chronic, progressive motor disorder that causes tremors, rigidity, slowed movements and postural instability. The most commonly-prescribed treatments for PD are levodopa-based therapies. Unfortunately, abnormal involuntary movements, called dyskinesias, gradually emerge as a prominent side-effect in response to previously beneficial doses of levodopa. Parkinson’s disease levodopa-induced dyskinesia (PD LID) can be severely disabling, rendering patients unable to perform routine daily tasks.

In a preclinical monkey model of PD, AV-101 resulted in a 30% reduction of the mean dyskinesia score associated with PD LID. Importantly, AV-101 did not reduce the anti-parkinsonian therapeutic benefit of levodopa. Moreover, the duration of levodopa response and delay to levodopa effect were not affected by treatment with AV-101. We believe AV-101 has potential to reduce troublesome dyskinesia experienced by many patients with PD as a result of their levodopa therapy, but without interfering with levodopa or causing side effects resulting from certain current PD LID treatments, such as amantadine, including hallucinations, dizziness, dry mouth, swelling of legs and feet, constipation and falls. We are planning to advance clinical development of AV-101 for PD LID in an exploratory Phase 2 clinical study, subject to securing sufficient capital, as our next initiative in PD LID.

PH94B

In September 2018, we acquired, on a non-cash basis through the issuance of unregistered shares of our common stock, a license from Pherin Pharmaceuticals, Inc. (Pherin) giving us the exclusive worldwide rights to develop and commercialize PH94B, a rapid-onset neurosteroid nasal spray with potential to be the first FDA-approved PRN treatment for SAD.

PH94B is a synthetic investigational neuroactive steroid for which Phase 2 clinical data showed that the product was well tolerated and demonstrated a rapid onset of effect, as measured by the Subjective Units of Distress (SUD) and the Liebowitz Social Anxiety Scale (LSAS) in SAD, a social phobia that affects as many as 22 million American adults according to the NIMH. SAD is characterized by an intense and persistent fear of embarrassment, humiliation, judgment and rejection in everyday social or performance situations, leading to avoidance of anxiety and fear-producing social situations when possible. SAD has a significant impact on the individual’s employment, social activities and overall quality of life. According to the NIMH, an estimated 7% of the U.S. population suffers from SAD. SAD is commonly treated chronically with antidepressants, which have slow onset of effect (several weeks or months) and known side effects that may make them unattractive to individuals intermittently or episodically affected by SAD.

Administered as a nasal spray, PH94B is designed to act locally on peripheral nasal chemosensory receptors to trigger rapid activation of the limbic system areas of the brain associated with SAD. In prior clinical studies, PH94B demonstrated rapid (10-15 minutes) anxiety reduction for subjects with SAD, measured by the SUD and LSAS, and was not observed to be addictive, sedative or have other adverse events. Benzodiazepines and beta blockers, which are currently prescribed off-label to treat SAD, have been found in third party literature to have these addictive or sedative properties, and have other adverse effects when used to treat SAD.

Based on clinical studies in which PH94B was observed to have rapid-onset of effect on anxiety reduction, as measured by the SUD and LSAS, and to be well-tolerated, and in light of its novel route of administration and on-demand dosing design, we believe PH94B has potential to be the first FDA-approved medication for long-term PRN treatment of individuals with SAD.

PH10

In October 2018, we acquired, on a non-cash basis through the issuance of unregistered shares of our common stock, a second license from Pherin giving us the exclusive worldwide rights to develop and commercialize PH10, a synthetic investigational neuroactive steroid nasal spray for which exploratory Phase 2 clinical data showed that it was well tolerated and demonstrated a rapid onset of antidepressant effects. PH10 is designed to bind locally on nasal chemosensory receptors and trigger responses in the hypothalamus, amygdala, prefrontal cortex and hippocampus affecting depression. It is believed that PH10 may initiate nerve impulses that follow defined pathways to directly affect brain function. In a small exploratory Phase 2a study in patients with MDD, PH10 showed a rapid-onset antidepressant effect, as measured by the Hamilton Depression Rating Scale (HAM-D), without psychological side effects or safety concerns. PH10 is a new generation antidepressant with a mechanism of action that is fundamentally different from all current antidepressants. As with AV-101, we believe PH10 intranasal has potential for multiple applications in global depression markets, as a stand-alone first line therapy and as an adjunctive therapy, if successfully developed and approved. In addition to its potential as a first-line monotherapy administered conveniently at-home, we believe PH10 has potential as an adjunctive therapy to (i) augment current antidepressants approved by the FDA for patients with MDD who have an inadequate response to standard antidepressants (SSRIs and SNRIs), and (ii) prevent relapse of MDD following successful treatment with ketamine, either intravenously- or intranasally-administered ketamine.

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VistaStem

In addition to our CNS business, we have two additional programs through our wholly-owned subsidiary VistaGen Therapeutics, Inc., a California corporation, dba VistaStem Therapeutics (VistaStem). VistaStem is focused on applying stem cell technology to rescue, develop and commercialize (i) proprietary new chemical entities (NCEs) for CNS and other diseases, and (ii) regenerative medicine (RM) involving stem cell-derived blood, cartilage, heart and liver cells. Our internal drug rescue programs are designed to utilize CardioSafe 3D, our customized cardiac bioassay system, to develop small molecule NCEs for our CNS pipeline or out-licensing. We have exclusively sublicensed to BlueRock Therapeutics LP, a next generation cell therapy and RM company established by Bayer and Versant Ventures (BlueRock Therapeutics), rights to certain proprietary technologies relating to the production of cardiac stem cells for the treatment of heart disease (the BlueRock Agreement). In a manner similar to the BlueRock Agreement, we may pursue additional VistaStem collaborations or licensing transactions involving stem cell-derived blood, cartilage, and/or liver cells RM applications.

Subsidiaries

VistaStem is our wholly-owned subsidiary. Our Condensed Consolidated Financial Statements in this Quarterly Report on Form 10-Q (Report) also include the accounts of VistaStem's two wholly-owned inactive subsidiaries, Artemis Neuroscience, Inc., a Maryland corporation, and VistaStem Canada, Inc., a corporation organized under the laws of Ontario, Canada.

Note 2. Basis of Presentation

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP) for interim financial information and with the instructions to Form 10-Q and Rule 8-03 of Regulation S-X. Accordingly, they do not contain all of the information and footnotes required for complete consolidated financial statements. In the opinion of management, the accompanying unaudited Condensed Consolidated Financial Statements reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly our interim financial information. The accompanying Condensed Consolidated Balance Sheet at March 31, 2018 has been derived from our audited consolidated financial statements at that date but does not include all disclosures required by U.S. GAAP. The operating results for the three and nine months ended December 31, 2018 are not necessarily indicative of the operating results to be expected for our fiscal year ending March 31, 2019, or for any other future interim or other period.

The accompanying unaudited Condensed Consolidated Financial Statements and notes to Condensed Consolidated Financial Statements contained in this Report should be read in conjunction with our audited Consolidated Financial Statements for our fiscal year ended March 31, 2018 contained in our Annual Report on Form 10-K, as filed with the Securities and Exchange Commission (SEC) on June 26, 2018.

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared assuming we will continue as a going concern. As a clinical-stage biopharmaceutical company having not yet developed commercial products or achieved sustainable revenues, we have experienced recurring losses and negative cash flows from operations resulting in a deficit of approximately $175.4 million accumulated from inception (May 1998) through December 31, 2018. We expect losses and negative cash flows from operations to continue for the foreseeable future as we engage in further development of AV-101, PH94B and PH10, execute our drug rescue programs and pursue potential drug development and regenerative medicine opportunities.

Since our inception in May 1998 through December 31, 2018, we have financed our operations and technology acquisitions primarily through the issuance and sale of our equity and debt securities for cash proceeds of approximately $68.6 million, as well as from an aggregate of approximately $17.6 million of government research grant awards (excluding the fair market value of the NIMH Study and the Baylor Study), strategic collaboration payments, intellectual property sublicensing and other revenues. Additionally, we have issued equity securities with an approximate value at issuance of $38.1 million in non-cash acquisitions of product licenses and in settlements of certain liabilities, including liabilities for professional services rendered to us or as compensation for such services.

At December 31, 2018, we had cash and cash equivalents of approximately $6.3 million.

Our cash position at December 31, 2018 considered with our recurring and anticipated losses, negative cash flows from operations and limited stockholders' equity make it probable, in the absence of additional financing, that we will not have sufficient resources to fund our planned operations for the twelve months following the issuance of these financial statements, during which time we plan to complete our ELEVATE study, prepare for pivotal Phase 3 development of PH94B, conduct additional clinical and preclinical studies involving AV-101 and prepare for a Phase 2 clinical trial of PH10, and raises substantial doubt that we can continue as a going concern. Nevertheless, when necessary and advantageous, we plan to raise additional capital, primarily through the sale of our equity securities in one or more private placements to accredited investors or in public offerings. Subject to certain restrictions, our effective Registration Statement on Form S-3 (Registration No. 333-215671) (the S-3 Registration Statement) remains available for future sales of our equity securities in one or more public offerings from time to time. While we may make additional sales of our equity securities under the S-3 Registration Statement, we do not have an obligation to do so. As in the past, we expect that, when and as necessary, we will be successful in raising additional capital from the sale of our equity securities either in one or more public offerings or in one or more private placement transactions with individual accredited investors or institutions.

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In addition to the potential sale of our equity securities, we may also seek to enter into research, development and/or commercialization collaborations that could generate revenue or provide funding, including non-dilutive funding, for development of AV-101, PH94B, PH10 and/or additional product candidates. We may also seek additional government grant awards or agreements similar, for example, to our current CRADA with the NIMH, which provides for the NIMH to fully fund the NIMH Study, or similar to our relationships with Baylor and the VA in connection with the Baylor Study. Such strategic collaborations may provide non-dilutive resources to advance our strategic initiatives while reducing a portion of our future cash outlays and working capital requirements. We may also pursue intellectual property arrangements similar to the BlueRock Agreement with other parties. Although we may seek additional collaborations that could generate revenue and/or non-dilutive funding for development of AV-101, PH94B, PH10 or other product candidates, as well as new government grant awards and/or agreements similar to our CRADA with NIMH, no assurance can be provided that any such collaborations, awards or agreements will occur in the future.

Our future working capital requirements will depend on many factors, including, without limitation, the timing, scope and nature of opportunities related to our success and the success of certain other companies in clinical trials, including our development and commercialization of our current product candidates and various potential drug rescue applications of our stem cell technology platform, the availability of, and our ability to obtain, government grant awards and agreements, and our ability to enter into collaborations on terms acceptable to us. To further advance the clinical development of AV-101, PH10 and PH94B, and, to a lesser extent, drug rescue applications of our stem cell technology platform, as well as support our operating activities, we plan to continue to carefully manage our routine operating costs, including our employee headcount and related expenses, as well as costs relating to regulatory consulting, contract research and development, investor relations and corporate development, legal, acquisition and protection of intellectual property, public company compliance and other professional services and operating costs.

Notwithstanding the foregoing, there can be no assurance that future financings or government or other strategic collaborations will be available to us in sufficient amounts, in a timely manner, or on terms acceptable to us, if at all. If we are unable to obtain substantial additional financing on a timely basis when needed in 2019 and beyond, our business, financial condition, and results of operations may be harmed, the price of our stock may decline, we may be required to reduce, defer, or discontinue certain of our research and development activities and we may not be able to continue as a going concern. As noted above, these Condensed Consolidated Financial Statements do not include any adjustments that might result from the negative outcome of this uncertainty.

Note 3. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates include those relating to share-based compensation, and assumptions that have been used historically to value warrants and warrant modifications. With the exception of the BlueRock Agreement pursuant to which we recorded sublicense revenue in the third quarter of our fiscal year ended March 31, 2017, we do not currently have, nor have we had during the periods covered by this Report, any arrangements requiring the recognition of revenue.

Research and Development Expenses

Research and development expenses are composed of both internal and external costs. Internal costs include salaries and employment-related expenses, including stock-based compensation expense, of scientific personnel and direct project costs. External research and development expenses consist primarily of costs associated with clinical and non-clinical development of AV-101, PH94B, PH10, and stem cell research and development costs, and costs related to the application and prosecution of patents related to those product candidates and, to a lesser extent, our stem cell technology platform. All such costs are charged to expense as incurred. We also record accruals for estimated ongoing clinical trial costs. Clinical trial costs represent costs incurred by contract research organizations (CROs) and clinical trial sites. Progress payments are generally made to CROs, clinical sites, investigators and other professional service providers. We analyze the progress of the clinical trial, including levels of subject enrollment, invoices received and contracted costs when evaluating the adequacy of accrued liabilities. Significant judgments and estimates must be made and used in determining the clinical trial accrual in any reporting period. Actual results could differ from those estimates under different assumptions. Revisions are charged to research and development expense in the period in which the facts that give rise to the revision become known. Costs incurred in obtaining product or technology licenses are charged immediately to research and development expense if the product or technology licensed has not achieved regulatory approval or reached technical feasibility and has no alternative future uses. In September 2018, we acquired an exclusive license to develop and commercialize PH94B and an option to acquire a license to develop and commercialize PH10 by issuing an aggregate of 1,630,435 unregistered shares of our Common Stock having a fair market value of $2,250,000. In October 2018, we exercised our option to acquire an exclusive license to develop and commercialize PH10 by issuing 925,926 shares of our unregistered Common Stock having a fair market value of $2,000,000. Since, at the date of each acquisition, neither product candidate has achieved regulatory approval and each will require significant additional development and expense, we have expensed the costs related to acquiring the licenses and the option.

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Stock-Based Compensation

We recognize compensation cost for all stock-based awards to employees and non-employee consultants based on the grant date fair value of the award. We record non-cash, stock-based compensation expense over the period during which the employee is required to perform services in exchange for the award, which generally represents the scheduled vesting period. We have not granted restricted stock awards to employees nor do we have any awards with market or performance conditions. For option grants to non-employees, we re-measure the fair value of the awards as they vest and the resulting value is recognized as an expense during the period over which the services are performed. Non-cash expense attributable to compensatory grants of stock to non-employees is determined by the quoted market price of the stock on the date of grant and is either recognized as fully-earned at the time of the grant or expensed ratably over the term of the related service agreement, depending on the terms of the specific agreement.

The table below summarizes stock-based compensation expense included in the accompanying Condensed Consolidated Statements of Operations and Comprehensive Loss for the three and nine months ended December 31, 2018 and 2017.

	Three Months Ended December 31,		Nine Months Ended December 31,	
	2018	2017	2018	2017
Research and development expense:				
Stock option grants	$274,900	$299,100	$955,600	$627,400
General and administrative expense:				
Stock option grants	459,800	390,200	1,564,100	759,500
Total stock-based compensation expense	$734,700	$689,300	$2,519,700	$1,386,900

In August 2018, our Board approved the grant of options from our 2016 Amended and Restated Stock Incentive Plan (the 2016 Plan) to purchase an aggregate of 860,000 shares of our Common Stock at an exercise price of $1.27 per share to the independent members of our Board, our officers and our employees. We valued the options granted in August 2018 using the Black-Scholes Option Pricing Model and the following weighted average assumptions:

Assumption:	August 2018
Market price per share at grant date	$1.27
Exercise price per share	$1.27
Risk-free interest rate	2.84%
Expected term in years	5.50
Volatility	99.29%

Dividend rate	0.0%
Shares	860,000
Fair Value per share	$0.98

In August 2018, our Board also approved the modification of outstanding options having exercise prices over $1.56 per share and held by independent members of our Board, our officers and our employees to reduce the exercise prices thereof to $1.50 per share. We calculated the fair value of the options immediately before and after the modification using the Black-Scholes Option Pricing Model and the weighted average assumptions indicated in the table below. We immediately recognized the additional fair value attributable to vested options, $258,100, as stock compensation expense, which is included in the figures reported above. The additional fair value resulting from the modification is being expensed over the remaining vesting period of the modified options.

Assumption:	Pre-modification	Post-modification
Market price per share	$1.49	$1.49
Exercise price per share	$3.57	$1.50
Risk-free interest rate	2.77%	2.77%
Remaining expected term in years	5.08	5.08
Volatility	94.9%	94.9%
Dividend rate	0.0%	0.0%
Number of option shares	2,419,503	2,419,503
Weighted average fair value per share	$0.91	$1.08

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During October 2018, we granted to certain professional service providers and consultants options to purchase an aggregate of 250,000 shares of our common stock at exercise prices ranging from $1.52 per share to $2.20 per share, reflecting the quoted closing price of our common stock on the Nasdaq Capital Market on the date of the grant. We valued the options granted in October 2018 using the Black-Scholes Option Pricing Model and the following weighted average assumptions:

Assumption:	October 2018
Market price per share at grant date	$1.83
Exercise price per share	$1.83
Risk-free interest rate	3.13%
Expected term in years	10.00
Volatility	89.98%
Dividend rate	0.0%
Shares	250,000
Fair Value per share	$1.59

At December 31, 2018, there were stock options outstanding to purchase 6,410,338 shares of our common stock at a weighted average exercise price of $1.47 per share.

See Note 10, Subsequent Events, for information regarding option grants and exercises occurring since December 31, 2018.

Comprehensive Loss

We have no components of other comprehensive loss other than net loss, and accordingly our comprehensive loss is equivalent to our net loss for the periods presented.

Loss per Common Share

Basic net loss attributable to common stockholders per share of common stock excludes the effect of dilution and is computed by dividing net loss increased by the accrual of dividends on outstanding shares of our Series B 10% Convertible Preferred Stock (Series B Preferred), by the weighted-average number of shares of common stock outstanding for the period. Diluted net loss attributable to common stockholders per share of common stock reflects the potential dilution that could occur if securities or other contracts to issue shares of common stock were exercised or converted into shares of common stock. In calculating diluted net loss attributable to common stockholders per share, we have generally not increased the denominator to include the number of potentially dilutive common shares assumed to be outstanding during the period using the treasury stock method because the result is antidilutive.

As a result of our net loss for all periods presented, potentially dilutive securities were excluded from the computation of diluted net loss per share, as their effect would be antidilutive. Potentially dilutive securities excluded in determining diluted net loss attributable to common stockholders per common share are as follows:

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	As of December 31,	
	2018	2017
Series A Preferred stock issued and outstanding (1)	750,000	750,000
Series B Preferred stock issued and outstanding (2)		