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)	1,160,240	1,160,240
Series C Preferred stock issued and outstanding (3)	2,318,012	2,318,012
Outstanding options under the Amended and Restated 2016 (formerly 2008) and 1999 Stock Incentive Plans (1999 Plan in 2017 only)	6,410,338	3,279,871
Outstanding warrants to purchase common stock	21,499,955	16,918,292
Total	32,138,545	24,426,415

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(1) Assumes exchange under the terms of the October 11, 2012 Note Exchange and Purchase Agreement, as amended.

(2) Assumes exchange under the terms of the Certificate of Designation of the Relative Rights and Preferences of the Series B 10% Convertible Preferred Stock, effective May 5, 2015.

(3) Assumes exchange under the terms of the Certificate of Designation of the Relative Rights and Preferences of the Series C Convertible

Preferred Stock,
effective January
25, 2016.

Fair Value Measurements

We do not use derivative instruments for hedging of market risks or for trading or speculative purposes. We carried no assets or liabilities that are measured on a recurring basis at fair value at December 31, 2018 or March 31, 2018.

Recent Accounting Pronouncements

Except as described below, there have been no recent accounting pronouncements or changes in accounting pronouncements during the nine months ended December 31, 2018, as compared to the recent accounting pronouncements described in our Form 10-K for our fiscal year ended March 31, 2018, that are of significance or potential significance to us.

In June 2018, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2018-07, Compensation-Stock Compensation (Topic 718), Improvements to Nonemployee Share-Based Payment Accounting (ASU 2018-07). ASU 2018-07 expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. Under ASU 2018-07, consistent with the accounting requirement for employee share-based payment awards, nonemployee share-based payment awards within the scope of Topic 718 are to be measured at the grant-date fair value of the equity instruments that an entity is obligated to issue when the good has been delivered or the service has been rendered and any other conditions necessary to earn the right to benefit from the instruments have been satisfied. Equity-classified nonemployee share-based payment awards are to be measured at the grant date. The definition of the term grant date is amended to generally state the date at which a grantor and a grantee reach a mutual understanding of the key terms and conditions of a share-based payment award. ASU 2018-07 specifies that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in its own operations by issuing share-based payment awards. ASU 2018-07 also clarifies that Topic 718 does not apply to share-based payments used to effectively provide (1) financing to the issuer or (2) awards granted in conjunction with selling goods or services to customers as part of a contract accounted for under Topic 606, Revenue from Contracts with Customers (Topic 606). ASU 2018-07 is effective for public companies for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted, but no earlier than an entity’s adoption date of Topic 606. We expect to adopt ASU 2018-07 as of April 1, 2019, and we are evaluating the expected impact of this new guidance on our consolidated financial statements. While we are still determining the value of our headquarters facility lease, we anticipate recording a right-of-use asset that will be amortized on a straight-line basis. We are evaluating our contracts with clinical research organizations, but do not believe such contracts contain embedded leases.

In February 2016, the FASB issued ASU 2016-02, Leases (ASC 842), which will replace the existing guidance in ASC 840, Leases, and which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e. lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less will be accounted for similar to the current guidance for operating leases. This standard will become effective for our fiscal year beginning April 1, 2019, with early adoption permitted. We expect to adopt the standard as of April 1, 2019, and are continuing to evaluate the expected impact of this new guidance on our consolidated financial statements.

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Note 4. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets are composed of the following at December 31, 2018 and March 31, 2018:

	December 31, 2018	March 31, 2018
AV-101 materials and services	$456,200	$505,900
Professional services	166,500	-
Insurance	89,900	88,300
Public offering filing fees and expenses	88,400	25,900
All other	52,800	24,700
	$853,800	$644,800

The increase in prepaid professional services is primarily attributable to the unexpensed portion of the fair value of securities we have issued to certain professional service providers as full or partial compensation for services. The fair value of the securities issued is being expensed ratably over the term of the related service agreement.

Note 5. Property and Equipment

Property and equipment is composed of the following at December 31, 2018 and March 31, 2018:

	December 31, 2018	March 31, 2018
Laboratory equipment	$888,300	$888,300
Tenant improvements	214,400	26,900
Computers and network equipment	54,600	54,600
Office furniture and equipment	84,500	79,700
	1,241,800	1,049,500
Accumulated depreciation and amortization	(906,900)	(842,100)
Property and equipment, net	$334,900	$207,400

The increase in tenant improvements reflects recently completed construction at our South San Francisco, California offices. Under the terms of our November 2016 lease extension agreement, our landlord has provided a cash

reimbursement of $158,600 of such tenant improvement costs. Such reimbursement is a component of the deferred rent liability shown on our Condensed Consolidated Balance Sheet at December 31, 2018.

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Note 6. Accrued Expenses

Accrued expenses are composed of the following at December 31, 2018 and March 31, 2018:

	December 31, 2018	March 31, 2018
Accrued AV-101 clinical trial, development and related expenses	$759,300	$176,600
Accrued professional services	59,000	27,000
All other	8,800	2,700
	$827,100	$206,300

Note 7. Notes Payable

The following table summarizes our unsecured promissory notes at December 31, 2018 and March 31, 2018:

	December 31, 2018			March 31, 2018		
	Principal Balance	Accrued Interest	Total	Principal Balance	Accrued Interest	Total
6.50% (2018) Notes payable to insurance premium financing company (current)	$49,100	$-	$49,100	$53,900	$-	$53,900

In May 2018, we executed a 6.50% promissory note in the principal amount of $160,500 in connection with certain insurance policy premiums. The note is payable in monthly installments of $16,500, including principal and interest, through March 2019, and had an outstanding principal balance of $49,100 at December 31, 2018. In February 2018, we executed a 7.15% promissory note in the principal amount of $59,700 in connection with other insurance policy premiums. That note was payable in monthly installments of $6,200, including principal and interest, through December 2018, and had been fully paid at December 31, 2018.

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Note 8. Capital Stock

Common Stock and Warrants Issued in Summer 2018 Private Placement

Between June 2018 and October 2018, we completed a self-placed private placement with accredited investors, pursuant to which we sold units, at a purchase price of $1.25 per unit, consisting of 4,605,000 unregistered shares of our common stock and warrants, exercisable through February 28, 2022, to purchase 4,605,000 unregistered shares of our common stock at an exercise price of $1.50 per share (the Summer 2018 Private Placement). The purchasers of the units have no registration rights with respect to the shares of common stock, warrants or the shares of common stock issuable upon exercise of the warrants comprising the units sold. The warrants are not exercisable until at least six months and one day following the date of issuance. We received aggregate cash proceeds of $5,756,200 in connection with the Summer 2018 Private Placement and the entire amount of the proceeds was credited to stockholders' equity.

Common Stock and Warrants Issued in Fall 2018 Private Placement

The Summer 2018 Private Placement was oversubscribed. To accommodate additional investor interest, during October 2018, we accepted subscription agreements from accredited investors, pursuant to which we sold to such investors units, at a unit purchase price equal to $0.15 above the closing quoted market price of our common stock on the Nasdaq Capital Market on the effective date of the investor's subscription agreement, consisting of an aggregate of 420,939 unregistered shares of our common stock and four-year, immediately exercisable warrants to purchase 420,939 unregistered shares of our Common Stock at a per share exercise price equal to the closing quoted market price of our common stock on the Nasdaq Capital Market on the effective date of the investor's subscription agreement (the Fall 2018 Private Placement). The purchasers of the units have no registration rights with respect to the shares of common stock, warrants or the shares of common stock issuable upon exercise of the warrants comprising the units sold. We received aggregate cash proceeds of $812,500 in connection with the Fall 2018 Private Placement and settled an outstanding professional service payable by accepting a subscription agreement in the amount of $40,000 and issuing the corresponding number of shares of common stock and warrants. The entire amount of the proceeds of the Fall 2018 Private Placement was credited to stockholders' equity. The fair value of the common stock and warrant issued in the Fall 2018 Private Placement in settlement of the professional services payable was determined to be $62,700 on the effective date of the agreement. Accordingly, we recognized a loss on extinguishment of accounts payable in the amount of $22,700 in the accompanying Condensed Consolidated Statement of Operations and Comprehensive Loss for the quarter and nine months ended December 31, 2018.

Modification of Warrants issued in Summer 2018 Private Placement

Subsequent to the completion of the Summer 2018 Private Placement, we amended warrants to purchase an aggregate of 304,000 shares of our common stock issued to investors who submitted Summer 2018 Private Placement subscription agreements between October 3, 2018 and October 5, 2018 to increase the exercise price of their warrants from $1.50 per share to $1.59 per share or $1.69 per share, depending on the effective date of the related subscription agreement, to comply with certain provisions of The Nasdaq Stock Market Rules applicable to the private placement. As additional consideration for agreeing to the increase in the warrant exercise price, we granted the investors additional warrants to purchase an aggregate of 23,800 unregistered shares of our common stock at an exercise price of $1.75 per share through February 28, 2022. We calculated the fair value of the modified warrants immediately before and after the modification using the Black Scholes Option Pricing Model and determined that the increase in the exercise price resulted in a decrease in the fair value of the warrants, which decrease is not recognized. We calculated the fair value of the new warrants using the Black Scholes Option Pricing Model and the weighted average assumptions indicated in the table below, recognizing $25,800 as the fair value of the new warrants and as warrant modification expense, included as a component of general and administrative expenses, in our Condensed

Consolidated Statement of Operations and Comprehensive Loss for the quarter and nine months ended December 31, 2018.

Assumption:	New Warrants
Market price per share	$1.80
Exercise price per share	$1.75
Risk-free interest rate	2.83%
Remaining contractual term in years	3.25
Volatility	88.80%
Dividend rate	0.0%
Number of warrant shares	23,800
Weighted average fair value per share	$1.08

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Issuance of Common Stock for Product Licenses and Option

As indicated in Note 1, Description of Business, and Note 3, Summary of Significant Accounting Policies, in September 2018 we issued an aggregate of 1,630,435 shares of our unregistered common stock having a fair market value of $2,250,000, based on the $1.38 per share quoted closing market price of our common stock on the Nasdaq Capital Market, to Pherin to acquire an exclusive worldwide license to develop and commercialize PH94B and an option to acquire a similar license for PH10. In October 2018, we exercised our option to acquire an exclusive worldwide 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, based on the $2.16 per share closing quoted market price of our common stock on the Nasdaq Capital Market, to Pherin under the terms of the PH10 license agreement. Under the terms of the PH94B and PH10 license agreements, we are obligated to make additional cash payments and pay royalties to Pherin in the event that certain regulatory and performance-based milestones and commercial sales are achieved. Additionally, in connection with the license agreements, we are obligated to pay to Pherin monthly support payments of $10,000 for a term of the earlier of 18 months or the termination of the license agreement, however no monthly support payment is required under the 18-month period identified in the PH10 license agreement if support payments are being made under the terms of the PH94B license agreement.

Issuance of Common Stock and Warrants to Professional Services Providers

During the quarter ended June 30, 2018, we issued an aggregate of 100,000 shares of our unregistered common stock having a fair value on the date of issuance of $123,000 as full or partial compensation to an investor relations service provider and under a financial advisory agreement. During the quarter ended September 30, 2018, we issued 50,000 shares of our unregistered common stock having a fair value on the date of issuance of $68,000 as partial compensation to a corporate awareness service provider. We also issued four-year warrants to three service providers to purchase an aggregate of 288,000 unregistered shares of our common stock at an exercise price of $1.50 per share as full or partial compensation for investor relations and corporate awareness services. We valued the warrants at an aggregate fair value of $266,900 using the Black-Scholes Option Pricing Model and the following grant date weighted average assumptions: exercise price per share: $1.50; market price per share: $1.40; risk-free interest rate: 2.71%; contractual term: 4 years; volatility: 94.17%; dividend rate: 0%; deriving a value per warrant share of $0.93. The fair value of the common stock and warrants is being recognized in expense ratably over the term of the underlying contracts.

Warrants Outstanding

Through December 31, 2018, the holders of warrants exercisable at $1.50 per share issued in our December 2017 public offering fully or partially exercised such warrants to purchase an aggregate of 403,800 registered shares of our common stock and we received cash proceeds of $605,700. Following the warrant issuances and exercises described above, at December 31, 2018, we had warrants outstanding to purchase shares of our common stock at a weighted average exercise price of $2.54 per share as follows:

Exercise Price per Share	Weighted Average Exercise Price per Share	Expiration Date	Warrants Outstanding at December 31, 2018
$1.50	$1.50	11/30/2021 to 12/13/2022	14,335,200

$1.59 to $1.80	$1.67	2/28/2022 to 10/10/2022	625,619
$1.82	$1.82	3/7/2023	1,388,931
$2.00 to $4.50	$2.23	9/216/2019 to 10/16/2022	721,693
$5.30	$5.30	5/16/2021	2,705,883
$6.00	$6.00	9/26/2019 to 11/30/2019	97,750
$7.00	$7.00	3/19/2019 to 3/3/2023	1,309,431
$8.00 to $20.00	$12.33	9/15/2019 to 3/25/2021	315,448
	$2.54		21,499,955

Of the warrants outstanding at December 31, 2018, 2,705,883 shares of common stock underlying the warrants exercisable at $5.30 per share issued in our May 2016 public offering, 1,388,931 shares of common stock underlying the warrants exercisable at $1.82 per share issued in our September 2017 public offering and 9,596,200 shares of common stock underlying the warrants exercisable at $1.50 per share issued in our December 2017 public offering are registered for resale by the warrant holders. The common shares issuable upon exercise of our remaining outstanding warrants are unregistered. At December 31, 2018, none of our outstanding warrants are subject to down round anti-dilution protection features and all of the outstanding warrants are exercisable by the holders only by payment in cash of the stated exercise price per share.

Note 9. Related Party Transactions

Cato Holding Company (CHC), doing business as Cato BioVentures (CBV), is the parent of Cato Research Ltd. (CRL). CRL is a contract research, development and regulatory services organization (CRO) that we have engaged for a wide range of material aspects related to the nonclinical and clinical development and regulatory affairs associated with our efforts to develop and commercialize AV-101 for MDD, including our ELEVATE Study, and other potential CNS indications, PH94B, PH10, and other potential product candidates. At December 31, 2018, CBV held approximately 3% of our outstanding Common Stock.

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In July 2017, we entered into a Master Services Agreement (MSA) with CRL, which replaced a substantially similar May 2007 master services agreement, pursuant to which CRL may assist us in the evaluation, development, commercialization and marketing of our potential product candidates, and provide regulatory and strategic consulting services as requested from time to time. Specific projects or services are and will be delineated in individual work orders negotiated from time-to-time under the MSA. Under the terms of work orders issued pursuant to the July 2017 MSA and our prior May 2007 master services agreement, we incurred expenses of $1,067,300 and $292,700 during the quarters ended December 31, 2018 and 2017, respectively, and $2,697,100 and $904,900 during the nine months ended December 31, 2018 and 2017, respectively. We anticipate periodic expenses for CRO services from CRL related to nonclinical and clinical development of, and regulatory affairs related to, AV-101, PH94B, PH10 and other potential product candidates will increase in future periods.

As noted above, in September 2018, we issued an aggregate of 1,630,435 shares of our unregistered common stock having a fair market value of $2,250,000 to acquire an exclusive worldwide license to develop and commercialize PH94B and an option to acquire a similar license for PH10. In October 2018, we issued an additional 925,926 shares of our unregistered common stock having a fair market value of $2,000,000 to exercise the option to acquire an exclusive worldwide license to develop and commercialize PH10. The acquisition of the licenses and option was recorded as research and development expense. Additionally, during the nine months ended December 31, 2018, we have recorded $40,000 of monthly support payments to Pherin under the terms of the PH94B license agreement. At December 31, 2018, Pherin held approximately 8% of our outstanding Common Stock.

Note 10. Subsequent Events

We have evaluated subsequent events through February 11, 2019 and have identified the following matters requiring disclosure:

Grants and Exercise of Options from 2016 Plan

During January 2019, in connection with the appointment of a new independent member to our Board, the Board authorized the grant of options to purchase 25,000 shares of our common stock under our 2016 Plan at an exercise price of $1.74 per share, the quoted closing price of our common stock on the Nasdaq Capital Market on the date of the grant. Additionally, one of our officers and one of our independent Board members exercised options to purchase an aggregate of 26,750 registered shares of our common stock at an exercise price of $1.50 per share and we received cash proceeds of $40,100. Also in January 2019, the Compensation Committee of the Board authorized the grant of options to purchase 220,000 shares of our common stock at an exercise price of $1.70 per share, the quoted closing price of our common stock on the Nasdaq Capital Market on the date of the grant, to one of our executive officers. In February 2019, we granted 25,000 shares of common stock from our 2016 Plan as partial compensation under the terms of a social media services contract.

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Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q (Report) includes forward-looking statements. All statements contained in this Report other than statements of historical fact, including statements regarding our future results of operations and financial position, our business strategy and plans, and our objectives for future operations, are forward-looking statements. The words "believe," "may," "estimate," "continue," "anticipate," "intend," "expect" and similar expressions are in to identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions. Our business is subject to significant risks including, but not limited to, our ability to obtain substantial additional financing, the results of our research and development efforts, the results of nonclinical and clinical testing, the effect of regulation by the U.S. Food and Drug Administration (FDA) and other agencies, the impact of competitive products, product development, commercialization and technological difficulties, the effect of our accounting policies, and other risks as detailed in the section entitled "Risk Factors" in this Report. Further, even if our product candidates appear promising at various stages of development, our share price may decrease such that we are unable to raise additional capital without significant dilution or other terms that may be unacceptable to our management, Board and stockholders.

Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management or Board to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the future events and trends discussed in this Report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. The events and circumstances reflected in the forward-looking statements may not be achieved or occur. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. We are under no duty to update any of these forward-looking statements after the date of this Report or to conform these statements to actual results or revised expectations. If we do update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements.

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.

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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. AV-101 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 intravenous or intranasal treatment with ketamine hydrochloride (ketamine), a member of a class of drugs that block NMDA receptor activity. Given its excellent tolerability profile, we believe it may also have potential as a first-line monotherapy conveniently administered at home. 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 standard antidepressants, which usually require many weeks or more of chronic usage to achieve similar antidepressant effects. We believe AV-101 may have potential to deliver fast-acting antidepressant effects similar to ketamine, but as an oral therapy on an at-home basis, without the requirement for administration in a medical setting or the required the use of needles, and without causing psychological, sedative or other side effects and safety concerns associated with ketamine and certain other fast-acting newer generation antidepressant drug candidates.

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.

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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, 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, 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.

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. 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.

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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.

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

As noted above, VistaStem is our wholly-owned subsidiary. Our Condensed Consolidated Financial Statements in this 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.

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Financial Operations Overview and Results of Operations

Our critical accounting policies and estimates and recent accounting pronouncements are disclosed in our Annual Report on Form 10-K for the fiscal year ended March 31, 2018, as filed with the SEC on June 26, 2018, and in Note 3 to the accompanying unaudited Condensed Consolidated Financial Statements included in Part 1, Item 1 of this Report.

Summary

Net Loss

We have not yet achieved recurring revenue-generating status from any of our product candidates or technologies. Since inception, we have devoted substantially all of our time and efforts to developing our initial CNS product candidate, AV-101, from early nonclinical studies to our ongoing Phase 2 clinical development program in MDD, as well as stem cell technology research and development, bioassay development, small molecule drug development, and creating, protecting and patenting intellectual property (IP) related to our product candidates and technologies, with the corollary initiatives of recruiting and retaining personnel and raising working capital. As disclosed above, we have recently acquired the rights to develop and commercialize PH94B and PH10. As of December 31, 2018, we had an accumulated deficit of approximately $175.4 million. Our net loss for the quarters ended December 31, 2018 and 2017 was approximately $7.2 million and $3.0 million, respectively. We expect losses to continue for the foreseeable future, primarily as we continue to conduct our ELEVATE Study, pursue further clinical development of AV-101 for the adjunctive treatment of MDD and for a range of other CNS indications, and further develop PH94B and PH10.

Summary of the Nine Months Ended December 31, 2018

During the nine months ended December 31, 2018, we continued to (i) advance nonclinical development, including manufacturing, and clinical development of AV-101 as a potential new generation antidepressant and as a potential new therapeutic alternative for several CNS indications with significant unmet need, (ii) expand the regulatory and intellectual property foundation to support broad clinical development and, ultimately, commercialization of AV-101 in the U.S. and foreign markets, (iii) expand our neuropsychiatry pipeline by acquiring exclusive worldwide licenses to PH94B, a novel drug candidate for treatment of SAD, and PH10, a novel drug candidate for treatment of MDD, and (iv) on a limited basis, advance drug rescue applications of our stem cell technology to further expand our CNS pipeline.

We have continued to conduct our ELEVATE Study throughout the fiscal year, in addition to producing supplies of AV-101 and conducting certain Phase 3-enabling nonclinical studies involving AV-101.

Pursuant to our CRADA with the NIH, the NIH continues to fund, and Dr. Carlos Zarate Jr. of the NIMH continues to conduct, the NIMH Study at no cost to us other than having supplied AV-101 and placebo for use in connection with the NIMH Study.

Pursuant to our MT CRADA with the VA and our arrangements with Baylor, Baylor commenced the Baylor Study to define a dose-response relationship between AV-101 and relevant biomarkers related to NMDA function and others possibly related to suicidal ideation in U.S. Military Veterans.

In September and October 2018, we acquired, on a non-cash basis through the issuance of our common stock, licenses from Pherin giving us the exclusive worldwide rights to develop and commercialize PH94B, a rapid-onset drug candidate designed to be administered as a nasal spray with potential to be the first FDA-approved PRN medication

for SAD, and PH10, a rapid-onset drug candidate designed to be administered as a nasal spray for treatment of MDD. We are actively pursuing nonclinical and regulatory initiatives necessary to facilitate pivotal Phase 3 clinical development of PH94B for SAD and Phase 2 clinical development of PH10 for MDD.

We continue to pursue initiatives to secure a broad portfolio of patent protection for AV-101 that covers the treatment of multiple CNS indications, unit dose formulations of AV-101 effective to treat depression and chemical synthesis methods. With respect to CNS treatments, we obtained patents in several countries for the treatment of depression and we are pursuing patent applications related to treatment of L-DOPA induced dyskinesias, certain types of neuropathic pain, tinnitus and obsessive-compulsive disorder. Additional patent applications to other aspects of prognostic testing and treatment using AV-101 are under consideration.

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During fiscal 2018 and subsequently, we have pursued patent applications in the U.S., Australia, China, Europe, Japan and other selected countries and regions with significant commercial potential. Several of these patent applications were allowed or have been granted in the U.S. and other major pharmaceutical markets during the nine months covered by this Report. Based on patent issuances or allowances to-date in several countries, we believe that pending counterpart patent applications related to AV-101 currently under review in other countries also are likely to be granted, although there can be no assurance that all pending applications will ultimately be granted.

We have an exclusive license from Pherin to its portfolio of patent assets around PH94B, under clinical development for the treatment of SAD. Patents have issued in several countries, including the U.S., Australia, Canada, China, Europe, Japan, Korea and Mexico.

We also have an exclusive license from Pherin to its portfolio of patent assets around PH10, under clinical development for the treatment of depressive disorders. Patents in this portfolio have issued in Australia, China, Europe and Japan. Applications are pending in the U.S., Canada, Korea and Mexico.

As with AV-101, we plan to seek regulatory exclusivity in countries where this is available for the therapeutic use of PH94B, with initial emphasis on treating SAD, as our lead indication in clinical development, and for the therapeutic use of PH10, with our lead indication being the treatment of major depressive disorder.

We have obtained and are pursuing patent rights to the production of several types of stem cells and cells differentiated from those stem cells, including cardiomyocytes, hematopoietic cells, chondrocytes, cartilage cells and hepatocytes, as well as the use of certain cell types that have been differentiated from pluripotent stem cells for therapeutic purposes, including cell-based therapy and regenerative medicine.

Between June 2018 and October 2018, we completed a self-placed private placement with accredited investors, pursuant to which we sold units, at a purchase price of $1.25 per unit, consisting of 4,605,000 unregistered shares of our common stock and warrants, exercisable through February 28, 2022, to purchase 4,605,000 unregistered shares of our common stock at an exercise price of $1.50 per share (the Summer 2018 Private Placement). We received aggregate cash proceeds of $5,756,200 from the Summer 2018 Private Placement. The Summer 2018 Private Placement was oversubscribed. To accommodate additional investor interest, during October 2018, we accepted subscription agreements from accredited investors, pursuant to which we sold to such investors units, at a unit purchase price equal to $0.15 above the closing quoted market price of our common stock on the Nasdaq Capital Market on the effective date of the investor’s subscription agreement, consisting of an aggregate of 420,939 unregistered shares of our common stock and four-year, immediately exercisable warrants to purchase 420,939 unregistered shares of our Common Stock at a per share exercise price equal to the closing quoted market price of our common stock on the Nasdaq Capital Market on the effective date of the investor’s subscription agreement (the Fall 2018 Private Placement). We received aggregate cash proceeds of $812,500 in connection with the Fall 2018 Private Placement and settled an outstanding professional service payable by accepting a subscription agreement in the amount of $40,000 and issuing the corresponding number of shares and warrants. During the nine months ended December 31, 2018, we have also received cash proceeds of $605,700 from the exercise of outstanding warrants to purchase an aggregate of 403,800 shares our common stock.

As a matter of course, we continue to minimize, to the greatest extent possible, cash commitments and expenditures for both internal and external research and development and general and administrative services. To further advance the clinical and nonclinical development of AV-101, PH94B, PH10 and our stem cell technology platform, as well as support our operating activities, we continue to carefully manage our routine operating costs, including our internal employee related expenses, as well as external 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 internal costs.

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Results of Operations

Comparison of Three Months Ended December 31, 2018 and 2017

The following table summarizes the results of our operations for the three months ended December 31, 2018 and 2017 (amounts in thousands).

	Three Months Ended December 31,	
	2018	2017
Operating expenses:		
Research and development	$5,335	$1,602
General and administrative	1,857	1,266
Total operating expenses	7,192	2,868
Loss from operations	(7,192)	(2,868)
Interest expense, net	(2)	(2)
Loss on extinguishment of accounts payable	(23)	(135)
Loss before income taxes	(7,217)	(3,005)
Income taxes	-	-
Net loss	(7,217)	(3,005)
Accrued dividend on Series B Preferred Stock	(291)	(263)
Deemed dividend from trigger of down round provision feature	-	(199)
Net loss attributable to common stockholders	$(7,508)	$(3,467)

Revenue

We reported no revenue for either the quarter ended December 31, 2018 or 2017 and we presently have no recurring revenue generating arrangements with respect to AV-101, PH94B, PH10 or other potential product candidates. While we may potentially receive payments or royalties under the BlueRock Agreement in the future in the event certain performance-based milestones and commercial sales are achieved, there can be no assurance that the BlueRock Agreement will provide revenue to us in the near term or at all.

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Research and Development Expense

Research and development expense increased to $5.3 million compared to $1.6 million for the quarters ended December 31, 2018 and 2017, respectively. The October 2018 acquisition of the PH10 license through the issuance of our common stock, which resulted in $2.0 million of noncash expense, coupled with continuing expenses of the ELEVATE Study and various nonclinical activities, including manufacturing additional quantities of AV-101, are the primary drivers of the increase in research and development expense. In addition to the PH10 license acquisition, other noncash expenses included in research and development expense, including stock compensation, depreciation and a portion of rent expense in both periods and a portion of AV-101 project expenses in the quarter ended December 31, 2018, aggregated approximately $297,000 and $385,000 for the quarters ended December 31, 2018 and 2017 respectively. The following table indicates the primary components of research and development expense for each of the periods (amounts in thousands):

	Three Months Ended December 31,	
	2018	2017
Salaries and benefits	$321	$347
Stock-based compensation	275	299
Consulting and other professional services	106	7
Technology license expense	144	149
Project-related research and supplies:		
ELEVATE study and other AV-101 expenses	2,291	665
PH94B and PH10 licenses and other expenses	2,059	-
VistaStem and all other projects	23	15
	4,373	680
Rent	104	104
Depreciation	12	16
Total Research and Development Expense	$5,335	$1,602

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The decrease in salaries and benefits expense reflects the impact of salary increases granted to our Chief Medical Officer (CMO), Chief Scientific Officer (CSO) and members of our scientific staff effective in July 2018 offset by decreased bonus payments in the quarter ended December 31, 2018 versus the quarter ended December 31, 2017.

Stock-based compensation expense reflects the routine amortization of option grants made to our CSO, CMO and scientific staff in June 2016 and thereafter, all earlier grants having become fully vested and amortized prior to the quarter ended December 31, 2018. Grants awarded after December 2017 account for approximately $92,000 of 2018 expense. Expense attributable to these grants is generally being amortized over two-year to four-year vesting periods, with one-quarter of the grants made in February 2018 and August 2018 being immediately vested and expensed upon grant, in accordance with the terms of the respective grants.

Consulting services reflects fees paid or accrued for scientific, nonclinical and clinical development and regulatory advisory services rendered to us by third-parties, in 2017, primarily by members of our Scientific Advisory Board and CNS Clinical and Regulatory Advisory Board. The increase in 2018 expense reflects consulting and support services in connection with our acquisition of the exclusive licenses to PH94B and PH10 and related consulting arrangements.

Technology license expense reflects both recurring annual license fees, as well as legal counsel and other costs related to patent prosecution and protection pursuant to our stem cell technology license agreements or that we have elected to pursue for commercial purposes. We recognize these costs as they are invoiced to us by the licensors or counsel and they do not occur ratably throughout the year or between years. In both periods, this expense includes legal counsel and other costs we have incurred to advance pending patent applications in the U.S. and numerous foreign countries with respect to AV-101 and our stem cell technology platform. Acquisition of the PH94B and PH10 licenses contributed only nominally to this expense in 2018.

AV-101 project expense for the quarter ended December 31, 2018, primarily reflects the continuing costs of conducting the ELEVATE Study, including various CRO, investigator and clinical site costs, as well as expense incurred to manufacture additional quantities of AV-101 for use in future Phase 3-enabling nonclinical trials and clinical development of AV-101 for MDD and other potential CNS indications. AV-101 project expense for the quarter ended December 31, 2017 included costs incurred to develop our current more efficient and cost-effective proprietary manufacturing methods for AV-101, and to produce quantities of AV-101 in preparation for the ELEVATE Study and Baylor Study.

As indicated above, PH94B and PH10 expense includes the non-cash expense related to the October 2018 acquisition of the PH10 license through the issuance of $2.0 million fair value of 925,926 unregistered shares of our common stock to Pherin under the terms of the option exercise and license. Additional expense relates to initiatives advancing the further development of PH94B.

Stem cell and other project related expenses reflects costs associated with drug rescue applications of our stem cell technology in both years.

Rent expense is essentially unchanged between the periods and reflects commercial property rents prevalent in the South San Francisco real estate market at the time of our November 2016 lease amendment extending the lease of our headquarters facilities in South San Francisco by five years from July 31, 2017 to July 31, 2022 and the related accounting for the amendment.

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General and Administrative Expense

General and administrative expense increased to approximately $1.8 million, from approximately $1.3 million for the quarters ended December 31, 2018 and 2017, respectively. Noncash expense, $588,000 in the quarter ended December 31, 2018, increased from $485,000 in the quarter ended December 31, 2017 primarily due to increases in stock-based compensation and in noncash components of investor and public relations and warrant modification expenses. The following table indicates the primary components of general and administrative expense for each of the periods (amounts in thousands):

	Three Months Ended December 31,	
	2018	2017
Salaries and benefits	$321	$339
Stock-based compensation	460	390
Board fees	39	39
Legal, accounting and other professional fees	132	44
Investor and public relations	645	232
Insurance	71	60
Travel expenses	40	33
Rent and utilities	72	69
Warrant modification expense	26	13
All other expenses	51	47
	$1,857	$1,266

The decrease in salaries and benefits primarily reflects the impact of salary increases granted effective July 2018 to our Chief Executive Officer (CEO), Chief Financial Officer (CFO), Vice President-Corporate Development (VP Corporate Development) and a non-officer member of our administrative staff, offset by reduced bonus payments in the quarter ended December 31, 2018.

Stock-based compensation expense reflects the routine amortization of option grants made to our CEO, CFO, VP Corporate Development and administrative staff in June 2016 and thereafter, all earlier grants having become fully vested and amortized prior to the quarter ended December 31, 2018. Grants awarded after December 2017 account for approximately $196,000 of 2018 expense. Expense attributable to these grants is generally being amortized over two-year to four-year vesting periods, with one-quarter of the grants made in February 2018 and August 2018 being immediately vested and expensed upon grant, in accordance with the terms of the respective grants.

Board fees represents fees paid as consideration for the Board and Board Committee services of the independent members of our Board.

Legal, accounting and other professional fees for the quarters ended December 31, 2018 and 2017 includes expense related to routine legal fees as well as the accounting expense related to the review of the financial statements for the third quarter of each fiscal year. In 2018, we also incurred $68,000 attributable to services provided by an international business development consultant. We incurred no non-cash expense in the quarters ended December 31, 2018 or 2017.

Investor and public relations expense includes the fees of our various external service providers for a broad spectrum of investor relations and public relations services, and well as market awareness and strategic advisory and support functions and initiatives that included numerous meetings in multiple U.S. markets and other communication activities focused on expanding market awareness of the Company and its research and development programs, including among registered investment professionals and investment advisors, and individual and institutional investors. In the quarter ended December 31, 2018, in addition to cash fees and expenses we incurred for such activities, we recognized $102,000 of noncash expense attributable to the amortization of the fair value of stock and warrants granted in the previous quarter to various corporate development, investor relations, and market awareness service providers. The balance of the fair value of the securities granted remains recorded as a prepaid expense at December 31, 2018 and is being amortized over the remaining service period of the respective contracts. In the quarter ended December 31, 2017, in addition to cash fees and expenses we incurred, we granted an aggregate of 70,000 unregistered shares of our common stock to certain investor relations, market awareness and strategic business advisory service providers for their services and recognized noncash expense of $84,000, representing the fair value of the stock at the time of issuance.

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In both periods, travel expense reflects costs associated with management presentations and meetings held in multiple U.S. markets, and certain international markets in 2018, with existing and potential individual and institutional investors, investment professionals and advisors, media, and securities analysts, as well as various investor relations, market awareness and corporate development and partnering initiatives and in monitoring the progress of our ELEVATE Study in 2018.

Rent expense is essentially unchanged between the periods and primarily reflects commercial property rents prevalent in the South San Francisco real estate market at the time of our November 2016 lease amendment extending the lease of our headquarters facilities in South San Francisco by five years from July 31, 2017 to July 31, 2022 and the related accounting for the amendment.

During the quarter ended December 31, 2018, we modified certain warrants issued in the Summer 2018 Private Placement to comply with certain provisions of The Nasdaq Stock Market Rules applicable to the private placement by increasing the exercise price of such warrants to purchase an aggregate of 304,000 shares of our common stock from $1.50 per share to $1.59 per share or $1.69 per share, depending on the effective date of the related subscription agreement. As additional consideration for the modification, we granted the investors additional warrants to purchase an aggregate of 23,800 unregistered shares of our common stock at an exercise price of $1.75 per share through February 28, 2022. We determined that the modification decreased the fair value of the modified warrants, which decrease is not recognized; however, the fair value of the new warrants was determined to be $25,800, which we recognized as noncash warrant modification expense. During the quarter ended December 31, 2017, we modified outstanding warrants issued in private placement transactions between August 2017 and November 2017 to purchase an aggregate of 178,572 shares of our common stock to reduce the exercise prices from a weighted average of $2.32 per share to a weighted average of $1.58 per share. We recognized the calculated increase in the fair value of the warrants, $13,000, as noncash warrant modification expense.

Interest and Other Expenses

Interest expense totaled $1,800 for the quarter ended December 31, 2018 compared to $2,000 for the quarter ended December 31, 2017. Interest expense in both periods relates to interest paid on insurance premium financing and on a capital lease of office equipment.

In connection with the Fall 2018 Private Placement, we settled an outstanding professional service payable by accepting a subscription agreement in the amount of $40,000 and issuing the corresponding number of shares of Common Stock and warrants. The fair value of the common stock and warrant issued in settlement of the payable was determined to be $62,700 on the effective date of the agreement. Accordingly, we recognized a loss on extinguishment of accounts payable in the amount of $22,700 in the quarter ended December 31, 2018. During the quarter ended December 31, 2017, we issued 500,000 unregistered shares of our common stock having a fair value at the time of issuance of $585,000 and a cash payment of $76,500 to a contract manufacturing organization in settlement of $526,500 of open accounts payable. We recognized a corresponding loss on settlement of accounts payable in the amount of $135,000 for the quarter ended December 31, 2017.

We recognized $290,900 and $263,000 for the quarters ended December 31, 2018 and 2017, respectively, representing the 10% cumulative dividend payable on outstanding shares of Series B Preferred as an additional deduction in arriving at net loss attributable to common stockholders in the accompanying Condensed Consolidated Statement of Operations and Comprehensive Loss included in Part I of this Report. There have been no conversions of outstanding shares of Series B Preferred stock into shares of our common stock since August 2016.

Our sale of units consisting of common stock and warrants in our December 2017 public offering at an offering price of $1.50 per unit triggered the anti-dilution provisions of the Series A2 Warrants to purchase an aggregate of 503,641 shares of our common stock issued in our September 2017 public offering. In accordance with the anti-dilution terms and formula contained in the Series A2 warrants, the exercise price of the Series A2 Warrants was reduced from the initial exercise price of $1.82 per share to $0.001 per share. We recognized the effect of triggering the down round feature, $199,200, as a component of net loss attributable to common stockholders in the quarter ended December 31, 2017.

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Comparison of Nine Months Ended December 31, 2018 and 2017

The following table summarizes the results of our operations for the nine months ended December 31, 2018 and 2017 (amounts in thousands).

	Nine Months Ended December 31,	
	2018	2017
Operating expenses:		
Research and development	$13,340	$5,125
General and administrative	5,494	4,997
Total operating expenses	18,834	10,122
Loss from operations	(18,834)	(10,122)
Interest expense (net)	(7)	(8)
Loss on extinguishment of accounts payable	(23)	(135)
Loss before income taxes	(18,864)	(10,265)
Income taxes	(2)	(2)
Net loss	(18,866)	(10,267)
Accrued dividend on Series B Preferred Stock	(848)	(767)
Deemed dividend from trigger of down round provision feature	-	(199)
Net loss attributable to common stockholders	$(19,714)	$(11,233)

Revenue

We reported no revenue for either period presented and we presently have no recurring revenue generating arrangements with respect to AV-101, PH94B, PH10, or other potential product candidates. While we may potentially receive additional payments and royalties under our December 2015 BlueRock Agreement in the future in the event certain performance-based milestones and commercial sales are achieved, there can be no assurance that the BlueRock Agreement will provide additional revenue to us in the near term or at all.

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Research and Development Expense

Research and development expense increased to $13.3 million compared to $5.1 million for the nine months ended December 31, 2018 and 2017, respectively. The noncash acquisition of the PH94B license and the PH10 option and license through the issuance of our common stock, which resulted in an aggregate of $4.25 million of expense, coupled with expenses related to conducting the ELEVATE Study and various nonclinical activities, including manufacturing additional quantities of AV-101, are the primary drivers of the increase in research and development expense. Other noncash expenses included in research and development expense, including stock compensation, depreciation and a portion of rent expense in both periods and a portion of AV-101 project expenses in the nine months ended December 31, 2018, aggregated approximately $1,026,000 and $1,228,000 for the nine months ended December 31, 2018 and 2017 respectively. The following table indicates the primary components of research and development expense for each of the periods (amounts in thousands):

	Nine Months Ended December 31,	
	2018	2017
Salaries and benefits	$1,293	$1,231
Stock-based compensation	956	627
Consulting and other professional services	149	23
Technology license expense	397	309
Project-related research and supplies:		
ELEVATE study and other AV-101 expenses	5,801	2,465
PH94B and PH10 licenses and other expenses	4,309	-
VistaStem and all other projects	85	105
	10,195	2,570
Rent	312	308
Depreciation	36	54
All other	2	3
Total Research and Development Expense	$13,340	$5,125

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The increase in salaries and benefits expense reflects the impact of salary increases and bonus payments granted to our CMO, CSO and members of our scientific staff effective in July 2018, offset by the impact of a staff termination in the quarter ended June 30, 2017.

Stock-based compensation expense increased significantly in the nine months ended December 31, 2018 as a result of (i) the impact of new options granted to our CMO, CSO, and members of our scientific staff in August 2018 which options were 25% vested upon grant and vest ratably until becoming fully-vested within two years thereafter, and (ii) the modification in August 2018 of outstanding options held by our CMO, CSO and members of our scientific staff having exercise prices over $1.56 per share to reduce the exercise price to $1.50 per share. Stock compensation expense attributable to grants made subsequent to December 31, 2017 and including the $104,000 immediately recognized impact of the modification of exercise prices accounted for approximately $312,000 in the nine months ended December 31, 2018. Current year expense is attributable to grants made in June 2016 and thereafter, all earlier grants having become fully vested and amortized prior to September 30, 2018.

Consulting services reflects fees paid or accrued for scientific, nonclinical and clinical development and regulatory advisory services rendered to us by third-parties, in 2017, primarily by members of our scientific and CNS clinical and regulatory advisory boards. The increase in 2018 expense reflects consulting and support services in connection with our acquisition of the exclusive licenses to PH94B and PH10 and related consulting arrangements.

Technology license expense reflects both recurring annual license fees as well as legal counsel and other costs related to patent prosecution and protection pursuant to our stem cell technology license agreements or that we have elected to pursue for commercial purposes. We recognize these costs as they are invoiced to us by the licensors or counsel and they do not occur ratably throughout the year or between years. In both periods, this expense includes legal counsel and other costs we have incurred to advance pending patent applications in the U.S. and numerous foreign countries with respect to AV-101 and our stem cell technology platform. Acquisition of the PH94B and PH10 licenses contributed only nominally to this expense in 2018.

AV-101 project expense for the nine months ended December 31, 2018, primarily reflects the continuing costs of conducting the ELEVATE Study, including various CRO, investigator and clinical site costs, as well as expense incurred to manufacture additional quantities of AV-101 for use in future nonclinical and clinical trials of AV-101 for MDD and other potential CNS indications. AV-101 project expense for the nine months ended December 31, 2017 primarily reflected costs incurred to develop our current more efficient and cost-effective proprietary manufacturing methods for AV-101, and to produce quantities of AV-101 in preparation for the ELEVATE Study and Baylor Study.

As indicated above, noncash expense related to the acquisition of the PH94B and PH10 licenses and PH10 option reflects the $4.25 million fair value of an aggregate of 2,556,361 unregistered shares of our common stock issued to Pherin in September 2018 and October 2018 under the terms of the license and option agreements. Additional expense relates to initiatives advancing the further development of PH94B.

Stem cell and other project related expenses reflects costs associated with drug rescue applications of our stem cell technology in both years.

Rent expense is essentially unchanged between the periods and reflects commercial property rents prevalent in the South San Francisco real estate market at the time of our November 2016 lease amendment extending the lease of our headquarters facilities in South San Francisco by five years from July 31, 2017 to July 31, 2022 and the related accounting for the amendment.

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General and Administrative Expense

General and administrative expense increased to approximately $5.5 million from approximately $5.0 million for the nine months ended December 31, 2018 and 2017, respectively, due to a modest increase in cash compensation costs and a significant increase in noncash stock-based compensation expense offset by reductions in certain professional services expenses and in noncash warrant modification expense. Noncash expense components represented approximately $1,883,000 and $2,232,000 for the nine months ended December 31, 2018 and 2017, respectively. Such non-cash expenses included, in both periods, stock compensation expense, a portion of professional services and investor relations expense, a portion of rent expense, and warrant modification expense. The following table indicates the primary components of general and administrative expense for each of the periods (amounts in thousands):

	Nine Months Ended December 31,	
	2018	2017
Salaries and benefits	$1,386	$1,260
Stock-based compensation	1,564	760
Board fees	117	117
Legal, accounting and other professional fees	488	739
Investor and public relations	1,244	1,229
Insurance	210	181
Travel expenses	116	95
Rent and utilities	215	209
Warrant modification expense	26	293
All other expenses	128	114
	$5,494	$4,997

The increase in salaries and benefits primarily reflects the impact of salary increases and bonus payments granted effective July 2018 to our CEO, CFO, VP Corporate Development and a non-officer member of our administrative staff.

Stock-based compensation expense increased significantly for the nine months ended December 31, 2018 as a result of (i) the impact of new options granted to our CEO in February 2018 and to our CFO, VP Corporate Development and our administrative staff in February 2018 and August 2018, each of which were 25% vested upon grant and vest ratably until becoming fully-vested within two years thereafter, and (ii) the modification in August 2018 of outstanding options held by our CEO, CFO, VP Corporate Development and our administrative staff having exercise prices over $1.56 per share to reduce the exercise price to $1.50 per share. Stock compensation expense attributable to grants made subsequent to December 31, 2017 and including the $154,000 immediately recognized impact of the modification of exercise prices accounted for approximately $660,000 in the nine months ended December 31, 2018. Current year expense is attributable to grants made in June 2016 and thereafter, all earlier grants having become fully vested and amortized prior to the quarter ended September 30, 2018.

Board fees represents fees paid as consideration for the Board and Board Committee services of the independent members of our Board.

Legal, accounting and other professional fees for the nine months ended December 31, 2018 and 2017 includes expense related to routine legal fees as well as the accounting expense related to the annual audit of the prior year's financial statements and the review of the financial statements for the first three quarters of the current fiscal year. Additionally, in 2018, we incurred $81,000 attributable to services provided by an international business development consultant. In addition to cash fees incurred, in the nine months ended December 31, 2017, we granted an aggregate of 20,000 unregistered shares of our common stock having an aggregate fair value of $30,800 to legal services providers as compensation for services and an aggregate of 150,000 unregistered shares of our common stock having an aggregate fair value of $234,000 to two investment banking firms pursuant to financial advisory agreements. We incurred no noncash expense in the nine months ended December 31, 2018.

Investor and public relations expense includes the fees of our various external service providers for a broad spectrum of investor relations and public relations services, as well as market awareness, strategic advisory and support functions and initiatives that included numerous meetings in multiple U.S. markets and other communication activities focused on expanding market awareness of the Company and its research and development programs, including among registered investment professionals and investment advisors, and individual and institutional investors. During the nine months ended December 31, 2018, in addition to cash fees and expenses, we granted: (i) an aggregate of 100,000 unregistered shares of our common stock to certain financial advisory service providers in the quarter ended June 30, 2018 as full or partial compensation for their services and recognized noncash expense of approximately $123,000 representing the fair value of the stock at the time of issuance; and (ii) an aggregate of 50,000 unregistered shares of our common stock and four-year warrants to purchase an aggregate of 288,000 unregistered shares of our common stock having an aggregate fair value of approximately $336,000 to various corporate development, investor relations, and market awareness service providers and recognized aggregate non-cash expense of approximately $169,000 in the two quarters ended December 31, 2018. The balance of the fair value of the securities granted in the quarter ended September 30, 2018 remains recorded as a prepaid expense and is being amortized over the remaining service period of the respective contracts. In the nine months ended December 31, 2017, in addition to cash fees and expenses we incurred, we granted an aggregate of 552,000 shares of our unregistered common stock to various corporate development, investor relations, market awareness and business advisory service providers as full or partial compensation for their services and recognized noncash expense totaling $847,300, representing the fair value of the stock at the time of issuance.

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In both periods, travel expense reflects costs associated with management presentations and meetings held in multiple U.S. markets, and certain international markets in 2018, with existing and potential individual and institutional investors, investment professionals and advisors, media, and securities analysts, as well as various investor relations, market awareness and corporate development and partnering initiatives and in monitoring the progress of our ELEVATE Study in 2018.

Rent expense is essentially unchanged between the periods and primarily reflects commercial property rents prevalent in the South San Francisco real estate market at the time of our November 2016 lease amendment extending the lease of our headquarters facilities in South San Francisco by five years from July 31, 2017 to July 31, 2022 and the related accounting for the amendment.

During the quarter ended December 31, 2018, we modified certain warrants issued in the Summer 2018 Private Placement to comply with certain provisions of The Nasdaq Stock Market Rules applicable to the offering by increasing the exercise price of such warrants to purchase an aggregate of 304,000 shares of our common stock from $1.50 per share to $1.59 per share or $1.69 per share, depending on the effective date of the related subscription agreement. As additional consideration for the modification, we granted the investors additional warrants to purchase an aggregate of 23,800 unregistered shares of our common stock at an exercise price of $1.75 per share through February 28, 2022. We determined that the modification decreased the fair value of the modified warrants, which decrease is not recognized; however, the fair value of the new warrants was determined to be $25,800, which we recognized as noncash warrant modification expense. In September 2017, we reduced the exercise price of 247,500 warrants issued in our Spring 2017 private placement offering from a weighted average exercise price of $3.99 per share to $2.00 per share. We also issued to each of the investors in the spring 2017 private placement additional warrants to purchase an aggregate total of 247,501 shares of common stock, with an exercise price of $2.00 per share. We recognized noncash expense of $279,700 in the quarter ended September 30, 2017 representing the increase in fair value of the warrants granted initially and the fair value of the additional warrants granted. During the quarter ended December 31, 2017, we modified outstanding warrants issued in private placement transactions between August 2017 and November 2017 to purchase an aggregate of 178,572 shares of our common stock to reduce the exercise prices from a weighted average of $2.32 per share to a weighted average of $1.58 per share. We recognized the calculated increase in the fair value of the warrants, $13,000, as noncash warrant modification expense.

Interest and Other Expenses

Interest expense totaled $6,800 for the nine months ended December 31, 2018 compared to $7,700 reported for the nine months ended December 31, 2017. Interest expense in both periods relates to interest paid on insurance premium financing and on a capital lease of office equipment.

In connection with the Fall 2018 Private Placement, we settled an outstanding professional service payable by accepting a subscription agreement in the amount of $40,000 and issuing the corresponding number of shares of common stock and warrants. The fair value of the common stock and warrant issued in settlement of the payable was determined to be $62,700 on the effective date of the agreement. Accordingly, we recognized a loss on extinguishment of accounts payable in the amount of $22,700 in the quarter and nine months ended December 31, 2018. During the quarter ended December 31, 2017, we issued 500,000 unregistered shares of our common stock having a fair value at the time of issuance of $585,000 and a cash payment of $76,500 to a contract manufacturing organization in settlement of $526,500 of open accounts payable. We recognized a corresponding loss on settlement of accounts payable in the amount of $135,000 for the quarter and nine months ended December 31, 2017.

We recognized $848,000 and $766,600 for the nine months ended December 31, 2018 and 2017, respectively, representing the 10% cumulative dividend payable on outstanding shares of our Series B Preferred stock as an

additional deduction in arriving at net loss attributable to common stockholders in the accompanying Condensed Consolidated Statement of Operations and Comprehensive Loss included in Part I of this Report. There have been no conversions of outstanding shares of Series B Preferred stock into shares of our common stock since August 2016.

Our sale of units consisting of common stock and warrants in our December 2017 public offering at an offering price of $1.50 per unit triggered the anti-dilution provisions of the Series A2 Warrants to purchase an aggregate of 503,641 shares of our common stock issued in our September 2017 public offering. In accordance with the anti-dilution terms and formula contained in the Series A2 warrants, the exercise price of the Series A2 Warrants was reduced from the initial exercise price of $1.82 per share to $0.001 per share. We recognized the effect of triggering the down round feature, $199,200, as a component of net loss attributable to common stockholders in the quarter and nine months ended December 31, 2017.

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Liquidity and Capital Resources

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.

Although 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 a pivotal Phase 3 clinical trial of PH94B, conduct additional clinical and nonclinical 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 we have been in the past, we expect that, if 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.

In addition to the potential sale of our equity securities, we may also seek to enter 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 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 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, PH94B, PH10 and, to a lesser extent, 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.

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Cash and Cash Equivalents

The following table summarizes changes in cash and cash equivalents for the periods stated (in thousands):

	Nine Months Ended December 31,	
	2018	2017
Net cash used in operating activities	$(10,970)	$(6,454)
Net cash used in investing activities	(170)	(2)
Net cash provided by financing activities	7,047	16,567
Net (decrease) increase in cash and cash equivalents	(4,093)	10,111
Cash and cash equivalents at beginning of period	10,378	2,921
Cash and cash equivalents at end of period	$6,285	$13,032

The increase in cash used in operations results primarily from the conduct of our ELEVATE Study, which commenced at the end of the fourth quarter of our fiscal year ended March 31, 2018. Contributing additionally to the increase are modest increases in employee cash compensation and benefits and an increase in various investor relations and corporate development and awareness initiatives. The increase in cash used in investing activities reflects the cost of tenant improvements at our office and laboratory facilities in South San Francisco, CA, substantially all of which were reimbursed by our landlord under the terms of our November 2016 lease extension, which reimbursement is reflected in operating activities. Cash provided by financing activities in 2018 primarily reflects the cash proceeds from our Summer 2018 Private Placement, Fall 2018 Private Placement and warrant exercises and, in 2017, the proceeds of our September 2017 and December 2017 public offerings, net of routine note and capital lease payments in both years.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements.

Recent Accounting Pronouncements

For information relating to recent accounting pronouncements and the expected impact of such pronouncements on our condensed consolidated financial statements, see Note 3 of the Notes to Condensed Consolidated Financial Statements included elsewhere in this Report.

Item 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) as of the end of the period covered by this Report. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this Report were effective.

Internal Control over Financial Reporting

In our Annual Report on Form 10-K for our fiscal year ended March 31, 2018 filed with the Securities and Exchange Commission on June 26, 2018, we identified two material weaknesses in our internal control over financial reporting relating to (i) segregation of duties and (ii) the functionality of our accounting software. Management has determined that current resources would be more appropriately applied elsewhere and when resources permit, they will alleviate such material weaknesses through various steps, which may include the addition of qualified financial personnel and/or the acquisition and implementation of alternative accounting software. Accordingly, there was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the fiscal quarter to which this Report relates that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II: OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

Investing in our securities involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this Quarterly Report on Form 10-Q (Report) and in our Annual Report on Form 10-K filed with the Securities and Exchange Commission for the fiscal year ended March 31, 2018 before investing in our securities. The risks described below are not the only risks facing our Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also materially adversely affect our business, financial condition and/or operating results. If any of the following risks are realized, our business, financial condition and results of operations could be materially and adversely affected.

Risks Related to Product Development, Regulatory Approval and Commercialization

We depend heavily on the success of one or more of our current drug candidates and we cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize any of our product candidates.

We currently have no drug products for sale and may never be able to develop and commercialize marketable drug products. Our business currently depends heavily on the successful development, regulatory approval and commercialization of one or more of our current drug candidates, as well as, but to a more limited extent, our ability to acquire, license or produce, develop and commercialize additional product candidates. Each of our current drug candidates will require substantial additional nonclinical and clinical development and regulatory approval before any of them may be commercialized, and there can be no assurance that any of them will ever achieve regulatory approval. Any drug rescue NCE we produce will require substantial nonclinical development, all phases of clinical development, and regulatory approval before it may be commercialized. The nonclinical and clinical development of our product candidates are, and the manufacturing and marketing of our product candidates will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and, if approved, market any product candidate. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must demonstrate through numerous nonclinical and clinical studies that the product candidate is safe and effective for use in each target indication. Research and development of product candidates in the pharmaceutical industry is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of nonclinical or clinical studies. This process takes many years and may also include post-marketing studies, surveillance obligations and drug safety programs, which would require the expenditure of substantial resources beyond the proceeds we have raised to date. Of the large number of drug candidates in development in the United States, only a small percentage will successfully complete the required FDA regulatory approval process and will be commercialized. Accordingly, we cannot assure you that any of our current drug candidates or any future product candidates will be successfully developed or commercialized.

We are not permitted to market our product candidates in the United States until we receive approval of an NDA from the FDA, or in any foreign countries until we receive the requisite approval from such countries. Obtaining FDA approval of a New Drug Application (NDA) is a complex, lengthy, expensive and uncertain process. The FDA may refuse to permit the filing of our NDA, delay, limit or deny approval of an NDA for many reasons, including, among others:

if we submit an NDA and it is reviewed by an FDA advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional nonclinical or clinical studies, limitations on approved labeling or distribution and use restrictions;

an FDA advisory committee may recommend, or the FDA may require, a Risk Evaluation and Mitigation Strategy (REMS) safety program as a condition of approval or post-approval;

an FDA advisory committee or the FDA or applicable regulatory agency may determine that there is insufficient evidence of overall effectiveness in an NDA and require additional clinical studies;

the FDA or the applicable foreign regulatory agency may determine that the manufacturing processes or facilities of third-party contract manufacturers with which we contract do not conform to applicable requirements, including current Good Manufacturing Practices (cGMPs); or

the FDA or applicable foreign regulatory agency may change its approval policies or adopt new regulations.

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Any of these factors, many of which are beyond our control, could jeopardize our ability to obtain regulatory approval for and successfully commercialize any current or future drug product candidate we may develop. Any such setback in our pursuit of regulatory approval for any product candidate would have a material adverse effect on our business and prospects.

Certain of our product candidates, including PH94B and PH10, may be subject to regulation as combination products, which means that they are composed of both a drug product and device product. If marketed individually, each component would be subject to different regulatory pathways and reviewed by different Centers within the FDA. Our product candidates that are considered to be drug-device combination products will require review and coordination by FDA's drug and device centers prior to approval, which may delay approval. A combination product with a drug primary mode of action generally would be reviewed and approved pursuant to the drug approval processes under the United States Federal Food, Drug and Cosmetic Act of 1938. In reviewing the NDA application for such a product, however, FDA reviewers in the drug center could consult with their counterparts in the device center to ensure that the device component of the combination product met applicable requirements regarding safety, effectiveness, durability and performance. Under FDA regulations, combination products are subject to cGMP requirements applicable to both drugs and devices, including the Quality System (QS) regulations applicable to medical devices. Problems associated with the device component of the combination product candidate may delay or prevent approval.

We have been granted Fast Track designation from the FDA for development of AV-101 for the adjunctive treatment of MDD and for the treatment of neuropathic pain. However, these designations may not actually lead to faster development or regulatory review or approval processes for AV-101. Further, there is no guarantee the FDA will grant Fast Track designation for AV-101 as a treatment option for other CNS indications or for any of our other product candidates in the future.

The Fast Track designation is a program offered by the FDA, pursuant to certain mandates under the FDA Modernization Act of 1997, designed to facilitate drug development and to expedite the review of new drugs that are intended to treat serious or life threatening conditions. Compounds selected must demonstrate the potential to address unmet medical needs. The FDA's Fast Track designation allows for close and frequent interaction with the FDA. A designated Fast Track drug may also be considered for priority review with a shortened review time, rolling submission, and accelerated approval if applicable. The designation does not, however, guarantee FDA approval or expedited approval of any application for the product candidate.

In December 2017, the FDA granted Fast Track designation for development of AV-101 for the adjunctive treatment of MDD in patients with an inadequate response to current antidepressants. In September 2018, the FDA granted Fast Track designation for development of AV-101 for the treatment of neuropathic pain. However, these FDA Fast Track designations may not lead to a faster development or regulatory review or approval process for AV-101 and the FDA may withdraw Fast Track designation of AV-101 for either or both indications if it believes that the respective designation is no longer supported by data from our clinical development programs.

In addition, we may apply for Fast Track designation for AV-101 as a treatment option for other CNS indications, as well as for other product candidates. The FDA has broad discretion whether or not to grant a Fast Track designation, and even if we believe AV-101 and other product candidates may be eligible for this designation, we cannot be sure that the review or approval will compare to conventional FDA procedures.

Results of earlier clinical trials may not be predictive of the results of later-stage clinical trials.

The results of preclinical studies and early clinical trials of AV-101, PH94B, PH10 and/or our other product candidates, if any, including positive results, may not be predictive of the results of later-stage clinical trials. AV-101,

PH94B, PH10 or other product candidates in later stages of clinical development may fail to show the desired safety and efficacy results despite having progressed through nonclinical studies and initial clinical trials. Many companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to adverse safety profiles or lack of efficacy, notwithstanding promising results in earlier studies. Similarly, our future clinical trial results may not be successful for these or other reasons.

Moreover, nonclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in nonclinical studies and clinical trials nonetheless failed to obtain FDA approval. With respect to our current product candidates, we have not yet completed a Phase 2 clinical trial for AV-101, and if the NIMH Study and/or our ELEVATE Study, or any future clinical study of AV-101, or if one or more of the future Phase 3 clinical trials of PH94B for SAD or future Phase 2 clinical trial of PH10 for MDD, fail(s) to produce positive results, the development timeline and regulatory approval and commercialization prospects for AV-101, PH94B, or PH10 and, correspondingly, our business and financial prospects, could be materially adversely affected.

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This drug candidate development risk is heightened by any changes in planned timing or nature of clinical trials compared to completed clinical trials. As product candidates are developed through preclinical to early- and late-stage clinical trials towards regulatory approval and commercialization, it is customary that various aspects of the development program, such as manufacturing and methods of administration, are altered along the way in an effort to optimize processes and results. While these types of changes are common and are intended to optimize the product candidates for later stage clinical trials, approval and commercialization, such changes do carry the risk that they will not achieve these intended objectives.

For example, the results of planned clinical trials may be adversely affected if we or our collaborator seek to optimize and scale-up production of a product candidate. In such case, we will need to demonstrate comparability between the newly manufactured drug substance and/or drug product relative to the previously manufactured drug substance and/or drug product. Demonstrating comparability may cause us to incur additional costs or delay initiation or completion of our clinical trials, including the need to initiate a dose escalation study and, if unsuccessful, could require us to complete additional nonclinical or clinical studies of our product candidates.

If serious adverse events or other undesirable side effects or safety concerns attributable to AV-101 are identified during the NIMH Study, Baylor Study, other investigator-sponsored clinical trials, in our clinical trials of AV-101, including our ELEVATE study, or our clinical trials of PH94B or PH10, it may adversely affect or delay our clinical development and commercialization of AV-101, PH94B or PH10.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA. AV-101 is currently being tested by the NIMH in the NIMH Study and by Baylor in the Baylor Study and may be subjected to testing in the future for other CNS indications in additional investigator-sponsored clinical trials. If serious adverse events or other undesirable side effects or safety concerns, or unexpected characteristics attributable to AV-101 are observed in the NIMH Study, Baylor Study, other investigator-sponsored clinical trials of AV-101, our clinical trials of AV-101, including our ELEVATE Study, or in our clinical trials of PH94B or PH10, it may adversely affect or delay our clinical development and commercialization of AV-101, PH94B or PH10, and the occurrence of these events could have a material adverse effect on our business and financial prospects. Results of our future clinical trials could reveal a high and unacceptable severity and prevalence of adverse side effects. In such an event, our trials could be suspended or terminated and the FDA could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims.

Additionally, if any of our product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by these product candidates, a number of potentially significant negative consequences could result, including:

regulatory authorities may withdraw, suspend, or limit approvals of such product and require us to take them off the market;

regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;

regulatory authorities may require a medication guide outlining the risks of such side effects for distribution to patients, or that we implement a REMS plan to ensure that the benefits of the product outweigh its risks;

we may be required to change the way a product is distributed or administered, conduct additional clinical trials or change the labeling of a product;

we may be required to conduct additional post-marketing studies or surveillance;

we may be subject to limitations on how we may promote the product;

sales of the product may decrease significantly;

we may be subject to regulatory investigations, government enforcement actions, litigation or product liability claims; and

our products may become less competitive or our reputation may suffer.

Any of these events could prevent us or any collaborators from achieving or maintaining market acceptance of our product candidates or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of our product candidates.

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Failures or delays in the commencement or completion of our planned clinical trials and nonclinical studies of AV-101, PH94B, PH10 or other our product candidates could result in increased costs to us and could delay, prevent or limit our ability to generate revenue and continue our business.

We will need to complete our ELEVATE Study, at least two pivotal Phase 3 clinical trials, additional toxicology and other standard nonclinical and clinical safety studies, as well as certain standard smaller clinical studies prior to the submission of an NDA to the FDA for AV-101 as an adjunctive treatment for MDD in patients with an inadequate response to current antidepressants, or any other CNS indication. Similarly, we will need to complete at least two pivotal Phase 3 clinical studies of PH94B, additional toxicology and other standard nonclinical and clinical safety studies, as well as certain standard smaller clinical studies prior to our submission of an NDA for PH94B as an on demand treatment for SAD. For PH10, we will need to complete at least one additional Phase 2 clinical study, two pivotal Phase 3 clinical trials, additional toxicology and other standard nonclinical and clinical safety studies, as well as certain standard smaller clinical studies prior to the submission of an NDA to the FDA for PH10 as treatment for MDD, or any other CNS indication. Successful completion of our nonclinical and clinical trials is a prerequisite to submitting an NDA to the FDA and, consequently, the ultimate approval required before commercial marketing of any product candidate we may develop. Except as disclosed herein, we do not know whether the NIMH Study, Baylor Study, our ELEVATE Study or any of our future-planned nonclinical and clinical trials of AV-101, PH94B, PH10 or any other product candidate will be completed on schedule, if at all, as the commencement and completion of nonclinical and clinical trials can be delayed or prevented for a number of reasons, including, among others:

- the FDA may deny permission to proceed with planned clinical trials or any other clinical trials we may initiate, or may place a planned or ongoing clinical trial on hold;
- delays in filing or receiving approvals from the FDA of additional Investigational New Drug applications (INDs) that may be required;
- negative results from nonclinical or clinical studies;
- delays in reaching or failing to reach agreement on acceptable terms with prospective CROs, investigators and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, investigators and clinical trial sites;
- delays in the manufacturing of, or insufficient supply of product candidates necessary to conduct nonclinical or clinical trials, including delays in the manufacturing of sufficient supply of drug substance or finished drug product;
- inability to manufacture or obtain clinical supplies of a product candidate meeting required quality standards;
- difficulties obtaining Institutional Review Board (IRB) approval to conduct a clinical trial at a prospective clinical site or sites;
- challenges in recruiting and enrolling patients to participate in clinical trials, including the proximity of patients to clinical trial sites;
- eligibility criteria for a clinical trial, the nature of a clinical trial protocol, the availability of approved effective treatments for the relevant disease and competition from other clinical trial programs for similar indications;
- severe or unexpected adverse drug-related side effects experienced by patients in a clinical trial;

delays in validating any endpoints utilized in a clinical trial;

the FDA may disagree with our clinical trial design and our interpretation of data from prior nonclinical studies or clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials;

reports from nonclinical or clinical testing of other CNS indications or therapies that raise safety or efficacy concerns; and

difficulties retaining patients who have enrolled in a clinical trial but may be prone to withdraw due to rigors of the clinical trial, lack of efficacy, side effects, personal issues or loss of interest.

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Clinical trials may also be delayed or terminated prior to completion as a result of ambiguous or negative interim results. In addition, a clinical trial may be suspended or terminated by us, the FDA, the IRBs at the sites where the IRBs are overseeing a clinical trial, a data and safety monitoring board (DSMB), overseeing the clinical trial at issue or other regulatory authorities due to a number of factors, including, among others:

- failure to conduct the clinical trial in accordance with regulatory requirements or approved clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities that reveals deficiencies or violations that require us to undertake corrective action, including the imposition of a clinical hold;
- unforeseen safety issues, including any that could be identified in nonclinical carcinogenicity studies, adverse side effects or lack of effectiveness;
- changes in government regulations or administrative actions;
- problems with clinical supply materials that may lead to regulatory actions; and
- lack of adequate funding to continue nonclinical or clinical studies.

Changes in regulatory requirements, FDA guidance or unanticipated events during our nonclinical studies and clinical trials of AV-101, PH94B, PH10 or other product candidates may occur, which may result in changes to nonclinical studies and clinical trial protocols or additional nonclinical studies and clinical trial requirements, which could result in increased costs to us and could delay our development timeline.

Changes in regulatory requirements, FDA guidance or unanticipated events during our nonclinical studies and clinical trials of AV-101, PH94B, PH10 or other product candidates may force us to amend nonclinical studies and clinical trial protocols or the FDA may impose additional nonclinical studies and clinical trial requirements. Amendments or changes to our clinical trial protocols would require resubmission to the FDA and IRBs for review and approval, which may adversely impact the cost, timing or successful completion of clinical trials. Similarly, amendments to our nonclinical studies may adversely impact the cost, timing, or successful completion of those nonclinical studies. If we experience delays completing, or if we terminate, any of our nonclinical studies or clinical trials, or if we are required to conduct additional nonclinical studies or clinical trials, the commercial prospects for AV-101, PH94B, PH10 or other product candidates may be harmed and our ability to generate product revenue will be delayed.

We rely, and expect that we will continue to rely, on third parties to conduct our nonclinical and clinical trials of our current product candidates and will continue to do so for any other product candidates. If these third parties do not successfully carry out their contractual duties and/or meet expected deadlines, completion of our nonclinical or clinical trials and development of AV-101, PH94B, PH10 or other product candidates may be delayed and we may not be able to obtain regulatory approval for or commercialize AV-101, PH94B, PH10 or other product candidates and our business could be substantially harmed.

We do not have the internal staff resources to independently conduct nonclinical and clinical trials of our product candidates completely on our own. We rely on our network of strategic relationships with various academic research centers, medical institutions, nonclinical and clinical investigators, contract laboratories and other third parties, such as CROs, to assist us to conduct and complete nonclinical and clinical trials of our product candidates. We enter into agreements with third-party CROs to provide monitors for and to manage data for our clinical trials, as well as provide other services necessary to prepare for, conduct and complete clinical trials. We rely heavily on these and other third-parties for execution of nonclinical and clinical trials for our product candidates and we control only certain

aspects of their activities. As a result, we have less direct control over the conduct, timing and completion of these nonclinical and clinical trials and the management of data developed through nonclinical and clinical trials than would be the case if we were relying entirely upon our own internal staff resources. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties and/or undertake obligations beyond their anticipated capabilities and resources;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- undergo changes in priorities or become financially distressed; or
- form relationships with other entities, some of which may be our competitors.

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These factors may materially adversely affect the willingness or ability of third parties to conduct our nonclinical and clinical trials and may subject us to unexpected cost increases that are beyond our control. Nevertheless, we are responsible for ensuring that each of our nonclinical studies and clinical trials is conducted and completed in accordance with the applicable protocol, legal, regulatory and scientific requirements and standards, and our reliance on CROs, the NIMH, Baylor or other independent investigators does not relieve us of our regulatory responsibilities. We and our CROs, the NIMH, Baylor and any investigator in an investigator-sponsored study are required to comply with regulations and guidelines, including current Good Clinical Practice regulations (cGCPs) for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial patients are adequately informed of the potential risks of participating in clinical trials. These regulations are enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for any products in clinical development. The FDA enforces cGCP regulations through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we, any of our CROs or any of our third-party collaborators fail to comply with applicable cGCPs, the clinical data generated in clinical trials involving our product candidates may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply with cGCPs. In addition, our clinical trials must be conducted with product candidates produced under cGMPs and will require a large number of test patients. Our failure or the failure of our CROs or other third-party collaborators to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action up to and including civil and criminal penalties.

Although we design our clinical trials for our product candidates, our clinical development strategy involves having CROs and other third-party investigators and medical institutions conduct clinical trials of our product candidates. As a result, many important aspects of our drug development programs are outside of our direct control. In addition, although CROs, or independent investigators or medical institutions, as the case may be, may not perform all of their obligations under arrangements with us or in compliance with applicable regulatory requirements, under certain circumstances, we may be responsible and subject to enforcement action that may include civil penalties up to and including criminal prosecution for any violations of FDA laws and regulations during the conduct of clinical trials of our product candidates. If such third parties do not perform clinical trials of our product candidates in a satisfactory manner, breach their obligations to us or fail to comply with applicable regulatory requirements, the development and commercialization of our product candidates may be delayed or our development program materially and irreversibly harmed. In certain cases, including the NIMH Study, Baylor Study and other investigator-sponsored clinical studies, we cannot control the amount and timing of resources these third-parties devote to clinical trials involving our product candidates. If we are unable to rely on nonclinical and clinical data collected by our third-party collaborators, we could be required to repeat, extend the duration of, or increase the size of our clinical trials and this could significantly delay commercialization and require significantly greater expenditures.

If our relationships with one or more of our third-party collaborators terminates, we may not be able to enter into arrangements with alternative third-party collaborators. If such third-party collaborators, including our CROs, the NIMH, Baylor or the VA do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to applicable clinical protocols, regulatory requirements or for other reasons, any clinical trials that such third-parties are associated with may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully develop and commercialize our product candidates. As a result, we believe that our financial results and the commercial prospects for our product candidates in the subject indication would be harmed, our costs would increase and our ability to generate revenue would be delayed.

We rely completely on third-parties to manufacture, formulate, hold and distribute supplies of our product candidates for all nonclinical and clinical studies, and we intend to continue to rely on third parties to produce all nonclinical, clinical and commercial supplies of our product candidates in the future.

We do not currently have, nor do we plan to acquire or develop, any internal infrastructure or technical capabilities to manufacture, formulate, hold or distribute supplies of our product candidates, for use in nonclinical and clinical studies or commercial scale. As a result, with respect to our product candidates, we rely, and will continue to rely, completely on contract manufacturing organizations (CMOs) to manufacture active pharmaceutical ingredient (API) and formulate, hold and distribute final drug product. The facilities used by our CMOs to manufacture AV-101, PH94B and PH10 API and AV-101, PH94B and PH10 final drug product are subject to a pre-approval inspection by the FDA and other comparable foreign regulatory agencies to assess compliance with applicable regulatory guidelines and requirements, including cGMPs, and may be required to undergo similar inspections by the FDA or other comparable foreign regulatory agencies, after we submit INDs, NDAs or relevant foreign regulatory submission equivalent to the applicable regulatory agency.

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We do not directly control the manufacturing process or the supply or quality of materials used in the manufacturing and formulation of our product candidates, and, with respect to all of our product candidates, we are completely dependent on our CMOs to comply with all applicable cGMPs for the manufacturing of both API and finished drug product. If our CMOs cannot secure adequate supplies of suitable raw materials or successfully manufacture our product candidates, including AV-101, PH94B and PH10 API and finished drug product, that conforms to our specifications and the strict regulatory requirements of the FDA or applicable foreign regulatory agencies, production of sufficient supplies of our product candidates, including AV-101, PH94B and PH10 API and finished drug product, may be delayed and our CMOs may not be able to secure and/or maintain regulatory approval for their manufacturing facilities, or the FDA may take other actions, including the imposition of a clinical hold. In addition, we have no direct control over our CMOs' ability to maintain adequate quality control, quality assurance and qualified personnel. All of our CMOs are engaged with other companies to supply and/or manufacture materials or products for such other companies, which exposes our CMOs to regulatory risks for the production of such materials and products. As a result, failure to satisfy the regulatory requirements for the production of those materials and products may affect the regulatory clearance of our CMO's facilities generally or affect the timing of manufacture of AV-101, PH94B and PH10 for required or planned nonclinical and/or clinical studies. If the FDA or an applicable foreign regulatory agency determines now or in the future that our CMOs' facilities are noncompliant, we may need to find alternative manufacturing facilities, which would adversely impact our ability to develop, obtain regulatory approval for or market our product candidates. Our reliance on CMOs also exposes us to the possibility that they, or third parties with access to their facilities, will have access to and may appropriate our trade secrets or other proprietary information.

With respect to AV-101, PH94B and PH10, we do not yet have long-term supply agreements in place with our CMOs and each batch of AV-101, PH94B and PH10 is or will be individually contracted under a separate supply agreement. If we engage new CMOs, such contractors must complete an inspection by the FDA and other applicable foreign regulatory agencies. We plan to continue to rely upon CMOs and, potentially, collaboration partners, to manufacture research and development scale, and, if approved, commercial quantities of our product candidates. Although we believe our current scale of API manufacturing for AV-101, and our contemplated scale of API manufacturing for PH94B and PH10, and the current and projected supply of AV-101, PH94B and PH10 API and finished drug product will be adequate to support our planned nonclinical and clinical studies of AV-101, PH94B and PH10, no assurance can be given that unanticipated supply shortages or CMO-related delays in the manufacture and formulation of AV-101, PH94B or PH10 API and/or finished drug product will not occur in the future.

Additionally, certain of our product candidates, including PH94B and PH10, may be considered drug-device combination products. Third-party manufacturers may not be able to comply with cGMP requirements applicable to drug/device combination products, including applicable provisions of the FDA's drug cGMP regulations, device cGMP requirements embodied in the Quality System Regulation (QSR) or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly affect supplies of our product candidates. The facilities used by our CMOs to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our CMO partners for compliance with cGMPs and QSRs. If our CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory

approval for or market our product candidates, if approved. CMOs may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP and QSR requirements. Any failure to comply with cGMP or QSR requirements or other FDA, EMA and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products following approval.

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Even if we receive marketing approval for AV-101, PH94B, PH10 or any other product candidate in the United States, we may never receive regulatory approval to market AV-101, PH94B, PH10 or any other product candidate outside of the United States.

We have not yet selected any markets outside of the United States where we intend to seek regulatory approval to market AV-101, PH94B, PH10 or any other product candidate. In order to market AV-101, PH94B, PH10 or any other product candidate outside of the United States, we must establish and comply with the numerous and varying safety, efficacy and other regulatory requirements of other countries. Approval procedures vary among countries and can involve additional product candidate testing and additional administrative review periods. The time required to obtain approvals in other countries might differ from that required to obtain FDA approval. The marketing approval processes in other countries may implicate all of the risks detailed above regarding FDA approval in the United States as well as other risks. In particular, in many countries outside of the United States, products must receive pricing and reimbursement approval before the product can be commercialized. Obtaining this approval can result in substantial delays in bringing products to market in such countries. Marketing approval in one country does not ensure marketing approval in another, but a failure or delay in obtaining marketing approval in one country may have a negative effect on the regulatory process in others. Failure to obtain marketing approval in other countries or any delay or other setback in obtaining such approval would impair our ability to market our product candidates in such foreign markets. Any such impairment would reduce the size of our potential market, which could have a material adverse impact on our business, results of operations and prospects.

If any of our product candidates are ultimately regulated as controlled substances, we, our CMOs, as well as future distributors, prescribers, and dispensers will be required to comply with additional regulatory requirements which could delay the marketing of our product candidates, and increase the cost and burden of manufacturing, distributing, dispensing, and prescribing our product candidates.

Before we can commercialize our product candidates, the United States Drug Enforcement Administration (DEA) may need to determine whether such product candidates will be considered to be a controlled substance, taking into account the recommendation of the FDA. This may be a lengthy process that could delay our marketing of a product candidate and could potentially diminish any regulatory exclusivity periods for which we may be eligible, which would increase the cost associated with commercializing such products and, in turn, may have an adverse impact on our results of operations. Although we currently do not know whether the DEA will consider any of our current or future product candidate to be controlled substances, we cannot yet give any assurance that such product candidates, including AV-101, will not be regulated as controlled substances.

If any of our product candidates are regulated as controlled substances, depending on the DEA controlled substance schedule in which the product candidates are placed, we, our CMOs, and any future distributers, prescribers, and dispensers of the scheduled product candidates may be subject to significant regulatory requirements, such as registration, security, recordkeeping, reporting, storage, distribution, importation, exportation, inventory, quota and other requirements administered by the DEA. Moreover, if any of our product candidates are regulated as controlled substances, we and our CMOs would be subject to initial and periodic DEA inspection. If we or our CMOs are not able to obtain or maintain any necessary DEA registrations, we may not be able to commercialize any product candidates that are deemed to be controlled substances or we may need to find alternative CMOs, which would take time and cause us to incur additional costs, delaying or limit our commercialization efforts.

Because of their restrictive nature, these laws and regulations could limit commercialization of our product candidates, should they be deemed to contain controlled substances. Failure to comply with the applicable controlled substance laws and regulations can also result in administrative, civil or criminal enforcement. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate administrative proceedings to revoke those registrations.

In some circumstances, violations could result in criminal proceedings or consent decrees. Individual states also independently regulate controlled substances.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate any revenue.

We do not currently have any internal resources for the sale, marketing and distribution of pharmaceutical products, and we may not create such internal capabilities in the foreseeable future. Therefore, to market our product candidates, if approved by the FDA or any other regulatory body, we must make contractual arrangements with third parties to perform services related to sales, marketing, managerial and other non-technical capabilities relating to the commercialization of our product candidates, or establish those capabilities prior to market approval. If we are unable to establish adequate contractual arrangements for such sales, marketing and distribution capabilities, or if we are unable to do so on commercially reasonable terms, or if we are unable to establish such capabilities on our own, our business, results of operations, financial condition and prospects will be materially adversely affected.

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Even if we receive marketing approval for our product candidates, our product candidates may not achieve broad market acceptance, which would limit the revenue that we generate from their sales.

The commercial success of our product candidates, if approved by the FDA or other applicable regulatory authorities, will depend upon the awareness and acceptance of our product candidates among the medical community, including physicians, patients and healthcare payors. Market acceptance of our product candidates, if approved, will depend on a number of factors, including, among others:

- the efficacy and safety of our product candidates as demonstrated in clinical trials, and, if required by any applicable regulatory authority in connection with the approval for the applicable indications, to provide patients with incremental health benefits, as compared with other available therapies;
- limitations or warnings contained in the labeling approved for our product candidates by the FDA or other applicable regulatory authorities;
- the clinical indications for which our product candidates are approved;
- availability of alternative treatments already approved or expected to be commercially launched in the near future;
- the potential and perceived advantages of our product candidates over current treatment options or alternative treatments, including future alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments;
- pricing and cost effectiveness;
- the effectiveness of our sales and marketing strategies;
- our ability to increase awareness of our product candidates through marketing efforts;
- our ability to obtain sufficient third-party coverage or reimbursement; or
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage.

If our product candidates are approved but do not achieve an adequate level of acceptance by patients, physicians and payors, we may not generate sufficient revenue from our product candidates to become or remain profitable. Before granting reimbursement approval, healthcare payors may require us to demonstrate that our product candidates, in addition to treating these target indications, also provide incremental health benefits to patients. Our efforts to educate the medical community and third-party payors about the benefits of our product candidates may require significant resources and may never be successful.

Our product candidates may cause undesirable safety concerns and side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable safety concerns and side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt nonclinical studies and clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities.

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Further, clinical trials by their nature utilize a sample of potential patient populations. With a limited number of patients and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate. If our product candidates receive marketing approval and we or others identify undesirable safety concerns or side effects caused by such product candidates (or any other similar products) after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such product candidates;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- we may be required to change the way such product candidates are distributed or administered, conduct additional clinical trials or change the labeling of the product candidates;
- we may be subject to regulatory investigations and government enforcement actions;
- we may decide to remove such product candidates from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking our product candidates; and
- our reputation may suffer.

We believe that any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidates and would substantially increase the costs of commercializing our product candidates and significantly impact our ability to successfully commercialize our product candidates and generate revenues.

Even if we receive marketing approval for our product candidates, we may still face future development and regulatory difficulties.

Even if we receive marketing approval for our product candidates, regulatory authorities may still impose significant restrictions on our product candidates, indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies. Our product candidates will also be subject to ongoing regulatory requirements governing the labeling, packaging, storage and promotion of the product and record keeping and submission of safety and other post-market information. The FDA has significant post-marketing authority, including, for example, the authority to require labeling changes based on new safety information and to require post-marketing studies or clinical trials to evaluate serious safety risks related to the use of a drug. The FDA also has the authority to require, as part of an NDA or post-approval, the submission of a REMS safety program. Any REMS safety program required by the FDA may lead to increased costs to assure compliance with new post-approval regulatory requirements and potential requirements or restrictions on the sale of approved products, all of which could lead to lower sales volume and revenue.

Manufacturers of drug and device products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMPs and other regulations. If we or a regulatory agency discover problems with our product candidates, such as adverse events of unanticipated severity or frequency, or problems with the facility where our product candidates are manufactured, a regulatory agency may impose restrictions on our product candidates, the manufacturer or us, including requiring withdrawal of our product candidates from the market or suspension of manufacturing. If we, our product candidates, or the manufacturing

facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may, among other things:

- issue warning letters or untitled letters;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw marketing approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications submitted by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products, or require that we initiate a product recall.

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Competing therapies could emerge adversely affecting our opportunity to generate revenue from the sale of our product candidates.

The pharmaceutical industry is highly competitive. There are many public and private pharmaceutical companies, universities, governmental agencies and other research organizations actively engaged in the research and development of product candidates that may be similar to and compete with our product candidates or address similar markets. It is probable that the number of companies seeking to develop product candidates similar to and competitive with our product candidates will increase.

Currently, management is unaware of any FDA-approved oral adjunctive therapy for MDD patients with an inadequate response to standard antidepressants having the same mechanism of action and safety profile as our orally administered AV-101 or our intranasally-administered PH10. However, new antidepressant products with other mechanisms of action or products approved for other indications, including the FDA-approved anesthetic ketamine hydrochloride administered intravenously, are being or may be used off-label for treatment of MDD, as well as other CNS indications for which AV-101 or PH10 may have therapeutic potential. Additionally, other non-pharmaceutical treatment options, such psychotherapy and electroconvulsive therapy (ECT) are used before or instead of standard antidepressant medications to treat patients with MDD. Management is also unaware of any FDA-approved rapid-onset, on-demand treatment for SAD having the same mechanism of action and safety profile as our PH94B.

In the field of new generation, oral adjunctive treatments for adult patients with MDD with an inadequate response to standard FDA-approved antidepressants, we believe our principal competitor may be Allergan's AGN-241751. Additional potential competitors may include, but not be limited to, academic and private commercial clinics providing intravenous ketamine therapy on an off-label basis, Alkermes' oral opioid system modulator ALKS-5461, Allergan's intravenous peptide rapastinel, and Johnson & Johnson/Janssen's intranasally-administered esketamine. With respect to PH94B and current FDA-approved treatment options for SAD, our competition may include, but is not limited to, certain current generic antidepressants approved by the FDA for treatment of SAD and certain classes of drugs used on an off-label basis for SAD, including benzodiazapines such as alprazolam, and beta blockers such as propranolol.

Many of our potential competitors, alone or with their strategic partners, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery, and development of product candidates, obtaining FDA and other regulatory approvals of treatments and the commercialization of those treatments. With respect to AV-101 and PH10, we believe that a range of pharmaceutical and biotechnology companies have programs to develop drug candidates for the treatment of depression, including MDD, Parkinson's disease levodopa-induced dyskinesia, neuropathic pain, epilepsy, and other neurological conditions and diseases, including, but not limited to, Abbott Laboratories, Acadia, Allergan, Alkermes, Aptynix, AstraZeneca, Eli Lilly, GlaxoSmithKline, IntraCellular, Johnson & Johnson/Janssen, Lundbeck, Merck, Novartis, Ono, Otsuka, Pfizer, Roche, Sage, Sumitomo Dainippon, and Takeda, as well as any affiliates of the foregoing companies. With respect to PH94B, in addition to potential competition from certain current FDA-approved antidepressants and off-label use of benzodiazepines and beta blockers, we believe additional drug candidates in development for SAD may include, but potentially not be limited to, an oral fatty acid amide hydrolase inhibitor in development by Johnson & Johnson/Janssen and a sublingual formulation of the sodium channel blocker riluzole in development by Biohaven. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

We may seek to establish collaborations, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our drug development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. For some of our product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of nonclinical and clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential markets for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for our product candidate. The terms of any collaboration or other arrangements that we may establish may not be favorable to us.

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We may also be restricted under existing collaboration agreements from entering into future agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

In addition, any future collaboration that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority. Collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation.

We may not be successful in our efforts to identify or discover additional product candidates, or we may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

The success of our business depends primarily upon our ability to identify, develop and commercialize product candidates with commercial and therapeutic potential. Although AV-101 is in Phase 2 clinical development for treatment of MDD, and we are preparing for Phase 2 development of AV-101 for treatment of neuropathic pain and PD LID, for Phase 3 development of PH94B for on-demand treatment of SAD, and a Phase 2 study of PH10 for treatment of MDD, we may fail to pursue additional development opportunities for AV-101, PH94B or PH10, or identify additional product candidates for clinical development for a number of reasons. Our research methodology may be unsuccessful in identifying new product candidates or our product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval.

Because we currently have limited financial and management resources, we necessarily focus on a limited number of research and development programs and product candidates and are currently focused primarily on development of AV-101, PH94B and PH10, with additional limited focus on NCE drug rescue and, through a third-party collaboration, RM. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other potential CNS-related indications for AV-101, PH94B and/or PH10 that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable drugs. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product

candidate through future collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operations. Research and development programs to identify and advance new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful.

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We are subject to healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Although we do not currently have any products on the market, once we begin commercializing our product candidates, we may be subject to additional healthcare statutory and regulatory requirements and enforcement by the federal government and the states and foreign governments in which we conduct our business. Healthcare providers, physicians and others will play a primary role in the recommendation and prescription of our product candidates, if approved. Our future arrangements with third-party payors will expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our product candidates, if we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

The federal anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid.

The federal False Claims Act imposes criminal and civil penalties, including those from civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government.

The federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.

The federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services.

The federal transparency requirements, sometimes referred to as the “Sunshine Act,” under the Patient Protection and Affordable Care Act, require manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children’s Health Insurance Program to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests.

Analogous state laws and regulations, such as state anti-kickback and false claims laws and transparency laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance.

Guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures and drug pricing.

Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could be costly. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations were found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines and exclusion from government funded healthcare programs, such as Medicare and Medicaid, any of which could substantially disrupt our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to be out of compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

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The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. If we are found to have improperly promoted off-label uses, we may become subject to significant liability.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as AV-101, PH94B and PH10, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. For example, if we receive FDA marketing approval for AV-101 as an adjunctive treatment of MDD, physicians may prescribe AV-101 to their patients in a manner that is inconsistent with the FDA-approved label. However, if we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper off-label promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or imposed permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Even if approved, reimbursement policies could limit our ability to sell our product candidates.

Market acceptance and sales of our product candidates will depend heavily on reimbursement policies and may be affected by healthcare reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels for those medications. Cost containment is a primary concern in the United States healthcare industry and elsewhere. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that reimbursement will be available for our product candidates and, if reimbursement is available, the level of such reimbursement. Reimbursement may impact the demand for, or the price of, our product candidates. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates.

In some foreign countries, particularly in Canada and European countries, the pricing of prescription pharmaceuticals is subject to strict governmental control. In these countries, pricing negotiations with governmental authorities can take six months or longer after the receipt of regulatory approval and product launch. To obtain favorable reimbursement for the indications sought or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidates with other available therapies. If reimbursement for our product candidates is unavailable in any country in which we seek reimbursement, if it is limited in scope or amount, if it is conditioned upon our completion of additional clinical trials, or if pricing is set at unsatisfactory levels, our operating results could be materially adversely affected.

We may seek FDA Orphan Drug designation for one or more of our product candidates. Even if we have obtained FDA Orphan Drug designation for a product candidate, there may be limits to the regulatory exclusivity afforded by such designation.

We may, in the future, choose to seek FDA Orphan Drug designation for one or more of our current or future product candidates. Even if we obtain Orphan Drug designation from the FDA for a product candidate, there are limitations to the exclusivity afforded by such designation. In the U.S., the company that first obtains FDA approval for a designated orphan drug for the specified rare disease or condition receives orphan drug marketing exclusivity for that drug for a period of seven years. This orphan drug exclusivity prevents the FDA from approving another application, including a full NDA to market the same drug for the same orphan indication, except in very limited circumstances,

including when the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. For purposes of small molecule drugs, the FDA defines “same drug” as a drug that contains the same active moiety and is intended for the same use as the drug in question. To obtain Orphan Drug status for a drug that shares the same active moiety as an already approved drug, it must be demonstrated to the FDA that the drug is safer or more effective than the approved orphan designated drug, or that it makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition or if another drug with the same active moiety is determined to be safer, more effective, or represents a major contribution to patient care.

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Our future growth may depend, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability may depend, in part, on our ability to commercialize our product candidates in foreign markets for which we may rely on collaboration with third parties. If we commercialize our product candidates in foreign markets, we would be subject to additional risks and uncertainties, including:

- our customers' ability to obtain reimbursement for our product candidates in foreign markets;
- our inability to directly control commercial activities because we are relying on third parties;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights, different standards of patentability and different availability of prior art in some foreign countries as compared with the U.S.;
- the existence of additional potentially relevant third party intellectual property rights;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of our product candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs.

We are a development stage biopharmaceutical company with no current revenues or approved products, and limited experience developing new therapeutic product candidates, including conducting clinical trials and other areas required for the successful development and commercialization of therapeutic products, which makes it difficult to assess our future viability.

We are a development stage biopharmaceutical company. Although we have one drug candidate in Phase 2 development and are preparing to advance another drug candidate into Phase 2 development and a third drug candidate into pivotal Phase 3 clinical trials, we currently have no approved products and currently generate no revenues, and we have not yet fully demonstrated an ability to overcome many of the fundamental risks and uncertainties frequently encountered by development stage companies in new and rapidly evolving fields of technology, particularly biotechnology. To execute our business plan successfully, we will need to accomplish the following fundamental objectives, either on our own or with collaborators:

develop and obtain required regulatory approvals for commercialization of AV-101, PH94B, PH10 and/or other product candidates;

maintain, leverage and expand our intellectual property portfolio;

establish and maintain sales, distribution and marketing capabilities, and/or enter into strategic partnering arrangements to access such capabilities;

gain market acceptance for our product candidates; and

obtain adequate capital resources and manage our spending as costs and expenses increase due to research, production, development, regulatory approval and commercialization of product candidates.

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Our future success is highly dependent upon our ability to successfully develop and commercialize any of our current product candidates, acquire or license additional product candidates, or discover, as well as produce, develop and commercialize proprietary drug rescue NCEs using our stem cell technology, and we cannot provide any assurance that we will successfully develop and commercialize AV-101, PH94B, PH10 or acquire or license additional product candidates or discover and develop drug rescue NCEs, or that, if produced, AV-101, PH94B, PH10 or any other product candidate will be successfully commercialized.

Business development and research and development programs designed to identify, acquire or license additional product candidates, or, as the case may be, produce drug rescue NCEs require substantial technical, financial and human resources, whether or not any additional product candidate is acquired or licensed or NCEs are ultimately identified and produced.

In addition, we do not have a sales or marketing infrastructure, and we, including our executive officers, do not have any significant pharmaceutical sales, marketing or distribution experience. We may seek to collaborate with others to develop and commercialize AV-101, PH94B, PH10, drug rescue NCEs and/or other product candidates if and when they are acquired and developed, or we may seek to establish those commercial capabilities ourselves. If we enter into arrangements with third parties to perform sales, marketing and distribution services for our products, the resulting revenues or the profitability from these revenues to us are likely to be lower than if we had sold, marketed and distributed our products ourselves. In addition, we may not be successful entering into arrangements with third parties to sell, market and distribute AV-101, PH94B, PH10, any drug rescue NCEs or other product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of these third parties may fail to devote the necessary resources and attention to sell, market and distribute our products effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

We have limited operating history with respect to drug development, including our anticipated focus on the identification and acquisition of additional product candidates or the assessment of potential drug rescue NCEs and no operating history with respect to the production of drug rescue NCEs, and we may never be able to produce a drug rescue NCE.

If we are unable to develop and commercialize AV-101, PH94B, PH10 or acquire or license additional product candidates, or produce suitable drug rescue NCEs, we may not be able to generate sufficient revenues to execute our business plan, which likely would result in significant harm to our financial position and results of operations, which could adversely impact our stock price.

With respect to drug rescue, there are a number of factors, in addition to the utility of CardioSafe 3D, that may impact our ability to identify and produce, develop or out-license and commercialize drug rescue NCEs, independently or with partners, including:

- our ability to identify potential drug rescue candidates in the public domain, obtain sufficient quantities of them, and assess them using our bioassay systems;
- if we seek to rescue drug rescue candidates that are not available to us in the public domain, the extent to which third parties may be willing to out-license or sell certain drug rescue candidates to us on commercially reasonable terms;
- our medicinal chemistry collaborator’s ability to design and produce proprietary drug rescue NCEs based on the novel biology and structure-function insight we provide using CardioSafe 3D; and

financial resources available to us to develop and commercialize lead drug rescue NCEs internally, or, if we sell or out-license them to partners, the resources such partners choose to dedicate to development and commercialization of any drug rescue NCEs they acquire or license from us.

Even if we do acquire additional product candidates or produce proprietary drug rescue NCEs, we can give no assurance that we will be able to develop and commercialize them as marketable drugs, on our own or in collaboration with others. Before we generate any revenues from AV-101, PH94B, PH10 or additional acquired or licensed products candidates or any drug rescue NCEs, we or our potential collaborators must complete preclinical and clinical development programs, submit clinical and manufacturing data to the FDA, qualify a third party CMO, receive regulatory approval in one or more jurisdictions, satisfy the FDA that our CMO is capable of manufacturing the product in compliance with cGMP, build a commercial organization, make substantial investments and undertake significant marketing efforts ourselves or in partnership with others. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates.

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If CardioSafe 3D fails to predict accurately and efficiently the cardiac effects, both toxic and nontoxic, of drug rescue candidates and drug rescue NCEs, then our drug rescue programs will be adversely affected.

Success of our subsidiary, VistaStem, is partly dependent on our ability to use CardioSafe 3D to identify and predict, accurately and efficiently, the potential toxic and nontoxic cardiac effects of drug rescue candidates and drug rescue NCEs. If CardioSafe 3D is not capable of providing physiologically relevant and clinically predictive information regarding human cardiac biology, our drug rescue business will be adversely affected.

CardioSafe 3D may not be meaningfully more predictive of the behavior of human cells than existing methods.

Although not currently requiring significant investment of capital, the success of our VistaStem drug rescue programs is highly dependent upon CardioSafe 3D being more accurate, efficient and clinically predictive than long-established surrogate safety models, including animal cells and live animals, and immortalized, primary and transformed cells, currently used by pharmaceutical companies and others. We cannot give assurance that CardioSafe 3D will be more efficient or accurate at predicting the heart safety of new drug candidates than the testing models currently used. If CardioSafe 3D fails to provide a meaningful difference compared to existing or new models in predicting the behavior of human heart, respectively, their utility for drug rescue will be limited and our drug rescue business will be adversely affected.

We may invest in producing drug rescue NCEs for which there proves to be no demand.

To generate revenue from our VistaStem drug rescue activities, we must produce proprietary drug rescue NCEs for which there proves to be demand within the healthcare marketplace, and, if we intend to out-license a particular drug rescue NCE for development and commercialization prior to market approval, then also among pharmaceutical companies and other potential collaborators. However, we may produce drug rescue NCEs for which there proves to be no or limited demand in the healthcare market and/or among pharmaceutical companies and others. If we misinterpret market conditions, underestimate development costs and/or seek to rescue the wrong drug rescue candidates, we may fail to generate sufficient revenue or other value, on our own or in collaboration with others, to justify our investments, and our drug rescue business may be adversely affected.

We may experience difficulty in producing human cells and our future stem cell technology research and development efforts may not be successful within the timeline anticipated, if at all.

Our human pluripotent stem cell technology is technically complex, and the time and resources necessary to develop various human cell types and customized bioassay systems, although not significant at present, are difficult to predict in advance. We might decide to devote significant additional personnel and financial resources to research and development activities designed to expand, in the case of drug rescue, and explore, in the case of drug discovery and RM, potential applications of our stem cell technology platform. In particular, we may conduct exploratory nonclinical RM programs involving blood, bone, cartilage, and/or liver cells. Although we and our third-party collaborators have developed proprietary protocols to produce multiple differentiated cell types, we could encounter difficulties in differentiating and producing sufficient quantities of particular cell types, even when following these proprietary protocols. These difficulties could result in delays in production of certain cells, assessment of certain drug rescue candidates and drug rescue NCEs, design and development of certain human cellular assays and performance of certain exploratory non-clinical regenerative medicine studies. In the past, our stem cell research and development projects have been significantly delayed when we encountered unanticipated difficulties in differentiating human pluripotent stem cells into heart and liver cells. Although we have overcome such difficulties in the past, we may have similar delays in the future, and we may not be able to overcome them or obtain any benefits from our future stem cell technology research and development activities. Any delay or failure by us, for example, to produce functional,

mature blood, bone, cartilage, and liver cells could have a substantial and material adverse effect on our potential drug discovery, drug rescue and regenerative medicine business opportunities and results of operations.

Restrictions on research and development involving human embryonic stem cells and religious and political pressure regarding such stem cell research and development could impair our ability to conduct or sponsor certain potential collaborative research and development programs and adversely affect our prospects, the market price of our common stock and our business model.

Some of our research and development programs may involve the use of human cells derived from our controlled differentiation of human embryonic stem cells (hESCs). Some believe the use of hESCs gives rise to ethical and social issues regarding the appropriate use of these cells. Our research related to differentiation of hESCs may become the subject of adverse commentary or publicity, which could significantly harm the market price of our common stock. Although now substantially less than in years past, certain political and religious groups in the United States and elsewhere voice opposition to hESC technology and practices. We may use hESCs derived from excess fertilized eggs that have been created for clinical use in in vitro fertilization (IVF) procedures and have been donated for research purposes with the informed consent of the donors after a successful IVF procedure because they are no longer desired or suitable for IVF. Certain academic research institutions have adopted policies regarding the ethical use of human embryonic tissue. These policies may have the effect of limiting the scope of future collaborative research opportunities with such institutions, thereby potentially impairing our ability to conduct certain research and development in this field that we believe is necessary to expand the drug rescue capabilities of our technology, which would have a material adverse effect on our business.

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The use of embryonic or fetal tissue in research (including the derivation of hESCs) in other countries is regulated by the government, and such regulation varies widely from country to country. Government-imposed restrictions with respect to use of hESCs in research and development could have a material adverse effect on us by harming our ability to establish critical collaborations, delaying or preventing progress in our research and development, and causing a decrease in the market interest in our stock.

The foregoing potential ethical concerns do not apply to our use of induced pluripotent stem cells (iPSCs) because their derivation does not involve the use of embryonic tissues.

We have assumed that the biological capabilities of iPSCs and hESCs are likely to be comparable. If it is discovered that this assumption is incorrect, our exploratory research and development activities focused on potential regenerative medicine applications of our stem cell technology platform could be harmed.

We may use both hESCs and iPSCs to produce human cells for our customized in vitro assays for drug discovery and drug rescue purposes. However, we anticipate that our future exploratory research and development, if any, focused on potential regenerative medicine applications of our stem cell technology platform primarily will involve iPSCs. With respect to iPSCs, we believe scientists are still somewhat uncertain about the clinical utility, life span, and safety of such cells, and whether such cells differ in any clinically significant ways from hESCs. If we discover that iPSCs will not be useful for whatever reason for potential regenerative medicine programs, this would negatively affect our ability to explore expansion of our platform in that manner, including, in particular, where it would be preferable to use iPSCs to reproduce rather than approximate the effects of certain specific genetic variations.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development, or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties, or other sanctions, which could have a material adverse effect on our operations.

To the extent our research and development activities involve using iPSCs, we will be subject to complex and evolving laws and regulations regarding privacy and informed consent. Many of these laws and regulations are subject to change and uncertain interpretation, and could result in claims, changes to our research and development programs and objectives, increased cost of operations or otherwise harm the Company.

To the extent that we pursue research and development activities involving iPSCs, we will be subject to a variety of laws and regulations in the United States and abroad that involve matters central to such research and development activities, including obligations to seek informed consent from donors for the use of their blood and other tissue to produce, or have produced for us, iPSCs, as well as state and federal laws that protect the privacy of such donors. United States federal and state and foreign laws and regulations are constantly evolving and can be subject to significant change. If we engage in iPSC-related research and development activities in countries other than the United States, we may become subject to foreign laws and regulations relating to human-subjects research and other laws and regulations that are often more restrictive than those in the United States. In addition, both the application and interpretation of these laws and regulations are often uncertain, particularly in the rapidly evolving stem cell technology sector. Compliance with these laws and regulations can be costly, can delay or impede our research and development activities, result in negative publicity, increase our operating costs, require significant management time and attention and subject us to claims or other remedies, including fines or demands that we modify or cease existing business practices.

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Legal, social and ethical concerns surrounding the use of iPSCs, biological materials and genetic information could impair our operations.

To the extent that our future stem cell research and development activities involve the use of iPSCs and the manipulation of human tissue and genetic information, the information we derive from such iPSC-related research and development activities could be used in a variety of applications, which may have underlying legal, social and ethical concerns, including the genetic engineering or modification of human cells, testing for genetic predisposition for certain medical conditions and stem cell banking. Governmental authorities could, for safety, social or other purposes, call for limits on or impose regulations on the use of iPSCs and genetic testing or the manufacture or use of certain biological materials involved in our iPSC-related research and development programs. Such concerns or governmental restrictions could limit our future research and development activities, which could have a material adverse effect on our business, financial condition and results of operations.

Our human cellular bioassay systems and human cells we derive from human pluripotent stem cells, although not currently subject to regulation by the FDA or other regulatory agencies as biological products or drugs, could become subject to regulation in the future.

The human cells we produce from hPSCs and our customized bioassay systems using such cells, including CardioSafe 3D, are not currently sold, for research purposes or any other purpose, to biotechnology or pharmaceutical companies, government research institutions, academic and nonprofit research institutions, medical research organizations or stem cell banks, and they are not therapeutic procedures. As a result, they are not subject to regulation as biological products or drugs by the FDA or comparable agencies in other countries. However, if, in the future, we seek to include human cells we derive from hPSCs in therapeutic applications or product candidates, such applications and/or product candidates would be subject to the FDA's pre- and post-market regulations. For example, if we seek to develop and market human cells we produce for use in performing regenerative medicine applications, such as tissue engineering or organ replacement, we would first need to obtain FDA pre-market clearance or approval. Obtaining such clearance or approval from the FDA is expensive, time-consuming and uncertain, generally requiring many years to obtain, and requiring detailed and comprehensive scientific and clinical data. Notwithstanding the time and expense, these efforts may not result in FDA approval or clearance. Even if we were to obtain regulatory approval or clearance, it may not be for the uses that we believe are important or commercially attractive.

Risks Related to Our Financial Position

We have incurred significant net losses since inception and we will continue to incur substantial operating losses for the foreseeable future. We may never achieve or sustain profitability, which would depress the market price of our common stock and could cause you to lose all or a part of your investment.

We have incurred significant net losses in each fiscal year since our inception in 1998, including net losses of $14.3 million and $10.3 million during the fiscal years ended March 31, 2018 and 2017, respectively. We incurred a net loss of approximately $18.9 million in the nine months ended December 31, 2018, and, as of that date, we had an accumulated deficit of approximately $175.4 million. We do not know whether or when we will become profitable. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to incur increasing levels of operating losses over the next several years and for the foreseeable future. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity (deficit) and working capital. We expect our research and development expenses to significantly increase in connection with nonclinical studies and clinical trials of our product candidates. In addition, if we obtain marketing approval for our product candidates, we may incur significant sales, marketing and outsourced-manufacturing

expenses should we elect not to collaborate with one or more third parties for such services and capabilities. As a public company, we incur additional costs associated with operating as a public company. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

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Our ability to become profitable depends upon our ability to generate revenues. To date, we have generated approximately $17.7 million in revenues, including receipt of non-dilutive cash payments from collaborators, sublicense revenue, and research and development grant awards from the NIH, however not including the fair market value of the NIMH Study sponsored and conducted by the NIMH under our NIMH CRADA, or the Baylor Study being conducted by Baylor. We have not yet commercialized any product or generated any revenues from product sales, and we do not know when, or if, we will generate any revenue from product sales. We do not expect to generate significant revenue unless and until we obtain marketing approval of, and begin to experience sales of, AV-101, PH94B, PH10 or another product candidate, or we enter into one or more development and commercialization agreements with respect to AV-101, PH94B, PH10 or one or more other product candidates. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- initiate and successfully complete nonclinical and clinical trials that meet their prescribed endpoints;
- initiate and successfully complete all safety studies required to obtain United States and foreign marketing approval for our product candidates;
- timely complete and compose successful regulatory submissions such as NDAs or comparable documents for both United States and foreign jurisdictions;
- commercialize our product candidates, if approved, by developing a sales force or entering into collaborations with third parties for sales and marketing capabilities; and
- achieve market acceptance of our product candidates in the medical community and with third-party payors.

Unless we enter into a commercialization collaboration or partnership with respect to the commercialization of our product candidates, we expect to incur significant sales and marketing costs as we prepare to commercialize our product candidates. Even if we initiate and successfully complete pivotal clinical trials of our product candidates, and our product candidates are approved for commercial sale, and despite expending these costs, our product candidates may not be commercially successful. We may not achieve profitability soon after generating product sales, if ever. If we are unable to generate product revenue, we will not become profitable and may be unable to continue operations without continued funding.

We require additional financing to execute our business plan and continue to operate as a going concern.

Our audited consolidated financial statements for the year ended March 31, 2018 as well as the unaudited condensed consolidated financial statements for the quarter ended December 31, 2018 included elsewhere in this Report were prepared assuming we will continue to operate as a going concern, although we and our auditors have indicated that our continuing losses and negative cash flows from operations raise substantial doubt about our ability to continue as such. Because we continue to experience net operating losses, our ability to continue as a going concern is subject to our ability to obtain necessary funding from outside sources, including obtaining additional funding from this offering as well as future sales of our securities or potentially obtaining loans and grant awards from financial institutions and/or government agencies where possible. Our continued net operating losses increase the difficulty in completing such sales or securing alternative sources of funding, and there can be no assurances that we will be able to obtain any future funding on favorable terms or at all. If we are unable to obtain sufficient financing from the sale of our securities or from alternative sources, we may be required to reduce, defer, or discontinue certain or all of our research and development activities or we may not be able to continue as a going concern.

Since our inception, most of our resources have been dedicated to research and development of AV-101 and the drug rescue capabilities of VistaStem's stem cell technology platform. In particular, we have expended substantial resources on research and development of methods and processes relating to the production of AV-101 API and drug product, advancing AV-101 through IND-enabling preclinical development, Phase 1 clinical safety studies, and into ongoing Phase 2 clinical development, including preparation for and launch of our ELEVATE Study, as well as research and development of our stem cell technology platform, including development of CardioSafe 3D for drug rescue and our cardiac stem cell technology for potential regenerative medicine applications in connection with the Bluerock Agreement, and we expect to continue to expend substantial resources for the foreseeable future developing and commercializing our product candidates on our own or in collaborations. These expenditures will include costs associated with general and administrative costs, facilities costs, research and development, acquiring new technologies, manufacturing product candidates, conducting nonclinical experiments and clinical trials and obtaining regulatory approvals, as well as commercializing any products approved for sale.

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At December 31, 2018, we had cash and cash equivalents of approximately $6.3 million. We do not believe this amount alone is sufficient to enable us to fund our planned operations for at least the twelve months following the issuance of the financial statements included elsewhere in this Report. We expect to seek additional capital to produce additional AV-101 study material for future nonclinical and clinical studies of AV-101, conduct AV-101 Phase 3-enabling studies, conduct pivotal Phase 3 clinical studies of AV-101 in MDD, conduct AV-101 Phase 2 studies in CNS indications other than MDD, produce PH94B study material, conduct PH94B pivotal Phase 3 clinical trials, produce PH10 study material and conduct a Phase 2 clinical trial of PH10, acquire or license and conduct research and development of additional product candidates and to fund our internal operations.

Further, we have no current source of revenue to sustain our present activities, and we do not expect to generate revenue until, and unless, we (i) out-license or sell a product candidate to a third-party, (ii) enter into additional license arrangements involving our stem cell technology, or (iii) obtain approval from the FDA or other regulatory authorities and successfully commercialize, on our own or through a future collaboration, one or more of our product candidates.

As the outcome of our ongoing research and development activities, including the outcome of ongoing and future anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates, on our own or in collaboration with others. In addition, other unanticipated costs may arise. As a result of these and other factors, we will need to seek additional capital in the near term to meet our future operating requirements, including capital necessary to develop, obtain regulatory approval for, and to commercialize our product candidates, and may seek additional capital in the event there exists favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. We have completed in the past, and are considering, a range of potential financing transactions, including the offering described herein, additional public or private equity or debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or a combination of these approaches, and we may complete additional financing arrangements later in 2018 or thereafter. Raising funds in the current economic environment may present additional challenges. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations.

Our future capital requirements depend on many factors, including:

- the number and characteristics of the product candidates we pursue;
- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical and clinical studies;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- the cost of commercialization activities if any of our product candidates are approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing our product candidates and any products we successfully commercialize;
- our ability to establish and maintain strategic partnerships, licensing or other collaborative arrangements and the financial terms of such agreements;

market acceptance of our product candidates;

the effect of competing technological and market developments;

our ability to obtain government funding for our research and development programs;

the costs involved in obtaining, maintaining and enforcing patents to preserve our intellectual property;

the costs involved in defending against such claims that we infringe third-party patents or violate other intellectual property rights and the outcome of such litigation;

the timing, receipt and amount of potential future licensee fees, milestone payments, and sales of, or royalties on, our future products, if any; and

the extent to which we may acquire or invest in additional businesses, product candidates and technologies.

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Any additional fundraising efforts will divert certain members of our management team from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts, in a timely manner, or on terms acceptable to us, if at all. The terms of any future financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity securities and the conversion, exchange or exercise of certain of our outstanding securities will dilute all of our stockholders. The incurrence of debt could result in increased fixed payment obligations and we could be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

If we are unable to obtain additional funding on a timely basis and on acceptable terms, we may be required to significantly curtail, delay or discontinue one or more of our research or product development programs or the commercialization of any product candidate or be unable to continue or expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

We have identified material weaknesses in our internal control over financial reporting, and our business and stock price may be adversely affected if we do not adequately address those weaknesses or if we have other material weaknesses or significant deficiencies in our internal control over financial reporting.

We have identified material weaknesses in our internal control over financial reporting. In particular, we concluded that (i) the size and capabilities of the Company’s staff does not permit appropriate segregation of duties to prevent one individual from overriding the internal control system by initiating, authorizing and completing all transactions, and (ii) the Company utilizes accounting software that does not prevent erroneous or unauthorized changes to previous reporting periods and/or can be adjusted so as to not provide an adequate auditing trail of entries made in the accounting software.

The existence of one or more material weaknesses or significant deficiencies could result in errors in our financial statements, and substantial costs and resources may be required to rectify any internal control deficiencies. If we cannot produce reliable financial reports, investors could lose confidence in our reported financial information, we may be unable to obtain additional financing to operate and expand our business and our business and financial condition could be harmed.

Raising additional capital will cause substantial dilution to our existing stockholders, may restrict our operations or require us to relinquish rights, and may require us to seek stockholder approval to authorize additional shares of our common stock.

We intend to pursue private and public equity offerings, debt financings, strategic collaborations and licensing arrangements during 2019 and beyond. To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, or to the extent, for strategic purposes, we convert or exchange certain of our outstanding securities into common stock, our current stockholders’ ownership interest in our company will be substantially diluted. In addition, the terms of any such securities may include liquidation or other preferences that materially adversely affect rights of our stockholders. Debt financing, if available, would increase our

fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration, strategic partnerships and licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, our intellectual property, future revenue streams or grant licenses on terms that are not favorable to us.

Some of our programs have been partially supported by government grant awards, which may not be available to us in the future.

Since inception, we have received substantial funds under grant award programs funded by state and federal governmental agencies, such as the NIH, the NIH's National Institute of Neurological Disease and Stroke (NINDS) and the NIMH, and the California Institute for Regenerative Medicine (CIRM). To fund a portion of our future research and development programs, we may apply for additional grant funding from such or similar governmental organizations. However, funding by these governmental organizations may be significantly reduced or eliminated in the future for a number of reasons. For example, some programs are subject to a yearly appropriations process in Congress. In addition, we may not receive funds under future grants because of budgeting constraints of the agency administering the program. Therefore, we cannot assure you that we will receive any future grant funding from any government organization or otherwise. A restriction on the government funding available to us could reduce the resources that we would be able to devote to future research and development efforts. Such a reduction could delay the introduction of new products and hurt our competitive position.

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Our ability to use net operating losses to offset future taxable income is subject to certain limitations.

As of March 31, 2018, we had federal and state net operating loss carryforwards of approximately $88.5 million and $63.5 million, respectively, which begin to expire in fiscal 2019. Under Section 382 of the Internal Revenue Code of 1986, as amended (the Code) changes in our ownership may limit the amount of our net operating loss carryforwards that could be utilized annually to offset our future taxable income, if any. This limitation would generally apply in the event of a cumulative change in ownership of our company of more than 50% within a three-year period. Any such limitation may significantly reduce our ability to utilize our net operating loss carryforwards and tax credit carryforwards before they expire. Any such limitation, whether as the result of future offerings, prior private placements, sales of our common stock by our existing stockholders or additional sales of our common stock by us in the future, could have a material adverse effect on our results of operations in future years. We have not completed a study to assess whether an ownership change for purposes of Section 382 has occurred, or whether there have been multiple ownership changes since our inception, due to the significant costs and complexities associated with such study.

General Company-Related Risks

If we fail to attract and retain senior management and key scientific personnel, we may be unable to successfully produce, develop and commercialize our product candidates.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management and scientific and technical personnel. We are highly dependent upon our Chief Executive Officer, President and Chief Scientific Officer, Chief Medical Officer, Chief Financial Officer, and Vice President – Corporate Development as well as our other employees, consultants and scientific collaborators. As of the date of this Report, we have nine full-time employees, which may make us more reliant on our individual employees than companies with a greater number of employees. The loss of services of any of these individuals could delay or prevent the successful development of our product candidates or disrupt our administrative functions.

Although we have not historically experienced unique difficulties attracting and retaining qualified employees, we could experience such problems in the future. For example, competition for qualified personnel in the biotechnology and pharmaceuticals field is intense. We will need to hire additional personnel should we elect to expand our research and development and administrative activities. We may not be able to attract and retain quality personnel on acceptable terms.

In addition, we rely on a broad and diverse range of strategic consultants and advisors, including manufacturing, nonclinical and clinical development, and regulatory advisors, to assist us in designing and implementing our research and development and regulatory strategies and plans for our product candidates. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

As we seek to advance development of our product candidates, we may need to expand our research and development capabilities and/or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners and other third parties. Future growth will impose significant added responsibilities on members of management. Our future financial performance and our ability to develop and commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our research and development efforts effectively and hire, train and integrate additional management, administrative and technical personnel. The hiring, training and integration of new employees may be more difficult, costly and/or time-consuming

for us because we have fewer resources than a larger organization. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing the company.

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If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

As we develop our product candidates. either on our own or in collaboration with others, we will face inherent risks of product liability as a result of the required clinical testing of such product candidates, and will face an even greater risk if we or our collaborators commercialize any such product candidates. For example, we may be sued if AV-101, PH94B, PH10, any drug rescue NCE, other product candidate, or RM product candidate we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

decreased demand for product candidates that we may develop;

injury to our reputation;

withdrawal of clinical trial participants;

costs to defend the related litigation;

a diversion of management's time and our resources;

substantial monetary awards to trial participants or patients; or

product recalls, withdrawals or labeling, marketing or promotional restrictions.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. Although we maintain general and product liability insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

As a public company, we incur significant administrative workload and expenses to comply with U.S. regulations and requirements imposed by the Nasdaq Stock Market concerning corporate governance and public disclosure.

As a public company with common stock listed on the Nasdaq Capital Market, we must comply with various laws, regulations and requirements, including certain provisions of the Sarbanes-Oxley Act of 2002, as well as rules implemented by the SEC and the Nasdaq Stock Market. Complying with these statutes, regulations and requirements, including our public company reporting requirements, continues to occupy a significant amount of the time of management and involves significant accounting, legal and other expenses. Our efforts to comply with these regulations are likely to result in increased general and administrative expenses and management time and attention

directed to compliance activities.

Unfavorable global economic or political conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by global political conditions, as well as general conditions in the global economy and in the global financial and stock markets. Global financial and political crises cause extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, such as the recent global financial crisis, could result in a variety of risks to our business, including, weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

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We or the third parties upon whom we depend may be adversely affected by natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third-party CMOs, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business.

Our business and operations would suffer in the event of cybersecurity or other system failures. Our business depends on complex information systems, and any failure to successfully maintain these systems or implement new systems to handle our changing needs could result in a material disruption of our product candidates' development programs or otherwise materially harm our operations.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our suppliers, as well as personally identifiable information of employees. Similarly, our third-party CROs, CMOs and other contractors and consultants possess certain of our sensitive data. The secure maintenance of this information is material to our operations and business strategy. Despite the implementation of security measures, our internal computer systems and those of our third-party CROs, CMOs and other contractors and consultants are vulnerable to attacks by hackers, damage from computer viruses, unauthorized access, breach due to employee error, malfeasance or other disruptions, natural disasters, terrorism and telecommunication and electrical failures. Any such attack or breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to affect our business, including recently enacted laws in a majority of states requiring security breach notification. Thus, any access, disclosure or other loss of information, including our data being breached at our partners or third-party providers, could result in legal claims or proceedings and liability under laws that protect the privacy of personal information, disruption of our operations, and damage to our reputation, which could adversely affect our business.

While we have not experienced any such system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs. For example, the loss of clinical trial data for AV-101, PH94B, PH10 or other product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications or other data or applications relating to our technology or product candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of our product candidates could be delayed.

We may acquire businesses or product candidates, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions.

We may acquire additional businesses or product candidates, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous

difficulties in developing, manufacturing and marketing any new product candidates resulting from a strategic alliance, licensing transaction or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition or licensing transaction, we will achieve the expected synergies to justify the transaction.

Risks Related to Our Intellectual Property Rights

If we are unable to adequately protect our proprietary technology or obtain and maintain issued patents that are sufficient to protect our product candidates, others could compete against us more directly, which would have a material adverse impact on our business, results of operations, financial condition and prospects.

We strive to protect and enhance the proprietary technologies that we believe are important to our business, including seeking patents intended to cover our products and compositions, their methods of use and any other inventions we consider important to the development of our business. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

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Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, to defend and enforce our patents, to preserve the confidentiality of our trade secrets and to operate without infringing the valid and enforceable patents and proprietary rights of third parties. We also rely on know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen and maintain the proprietary position of our product candidates. We own or have licensed patents and patent applications related to AV-101, PH94B, PH10 and human pluripotent stem cell technology.

Although we own or have licensed issued patents and patent applications relating to AV-101, PH94B and PH10 in the United States, selected countries in the European Union and other jurisdictions, we cannot yet, with respect to AV-101 or PH10, provide any assurances that any of our pending United States and additional foreign patent applications will mature into issued patents and, if they do, that any of our patents will include claims with a scope sufficient to protect our product candidates or otherwise provide any competitive advantage. Nor can we provide any assurances that any of our issued patents, if challenged, will be found to be valid and enforceable. Moreover, other parties may have developed technologies that may be related or competitive to our approach and may have filed or may file patent applications and may have received or may receive patents that may overlap or conflict with our patent applications, either by claiming the same methods or formulations or by claiming subject matter that could dominate our patent position. Such third-party patent positions may limit or even eliminate our ability to obtain or maintain patent protection.

The patent positions of biotechnology and pharmaceutical companies, including our patent positions with respect to our product candidates, involve complex legal and factual questions, and, therefore, the issuance, scope, validity and enforceability of any additional patent claims that we may obtain cannot be predicted with certainty. This uncertainty includes changes to the patent laws through either legislative action to change statutory patent law or court action that may reinterpret existing law in ways affecting the scope or validity of issued patents.

In addition, some patent-related uncertainty exists because of the challenge in finding and addressing all of the relevant and material prior art in the biotechnology and pharmaceutical fields. Such prior art includes scientific publications, investment blogs, granted patents and published patent applications. For example, some reports in the trade press and announcements by the Company, made public before the filing date of our AV-101 patent applications, mentioned that AV-101 was in development for certain therapeutic purposes. These include a web post, published by the Company on the NIH clinical trials website prior to filing the Company’s initial AV-101 patent applications, which stated that our then contemplated Phase 1b study would assess the safety, pharmacokinetics and antihyperalgesic effect of AV-101 at particular unit doses on capsaicin-induced hyperalgesia. This web post was not submitted to the United States Patent and Trademark Office (USPTO) in our two granted US patents related to (1) unit dose formulations of AV-101 effective to treat depression and (2) methods of treating depression with AV-101, respectively. It has been submitted in our pending AV-101 patent applications which also claim (1) unit dose formulations of AV-101 effective to treat depression and (2) methods of treating depression with AV-101. This prior art web post describes unit doses for a then future study contemplated by the Company, does not mention treatment of depression and does not provide any preclinical or clinical study data relating to depression or any other medical condition, disease or disorder. The Company is considering entering this web post in the record for the aforementioned two issued US patents. Such prior art, as well as the potential existence of other prior art about which we are currently unaware may be related to our patent applications and patents, may provide patent uncertainty and could prevent a pending patent application from being granted or result in an issued patent being held invalid or unenforceable.

Our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Even if patents do successfully

issue, third parties may challenge the validity, enforceability or scope of such issued patents or any other issued patents we own or license, which may result in such patents being narrowed, invalidated or held unenforceable. United States patents and patent applications may also be subject to interference proceedings, ex parte reexamination, or inter partes review proceedings, supplemental examination and challenges in district court. Patents may be subjected to opposition, post-grant review, invalidity actions, or comparable proceedings lodged in various foreign, both national and regional, patent offices or courts. These proceedings could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such proceedings may be costly. Thus, any patents that we may own or exclusively license ultimately may not provide any protection against competitors. Furthermore, an adverse decision in an interference proceeding can result in a third party receiving the patent right sought by us, which in turn could affect our ability to develop, market or otherwise commercialize our product candidates.

Furthermore, though an issued patent is presumed valid and enforceable, its issuance is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Even if a patent issues and is held to be valid and enforceable, competitors may be able to design around our patents, such as using pre-existing or newly developed technology. Other parties may develop and obtain patent protection for more effectivetechnologies, designs or methods. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, vendors, or former or current employees. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries. If these developments were to occur, they could have a material adverse effect on our sales.

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Our ability to enforce our patent rights depends on our ability to detect infringement. It is difficult to detect infringers who do not advertise the components that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product. Any litigation to enforce or defend our patent rights, even if we were to prevail, could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

In addition, proceedings to enforce or defend our patents could put our patents at risk of being invalidated, held unenforceable, or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. If any patents covering our product candidates are invalidated or found unenforceable, our financial position and results of operations would be materially and adversely impacted. In addition, if a court found that valid, enforceable patents held by third parties covered our product candidates, our financial position and results of operations would also be materially and adversely impacted.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- any issued patents related to AV-101, PH94B, PH10 or any pending patent applications, if issued, will include claims having a scope sufficient to protect AV-101, PH94B, PH10 or any other products or product candidates, particularly considering that the compound patent to AV-101 has expired;
- any of our pending patent applications will issue as patents at all;
- we will be able to successfully commercialize our product candidates, if approved, before our relevant patents expire;
- we were the first to make the inventions covered by each of our patents and pending patent applications;
- we were the first to file patent applications for these inventions;
- others will not develop similar or alternative technologies that do not infringe our patents;
- others will not use pre-existing technology to effectively compete against us;
- any of our patents, if issued, will ultimately be found to be valid and enforceable, including on the basis of prior art relating to our patent applications and patents;
- any patents currently held or issued to us in the future will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies or product candidates that are separately patentable; or
- our commercial activities or products will not infringe upon the patents or proprietary rights of others.

We also rely upon unpatented trade secrets, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our

employees and our collaborators and consultants. It is possible that technology relevant to our business will be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees and consultants who are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could otherwise become known or be independently discovered by our competitors.

We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing or increase the costs of commercializing our product candidates, if approved.

Our success will depend in part on our ability to operate without infringing the intellectual property and proprietary rights of third parties. We cannot assure you that our business, products and methods do not or will not infringe the patents or other intellectual property rights of third parties.

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The pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may allege that our product candidates or the use of our technologies infringes patent claims or other intellectual property rights held by them or that we are employing their proprietary technology without authorization. As we continue to develop and, if approved, commercialize our current product candidates and future product candidates, competitors may claim that our technology infringes their intellectual property rights as part of business strategies designed to impede our successful commercialization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, third parties may have currently pending patent applications that may later result in issued patents that our product candidates may infringe, or which such third parties claim are infringed by our technologies. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on us. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

Patent and other types of intellectual property litigation can involve complex factual and legal questions, and their outcome is uncertain. Any claim relating to intellectual property infringement that is successfully asserted against us may require us to pay substantial damages, including treble damages and attorney's fees if we are found to be willfully infringing another party's patents, for past use of the asserted intellectual property and royalties and other consideration going forward if we are forced to take a license. In addition, if any such claim was successfully asserted against us and we could not obtain such a license, we may be forced to stop or delay developing, manufacturing, selling or otherwise commercializing our product candidates.

Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court, or redesign our products. Patent litigation is costly and time-consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, intellectual property litigation or claims could force us to do one or more of the following:

- cease developing, selling or otherwise commercializing our product candidates;
- pay substantial damages for past use of the asserted intellectual property;
- obtain a license from the holder of the asserted intellectual property, which license may not be available on reasonable terms, if at all; and
- in the case of trademark claims, redesign, or rename, some or all of our product candidates to avoid infringing the intellectual property rights of third parties, which may not be possible and, even if possible, could be costly and time-consuming.

Any of these risks coming to fruition could have a material adverse effect on our business, results of operations, financial condition and prospects.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We enter into confidentiality and intellectual property assignment agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. For example, even if we have a consulting agreement in place with an academic advisor pursuant to which such academic advisor is required to assign any inventions developed in connection with providing services to us, such academic advisor may not have the right to assign such inventions to us, as it may conflict with his or her obligations to assign all such intellectual property to his or her employing institution.

Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO, the European Patent Office (EPO) and various other foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

Third parties may initiate legal proceedings against us alleging that we infringe their intellectual property rights or we may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, the outcome of which would be uncertain and could have a material adverse effect on the success of our business. Any lawsuit we are engaged in to protect or enforce our patents or the patents of our licensors could be expensive, time-consuming and unsuccessful.

Even if the patent applications we own or license are issued, competitors may infringe these patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid, is unenforceable and/or is not infringed, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Further, third parties may initiate legal proceedings against us or our licensors or collaborators alleging that we or our licensors or collaborators infringe their intellectual property rights or we or our licensors or collaborators may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, including in oppositions, interferences, reexaminations, inter partes reviews or derivation proceedings before the United States or other jurisdictions. These proceedings can be expensive and time-consuming and many of our or our licensors' or collaborators' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors or collaborators can. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States or European Union.

An unfavorable outcome could require us or our licensors or collaborators to cease using the related technology or developing or commercializing our product candidates, or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our licensors or collaborators a license on commercially reasonable terms or at all. Even if we or our licensors or collaborators obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors or collaborators. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this

type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court.

If we or one of our licensing partners initiated legal proceedings against a third-party to enforce a patent covering one of our product candidates, including patents related to AV-101, PH94B or PH10, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include alleged failures to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for unenforceability assertions include allegations that someone connected with prosecution of the patent withheld relevant information from the USPTO or EPO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review and equivalent proceedings in foreign jurisdictions, e.g., opposition proceedings. Such proceedings could result in revocation or amendment of our patents in such a way that they no longer cover our product candidates or competitive products. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection would have a material adverse impact on our business.

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We will not seek to protect our intellectual property rights in all jurisdictions throughout the world and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

Filing, prosecuting and defending patents on product candidates in all countries and jurisdictions throughout the world is prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States, assuming that rights are obtained in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. The statutory deadlines for pursuing patent protection in individual foreign jurisdictions are based on the priority date of each of our patent applications. For the patent applications relating to AV-101, as well as for many of the patent families that we own or license, the relevant statutory deadlines have not yet expired. Thus, for each of the patent families that we believe provide coverage for our lead product candidates or technologies, we will need to decide whether and where to pursue protection outside the United States.

Competitors may use our technologies in jurisdictions where we do not pursue and obtain patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Even if we pursue and obtain issued patents in particular jurisdictions, our patent claims or other intellectual property rights may not be effective or sufficient to prevent third parties from so competing.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to biotechnology. This could make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

An unfavorable outcome could require us or our licensors or collaborators to cease using the related technology or developing or commercializing our product candidates, or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our licensors or collaborators a license on commercially reasonable terms or at all. Even if we or our licensors or collaborators obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors or collaborators. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim

proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

Furthermore, proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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We are dependent, in part, on licensed intellectual property. If we were to lose our rights to licensed intellectual property, we may not be able to continue developing or commercializing our product candidates, if approved. If we breach any of the agreements under which we license the use, development and commercialization rights to our product candidates or technology from third parties or, in certain cases, we fail to meet certain development or payment deadlines, we could lose license rights that are important to our business.

We are a party to a number of license agreements under which we are granted rights to intellectual properties that are or could become important to our business, and we expect that we may need to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose on us, various development, regulatory and/or commercial diligence obligations, payment of fees, milestones and/or royalties and other obligations. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to develop or market products, which could be covered by the license. Our business could suffer, for example, if any current or future licenses terminate, if the licensors fail to abide by the terms of the license, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms.

As we have done previously, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we cannot provide any assurances that third-party patents do not exist that might be enforced against our current product candidates or future products in the absence of such a license. We may fail to obtain any of these licenses on commercially reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We have entered into several licenses to support our various stem cell technology-related programs. We may enter into additional license(s) to third-party intellectual property that are necessary or useful to our business. Our current licenses and any future licenses that we may enter into impose various royalty payments, milestone, and other obligations on us. For example, the licensor may retain control over patent prosecution and maintenance under a license agreement, in which case, we may not be able to adequately influence patent prosecution or prevent inadvertent lapses of coverage due to failure to pay maintenance fees. If we fail to comply with any of our obligations under a current or future license agreement, our licensor(s) may allege that we have breached our license agreement and may accordingly seek to terminate our license with them. In addition, future licensor(s) may decide to terminate our license at will. Termination of any of our current or future licenses could result in our loss of the right to use the licensed intellectual property, which could materially adversely affect our ability to develop and commercialize a product candidate or product, if approved, as well as harm our competitive business position and our business prospects.

In addition, if our licensors fail to abide by the terms of the license, if the licensors fail to prevent infringement by third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms our business could suffer.

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Some intellectual property which we have licensed may have been discovered through government funded programs and thus may be subject to federal regulations such as “march-in” rights, certain reporting requirements, and a preference for U.S. industry. Compliance with such regulations may limit our exclusive rights, subject us to expenditure of resources with respect to reporting requirements, and limit our ability to contract with non-U.S. manufacturers.

Some of the intellectual property rights we have licensed or license in the future may have been generated through the use of U.S. government funding and may therefore be subject to certain federal regulations. As a result, the U.S. government may have certain rights to intellectual property embodied in our current or future product candidates pursuant to the Bayh-Dole Act of 1980 (Bayh-Dole Act). These U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as “march-in rights”). The U.S. government also has the right to take title to these inventions if we fail, or the applicable licensor fails, to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. In addition, the U.S. government may acquire title to these inventions in any country in which a patent application is not filed within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us, or the applicable licensor, to expend substantial resources. In addition, the U.S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the U.S. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the U.S. or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. manufacturers may limit our ability to contract with non-United States product manufacturers for products covered by such intellectual property.

In the event we apply for additional United States government funding, and we discover compounds or drug candidates as a result of such funding, intellectual property rights to such discoveries may be subject to the applicable provisions of the Bayh-Dole Act.

If we do not obtain additional protection under the Hatch-Waxman Amendments and similar foreign legislation by extending the patent terms and obtaining data exclusivity for our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one or more of the United States patents we own or license may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. For example, we may not be granted an extension if the active ingredient of AV-101, PH94B or PH10 is used in another drug company’s product candidate and that product candidate is the first to obtain FDA approval. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our

patent expiration, and our ability to generate revenues could be materially adversely affected.

Changes in United States patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation: the Leahy-Smith America Invents Act, referred to as the America Invents Act. The America Invents Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. It is not yet clear what, if any, impact the America Invents Act will have on the operation of our business. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any patents that may issue from our patent applications, all of which could have a material adverse effect on our business and financial condition.

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In addition, recent United States Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. The full impact of these decisions is not yet known. For example, on March 20, 2012 in Mayo Collaborative Services, DBA Mayo Medical Laboratories, et al. v. Prometheus Laboratories, Inc., the Court held that several claims drawn to measuring drug metabolite levels from patient samples and correlating them to drug doses were not patentable subject matter. The decision appears to impact diagnostics patents that merely apply a law of nature via a series of routine steps and it has created uncertainty around the ability to obtain patent protection for certain inventions. Additionally, on June 13, 2013 in Association for Molecular Pathology v. Myriad Genetics, Inc., the Court held that claims to isolated genomic DNA are not patentable, but claims to complementary DNA molecules are patent eligible because they are not a natural product. The effect of the decision on patents for other isolated natural products is uncertain. Additionally, on March 4, 2014, the USPTO issued a memorandum to patent examiners providing guidance for examining claims that recite laws of nature, natural phenomena or natural products under the Myriad and Prometheus decisions. This guidance did not limit the application of Myriad to DNA but, rather, applied the decision to other natural products. Further, in 2015, in Ariosa Diagnostics, Inc. v. Sequenom, Inc., the Court of Appeals for the Federal Circuit held that methods for detecting fetal genetic defects were not patent eligible subject matter.

In addition to increasing uncertainty regarding our ability to obtain future patents, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on these and other decisions by the United States Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce any patents that may issue in the future.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Certain of our current employees have been, and certain of our future employees may have been, previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We also engage advisors and consultants who are concurrently employed at universities or who perform services for other entities.

Although we are not aware of any claims currently pending or threatened against us, we may be subject to claims that we or our employees, advisors or consultants have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third party. We have and may in the future also be subject to claims that an employee, advisor or consultant performed work for us that conflicts with that person’s obligations to a third party, such as an employer, and thus, that the third party has an ownership interest in the intellectual property arising out of work performed for us. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we fail in defending such claims, in addition to paying monetary claims, we may lose valuable intellectual property rights or personnel. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our product candidates, which would materially adversely affect our commercial development efforts.

Numerous factors may limit any potential competitive advantage provided by our intellectual property rights.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from

our intellectual property rights. The following examples are illustrative:

- others may be able to develop and/or practice technology that is similar to our technology or aspects of our technology but that is not covered by the claims of patents, should such patents issue from our patent applications;
- we might not have been the first to make the inventions covered by a pending patent application that we own;
- we might not have been the first to file patent applications covering an invention;
- others may independently develop similar or alternative technologies without infringing our intellectual property rights;
- pending patent applications that we own or license may not lead to issued patents;
- patents, if issued, that we own or license may not provide us with any competitive advantages, or may be held invalid or unenforceable or be narrowed, as a result of legal challenges by our competitors;
- third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection;
- we may not be able to obtain and/or maintain necessary or useful licenses on reasonable terms or at all; and
- the patents of others may have an adverse effect on our business.

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Should any of these events occur, they could significantly harm our business and results of operations.

If, instead of identifying drug rescue candidates based on information available to us in the public domain, we seek to in-license drug rescue candidates from biotechnology, medicinal chemistry and pharmaceutical companies, academic, governmental and nonprofit research institutions, including the NIH, or other third parties, there can be no assurances that we will obtain material ownership or economic participation rights over intellectual property we may derive from such licenses or similar rights to the drug rescue NCEs we may produce and develop. If we are unable to obtain ownership or substantial economic participation rights over intellectual property related to drug rescue NCEs we produce and develop, our business may be adversely affected.

Risks Related to our Securities

Market volatility may affect our stock price and the value of your investment.

The market price for our common stock, similar to other biopharmaceutical companies, is likely to be highly volatile. The market price of our common stock may fluctuate significantly in response to a number of factors, most of which we cannot control, including, among others:

- plans for, progress of or results from nonclinical and clinical development activities related to our product candidates;
- the failure of the FDA to approve our product candidates;
- announcements of new products, technologies, commercial relationships, acquisitions or other events by us or our competitors;
- the success or failure of other CNS therapies;
- regulatory or legal developments in the United States and other countries;
- announcements regarding our intellectual property portfolio;
- failure of our product candidates, if approved, to achieve commercial success;
- fluctuations in stock market prices and trading volumes of similar companies;
- general market conditions and overall fluctuations in U.S. equity markets;
- variations in our quarterly operating results;
- changes in our financial guidance or securities analysts’ estimates of our financial performance;
- changes in accounting principles;
- our ability to raise additional capital and the terms on which we can raise it;

sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders;

additions or departures of key personnel;

discussion of us or our stock price by the press and by online investor communities; and

other risks and uncertainties described in these risk factors.

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Future sales and issuances of our common stock may cause our stock price to decline.

Sales or issuances of a substantial number of shares of our common stock in the public market, or the perception that such sales or issuances are occurring or might occur, could significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity securities.

The stock market in general, and small biopharmaceutical companies like ours in particular, have frequently experienced significant volatility in the market prices for securities that often has been unrelated to the operating performance of the underlying companies. These broad market and industry fluctuations may adversely affect the market price of our common stock, regardless of our actual operating performance. In certain situations in which the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit against us, the defense and disposition of the lawsuit could be costly and divert the time and attention of our management and harm our operating results. Additionally, if the trading volume of our common stock remains low and limited there will be an increased level of volatility and you may not be able to generate a return on your investment.

A portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future. Future sales of shares by existing stockholders could cause our stock price to decline, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Historically, there has been a limited public market for shares of our common stock. Future sales and issuances of a substantial number of shares of our common stock in the public market, including shares issued upon the conversion of our Series A Preferred, Series B Preferred or Series C Preferred, and the exercise of outstanding options and warrants for common stock which are issuable upon exercise, in the public market, or the perception that these sales and issuances are occurring or might occur, could significantly reduce the market price for our common stock and impair our ability to raise adequate capital through the sale of equity securities.

A limited number of institutional stockholders could limit your ability to influence the outcome of key transactions, including changes in control.

A limited number of institutional stockholders own a substantial portion of our outstanding preferred stock, consisting of shares of our Series A Preferred, Series B Preferred, and Series C Preferred, all of which is convertible, at the option of the holders (but subject to certain beneficial ownership restrictions), into a substantial number of shares of our common stock. Accordingly, should a few of these institutional holders convert their shares of preferred stock into common stock, such stockholders may exert influence over us and over the outcome of any corporate actions requiring approval of holders of our common stock, including the election of directors and amendments to our organizational documents, such as increases in our authorized shares of common stock, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transactions. These stockholders may also delay or prevent a change of control of the Company, even if such a change of control is approved by our Board and would benefit our other stockholders. Furthermore, the interests of such institutional stockholders may not always coincide with your interests or the interests of other common stockholders and an institutional holder may act in a manner that advances its best interests and not necessarily those of other stockholders.

If equity research analysts do not publish research or reports about our business or if they issue unfavorable commentary or downgrade our common stock, the price of our common stock could decline.

The trading market for our common stock relies in part on the research and reports that equity research analysts publish about us and our business. We do not control these analysts. The price of our common stock could decline if one or more equity research analysts downgrade our common stock or if such analysts issue other unfavorable commentary or cease publishing reports about us or our business.

There may be additional issuances of shares of preferred stock in the future.

Our Restated Articles of Incorporation (the Articles) permit us to issue up to 10.0 million shares of preferred stock. Our Board has authorized the issuance of (i) 500,000 shares of Series A Preferred, all of which shares are issued and outstanding at December 31, 2018; (ii) 4.0 million shares of Series B 10% Convertible Preferred stock, of which approximately 1.2 million shares remain issued and outstanding at December 31, 2018; and (iii) 3.0 million shares of Series C Convertible Preferred Stock, of which approximately 2.3 million shares are issued and outstanding at December 31, 2018. Our Board could authorize the issuance of additional series of preferred stock in the future and such preferred stock could grant holders preferred rights to our assets upon liquidation, the right to receive dividends before dividends would be declared to holders of our common stock, and the right to the redemption of such shares, possibly together with a premium, prior to the redemption of the common stock. In the event and to the extent that we do issue additional preferred stock in the future, the rights of holders of our common stock could be impaired thereby, including without limitation, with respect to liquidation.

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We do not intend to pay dividends on our common stock and, consequently, our stockholders' ability to achieve a return on their investment will depend on appreciation in the price of our common stock.

We have never declared or paid any cash dividend on our common stock and do not currently intend to do so in the foreseeable future. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends in the foreseeable future. Therefore, the success of an investment in shares of our common stock will depend upon any future appreciation in their value. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which our stockholders purchased them.

We incur significant costs to ensure compliance with corporate governance, federal securities law and accounting requirements.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (Exchange Act), which requires that we file annual, quarterly and current reports with respect to our business and financial condition, and the rules and regulations implemented by the SEC, the Sarbanes-Oxley Act of 2002, the Dodd-Frank Act, and the Public Company Accounting Oversight Board, each of which imposes additional reporting and other obligations on public companies. We have incurred and will continue to incur significant costs to comply with these public company reporting requirements, including accounting and related audit costs, legal costs to comply with corporate governance requirements and other costs of operating as a public company. These legal and financial compliance costs will continue to require us to divert a significant amount of resources that we could otherwise use to achieve our research and development and other strategic objectives.

The filing and internal control reporting requirements imposed by federal securities laws, rules and regulations on companies that are not "smaller reporting companies" under federal securities laws are rigorous and, once we are no longer a smaller reporting company, we may not be able to meet them, resulting in a possible decline in the price of our common stock and our inability to obtain future financing. Certain of these requirements may require us to carry out activities we have not done previously and complying with such requirements may divert management's attention from other business concerns, which could have a material adverse effect on our business, results of operations, financial condition and cash flows. Any failure to adequately comply with applicable federal securities laws, rules or regulations could subject us to fines or regulatory actions, which may materially adversely affect our business, results of operations and financial condition.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We will continue to invest resources to comply with evolving laws, regulations and standards, however this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be adversely affected.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

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Item 6. EXHIBITS

Exhibit Number	Description
10.1	Indemnification Agreement, dated January 10, 2019, by and between VistaGen Therapeutics, Inc. and Ann Cunningham, incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 15, 2019.
31.1	Certification of the Principal Executive Officer required by Rule 13a-14(a) under the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of the Principal Financial Officer required by Rule 13a-14(a) under the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32	Certification of the Principal Executive and Financial Officers required by Rule 13a-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

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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.

/s/ Shawn K. Singh
Shawn K. Singh
Chief Executive Officer (Principal Executive Officer)

/s/ Jerrold D. Dotson
Jerrold D. Dotson
Chief Financial Officer (Principal Financial and Accounting Officer)

Dated: February 12, 2019