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 September 30, 2019
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 ☒

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	VTGN	Nasdaq Capital Market

As of November 6, 2019, 43,222,965 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 September 30, 2019

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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)

	September 30, 2019 (Unaudited)	March 31, 2019 (Note 2)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,072,400	$ 13,100,300
Receivable from supplier	-	300,000
Prepaid expenses and other current assets	604,500	250,900
Total current assets	4,676,900	13,651,200
Property and equipment, net	260,600	312,700
Right of use asset - operating lease	3,750,200	-
Security deposits and other assets	47,800	47,800
Total assets	$ 8,735,500	$ 14,011,700
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable	$ 1,449,800	$ 1,055,000
Accrued expenses	2,215,500	1,685,600
Current notes payable	159,300	57,300
Operating lease oligation	289,600	-
Financing lease obligation	3,100	3,000
Total current liabilities	4,117,300	2,800,900
Non-current liabilities:		
Accrued dividends on Series B Preferred Stock	4,364,500	3,748,200
Deferred rent liability	-	381,100
Operating lease obligation	3,879,400	-
Financing lease obligation	4,700	6,300
Total non-current liabilities	8,248,600	4,135,600
Total liabilities	12,365,900	6,936,500
Commitments and contingencies		
Stockholders' (deficit) equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at September 30, 2019 and March 31, 2019:		
Series A Preferred, 500,000 shares authorized, issued and outstanding at September 30, 2019 and March 31, 2019	$ 500	$ 500
Series B Preferred; 4,000,000 shares authorized at September 30, 2019 and March 31, 2019; 1,160,240 shares issued and outstanding at September 30, 2019 and March 31, 2019	1,200	1,200
Series C Preferred; 3,000,000 shares authorized at September 30, 2019 and March 31, 2019; 2,318,012 share issued and outstanding at September 30, 2019 and March 31, 2019	2,300	2,300
Common stock, $0.001 par value; 175,000,000 and 100,000,000 shares authorized at September 30, 2019 and March 31, 2019, respectively; 42,758,630 shares issued and outstanding at September 30, 2019 and March 31, 2019	42,800	42,800
Additional paid-in capital	192,970,100	192,129,900
Treasury stock, at cost, 135,665 shares of common stock held at September 30, 2019 and March 31, 2019	(3,968,100)	(3,968,100)
Accumulated deficit	(192,679,200)	(181,133,400)
Total stockholders' (deficit) equity	(3,630,400)	7,075,200
Total liabilities and stockholders' (deficit) equity	$ 8,735,500	$ 14,011,700

See accompanying notes to Condensed Consolidated Financial Statements.

VISTAGEN THERAPEUTICS, INC.

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

	Three Months Ended September 30,		Six Months Ended September 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	$ 4,205,200	$ 5,261,100	$ 8,519,100	$ 8,004,800
General and administrative	1,146,100	2,171,000	3,056,200	3,637,300
Total operating expenses	5,351,300	7,432,100	11,575,300	11,642,100
Loss from operations	(5,351,300)	(7,432,100)	(11,575,300)	(11,642,100)
Other income (expenses), net:				
Interest income (expense), net	15,400	(2,900)	31,900	(5,000)
Loss before income taxes	(5,335,900)	(7,435,000)	(11,543,400)	(11,647,100)
Income taxes	-	-	(2,400)	(2,400)
Net loss and comprehensive loss	$ (5,335,900)	$ (7,435,000)	$ (11,545,800)	$ (11,649,500)
Accrued dividend on Series B Preferred stock	(313,800)	(283,600)	(616,300)	(557,100)
Net loss attributable to common stockholders	$ (5,649,700)	$ (7,718,600)	$ (12,162,100)	$ (12,206,600)
Basic and diluted net loss attributable to common stockholders per common share	$ (0.13)	$ (0.30)	$ (0.29)	$ (0.50)
Weighted average shares used in computing basic and diluted net loss attributable to common stockholders per common share	42,622,965	25,815,245	42,622,965	24,267,816

See accompanying notes to Condensed Consolidated Financial Statements.

VISTAGEN THERAPEUTICS, INC.

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

	Six Months Ended September 30,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (11,545,800)	$ (11,649,500)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	52,100	37,900
Stock-based compensation	1,456,500	1,785,000
Amortization of fair value of common stock issued for services	92,100	207,300
Fair value of common stock issued for product licenses and option	-	2,250,000
Amortization of fair value of warrants issued for services	13,800	25,100
Changes in operating assets and liabilities:		
Receivable from supplier	300,000	-
Prepaid expenses and other current assets	(229,200)	365,400
Right of use asset - operating lease	164,900	-
Operating lease liability	(127,100)	-
Accounts payable and accrued expenses	924,500	(212,300)
Deferred rent	-	128,000
Net cash used in operating activities	(8,898,200)	(7,063,100)
Cash flows from property and investing activities:		
Construction of tenant improvements	-	(169,800)
Net cash used in investing activities	-	(169,800)
Cash flows from financing activities:		
Net proceeds from issuance of common stock and warrants, including Units	-	4,778,700
Proceeds from exercise of warrants	-	7,500
Repayment of financing lease obligation	(1,500)	(1,300)
Repayment of notes payable	(128,200)	(98,700)
Net cash (used in) provided by financing activities	(129,700)	4,686,200
Net decrease in cash and cash equivalents	(9,027,900)	(2,546,700)
Cash and cash equivalents at beginning of period	13,100,300	10,378,300
Cash and cash equivalents at end of period	$ 4,072,400	$ 7,831,600
Supplemental disclosure of noncash activities:		
Insurance premiums settled by issuing note payable	$ 230,200	$ 160,500
Accrued dividends on Series B Preferred	$ 616,300	$ 557,100

See accompanying notes to Condensed Consolidated Financial Statements.

VISTAGEN THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' (DEFICIT) EQUITY
FOR THE SIX MONTHS ENDED SEPTEMBER 30, 2019 AND 2018
(Unaudited)
(Amounts in Dollars, except share amounts)

	Series A Preferred Stock		Series B Preferred Stock		Series C Preferred Stock		Common Stock		Additional Paid-in	Treasury	Accumulated	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Stock	Deficit	(Deficit)
Balances at March 31, 2018	**500,000**	**$ 500**	**1,160,240**	**$ 1,200**	**2,318,012**	**$ 2,300**	**23,068,280**	**$ 23,100**	**$167,401,400**	**$(3,968,100)**	**$(156,543,800)**	**$ 6,916,600**
Proceeds from sale of common stock and warrants for	-	-	-	-	-	-	40,000	-	50,000	-	-	50,000
Proceeds from exercise of warrants	-	-	-	-	-	-	5,000	-	7,500	-	-	7,500
Accrued dividends on Series B Preferred stock	-	-	-	-	-	-	-	-	(273,500)	-	-	(273,500)
Stock-based compensation expense	-	-	-	-	-	-	-	-	612,600	-	-	612,600
Fair value of common stock issued for services	-	-	-	-	-	-	100,000	100	122,900	-	-	123,000
Net loss for the quarter ended June 30, 2018	-	-	-	-	-	-	-	-	-	-	(4,214,500)	(4,214,500)
Balances at June 30, 2018	**500,000**	**$ 500**	**1,160,240**	**$ 1,200**	**2,318,012**	**$ 2,300**	**23,213,280**	**$ 23,200**	**$167,920,900**	**$(3,968,100)**	**$(160,758,300)**	**$ 3,221,700**
Proceeds from sale of common stock and warrants for cash in private placement offering	-	-	-	-	-	-	3,783,000	3,800	4,725,000	-	-	4,728,800
Accrued dividends on Series B Preferred stock	-	-	-	-	-	-	-	-	(283,600)	-	-	(283,600)
Stock-based compensation expense	-	-	-	-	-	-	-	-	1,172,400	-	-	1,172,400
Fair value of common stock issued for PH94B license and PH10 option	-	-	-	-	-	-	1,630,435	1,600	2,248,400	-	-	2,250,000
Fair value of common	-	-	-	-	-	-	50,000	100	334,800	-	-	334,900

stock and warrants issued for services												
Net loss for the quarter ended September 30, 2018	-	-	-	-	-	-	-	-	-	-	(7,435,000)	(7,435,000)
Balances at September 30, 2018	**500,000**	**$ 500**	**1,160,240**	**$ 1,200**	**2,318,012**	**$ 2,300**	**28,676,715**	**$ 28,700**	**$176,117,900**	**$(3,968,100)**	**$(168,193,300)**	**$ 3,989,200**
Balances at March 31, 2019	**500,000**	**$ 500**	**1,160,240**	**$ 1,200**	**2,318,012**	**$ 2,300**	**42,758,630**	**$ 42,800**	**$192,129,900**	**$(3,968,100)**	**$(181,133,400)**	**$ 7,075,200**
Accrued dividends on Series B Preferred stock	-	-	-	-	-	-	-	-	(302,500)	-	-	(302,500)
Stock-based compensation expense	-	-	-	-	-	-	-	-	1,063,000	-	-	1,063,000
Net loss for the quarter ended June 30, 2019	-	-	-	-	-	-	-	-	-	-	(6,209,900)	(6,209,900)
Balances at June 30, 2019	**500,000**	**$ 500**	**1,160,240**	**$ 1,200**	**2,318,012**	**$ 2,300**	**42,758,630**	**$ 42,800**	**$192,890,400**	**$(3,968,100)**	**$(187,343,300)**	**$ 1,625,800**
Accrued dividends on Series B Preferred stock	-	-	-	-	-	-	-	-	(313,800)	-	-	(313,800)
Stock-based compensation expense	-	-	-	-	-	-	-	-	393,500	-	-	393,500
Net loss for the quarter ended September 30, 2019	-	-	-	-	-	-	-	-	-	-	(5,335,900)	(5,335,900)
Balances at September 30, 2019	**500,000**	**$ 500**	**1,160,240**	**$ 1,200**	**2,318,012**	**$ 2,300**	**42,758,630**	**$ 42,800**	**$192,970,100**	**$(3,968,100)**	**$(192,679,200)**	**$(3,630,400)**

See accompanying notes to Condensed Consolidated Financial Statements.

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

Note 1. Description of Business

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 committed to developing differentiated new generation medications for central nervous system (*CNS*) diseases and disorders with high unmet need. Our product candidate portfolio includes three differentiated clinical-stage candidates, AV-101, PH10 and PH94B, which we are developing for multiple CNS indications. We aim to become a fully-integrated biopharmaceutical company that develops and commercializes innovative CNS therapies for large and growing mental health and neurology markets where current treatments are inadequate to meet the needs of millions of patients and caregivers worldwide.

AV-101 (4-Chlorokynurenine or 4-Cl-KYN) belongs to a new generation of investigational medicines in neuropsychiatry and neurology known as NMDA (N-methyl-D-aspartate) glutamate receptor modulators. The NMDA receptor is a pivotal receptor in the brain and abnormal NMDA function is associated with multiple CNS diseases and disorders, including major depressive disorder (*MDD*), chronic neuropathic pain, epilepsy, levodopa-induced dyskinesia and many others. AV-101 is an oral prodrug of 7-Cl-KYNA which binds uniquely at the glycine site of the NMDA receptor. We are developing AV-101 initially for the treatment of MDD, a serious neurobiologically-based mood disorder which is a leading cause of disability globally, affecting approximately 17 million adults in the United States and nearly 300 million people worldwide according to the U.S. National Institutes of Health (*NIH*). AV-101 is currently in development in the U.S. as an adjunctive or add-on treatment (together with current FDA-approved antidepressants (SSRIs and SNRIs)) through the ELEVATE study, our U.S. multi-center, randomized, double-blind, placebo-controlled Phase 2 clinical study to evaluate the efficacy and safety of adjunctive use of AV-101 in adult MDD patients who have an inadequate response to standard FDA-approved oral antidepressant therapy (the *ELEVATE Study*). In addition to the ELEVATE Study, we are collaborating with Baylor College of Medicine (*Baylor*) and the U.S. Department of Veterans Affairs (*VA*) on a small Phase 1b clinical trial of AV-101 in healthy volunteer U.S. Military Veterans from Operation Enduring Freedom, Operation Iraqi Freedom or Operation New Dawn to define a dose-response relationship between AV-101 and relevant biomarkers related to NMDA receptor function and other biomarkers possibly related to suicidal ideation in U.S. Military Veterans (the *Baylor Study*). The FDA has granted Fast Track designation for development of AV-101 as an add-on, or adjunctive, treatment for MDD. We believe AV-101 has potential as a novel treatment for multiple additional CNS indications, including as a non-opioid treatment for chronic neuropathic pain, for which the FDA has granted a second AV-101 Fast Track designation, as well as a novel oral therapy for dyskinesia associated with levodopa therapy for Parkinson's disease and suicidal ideation.

PH10 is a novel, rapid-acting CNS neuroactive nasal spray for MDD. Administered in microgram doses, PH10 activates nasal chemosensory receptors that, in turn, engage neural circuits that lead to rapid antidepressant effects without the psychological side effects, systemic exposure or safety concerns often associated with current oral antidepressants and ketamine-based therapies (intravenous ketamine or esketamine nasal spray) (*KBT*). In an exploratory 30-patient Phase 2a clinical study, PH10 was well-tolerated and, at microgram doses, demonstrated rapid-onset antidepressant effects, as measured by the Hamilton Depression Rating Scale (*HAM-D*), without psychological side effects or safety concerns. Based on positive results from this exploratory Phase 2a study, we are planning Phase 2b clinical development of PH10 in 2020, initially as a new stand-alone treatment for MDD. In a manner similar to the potential of AV-101, with its exceptional safety profile during clinical development to date, PH10 also has potential to change the current paradigm for treatment of treatment-resistant depression (*TRD*) with KBT, which must be administered in a clinical setting, by enabling those who respond to KBT to transition to more convenient home-based use of PH10 to maintain the initial therapeutic benefits of KBT.

PH94B is also a novel, rapid-acting CNS neuroactive nasal spray administered in microgram doses. We are initially developing PH94B for treatment of social anxiety disorder (*SAD*), which affects over 20 million Americans and, according to the NIH, is the third most common psychiatric condition after depression and substance abuse. A person with SAD feels symptoms of anxiety or fear in certain social situations, such as meeting new people, dating, being on a job interview, answering a question in class, or having to talk to a cashier in a store. Doing everyday things in front of people - such as eating or drinking in front of others or using a public restroom - also causes anxiety or fear. The person is afraid that he or she will be humiliated, judged, and rejected. The fear that people with SAD have in social situations is so strong that they feel it is beyond their ability to control. As a result, it gets in the way of going to work, attending school, or doing everyday things. People with SAD may worry about these and other things for weeks before they happen. Sometimes, they end up staying away from places or events where they think they might have to do something that will embarrass them. Some people with SAD do not have anxiety in social situations but have performance anxiety instead. They feel physical symptoms of anxiety in performance situations, such as giving a speech, playing a sports game, or dancing or playing a musical instrument on stage. SAD usually starts during youth in people who are extremely shy. Without treatment, social anxiety disorder can last for many years or a lifetime and prevent a person from reaching his or her full potential. Unfortunately, SAD often predisposes to depression and substance abuse. Only three drugs, all antidepressants, are approved by the U.S Food and Drug Administration (*FDA*) specifically for treatment of SAD. However, for treatment of both MDD and SAD, current oral antidepressants (*ADs*) have slow onset of effect (often several weeks to months) and significant side effects that may make them inadequate treatment alternatives for many individuals affected by MDD and SAD.

PH94B is fundamentally differentiated from all current treatments for SAD. PH94B activates nasal chemosensory receptors that, in turn, engage neural circuits that lead to rapid suppression of fear and anxiety. In clinical studies to date, PH94B has not shown psychological side effects, systemic exposure, sedation or other safety concerns often associated with current antidepressants approved by the FDA for treatment of SAD, as well as benzodiazepines and beta blockers, which are not approved by the FDA to treat SAD but are often prescribed for treatment of SAD off-label. In a peer-reviewed, published double-blind, placebo-controlled Phase 2 clinical trial, PH94B neuroactive nasal spray was significantly more effective than placebo in reducing public-speaking and social interaction anxiety on laboratory challenges of individuals with SAD within 10 to 15 minutes of self-administration. Based on its novel mechanism of pharmacological action, rapid-onset of therapeutic effects and exceptional safety and tolerability profile in Phase 2 clinical trials to date, we are preparing to begin pivotal Phase 3 development of PH94B neuroactive nasal spray to become the first FDA-approved on-demand treatment for SAD. Additional potential CNS indications for PH94B include, general anxiety disorder (*GAD*), peripartum anxiety, preoperative anxiety, panic disorder and post-traumatic stress disorder (*PTSD*).

In addition to our current CNS product candidates, we have pipeline-enabling programs through our wholly-owned subsidiary, VistaStem Therapeutics (*VistaStem*). VistaStem is focused on applying pluripotent stem cell (*hPSC*) technology to discover, rescue, develop and commercialize proprietary new chemical entities (*NCEs*) for CNS and other diseases and regenerative medicine (*RM*) involving hPSC-derived blood, cartilage, heart and liver cells. Our internal drug rescue programs are designed to utilize *CardioSafe 3D*, our customized cardiac bioassay system, to discover and develop small molecule NCEs for our CNS pipeline or for out-licensing. To advance potential RM applications of our cardiac stem cell technology, we have sublicensed to BlueRock Therapeutics LP, a next generation cell therapy and RM company recently acquired by Bayer AG (*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 collaborations or licensing transactions involving blood, cartilage, and/or liver cells derived from hPSCs for cell-based therapy, cell repair therapy, RM and/or tissue engineering.

Subsidiaries

As noted above, VistaStem, a California corporation, 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 and 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, 2019 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 six months ended September 30, 2019 are not necessarily indicative of the operating results to be expected for our fiscal year ending March 31, 2020, or for any other future interim or other period.

The accompanying unaudited Condensed Consolidated Financial Statements and notes to the 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, 2019 contained in our Annual Report on Form 10-K, as filed with the Securities and Exchange Commission (*SEC*) on June 25, 2019.

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 $192.7 million accumulated from inception (May 1998) through September 30, 2019. 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 September 30, 2019, 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 $79.0 million, as well as from an aggregate of approximately $17.7 million of government research grant awards (excluding the fair market value of government sponsored and funded clinical trials), 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 noncash 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 September 30, 2019, we had cash and cash equivalents of approximately $4.1 million. As disclosed in Note 11, *Subsequent Events*, since September 30, 2019, we have completed a self-placed private placement of units consisting of unregistered shares of our common stock and warrants to purchase unregistered shares of our common stock pursuant to which we have received cash proceeds of $600,000 (the *Fall 2019 Private Placement*). Nevertheless, we believe that our cash position at September 30, 2019, including the proceeds from the Fall 2019 Private Placement, considered with our recurring and anticipated losses, negative cash flows from operations and stockholders' deficit 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 finalize the ELEVATE Study, prepare for and potentially launch Phase 3 clinical trials of AV-101 and/or PH94B, prepare for additional Phase 2 clinical studies and certain nonclinical studies involving AV-101, PH10 and PH94B and prepare for a Phase 2b clinical trial of PH10, and raises substantial doubt that we can continue as a going concern. 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 Registration Statement on Form S-3 (Registration No. 333-234025) (the *S-3 Registration Statement*), which became effective on October 7, 2019, is 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, 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.

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 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 provide non-dilutive funding for development of AV-101, PH94B, PH10 or other product candidates, as well as new government grant awards and/or agreements, 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. 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, right-of-use assets and lease liabilities 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 (*CRO*s) 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 and October 2018, we acquired exclusive worldwide licenses to develop and commercialize PH94B and PH10, respectively, by issuing an aggregate of 2,556,361 unregistered shares of our common stock having an issuance-date fair market value of $4,250,000. Since, at the date of each acquisition, neither product candidate had achieved regulatory approval and each will require significant additional development and expense, we expensed the costs related to acquiring the licenses and the option during our fiscal year ended March 31, 2019.

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 or other grantee 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. 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 amortized 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 six months ended September 30, 2019 and 2018.

	Three Months Ended September 30,		Six Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Research and development expense	$ 167,500	$ 450,600	$ 558,100	$ 680,700
General and administrative expense	226,000	721,800	898,400	1,104,300
Total stock-based compensation expense	$ 393,500	$ 1,172,400	$ 1,456,500	$ 1,785,000

In May 2019, the Compensation Committee of our Board of Directors (the *Board*) approved the grant of options from our 2016 Amended and Restated Stock Incentive Plan (the *2016 Plan*) to purchase an aggregate of 1,220,000 shares of our common stock at a then above-market exercise price of $1.00 per share to the independent members of our Board, our officers and employees and certain consultants. The options vested 25% upon grant with the remaining shares vesting ratably over three years for independent directors, officers and employees, and over two years for consultants. We valued the options granted in May 2019 using the Black-Scholes Option Pricing Model and the following weighted average assumptions:

Assumption:	May 2019
Market price per share at grant date	$ 0.80
Exercise price per share	$ 1.00
Risk-free interest rate	2.12%
Expected term in years	5.53
Volatility	85.90%
Dividend rate	0.0%
Shares	1,220,000
Fair Value per share	**$ 0.54**

Additionally, in May 2019, the Compensation Committee approved, subject to subsequent stockholder approval at our 2019 Annual Meeting of Stockholders (*Annual Meeting*) held in September 2019, the 2019 Omnibus Equity Incentive Plan (the *2019 Plan*) and designated 7.5 million shares of our authorized common stock to be reserved thereunder. Further, in May 2019, the Compensation Committee granted options pursuant to the 2019 Plan to one of our officers to purchase 170,000 shares of our common stock at a then above-market exercise price of $1.00 per share, which grant was contingent upon the approval of the 2019 Plan by our stockholders. Our stockholders approved the 2019 Plan at our Annual Meeting and ratified the contingent grant. The option vested 25% upon approval of the 2019 Plan and the remaining shares vest ratably over three years. We valued the option using the Black-Scholes Option Pricing Model and the following assumptions:

Assumption:	September 2019
Market price per share at grant date	$ 0.84
Exercise price per share	$ 1.00
Risk-free interest rate	1.45%
Expected term in years	5.58
Volatility	86.04%
Dividend rate	0.0%
Shares	170,000
Fair Value per share	**$ 0.56**

Upon approval of the 2019 Plan by our stockholders, no further option or other equity awards were permitted from our 2016 Plan and all remaining authorized shares of our common stock available for issuance under the 2016 Plan, 1,388,412 shares, became available for issuance under the 2019 Plan.

At September 30, 2019, there were stock options outstanding under our 2016 Plan and 2019 Plan to purchase 8,014,838 shares of our common stock at a weighted average exercise price of $1.40 per share. At that date, there were also 8,718,412 shares of our common stock available for future issuance under the 2019 Plan. See Note 11, *Subsequent Events*, for disclosure of additional option grants made in October 2019.

Leases, Right-of-Use Assets and Lease Liabilities

On April 1, 2019, we adopted Financial Accounting Standards Board (*FASB*) Accounting Standards Update (*ASU*) No. 2016-02, *Leases*, which replaced the existing guidance in Accounting Standards Codification (*ASC*) 840, "Leases", and its subsequent amendments including ASU No. 2018-11, *Leases (Topic 842):* Targeted Improvements (*ASC 842*) using the modified transition method.

We determine whether an arrangement is an operating or financing lease at contract inception. Operating lease assets represent our right to use an underlying asset for the lease term and operating lease liabilities represent our obligation to make lease payments arising from the lease. Operating lease assets and liabilities are recognized at the commencement date of the lease based upon the present value of lease payments over the lease term. When determining the lease term, we include options to extend or terminate the lease when it is reasonably certain that we will exercise that option. In determining the present value of the lease payments, we use the interest rate implicit in the lease when it is readily determinable and we use our estimated incremental borrowing rate based upon information available at the commencement date when the implicit rate is not readily determinable.

The lease payments used to determine our operating lease assets include lease incentives and stated rent increases and may include escalation or other clauses linked to rates of inflation or other factors when determinable and are recognized in our operating lease assets in our condensed consolidated balance sheets.

Our operating leases are reflected in right of use asset – operating leases, other current liabilities and non-current operating lease liability in our condensed consolidated balance sheets. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. Short-term leases, defined as leases that have a lease term of 12 months or less at the commencement date, are excluded from this treatment and are recognized on a straight-line basis over the term of the lease.

Our accounting for financing leases, previously referred to as "capital leases" under prior guidance, remained substantially unchanged with our adoption of ASC 842. Financing leases are included in property and equipment, net and as current and non-current financing lease liabilities in our condensed consolidated balance sheets. Refer to "Recent Accounting Pronouncements" below and Note 10, *Commitments and Contingencies*, for additional information regarding our adoption of ASC 842 and its impact on our condensed consolidated financial statements.

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:

	As of September 30,	
	2019	**2018**
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 Company's Amended and Restated 2016 (formerly 2008) Stock Incentive Plan and 2019 Omnibus Equity Incentive Plan	8,014,838	6,160,338
Outstanding warrants to purchase common stock	21,242,954	20,709,516
Total	33,486,044	31,098,106

[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; excludes common shares issuable in payment of dividends on Series B Preferred upon conversion.
[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 September 30, 2019 or March 31, 2019.

Recent Accounting Pronouncements

Except as described below, there have been no recent accounting pronouncements or changes in accounting pronouncements during the six months ended September 30, 2019, as compared to the recent accounting pronouncements described in our Form 10-K for our fiscal year ended March 31, 2019, that are of significance or potential significance to us.

In February 2016, the FASB issued ASU No. 2016-02, *Leases*, which replaced the existing guidance in ASC 840, "Leases", and in July 2018, the FASB issued ASU No. 2018-11, *Leases (Topic 842):* Targeted Improvements (together, *ASC 842*). The new leasing standards set 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 standards require 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 prior guidance for operating leases. We adopted the standards on the required effective date of April 1, 2019 and did not restate lease expense or lease-related assets or liabilities reported in prior comparative periods. Presentation of our financing lease for office equipment in the consolidated balance sheet is generally consistent with capitalized lease presentation under the prior lease accounting guidance. Presentation of leases within the consolidated statements of operations and consolidated statements of cash flows is generally consistent with the prior lease accounting guidance. We elected the package of practical expedients permitted under the transition guidance and, accordingly, the adoption of ASC 842 did not change the prior classification of any of our leases. We elected not to record a right-of-use asset or a lease liability on the balance sheet for leases with a term of 12 months or less and will recognize the associated lease payments in the consolidated statements of operations over the lease term. On the April 1, 2019 adoption date, we recognized approximately $4.3 million as total lease liabilities and $3.9 million as total right-of-use assets in our Condensed Consolidated Balance Sheet and derecognized a deferred rent liability of approximately $0.4 million attributable to the operating lease of our primary office and laboratory facilities recorded in accordance with prior guidance.

Note 4. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets are composed of the following at September 30, 2019 and March 31, 2019:

	September 30, 2019	March 31, 2019
AV-101, PH94B and PH10 materials and contract services	$ 357,900	$ 5,900
Fair value of securities issued for professional services	-	105,900
Insurance	206,000	96,300
Public offering filing fees and expenses	30,500	22,300
All other	10,100	20,500
	$ 604,500	$ 250,900

The fair value of securities issued for professional services reflects the unamortized 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 amortized ratably over the term of the related service agreement.

Note 5. Property and Equipment

Property and equipment is composed of the following at September 30, 2019 and March 31, 2019:

	September 30, 2019	March 31, 2019
Laboratory equipment	$ 892,500	$ 892,500
Tenant improvements	214,400	214,400
Computers and network equipment	54,600	54,600
Office furniture and equipment	84,600	84,600
	1,246,100	1,246,100
Accumulated depreciation and amortization	(985,500)	(933,400)
Property and equipment, net	$ 260,600	$ 312,700

Included in amounts reported above for office furniture and equipment is the right-of-use asset related to a financing lease of certain office equipment. Amounts associated with assets subject to the financing lease at September 30, 2019 and March 31, 2019 are as follows:

	September 30, 2019	March 31, 2019
Office equipment subject to financing lease	$ 14,700	$ 14,700
Accumulated depreciation	(8,000)	(6,500)
Net book value of office equipment subject to financing lease	$ 6,700	$ 8,200

Note 6. Accrued Expenses

Accrued expenses are composed of the following at September 30, 2019 and March 31, 2019:

	September 30, 2019	March 31, 2019
Accrued expenses for AV-101, PH94B, and PH10 clinical trial, development and related expenses	$ 2,080,700	$ 1,067,600
Accrued compensation	-	439,200
Accrued professional services	127,600	172,100
All other	7,200	6,700
	$ 2,215,500	$ 1,685,600

Note 7. Notes Payable

The following table summarizes our unsecured promissory notes at September 30, 2019 and March 31, 2019:

	September 30, 2019			March 31, 2019		
	Principal Balance	Accrued Interest	Total	Principal Balance	Accrued Interest	Total
7.75% and 7.15% Notes payable to insurance premium financing company (current)	$ 159,300	$ -	$ 159,300	$ 57,300	$ -	$ 57,300

In May 2019, we executed a 7.15% promissory note in the principal amount of $230,200 in connection with certain insurance policy premiums. The note is payable in monthly installments of $23,800, including principal and interest, through March 2020, and had an outstanding principal balance of $139,800 at September 30, 2019. In February 2019, we executed a 7.75% promissory note in the principal amount of $63,500 in connection with other insurance policy premiums. That note is payable in monthly installments of $6,600 including principal and interest, through December 2019 and had an outstanding principal balance of $19,500 at September 30, 2019.

Note 8. Capital Stock

During the six months ended September 30, 2019, we did not engage in any capital-raising transactions, nor did we grant any equity securities as full or partial compensation to consultants, other than stock options as described in Stock-Based Compensation in Note 3, *Summary of Significant Accounting Policies*.

Warrants Outstanding

During the quarter ended June 30, 2019, warrants issued in private placement transactions during calendar 2018 to purchase an aggregate of 805,800 shares of our common stock at exercise prices between $1.50 per share and $1.75 per share became fully-exercisable in accordance with their terms. Accordingly, all warrants outstanding at September 30, 2019 are now fully-exercisable at a weighted average exercise price of $2.43 per share as follows:

Exercise Price per Share	Weighted Average per Share	Expiration Date	Warrants Outstanding and Exercisable at September 30, 2019
$ 1.50	$ 1.50	11/30/2021 to 12/13/2022	14,335,200
$ 1.59 - $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 - $3.51	$ 2.14	4/30/2021 to 10/19/2022	696,693
$ 5.30	$ 5.30	5/16/2021	2,705,883
$ 6.00 - $10.00	$ 7.15	10/11/2019 to 3/3/2023	1,490,628
	$ 2.43		21,242,954

Of the warrants outstanding at September 30, 2019, 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 September 30, 2019, 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, manufacturing and regulatory affairs associated with our efforts to develop and commercialize AV-101 for MDD, including our ELEVATE Study and other potential CNS indications, as well as PH94B, PH10, and other potential product candidates. At September 30, 2019, CBV held approximately 2% of our outstanding common stock.

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 $1,610,900 and $752,200 during the quarters ended September 30, 2019 and 2018, respectively, and $3,016,000 and $1,603,000 for the six months ended September 30, 2019 and 2018, respectively. At September 30, 2019 and March 31, 2019, we had recorded accounts payable and accrued expenses related to CRL aggregating $1,646,800 and $657,800, 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.

During our fiscal year ended March 31, 2019, we issued an aggregate of 2,556,361 shares of our unregistered common stock having an issue-date fair market value of $4,250,000 to Pherin Pharmaceuticals, Inc. (*Pherin*) to acquire exclusive worldwide licenses to develop and commercialize PH94B and PH10. We recorded the acquisition of the licenses as research and development expense during our fiscal year ended March 31, 2019. During the quarters ended September 30, 2019 and 2018, we recorded $30,000 and $10,000, respectively, and during the six months ended September 30, 3019 and 2018, we recorded $60,000 and $10,000 respectively, representing monthly support payments to Pherin under the terms of the PH94B license agreement. We recorded no amounts payable to Pherin at September 30, 2019 or March 31, 2019. At September 30, 2019, Pherin held approximately 4% of our outstanding common stock.

During the six months ended September 30, 2019, we engaged the consulting firm headed by one of the independent members of our Board to provide various market research studies for certain of our product pipeline candidates and recorded research and development expense of $75,100 for the quarter ended September 30, 2019 and $102,800 for the six months ended September 30, 2019 related to such studies. We incurred no such expenses for the three and six months ended September 30, 2018. At September 30, 2019, we recorded $45,000 of accrued expenses related to these studies.

Note 10. Commitments and Contingencies

Operating Leases

We lease our headquarters office and laboratory space in South San Francisco, California under the terms of a lease that expires on July 31, 2022 and that provides an option to renew for an additional five years at then-current market rates. Consistent with the guidance in ASC 842, effective beginning April 1, 2019, we have recorded this lease in our Condensed Consolidated Balance Sheet as an operating lease. For the purpose of determining the right-of-use asset and associated lease liability, we determined that the renewal of this lease is reasonably probable. The lease of our South San Francisco facilities does not include any restrictions or covenants requiring special treatment under ASC 842.

The following table summarizes the presentation of the operating lease in our Condensed Consolidated Balance Sheet at September 30, 2019:

	As of September 30, 2019
Assets	
Right of use asset – operating lease	$ 3,750,200
Liabilities	
Current operating lease obligation	$ 289,600
Non-current operating lease obligation	3,879,400
Total operating lease liability	$ 4,169,000

The following table summarizes the effect of operating lease costs in the Company's condensed consolidated statements of operations:

	For the Three Months Ended September 30, 2019	For the Six Months Ended September 30, 2019
Operating lease cost	$ 203,100	$ 411,900

The minimum (base rental) lease payments related to our South San Francisco operating lease are expected to be as follows:

Fiscal Years Ending March 31,	
2020 (remaining six months)	$ 315,500
2021	645,800
2022	668,400
2023	726,000
2024	766,000
Thereafter	2,720,400
Total lease expense	5,842,100
Less imputed interest	(1,673,100)
Present value of operating lease liabilities	$ 4,169,000

Under the prior lease guidance, future minimum lease payments, under the non-cancellable portion (excluding the five-year extension assumed under ASC 842) of the South San Francisco operating lease were as follows at March 31, 2019:

Fiscal Years Ending March 31,	
2020	$ 623,900
2021	645,800
2022	668,400
2023	225,300
2024	-
Thereafter	-
	$ 2,163,400

The remaining lease term, including the assumed five-year extension at the expiration of the current lease period, and the discount rate assumption for our South San Francisco operating lease is as follows:

	As of September 30, 2019
Assumed remaining lease term in years	7.84
Assumed discount rate	8.54%

The interest rate implicit in lease contracts is typically not readily determinable and, as such, we used our estimated incremental borrowing rate based on information available at the adoption of ASC 842, which represents an internally developed rate that would be incurred to borrow, on a collateralized basis, over a similar term, an amount equal to the lease payments in a similar economic environment.

Supplemental disclosure of cash flow information related to the Company's operating leases included in cash flows used by operating activities in the condensed consolidated statements of cash flows is as follows:

	For the Six Months Ended September 30, 2019
Cash paid for amounts included in the measurement of lease liabilities	$ 374,200

During the six months ended September 30, 2019, other than the initial adoption of ASC 842 that required right of use assets and lease liabilities to be recorded, we recorded no new right of use assets arising from new lease liabilities.

We also lease a small office in the San Francisco Bay Area under a month-to-month arrangement at insignificant cost and have made an accounting policy election not to apply the ASC 842 operating lease recognition requirements to such short-term lease. We recognize the lease payments for this lease in general and administrative expense over the lease term. We recorded rent expense of $3,500 and $6,900 for the three and six months ended September 30, 2019, respectively, attributable to this lease.

Note 11. Subsequent Events

We have evaluated subsequent events through November 6, 2019 and have identified the following matters requiring disclosure:

Grant of Options from the 2019 Plan

During October 2019, we granted options from our 2019 Plan to the independent members of our Board, our officers and employees and certain consultants to purchase an aggregate of 1,575,000 shares of our common stock at an exercise price of $1.41 per share, the quoted closing market price of our common stock on the Nasdaq Capital Market on the grant date. The options were vested 25% at grant with the remaining options vesting ratably over the following 24 months.

Common Stock and Warrants Issued in Fall 2019 Private Placement

Between October 30, 2019 and November 6, 2019, in a self-placed private placement and pursuant to subscription agreements from accredited investors, we sold to such investors units, at a purchase price of $1.00 per unit, consisting of an aggregate of 600,000 unregistered shares of our common stock and warrants, exercisable through November 1, 2023, to purchase 300,000 unregistered shares of our common stock at an exercise price of $2.00 per share. 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 prior to six months and one day following issuance. We received aggregate cash proceeds of $600,000 from the sale of the units.

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 intended 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 of Directors (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 committed to developing differentiated new generation medications for central nervous system (*CNS*) diseases and disorders with high unmet need. Our product candidate portfolio includes three differentiated clinical-stage candidates, AV-101, PH10 and PH94B, which we are developing for multiple CNS indications. We aim to become a fully-integrated biopharmaceutical company that develops and commercializes innovative CNS therapies for large and growing mental health and neurology markets where current treatments are inadequate to meet the needs of millions of patients and caregivers worldwide.

AV-101 (4-Chlorokynurenine or 4-Cl-KYN) belongs to a new generation of investigational medicines in neuropsychiatry and neurology known as NMDA (N-methyl-D-aspartate) glutamate receptor modulators. The NMDA receptor is a pivotal receptor in the brain and abnormal NMDA function is associated with multiple CNS diseases and disorders, including major depressive disorder (*MDD*), chronic neuropathic pain, epilepsy, levodopa-induced dyskinesia and many others. AV-101 is an oral prodrug of 7-Cl-KYNA, an NMDA receptor antagonist which binds at the glycine site of the NMDA receptor. We are developing AV-101 initially for the treatment of MDD, a serious neurobiologically-based mood disorder which is a leading cause of disability globally, affecting approximately 17 million adults in the United States and nearly 300 million people worldwide according to the U.S. National Institutes of Health (*NIH*). AV-101 is currently in Phase 2 development in the U.S. as an adjunctive, or add-on, treatment (together with current FDA-approved oral antidepressants (SSRIs and SNRIs)) through the ELEVATE study, our U.S. multi-center, randomized, double-blind, placebo-controlled Phase 2 clinical study to evaluate the efficacy and safety of adjunctive use of AV-101 in adult MDD patients who have an inadequate response to standard FDA-approved oral antidepressant therapy (the *ELEVATE Study*). In addition to the ELEVATE Study, we are collaborating with Baylor College of Medicine (*Baylor*) and the U.S. Department of Veterans Affairs (*VA*) on a small Phase 1b clinical trial of AV-101 in healthy volunteer U.S. Military Veterans from Operation Enduring Freedom, Operation Iraqi Freedom or Operation New Dawn (the *Baylor Study*). The FDA has granted Fast Track designation for development of AV-101 as an adjunctive, treatment for MDD. We believe AV-101 has potential as a novel treatment for multiple additional CNS indications, including as a non-opioid treatment for chronic neuropathic pain, for which the FDA has granted a second AV-101 Fast Track designation, as well as a novel oral therapy for dyskinesia associated with levodopa therapy for Parkinson's disease and suicidal ideation.

PH10 is a novel, rapid-acting CNS neuroactive nasal spray for MDD. Administered in microgram doses, PH10 activates nasal chemosensory receptors that, in turn, engage neural circuits that lead to rapid antidepressant effects without the psychological side effects, systemic exposure or safety concerns often associated with current oral antidepressants and ketamine-based therapies (intravenous ketamine or esketamine nasal spray) (*KBT*). In an exploratory 30-patient Phase 2a clinical study, PH10 was well-tolerated and, at microgram doses, demonstrated rapid-onset and sustained antidepressant effects, as measured by the Hamilton Depression Rating Scale (*HAM-D*), without psychological side effects or safety concerns often associated with KBT. Based on positive results from this exploratory Phase 2a study, we are preparing for Phase 2b clinical development of PH10 in late-2020, initially as a new stand-alone treatment for MDD. In a manner similar to the potential of AV-101, with its exceptional safety profile during clinical development to date, PH10 also has potential to change the current paradigm for treatment of treatment-resistant depression (*TRD*) with KBT, which must be administered in a clinical setting, by enabling those who respond to such therapy to transition to more convenient home-based administration of PH10 to maintain the therapeutic benefits of KBT.

PH94B is also a first-in-class, rapid-acting CNS neuroactive nasal spray administered in microgram doses. We are initially developing PH94B initially for treatment of social anxiety disorder (*SAD*), which affects over 20 million Americans and, according to the NIH, is the third most common psychiatric condition after depression and substance abuse. A person with SAD feels symptoms of anxiety or fear in certain social situations, such as meeting new people, dating, being on a job interview, answering a question in class, or having to talk to a cashier in a store. Doing everyday things in front of people - such as eating or drinking in front of others or using a public restroom - also causes anxiety or fear. The person is afraid that he or she will be humiliated, judged, and rejected. The fear that people with SAD have in social situations is so strong that they feel it is beyond their ability to control. As a result, it gets in the way of going to work, attending school, or doing everyday things. People with SAD may worry about these and other things for weeks before they happen. Sometimes, they end up staying away from places or events where they think they might have to do something that will embarrass them. Some people with SAD do not have anxiety in social situations but have performance anxiety instead. They feel physical symptoms of anxiety in performance situations, such as giving a speech, playing a sports game, or dancing or playing a musical instrument on stage. SAD usually starts during youth in people who are extremely shy. Without treatment, social anxiety disorder can last for many years or a lifetime and prevent a person from reaching his or her full potential.

PH94B is fundamentally differentiated from all current treatments for SAD. PH94B activates nasal chemosensory receptors that, in turn, engage neural circuits that lead to rapid suppression of fear and anxiety. In clinical studies to date, PH94B has not shown psychological side effects, systemic exposure, sedation or other safety concerns often associated with current antidepressants approved by the FDA for treatment of SAD, as well as benzodiazepines and beta blockers, which are not approved by the FDA to treat SAD but are often prescribed for treatment of SAD off-label. In a peer-reviewed, published double-blind, placebo-controlled Phase 2 clinical trial, PH94B neuroactive nasal spray was significantly more effective than placebo in reducing social interaction and public speaking anxiety on laboratory challenges of individuals with SAD within 10 to 15 minutes of self-administration. Based on its novel mechanism of pharmacological action, rapid-onset of therapeutic effects and exceptional safety and tolerability profile in Phase 2 clinical trials to date, we are preparing to begin pivotal Phase 3 development of PH94B neuroactive nasal spray to become the first FDA-approved as-needed, on-demand treatment for SAD. Additional potential CNS indications for PH94B include, general anxiety disorder (*GAD*), peripartum anxiety, preoperative anxiety, panic disorder and post-traumatic stress disorder (*PTSD*).

In addition to our current CNS product candidates, we have pipeline-enabling programs through our wholly-owned subsidiary, VistaStem Therapeutics (*VistaStem*). VistaStem is focused on applying pluripotent stem cell (*hPSC*) technology to discover, rescue, develop and commercialize proprietary new chemical entities (*NCEs*) for CNS and other diseases and regenerative medicine (*RM*) involving hPSC-derived blood, cartilage, heart and liver cells. Our internal drug rescue programs are designed to utilize *CardioSafe 3D*, our customized cardiac bioassay system, to discover and develop small molecule NCEs for our CNS pipeline or for out-licensing. To advance potential RM applications of our cardiac stem cell technology, we have sublicensed to BlueRock Therapeutics LP, a next generation cell therapy and RM company recently acquired by Bayer AG (*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 collaborations or licensing transactions involving blood, cartilage, and/or liver cells derived from hPSCs for cell-based therapy, cell repair therapy, RM and/or tissue engineering.

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, 2019, as filed with the SEC on June 25, 2019, 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, including the ELEVATE Study. In addition, we have devoted resources to stem cell technology research and development, bioassay development and small molecule drug development, as well as 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, during our fiscal year ended March 31, 2019, we acquired the rights to develop and commercialize PH94B and PH10 and are actively pursuing initiatives to advance their nonclinical and clinical development. As of September 30, 2019, we had an accumulated deficit of approximately $192.7 million. Our net loss for the six months ended September 30, 2019 and 2018 was approximately $11.5 million and $11.6 million, respectively, including $2.25 million in non-cash expense in 2018 for the acquisition of the PH94B license and the option to acquire a similar license for PH10. We expect losses to continue for the foreseeable future, as we finalize our ELEVATE Study, pursue further clinical development of AV-101 for the adjunctive treatment of MDD, PH94B for SAD, PH10 for MDD, and for additional CNS indications with respect to each of these drug candidates.

Summary of the Six Months Ended September 30, 2019

During the six months ended September 30, 2019, 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) advance the nonclinical, including manufacturing, and regulatory initiatives necessary to facilitate Phase 3 clinical development of PH94B for SAD and Phase 2 clinical development of PH10 for MDD, (iii) 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, and (iv) on a limited basis, advance drug rescue applications of our stem cell technology to further expand our CNS pipeline.

In particular, during the six months ended September 30, 2019, we continued to conduct the ELEVATE Study, for which the final patient was dosed at the end of September 2019, produced supplies of AV-101, and conducted and/or initiated certain Phase 3-enabling nonclinical studies involving AV-101.

Pursuant to our Material Transfer Cooperative Research and Development Agreement with the VA and our arrangements with Baylor, Baylor has recently completed dosing of healthy volunteer U.S. Military Veterans in the Baylor Study to define a dose-response relationship between AV-101 and relevant biomarkers related to NMDA receptor function and other biomarkers possibly related to suicidal ideation in U.S. Military Veterans.

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 levodopa-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.

Over the recent and current fiscal years, 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, including a patent for treatment of MDD with AV-101 granted in Australia, were recently allowed or have been granted in the U.S. and other major pharmaceutical markets. 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 the U.S., Australia, China, Europe, Japan and Hong Kong. Applications are pending in 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, and for the therapeutic use of PH10, with our lead indication being the treatment of MDD.

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.

Subsequent to the completion of our public offering of common stock in February 2019, which generated $11.5 million in gross proceeds to us, we have not completed any additional financing transactions during the six months ended September 30, 2019. 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 nonclinical and clinical 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.

Results of Operations

Comparison of Three Months Ended September 30, 2019 and 2018

The following table summarizes the results of our operations for the three months ended September 30, 2019 and 2018 (amounts in thousands).

	Three Months Ended September 30,	
	2019	**2018**
Operating expenses:		
Research and development	$ 4,205	$ 5,261
General and administrative	1,146	2,171
Total operating expenses	5,351	7,432
Loss from operations	(5,351)	(7,432)
Interest income (expense), net	15	(3)
Loss before income taxes	(5,336)	(7,435)
Income taxes	-	-
Net loss	(5,336)	(7,435)
Accrued dividend on Series B Preferred Stock	(314)	(284)
Net loss attributable to common stockholders	$ (5,650)	$ (7,719)

Revenue

We reported no revenue for either the quarter ended September 30, 2019 or September 30, 2018 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 in the future under our December 2016 BlueRock Agreement, which has been assumed by Bayer in connection with its acquisition of BlueRock, 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.

Research and Development Expense

Research and development expense decreased from $5.3 million to $4.2 million for the quarters ended September 30, 2019 and 2018, respectively. Expense for the quarter ended September 30, 2018 included $2.25 million noncash expense associated with the acquisition of our license to develop and commercialize PH94B and an option to acquire a similar license for PH10, which was subsequently exercised. While this expense did not recur in the quarter ended September 30, 2019, we incurred increased expenses for the ELEVATE Study and various AV-101 nonclinical activities, including manufacturing additional quantities of AV-101 and other developmental studies, as well as nonclinical activities, including manufacturing, supporting the continuing development of PH94B and PH10. Additional noncash expenses included in research and development expense (excluding the noncash PH94B license and PH10 option acquisition in 2018), primarily stock-based compensation and depreciation, accounted for approximately $190,000 and $474,000 in the quarters ended September 30, 2019 and 2018, respectively. The following table indicates the primary components of research and development expense for each of the periods (amounts in thousands):

	Three Months Ended September 30,	
	2019	**2018**
Salaries and benefits	$ 343	$ 656
Stock-based compensation	167	451
Consulting and other professional services	188	29
Technology licenses and royalties	142	129
Project-related research and supplies:		
ELEVATE Study and other AV-101 expenses	2,521	1,607
PH94B and PH10 license and other expenses	670	2,250
Stem cell and all other	30	23
	3,221	3,880
Rent	132	104
Depreciation	12	12
Total Research and Development Expense	$ 4,205	$ 5,261

Salaries and benefits expense reported for the quarter ended September 30, 2018 includes a total of approximately $319,000 for bonus payments made to our Chief Medical Officer (*CMO*), Chief Scientific Officer (*CSO*) and members of our scientific staff during the quarter based on achievement of goals and objectives for the fiscal year ended March 31, 2018. Partially offsetting the absence of a comparable bonus amount in the quarter ended September 30, 2019 is the impact of salary increases granted to our CMO, CSO and members of our scientific staff effective in April 2019. Bonuses based on the achievement of goals and objectives for the fiscal year ended March 31, 2019 were accrued during that fiscal year and had no expense impact during the quarter ended September 30, 2019.

Stock-based compensation expense reflects the amortization of option grants made to our CSO, CMO, scientific staff and certain consultants since June 2016, all earlier outstanding grants having become fully vested and amortized. Grants awarded after September 30, 2018 account for approximately $39,000 of expense in the quarter ended September 30, 2019. Stock-based compensation expense for the quarter ended September 30, 2018 included (i) the impact of new options granted to our CMO, CSO, and members of our scientific staff in early 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 late 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, resulting in approximately $265,000 of expense attributable to the new option grants and modifications, including immediate recognition of $104,000 attributable to the modification of exercise prices. Expense attributable to recent option grants is generally being amortized over two-year to three-year vesting periods, with one-quarter of the grants made in August 2018 and May 2019 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 2018, primarily by members of our Scientific Advisory Board and CNS Clinical and Regulatory Advisory Board. The increase in 2019 expense also reflects consulting and analytical services in support of our PH94B and PH10 initiatives.

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 various patent applications in the U.S. and numerous foreign countries with respect to AV-101 and our stem cell technology platform. Support of the intellectual property portfolios of PH94B and PH10 contributed only nominally to this expense in 2019.

AV-101 project expense for each of the quarters presented primarily reflects the 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. In addition to increased ELEVATE Study costs in 2019, we have incurred further costs associated with various Phase 3-enabling initiatives and nonclinical studies.

Project expenses for the quarter ended September 30, 2019 related to PH94B and PH10 primarily reflect manufacturing and regulatory initiatives necessary to facilitate pivotal Phase 3 clinical development of PH94B for SAD and to facilitate Phase 2 development of PH10 for MDD. As disclosed earlier, noncash expense of $2.25 million in 2018 related to the acquisition of the PH94B license and PH10 option and represents the fair value of an aggregate of 1,630,435 unregistered shares of our common stock issued to Pherin in September 2018 under the terms of the license and option agreements.

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

The increase in rent expense reflects our implementation of ASC 842 effective April 1, 2019 and the requirement to recognize, as an operating lease, a right-of-use asset and a lease liability, both of which must be amortized over the expected lease term, for our South San Francisco office and laboratory facility lease. The underlying lease 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. In implementing ASC 842, we also projected that we would exercise a five-year option to extend our tenancy under the lease when it expires in 2022, which extension would be subject to market rent conditions at that time. We allocate total rent expense for our South San Francisco facility between research and development expense and general and administrative expense based generally on square footage dedicated to each function. Refer to Note 10, *Commitments and Contingencies*, in the accompanying Condensed Consolidated Financial Statements in Part I of this Report for additional information.

General and Administrative Expense

General and administrative expense decreased to approximately $1.1 million, from approximately $2.2 million for the quarters ended September 30, 2019 and 2018, respectively. Noncash expense, $272,000 in the quarter ended September 30, 2019, decreased from $792,000 in the quarter ended September 30, 2018 primarily due to decreases in stock-based compensation and noncash components of investor and public relations expenses, while cash-based salaries and benefits decreased by $426,000. The following table indicates the primary components of general and administrative expense for each of the periods (amounts in thousands):

	Three Months Ended September 30,	
	2019	**2018**
Salaries and benefits	$ 340	$ 766
Stock-based compensation	226	722
Board fees	46	39
Legal, accounting and other professional fees	90	105
Investor and public relations	197	313
Insurance	88	71
Travel expenses	6	39
Rent and utilities	87	72
All other expenses	66	44
	$ 1,146	$ 2,171

Salaries and benefits expense reported for the quarter ended September 30, 2018 includes a total of approximately $435,000 for bonus payments made 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 during the quarter based on achievement of goals and objectives for the fiscal year ended March 31, 2018. Partially offsetting the absence of a comparable bonus amount in the quarter ended September 30, 2019 is the impact of salary increases granted to our CEO, CFO, VP-Corporate Development and a member of our administrative staff effective in April 2019. Bonuses based on the achievement of goals and objectives for the fiscal year ended March 31, 2019 were accrued during that fiscal year and had no expense impact during the quarter ended September 30, 2019.

Stock-based compensation expense reflects the amortization of option grants made to our CEO, CFO, VP Corporate Development, administrative staff, independent members of our Board and certain consultants since June 2016, all earlier grants having become fully vested and amortized. Grants awarded after September 30, 2018 account for approximately $89,000 of the expense in the quarter ended September 30, 2019. Stock-based compensation expense for the quarter ended September 30, 2018 included (i) the impact of new options granted to our CEO, CFO, VP-Corporate Development and a member of our administrative staff in early 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 late August 2018 of outstanding options held by our CEO, CFO, VP-Corporate Development and a member of our administrative staff having exercise prices over $1.56 per share to reduce the exercise price to $1.50 per share, resulting in approximately $459,000 of expense attributable to the new option grants and modifications, including immediate recognition of $154,000 attributable to the modification of exercise prices. Expense attributable to recent option grants is generally being amortized over two-year to three-year vesting periods, with one-quarter of the grants made in August 2018, January 2019, May 2019 and September 2019 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 to the independent members of our Board. The 2019 increase reflects the addition of a new independent member to our Board in January 2019.

Legal, accounting and other professional fees for the quarters ended September 30, 2019 and 2018 includes expense related to routine legal fees as well as the accounting expense related to the quarterly review of our financial statements. In 2019 and 2018, we also incurred $30,000 and $3,000, respectively, attributable to services provided by international business development consultants.

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 September 30, 2019, in addition to cash fees and expenses we incurred for such activities, we recognized approximately $26,000 of noncash expense attributable to the amortization of the fair value of stock and warrants granted in the prior fiscal year to various corporate development, investor relations, and market awareness service providers. At September 30, 2019, the fair value of the securities granted has been fully amortized. In the quarter ended September 30, 2018, in addition to cash fees and expenses we incurred, we granted 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 non-cash expense of approximately $65,000. The balance of the fair value of the securities granted was recorded as a prepaid expense at September 30, 2018 and was amortized over the remaining period of the respective contracts.

In both periods, travel expense reflects costs associated with management presentations and meetings held in multiple U.S. markets, and certain international markets in 2019, 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 both years.

The increase in rent expense reflects our implementation of ASC 842 effective April 1, 2019 and the requirement to recognize, as an operating lease, a right-of-use asset and a lease liability, both of which must be amortized over the expected lease term, for our South San Francisco office and laboratory facility lease. The underlying lease 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. In implementing ASC 842, we also projected that we would exercise a five-year option to extend our tenancy under the lease when it expires in 2022, which extension would be subject to market rent conditions at that time. We allocate total rent expense for our South San Francisco facility between research and development expense and general and administrative expense based generally on square footage dedicated to each function. Refer to Note 10, *Commitments and Contingencies*, in the accompanying Condensed Consolidated Financial Statements in Part I of this Report for additional information.

Interest and Other Expenses

Interest income, net of interest expense, totaled $15,400 for the quarter ended September 30, 2019 compared to interest expense of $2,900 for the quarter ended September 30, 2018. The following table indicates the primary components of interest income and expense for each of the periods (amounts in thousands):

	Three Months Ended September 30,	
	2019	**2018**
Interest income	$ 19	$ -
Interest expense on premium financing and capital lease (2018)	(4)	(3)
Interest income (expense), net	$ 15	$ (3)

Following the completion of our public offering in February 2019, which generated $11.5 million in gross proceeds to us, during the current fiscal year, we deposited a portion of the proceeds in interest-bearing cash equivalent accounts and earned interest income. Interest expense in both periods relates to interest paid on insurance premium financing notes and on a lease of office equipment treated as a capitalized lease in 2018 and as a financing lease subject to ASC 842 in 2019.

We recognized $313,800 and $283,600 for the quarters ended September 30, 2019 and 2018, 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.

Comparison of Six Months Ended September 30, 2019 and 2018

The following table summarizes the results of our operations for the six months ended September 30, 2019 and 2018 (amounts in thousands).

	Six Months Ended September 30,	
	2019	**2018**
Operating expenses:		
Research and development	$ 8,519	$ 8,005
General and administrative	3,056	3,637
Total operating expenses	11,575	11,642
Loss from operations	(11,575)	(11,642)
Interest income (expense), net	32	(5)
Loss before income taxes	(11,543)	(11,647)
Income taxes	(2)	(2)
Net loss	(11,545)	(11,649)
Accrued dividend on Series B Preferred Stock	(616)	(557)
Net loss attributable to common stockholders	$ (12,161)	$ (12,206)

Revenue

We reported no revenue for either the six months ended September 30, 2019 or 2018 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 in the future under our December 2016 BlueRock Agreement 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.

Research and Development Expense

Research and development expense increased to $8.5 million compared to $8.0 million for the six months ended September 30, 2019 and 2018, respectively. Continuing expenses of the ELEVATE Study and various AV-101 nonclinical activities, including manufacturing additional quantities of AV-101 and other developmental studies, as well as nonclinical activities supporting the continuing development of PH94B for SAD and PH10 for MDD are the primary contributors to the increase in research and development expense, more than offsetting the $2.25 million noncash expense in the six months ended September 30, 2018 associated with the acquisition of our license to develop and commercialize PH94B and an option to acquire a similar license for PH10, which was subsequently exercised. Additional noncash expenses included in research and development expense (excluding the noncash PH94B license and PH10 option acquisition in 2018), primarily stock compensation and depreciation, accounted for approximately $607,000 and $729,000 in the six months ended September 30, 2019 and 2018, respectively. The following table indicates the primary components of research and development expense for each of the periods (amounts in thousands):

	Six Months Ended September 30,	
	2019	**2018**
Salaries and benefits	$ 683	$ 972
Stock-based compensation	558	681
Consulting and other professional services	324	43
Technology licenses and royalties	309	253
Project-related research and supplies:		
ELEVATE Study and other AV-101 expenses	5,187	3,510
PH94B and PH10 licenses and other expenses	1,094	2,250
Stem cell and all other	72	62
	6,353	5,822
Rent	268	208
Depreciation	24	24
All other	-	2
Total Research and Development Expense	$ 8,519	$ 8,005

Salaries and benefits expense reported for the six months ended September 30, 2018 includes a total of approximately $319,000 for bonus payments made to our CMO, CSO and members of our scientific staff during the second quarter based on achievement of goals and objectives for the fiscal year ended March 31, 2018. Partially offsetting the absence of a comparable bonus amount in the six months ended September 30, 2019 is the impact of salary increases granted to our CMO, CSO and members of our scientific staff effective in April 2019. Bonuses based on the achievement of goals and objectives for the fiscal year ended March 31, 2019 were accrued during that fiscal year and had no expense impact during the six months ended September 30, 2019.

Stock-based compensation expense reflects the amortization of option grants made to our CSO, CMO, scientific staff and certain consultants since June 2016, all earlier outstanding grants having become fully vested and amortized. Grants awarded after September 30, 2018 account for approximately $135,000 of expense in the six months ended September 30, 2019. Stock-based compensation expense for the six months ended September 30, 2018 included (i) the impact of new options granted to our CMO, CSO, and members of our scientific staff in early 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 late 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, resulting in approximately $362,000 of expense attributable to the new option grants and modifications, including immediate recognition of $104,000 attributable to the modification of exercise prices. Expense attributable to recent option grants is generally being amortized over two-year to three-year vesting periods, with one-quarter of the grants made in August 2018 and May 2019 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 2018, primarily by members of our Scientific Advisory Board and CNS Clinical and Regulatory Advisory Board. The increase in 2019 expense also reflects consulting and analytical services in support of our PH94B and PH10 initiatives.

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 various patent applications in the U.S. and numerous foreign countries with respect to AV-101 and our stem cell technology platform. Support of the intellectual property portfolios of PH94B and PH10 contributed only nominally to this expense in 2019.

AV-101 project expense for each of the periods presented primarily reflects the 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. In addition to increased ELEVATE Study costs in 2019, we have incurred further costs associated with various Phase 3-enabling initiatives and nonclinical studies.

Expenses for the six months ended September 30, 2019 related to PH94B and PH10 primarily reflect manufacturing and regulatory initiatives necessary to facilitate pivotal Phase 3 clinical development of PH94B for SAD and to facilitate Phase 2 development of PH10 for MDD. As disclosed earlier, noncash expense of $2.25 million in 2018 related to the acquisition of the PH94B license and PH10 option and represents the fair value of an aggregate of 1,630,435 unregistered shares of our common stock issued to Pherin in September 2018 under the terms of the license and option agreements.

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

The increase in rent expense reflects our implementation of ASC 842 effective April 1, 2019 and the requirement to recognize, as an operating lease, a right-of-use asset and a lease liability, both of which must be amortized over the expected lease term, for our South San Francisco office and laboratory facility lease. The underlying lease 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. In implementing ASC 842, we also projected that we would exercise a five-year option to extend our tenancy under the lease when it expires in 2022, which extension would be subject to market rent conditions at that time. We allocate total rent expense for our South San Francisco facility between research and development expense and general and administrative expense based generally on square footage dedicated to each function. Refer to Note 10, *Commitments and Contingencies*, in the accompanying Condensed Consolidated Financial Statements in Part I of this Report for additional information.

General and Administrative Expense

General and administrative expense decreased to approximately $3.1 million, from approximately $3.6 million for the six months ended September 30, 2019 and 2018, respectively. Noncash expense, $1,044,000 for the six months ended September 30, 2019, decreased from $1,295,000 for the six months ended September 30, 2018, primarily due to reductions in stock-based compensation and cash and noncash components of investor and public relations expenses, coupled with a decrease in cash-based salaries and benefits expense. The following table indicates the primary components of general and administrative expense for each of the periods (amounts in thousands):

	Six Months Ended September 30,	
	2019	**2018**
Salaries and benefits	$ 684	$ 1,065
Stock-based compensation	898	1,104
Board fees	92	78
Legal, accounting and other professional fees	369	356
Investor relations	501	599
Insurance	170	139
Travel expenses	36	76
Rent and utilities	177	143
All other expenses	129	77
	$ 3,056	$ 3,637

Salaries and benefits expense reported for the six months ended September 30, 2018 includes a total of approximately $435,000 for bonus payments made to our CEO, CFO, VP-Corporate Development and a non-officer member of our administrative staff during the second quarter based on achievement of goals and objectives for the fiscal year ended March 31, 2018. Partially offsetting the absence of a comparable bonus amount in the six months ended September 30, 2019 is the impact of salary increases granted to our CEO, CFO, VP-Corporate Development and a member of our administrative staff effective in April 2019. Bonuses based on the achievement of goals and objectives for the fiscal year ended March 31, 2019 were accrued during that fiscal year and had no expense impact during the six months ended September 30, 2019.

Stock-based compensation expense reflects the amortization of option grants made to our CEO, CFO, VP Corporate Development, administrative staff, independent members of our Board and certain consultants since June 2016, all earlier grants having become fully vested and amortized. Grants awarded after September 30, 2018 account for approximately $274,000 of the expense in the six months ended September 30, 2019. Stock-based compensation expense for the six months ended September 30, 2018 included (i) the impact of new options granted to our CEO, CFO, VP-Corporate Development and a member of our administrative staff in early 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 late August 2018 of outstanding options held by our CEO, CFO, VP-Corporate Development and a member of our administrative staff having exercise prices over $1.56 per share to reduce the exercise price to $1.50 per share, resulting in approximately $310,000 of expense attributable to the new option grants and modifications, including immediate recognition of $154,000 attributable to the modification of exercise prices. Expense attributable to recent option grants is generally being amortized over two-year to three-year vesting periods, with one-quarter of the grants made in August 2018, January 2019, May 2019 and September 2019 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. The 2019 increase reflects the addition of a new independent member to our Board in January 2019.

Legal, accounting and other professional fees for the six months ended September 30, 2019 and 2018 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 quarterly financial statements for the current fiscal year. In 2019 and 2018, we also incurred $60,000 and $13,000, respectively, attributable to services provided by international business development consultants.

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 six months ended September 30, 2019, in addition to cash fees and expenses we incurred for such activities, we recognized $105,900 of noncash expense attributable to the amortization of the fair value of stock and warrants granted in the prior fiscal year to various corporate development, investor relations, and market awareness service providers. At September 30, 2019, the fair value of the securities granted has been fully amortized. In the six months ended September 30, 2018, in addition to cash fees and expenses, we granted an aggregate of 100,000 unregistered shares of our common stock to certain investor relations, market awareness and financial advisory service providers 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 in the quarter ended June 30, 2018; in the quarter ended September 30, 2018 we granted 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 non-cash expense of approximately $65,000. The balance of the fair value of the securities granted was recorded as a prepaid expense and was amortized over the remaining period of the respective contracts, certain of which extended into 2019.

In both periods, travel expense reflects costs associated with management presentations and meetings held in multiple U.S. markets, and certain international markets in 2019, 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 both years.

The increase in rent expense reflects our implementation of ASC 842 effective April 1, 2019 and the requirement to recognize, as an operating lease, a right-of-use asset and a lease liability, both of which must be amortized over the expected lease term, for our South San Francisco office and laboratory facility lease. The underlying lease 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. In implementing ASC 842, we also projected that we would exercise a five-year option to extend our tenancy under the lease when it expires in 2022, which extension would be subject to market rent conditions at that time. We allocate total rent expense for our South San Francisco facility between research and development expense and general and administrative expense based generally on square footage dedicated to each function. Refer to Note 10, *Commitments and Contingencies*, in the accompanying Condensed Consolidated Financial Statements in Part I of this Report for additional information.

Interest and Other Expenses

Interest income, net of interest expense, totaled $31,900 for the six months ended September 30, 2019 compared to interest expense of $5,000 for the six months ended September 30, 2018. The following table indicates the primary components of interest income and expense for each of the periods (amounts in thousands):

	Six Months Ended September 30,	
	2019	**2018**
Interest income	$ 39	$ -
Interest expense on premium financing and capital lease (2018)	(7)	(5)
Interest income (expense), net	$ 32	$ (5)

Following the completion of our public offering in February 2019, which generated $11.5 million in gross proceeds to us, during the quarter ended June 30, 2019, we deposited a portion of the proceeds in interest-bearing cash equivalent accounts and earned interest income. Interest expense in both periods relates to interest paid on insurance premium financing notes and on a lease of office equipment treated as a capitalized lease in 2018 and as a financing lease subject to ASC 842 in 2019.

We recognized $616,300 and $557,100 for the six months ended September 30, 2019 and 2018, 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.

Liquidity and Capital Resources

Since our inception in May 1998 through September 30, 2019, 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 $79.0 million, as well as from an aggregate of approximately $17.7 million of government research grant awards (excluding the fair market value of government sponsored and funded clinical trials such as 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 September 30, 2019, we had cash and cash equivalents of approximately $4.1 million. As disclosed in Note 11, *Subsequent Events*, in the Condensed Consolidated Financial Statements included in Item 1 of this Report, since September 30, 2019, we have completed a self-placed private placement of units consisting of unregistered shares of our common stock and warrants to purchase unregistered shares of our common stock pursuant to which we have received cash proceeds of $600,000 (the *Fall 2019 Private Placement*). Nevertheless, we believe that our cash position at September 30, 2019, including the proceeds from the Fall 2019 Private Placement, 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 finalize our ELEVATE study, prepare for and launch a pivotal Phase 3 clinical trial of PH94B for SAD, prepare for additional Phase 2 clinical studies and certain nonclinical studies involving AV-101 and prepare for a Phase 2b clinical trial of PH10 for MDD, and raises substantial doubt that we can continue as a going concern. 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 Registration Statement on Form S-3 (Registration No. 333-234025) (the *S-3 Registration Statement*), which became effective on October 7, 2019, is 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, 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.

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 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 provide non-dilutive funding for development of AV-101, PH94B, PH10 or other product candidates, as well as new government grant awards and/or agreements, 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. As noted above, these Condensed Consolidated Financial Statements do not include any adjustments that might result from the negative outcome of this uncertainty.

Cash and Cash Equivalents

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

	Six Months Ended September 30,	
	2019	**2018**
Net cash used in operating activities	$ (8,898)	$ (7,063)
Net cash used in investing activities	-	(170)
Net cash (used in) provided by financing activities	(130)	4,686
Net decrease in cash and cash equivalents	(9,028)	(2,547)
Cash and cash equivalents at beginning of period	13,100	10,378
Cash and cash equivalents at end of period	$ 4,072	$ 7,831

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, and the nonclinical advancement of PH94B and PH10. Cash used in investing activities in 2018 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 reflects the first cash proceeds from our Summer 2018 Private Placement net of routine insurance premium financing note and 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, 2019 filed with the Securities and Exchange Commission on June 25, 2019, 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 does not believe that these weaknesses have resulted in any deficient financial reporting and believes 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.

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, 2019 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, manufacturing, 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, manufacturing 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 DR NCE we produce will require substantial nonclinical development, all phases of clinical development, manufacturing 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 U.S. 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 U.S., 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 in the U.S. or any market outside the U.S.

We are not permitted to market our product candidates in the U.S. until we receive approval of a NDA from the FDA, or in any foreign countries until we receive the requisite approval from such countries. Obtaining FDA approval of a 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 a NDA for many reasons, including, among others:

- if we submit a NDA and it is reviewed by a 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;

- a FDA advisory committee may recommend, or the FDA may require, a REMS safety program as a condition of approval or post-approval;

- a FDA advisory committee or the FDA or applicable regulatory agency may determine that there is insufficient evidence of overall effectiveness or safety in a 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.

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.

In addition, we anticipate that certain of our product candidates, including PH94B and PH10, will 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 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 NP. 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 (add-on) 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 NP. 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, and for our other product candidates. The FDA has broad discretion whether or not to grant a Fast Track designation, and even if we believe AV-101, PH94B, PH10 and/or 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 future product candidates, if any, including positive results, may not be predictive of the results of later-stage clinical trials. AV-101, PH94B, PH10 or any other future 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, if our ELEVATE Study, any future clinical study of AV-101, one or more of the future Phase 3 clinical trials of PH94B for SAD or a 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.

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 any of our collaborators 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 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 or safety concerns 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. AV-101 was previously tested by the NIMH in the NIMH Study, is currently being tested 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. Although no treatment-related serious adverse events (*SAEs*) were observed in the NIMH Study, if treatment-related SAEs or other undesirable side effects or safety concerns, or unexpected characteristics attributable to AV-101 are observed in the Baylor Study other investigator-sponsored clinical trials of AV-101, our clinical trials of AV-101, including our ELEVATE Study, or in our future 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 or other regulatory agency 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 or safety concerns 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 or REMS-like 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.

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 any NDA for regulatory approval for AV-101 as an add-on treatment for MDD in patients with an inadequate response to current ADs, 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 regulatory approval of PH94B as an on-demand treatment for SAD or any CNS other indication. 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 for regulatory approval of 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 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 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 regulatory authority 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 regulatory authorities of additional INDs that may be required;
- negative or ambiguous 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 regulatory authority 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.

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 regulatory authority, 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 regulatory authority 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, regulatory 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, 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 regulatory authority may impose additional nonclinical studies and clinical trial requirements. Amendments or changes to our clinical trial protocols would require resubmission to the regulatory authority 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 future 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 future product candidates may be delayed and we may not be able to obtain regulatory approval for or commercialize AV-101, PH94B, PH10 or other future product candidates and our business could be substantially harmed.

By strategic design, 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 extensive 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.

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, Baylor or other independent investigators does not relieve us of our regulatory responsibilities. We and our CROs, 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 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, 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.

By strategic design, we do not currently have, nor do we plan to acquire or develop, 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 all of our product candidates, we rely, and will continue to rely, completely on CMOs to manufacture 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.

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, we anticipate that PH94B and PH10 will 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 or a comparable foreign regulatory authority's drug cGMP regulations, device cGMP requirements embodied in the Quality System Regulation (*QSR*) or similar regulatory requirements outside the U.S. 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 anf comparable foreign regulatory authorities pursuant to inspections that will or may be conducted after we submit our NDA. 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 other comparable foreign regulatory authorities, 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.

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

In order to market AV-101, PH94B, PH10 or any other product candidate outside of the U.S., 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 U.S. as well as other risks. In particular, in many countries outside of the U.S., 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 in the U.S. or any market outside the U.S., the U.S. Drug Enforcement Administration (*DEA*) or its foreign counterpart may need to determine whether such product candidates will be considered to be a controlled substance, taking into account the recommendation of the FDA or its foreign counterpart, as the case may be. 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 or any foreign counterpart 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, PH94B and PH10 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 or that of its foreign counterpart, 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 or a foreign counterpart of the DEA as the case may be. 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 or comparable foreign 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 or its foreign counterparts 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.

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.

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 and other regulatory authorities have 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 and other regulatory authorities also have the authority to require, as part of an NDA or post-approval, the submission of a REMS or comparable safety program. Any REMS or comparable safety program required by the FDA or other regulatory authority 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.

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 pharmacological action and safety profile as our orally-administered AV-101 or our intranasally-administered PH10. However, new antidepressant products with other mechanisms of pharmacological 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 pharmacological 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 ADs, we believe our principal competitors may be Axsome's AX-05, Alkermes' ALKS-5461, Allergan's AGN-241751 and Sage's Sage-217. Additional potential competitors may include, but not be limited to, academic and private commercial clinics providing intravenous ketamine therapy on an off-label basis and Janssen's intranasally-administered Spravato (esketamine). With respect to PH94B and current FDA-approved treatment options for SAD in the U.S., our competition may include, but is not limited to, certain current generic ADs approved by the FDA for treatment of SAD and certain classes of drugs used on an off-label basis for treatment of SAD, including benzodiazepines 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, 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 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.

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 planning for Phase 2a studies of AV-101 for treatment of NP and LID, for Phase 3 development of PH94B for on-demand treatment of SAD, and a Phase 2b 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 DR 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.

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.

- Foreign Corrupt Practices Act and its application to marketing and selling practices as well as to clinical trials.

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.

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 U.S. 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.

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.

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 DR 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 DR 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 DR 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 DR NCEs and no operating history with respect to the production of DR NCEs, and we may never be able to produce a DR NCE.

If we are unable to develop and commercialize AV-101, PH94B, PH10 or acquire or license additional product candidates, or produce suitable DR 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 DR, 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 DR NCEs, independently or with partners, including:

- our ability to identify potential DR candidates in the public domain, obtain sufficient quantities of them, and assess them using our bioassay systems;
- if we seek to rescue DR 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 DR candidates to us on commercially reasonable terms;
- our medicinal chemistry collaborator’s ability to design and produce proprietary DR 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 DR 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 DR NCEs they acquire or license from us.

Even if we do acquire additional product candidates or produce proprietary DR 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 DR 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.

If CardioSafe 3D fails to predict accurately and efficiently the cardiac effects, both toxic and nontoxic, of DR candidates and DR NCEs, then our DR 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 DR candidates and DR NCEs. If *CardioSafe* 3D is not capable of providing physiologically relevant and clinically predictive information regarding human cardiac biology, our DR business will be adversely affected.

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

DR 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 DR will be limited and our DR business will be adversely affected.

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

To generate revenue from our DR activities, we must produce proprietary DR NCEs for which there proves to be demand within the healthcare marketplace, and, if we intend to out-license a particular DR NCE for development and commercialization prior to market approval, then also among pharmaceutical companies and other potential collaborators. However, we may produce DR 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 DR 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 DR 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 hPSC 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 DR, 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 DR candidates and DR NCEs, design and development of certain human cellular assays and performance of certain exploratory nonclinical RM studies. In the past, our stem cell research and development projects have been significantly delayed when we encountered unanticipated difficulties in differentiating hPSCs 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, DR and RM 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 U.S. 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 DR capabilities of our technology, which would have a material adverse effect on our business.

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 *(iPSC*s) 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 U.S. 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. U.S. 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 U.S., 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 U.S. 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.

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 RM 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 approximately $24.6 million and $14.3 million during our fiscal years ended March 31, 2019 and 2018, respectively, and approximately $11.5 million for the six months ended September 30, 2019. At September 30, 2019, we had an accumulated deficit of approximately $192.7 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 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.

Our ability to become profitable depends upon our ability to generate revenues. To date, we have generated approximately $17.7 million in revenues, consisting of receipt of non-dilutive cash payments from collaborators, sublicense revenue, and research and development grant awards from the NIH. 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 future 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 future 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 U.S. and foreign marketing approval for our product candidates;
- timely complete and compose successful regulatory submissions such as NDAs or comparable documents for both the U.S. 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, 2019 included in our Annual Report on Form 10-K for the year ended March 31, 2019 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 DR 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 and regulatory expenses related to the production of PH94B and PH10 and our stem cell technology platform, including development of *CardioSafe* 3D for DR and our cardiac stem cell technology for potential RM 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.

At September 30, 2019, we had cash and cash equivalents of approximately $4.1 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 PH94B study material, conduct PH94B pivotal Phase 3 clinical trials, produce additional AV-101 study material for future nonclinical and clinical studies, conduct AV-101 Phase 3-enabling toxicology studies, conduct pivotal Phase 3 clinical studies of AV-101 in MDD, conduct AV-101 Phase 2 studies in LID, MDD, NP and SI, produce PH10 study material and conduct a Phase 2b clinical trial of PH10 in MDD, 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. Most recently, we completed dosing patients enrolled in the ELEVATE Study, and we expect to report top line results from the ELEVATE Study by the end of 2019. If the results of the ELEVATE Study are supportive of further clinical studies, including a larger, Phase 3 pivotal study, we will experience a substantial increase in research and development costs. This, in turn, will require that we seek additional capital that may result in debt or dilution to our current stockholders. Even if the results of the ELEVATE Study do not warrant additional clinical development of AV-101 as an add-on treatment for MDD, we will continue to incur costs associated with other development programs for AV-101, as well as PH94B and PH10. 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 currently considering a range of potential financing transactions, including 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 2019 and 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.

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, our ability to engage in certain types of capital raising transactions may be limited by the Listing Rules of the Nasdaq Stock Market and/or General Instruction I.B.6 of Form S-3 so long as the market value of our common stock held by non-affiliates remains below $75 million. 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 of our staff does not permit appropriate segregation of duties to (a) permit appropriate review of accounting transactions and/or accounting treatment by multiple qualified individuals, and (b) prevent one individual from overriding the internal control system by initiating, authorizing and completing all transactions, and (ii) we utilize 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.

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

As of March 31, 2019, we had federal and state net operating loss carryforwards of approximately $109.0 million and $63.6 million, respectively, which begin to expire in fiscal 2020. 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 Annual 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.

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 DR 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.

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.

Current politics in the U.S. could diminish the value of the pharmaceutical industry, thereby diminishing the value of our securities.

The current political environment in the U.S. has led many incumbents and political candidates to propose various measures to reduce the prices for pharmaceuticals. As we near the U.S. presidential 2020 elections, it is likely that these proposals will receive increasing publicity which, in turn, may cause the investing public to reduce the perceived value of pharmaceutical companies. Any decrease in the overall perception of the pharmaceutical industry may have an adverse impact on our share price and may limit our ability to raise capital needed to continue our drug development programs.

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 product candidates, their compositions and formulations, their methods of use and methods of manufacturing 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.

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 and have licensed patents and patent applications related to product candidates AV-101, PH94B, PH10 and also to hPSC technology.

Although we own and have licensed issued and allowed patents and patent applications relating to AV-101, PH94B and PH10 in the U.S., selected countries in the EU and other jurisdictions, we cannot yet provide any assurances that any of our pending U.S. 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.

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 properties, for example, 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 uncertainty about adequate protection 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. Moreover, relevant laws differ from country-to-country.

The patent positions of biotechnology and pharmaceutical companies, including our patent portfolio 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.

Our ability to obtain valid and enforceable patents depends in large measure on whether the differences between our technology and the prior art allow our inventions to be patentable over relevant prior art. Such prior art includes scientific publications, investment blogs, granted patents and published patent applications. Patent uncertainty cannot be eliminated because of the potential existence of other prior art about which we are currently unaware that may be relevant to our patent applications and patents, which may prevent a pending patent application from being granted or result in an issued patent being held invalid or unenforceable.

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. For example, there are numerous reports in the scientific literature of compounds that target similar cellular receptors as certain of our product candidates or were evaluated in early (often pre-clinical) studies. In addition, even some reports in the trade press and public announcements made us before the filing date of our AV-101 patent applications mentioned that AV-101 was in development for certain therapeutic purposes. For example, we published a web post on the NIH clinical trials website prior to our filing of our initial AV-101 patent applications, which describes unit doses for a then future study, but 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. This post was not submitted to the United States Patent and Trademark Office (*USPTO*) in our two granted U.S. patents related to (i) unit dose formulations of AV-101 effective to treat depression and (ii) methods of treating depression with AV-101, respectively. However, it was submitted in our pending AV-101 patent applications that make similar claims, and we are considering entering this web post in the record of the aforementioned two issued U.S. patents. Another source of uncertainty pertains to patent properties that were in-licensed by us for which prior art submissions were under the control of the licensor. We rely on these licensors to have satisfied the relevant disclosure obligations.

In the event any previously published prior art is deemed to be invalidating prior art, it may cause certain of our issued patents to be invalid and/or unenforceable which would cause us to 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.

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.

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 and foreign patents and patent applications may be subject to various types of infringement and validity proceedings, including interference proceedings, *ex parte* reexamination, *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 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 in such a way that they no longer cover our product candidates or competitive products.

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, for example, by using pre-existing or newly developed technology. Other parties may develop and obtain patent protection for more effective technologies, designs or methods.

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 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. 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.

In addition, such patent-related proceedings may be costly. Thus, any patent properties that we may own or exclusively license ultimately may not provide commercially meaningful 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.

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.

Our ability to enforce our patent rights also depends on our ability to detect infringement. It is difficult to detect infringers who do not advertise the components or manufacturing processes 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.

Overall, 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 and challenged by others, will include or maintain claims having a scope sufficient to protect AV-101, PH94B, PH10 or any other products or product candidates against generic or other competition, particularly considering that any patent rights to these compounds *per se* have 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, collaborators and consultants who are parties to these agreements breach or violate the terms of these agreements, we may not discover or 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.

Third parties may initiate legal proceedings against us alleging that we infringe their intellectual property rights, which may prevent or delay our product development efforts and stop us from commercializing candidate products or increase the costs of commercializing them, if approved. Also, we may file counterclaims or initiate other legal proceedings against third parties to challenge the validity or scope of their intellectual property rights, the outcomes of which also would be uncertain and could have a material adverse effect on the success of our business.

We cannot assure that our business, product candidates and methods do not or will not infringe the patents or other intellectual property rights of third parties. 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. In addition, we or our licensors or collaborators may file counterclaims in such proceedings or initiate separate legal proceedings against third parties to challenge the validity or scope of their intellectual property rights, including in oppositions, interferences, reexaminations, *inter partes* reviews or derivation proceedings before the United States or other jurisdictions.

Our success will depend in part on our ability to operate without infringing the intellectual property and proprietary rights of third parties. Success also will depend on our ability to prevail in litigation if we are sued for infringement or to resolve litigation matters with rights and at costs favorable to us.

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 their 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 later result in issued patents that our product candidates may infringe, or that such third parties assert are infringed by our technologies.

The foregoing types of proceedings can be expensive and time-consuming and many of our own 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 other 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.

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 financial resources to bring these actions to a successful conclusion.

An unfavorable outcome in the foregoing kinds of proceedings 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.

Patent and other types of intellectual property litigation can involve complex factual and legal questions, and their outcomes are 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 have willfully infringed a third 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 is 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.

Patent litigation is costly and time-consuming. We may not have sufficient resources to bring these actions to a successful conclusion. 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.

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.

The Company 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 their 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.

We do 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 U.S. could be less extensive than those in the United States, assuming that rights are obtained in the U.S. 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 U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., 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 pending patent applications relating to AV-101, as well as for other 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 U.S.

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 U.S. 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 U.S. 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 and pharmaceuticals. 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 under certain circumstances. 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.

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.

For our PH10, PH94B and certain stem cell technologies, 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, both in-license agreements and out-license agreements, to support and leverage 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.

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 will 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. Also, 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 further 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-U.S. product manufacturers for products covered by such intellectual property.

In the event we apply for additional U.S. 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.

In the U.S., depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one or more of the U.S. 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, for example, 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.

Similar kinds of patent term and regulatory and data protection periods are available outside of the U.S. We will pursue such opportunities to extend the exclusivity of our products, but we cannot predict the availability of such exclusivity pathways or that we will be successful in pursuing them.

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

As is the case with other pharmaceutical and 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 U.S. in recent years 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 U.S. 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.

In addition, recent U.S. 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. Other more recent court decisions and related USPTO examination guidelines must be taken into account, particularly as they relate to changes in what types of inventions are eligible for patent protection. Foreign patent and intellectual property laws also are evolving and are not predictable as to their impact on the Company and other biopharmaceutical companies.

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 U.S. 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.

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

With regard to our stem cell technology, if, instead of identifying DR candidates based on information available to us in the public domain, we seek to in-license DR 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 DR NCEs that we may produce and develop. If we are unable to obtain ownership or substantial economic participation rights over intellectual property related to DR NCEs we produce and develop, our DR 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 or other regulatory authority 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 U.S. 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 or purchases of large blocks of our common stock, including sales or purchases by our executive officers, directors and significant stockholders;
- establishment of short positions by holders or non-holders of our stock or warrants;
- 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.

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, as amended (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 September 30, 2019; (ii) 4.0 million shares of Series B 10% Convertible Preferred stock, of which approximately 1.2 million shares remain issued and outstanding at September 30, 2019; and (iii) 3.0 million shares of Series C Convertible Preferred Stock, of which approximately 2.3 million shares are issued and outstanding at September 30, 2019. 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.

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

Common Stock and Warrants Issued in Fall 2019 Private Placement

Between October 30, 2019 and November 6, 2019, in a self-placed private placement and pursuant to subscription agreements from accredited investors, we sold to such investors units, at a purchase price of $1.00 per unit, consisting of an aggregate of 600,000 unregistered shares of our common stock and warrants, exercisable through November 1, 2023, to purchase 300,000 unregistered shares of our common stock at an exercise price of $2.00 per share. 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 prior to six months and one day following issuance. We received aggregate cash proceeds of $600,000 from the sale of the units.

Proceeds from the offering will be used for general corporate purposes. The sales described above were made in reliance on Section 4(a)(2) of the Securities Act as transactions by an issuer not involving any public offering, Regulation D of the Securities Act, and/or Section 3(a)(9) under the Securities Act. In these transactions, certain inquiries were made by the Company to establish that such sales qualified for such exemption from the registration requirements. In particular, the Company confirmed that, with respect to the exemption claimed under Section 4(a)(2) of the Securities Act, that (i) all offers of sales and sales were made by personal contact from officers or directors of the Company or other persons closely associated with the Company, (ii) each investor made representations that he or she was an accredited investor as defined in Rule 501 of Regulation D under the Securities Act (and the Company had no reason to believe that such representations were incorrect), (iii) each purchaser gave assurance of investment intent, and (iv) offers and sales within the offering were made only to a limited number of persons.

Item 3. Defaults Upon Senior Securities

None.

Item 6. EXHIBITS

Exhibit Number	Description
10.1	Form of Subscription Agreement for Fall 2019 Private Placement
10.2	Form of Warrant for Fall 2019 Private Placement
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

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: November 6, 2019

Exhibit 10.1

SUBSCRIPTION AGREEMENT

UNITS

TO: VistaGen Therapeutics, Inc., a Nevada corporation (the "*Company*")

RE: Purchase of Units of the Company

Instructions: Complete and sign this Subscription Agreement. Please be sure to initial the appropriate "Accredited Investor" category in Box C.

A completed and originally executed copy of, and the other documents required to be delivered with, this Subscription Agreement, must be delivered to the following address:

Jerrold Dotson
Chief Financial Officer
VistaGen Therapeutics, Inc.
343 Allerton Avenue
South San Francisco, CA 94080
(650) 577-3600
jdotson@vistagen.com

1. Subscription. The undersigned (the "*Subscriber*") hereby irrevocably subscribes for and agrees to purchase from the Company the number of units of the Company ("*Units*") at the price and for the aggregate consideration set forth in Box A of Section 7 below (the "*Subscription Price*"). Each Unit will consist of (i) one share of the Company's Common Stock, par value $0.001 per share ("*Common Stock*"); and (ii) a warrant to purchase one-half (1/2) of one unregistered share of the Company's Common Stock (the "*Warrant Shares*") of the Company at a price of Two Dollars ($2.00) per share (each warrant to purchase shares of Common Stock, a "*Warrant*"). The Warrants shall first become exercisable on May 2, 2020 and will expire on November 1, 2023. The Subscription Price for each Unit shall be equal to One Dollar ($1.00) per Unit. The Subscriber acknowledges that this Subscription Agreement is subject to acceptance by the Company on or before close of business on November 1, 2019 (the "*Closing Date*"). The Company may also accept this Subscription Agreement in part on or before the Closing Date. The Company agrees that if this Subscription Agreement is not accepted in part or in full on or before the Closing Date, any funds related to the portion of this Subscription Agreement not accepted will be promptly returned to the undersigned, without interest.

2. The Company may also accept this Subscription Agreement in part. The Company and Subscriber agree that if this Subscription Agreement is not accepted in full, any funds related to the portion of this Subscription Agreement not accepted will be promptly returned to the Subscriber, without interest.

3. Subscriber Representations, Warranties and Agreements. By executing this Subscription Agreement, the Subscriber represents, warrants and covenants (on its own behalf and, if applicable, on behalf of each beneficial purchaser for whom it is contracting hereunder) to the Company (and acknowledges that the Company is relying thereon) that:

(a) it is authorized to consummate the purchase of the Units;

(b) it understands that the shares of Common Stock, the Warrants and the Warrant Shares (collectively, the "*Securities*") have not been and will not be registered under the Securities Act of 1933 (the "*Securities Act*"), or any applicable state securities laws, and that the offer and sale of the Units and Warrants to it is being made in reliance on a private placement exemption available under Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D under the Securities Act ("*Regulation D*") to accredited investors ("*Accredited Investors*"), as defined in Rule 501(a) of Regulation D;

(c) it has reviewed copies of any documents considered by it to be important in making an investment decision whether to purchase the Units. In addition, it has had access to such additional information, if any, concerning the Company as it has considered necessary in connection with its investment decision to acquire the Units, and it acknowledges that it has been offered the opportunity to ask questions and receive answers from management of the Company concerning the terms and conditions of the offering of the Units, and to obtain any additional information which the Company possesses or can acquire without unreasonable effort or expense that is necessary to verify the accuracy of the information contained in any documents provided to it;

(d) it has such knowledge and experience in financial and business matters as to be capable of evaluating the merits and risks of its investment in the Units and is able to bear the economic risks of, and withstand the complete loss of, such investment;

(e) it is an Accredited Investor acquiring the Units for its own account or, if the Units are to be purchased for one or more accounts ("*Investor Accounts*") with respect to whom it is exercising sole investment discretion, each such investor account is an Accredited Investor on a like basis. In each case, the undersigned has completed the Accredited Investor Status questionnaire attached hereto to indicate under which category of Rule 501(a) the investor qualifies as an Accredited Investor;

(f) it is not acquiring the Units with a view to any resale, distribution or other disposition of the Units in violation of federal or applicable state securities laws, and, in particular, it has no intention to distribute either directly or indirectly any of the Units in the U.S. or to U.S. persons; *provided*, *however*, that the holder may sell or otherwise dispose of any of the Units pursuant to registration thereof under the Securities Act and any applicable state securities laws or pursuant to an exemption from such registration requirements;

(g) in the case of the purchase by the Subscriber of the Units as agent or trustee for any other person, the Subscriber has due and proper authority to act as agent or trustee for and on behalf of such beneficial purchaser in connection with the transactions contemplated hereby;

(h) it is not purchasing the Units as a result of any general solicitation or general advertising (as those terms are used in Regulation D under the Securities Act), including advertisements, articles, notices or other communications published in any newspaper, magazine or similar media or broadcast over radio or television, or any seminar or meeting whose attendees have been invited by general solicitation or general advertising;

(i) neither the Subscriber nor, to the extent it has them, any of its shareholders, members, managers, general or limited partners, directors, affiliates or executive officers (collectively with the Subscriber, the "*Covered Persons*"), are subject to any of the "Bad Actor" disqualifications described in Rule 506(d)(1)(i) to (viii) under the Securities Act (a "*Disqualification Event*"), except for a Disqualification Event covered by Rule 506(d)(2) or (d)(3). The Subscriber has exercised reasonable care to determine whether any Covered Person is subject to a Disqualification Event. The purchase of the Units by the Subscriber will not subject the Company to any Disqualification Event;

(j) it understands that the Securities are "restricted securities" as defined in Rule 144(a)(3) under the Securities Act and agrees that if it decides to offer, sell or otherwise transfer the Securities, such Securities may be offered, sold or otherwise transferred only (A) to the Company, (B) outside the U.S. in accordance with Rule 904 of Regulation S under the Securities Act, (C) within the U.S. or to or for the account or benefit of a U.S. Person in accordance with an exemption from the registration requirements of the Securities Act and all applicable state securities laws, (D) in a transaction that does not require registration under the Securities Act or any applicable U.S. state securities laws or (E) pursuant to an effective registration statement under the Securities Act, and in each case in accordance with any applicable state securities laws in the U.S. or securities laws of any other applicable jurisdiction; provided that with respect to sales or transfers under clauses (C) or (D), only if the holder has furnished to the Company a written opinion of counsel, reasonably satisfactory to the Company, prior to such sale or transfer;

(k) it has been independently advised as to the applicable holding period and resale restrictions with respect to trading imposed in respect of the Securities, by securities legislation in the jurisdiction in which it resides or to which it is otherwise subject, and confirms that no representation has been made respecting the applicable holding periods for the Securities and is aware of the risks and other characteristics of the Securities and of the fact that the undersigned may not be able to resell the Securities except in accordance with applicable securities legislation and regulations;

(l) no person has made to the Subscriber any written or oral representations:

(i) that any person will resell or repurchase any of the Securities;

(ii) that any person will refund the purchase price of the Securities; or

(iii) as to the future price or value of any of the Securities;

(m) it understands and acknowledges that certificates representing the Shares and the Warrant Shares shall bear the following legend or another legend of substantially similar substance:

"THE SECURITIES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE U.S. SECURITIES ACT OF 1933, AS AMENDED (THE "*SECURITIES ACT*"), OR UNDER ANY STATE SECURITIES LAWS. THE HOLDER HEREOF, BY PURCHASING THESE SECURITIES, AGREES FOR THE BENEFIT OF THE COMPANY, THAT THESE SECURITIES MAY BE OFFERED, SOLD, PLEDGED OR OTHERWISE TRANSFERRED ONLY (A) TO THE COMPANY, (B) OUTSIDE THE U.S. IN ACCORDANCE WITH REGULATION S UNDER THE SECURITIES ACT, (C) IN COMPLIANCE WITH AN EXEMPTION FROM THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS, (D) IN ANOTHER TRANSACTION THAT DOES NOT REQUIRE REGISTRATION UNDER THE SECURITIES ACT OR ANY APPLICABLE STATE SECURITIES LAWS, OR (E) PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT, AND, IN THE CASE OF (C) AND (D), THE SELLER FURNISHES TO THE COMPANY A WRITTEN OPINION OF COUNSEL OF RECOGNIZED STANDING IN FORM AND SUBSTANCE SATISFACTORY TO THE COMPANY TO SUCH EFFECT."

(n) it consents to the Company making a notation on its records or giving instructions to any transfer agent of the Shares in order to implement the restrictions on transfer set forth and described herein.

(o) the office or other address of the undersigned at which the undersigned received and accepted the offer to purchase the Units is the address listed in Box B of Section 6 below.

(p) if required by applicable securities laws, regulations, rule or order or by any securities commission, stock exchange or other regulatory authority, it will execute, deliver and file, within the approved time periods, all documentation as may be required thereunder, and otherwise assist the Company in filing reports, questionnaires, undertakings and other documents with respect to the issuance of the Units.

(q) this subscription agreement has been duly and validly authorized, executed and delivered by and constitutes a legal, valid, binding and enforceable obligation of the Subscriber; and

(r) it is not an affiliate (as defined in Rule 144 under the Securities Act) of the Company and is not acting on behalf of an affiliate of the Company.

4. Representations, Warranties and Covenants of the Company. As a material inducement of Subscriber to enter into this Subscription Agreement and subscribe for the Units, the Company represents and warrants to Subscriber, as of the date hereof, as follows:

(a) Organization and Standing. The Company is a corporation duly organized, validly existing and in good standing under the laws of the State of Nevada, has full power to carry on its business as and where such business is now being conducted and to own, lease and operate the properties and assets now owned or operated by it, and is duly qualified to do business and is in good standing in each jurisdiction where the conduct of its business or the ownership of its properties requires such qualification, except where the failure to be so qualified would not have a Material Adverse Effect on the Company. "*Material Adverse Effect*" means any circumstance, change in, or effect on the Company that, individually or in the aggregate with any other similar circumstances, changes in, or effects on, the Company taken as a whole: (i) is, or is reasonably expected to be, materially adverse to the business, operations, assets, liabilities, employee relationships, customer or supplier relationships, prospects, results of operations or the condition (financial or otherwise) of the Company taken as a whole, or (ii) is reasonably expected to adversely affect the ability of the Company to operate or conduct the Company's business in the manner in which it is currently operated or conducted or proposed to be operated or conducted by the Company; *provided*, *however*, that none of the following shall be deemed in and of themselves, either alone or in combination, to constitute, and none of the following shall be taken into account in determining whether there has been or will be, a Material Adverse Effect: (A) any change, event, state of facts or development generally affecting the general political, economic or business conditions of the United States, (B) any change, event, state of facts or development generally affecting the industry in which the Company operates, (C) any change, event, state of facts or development arising from or relating to compliance with the terms of this Subscription Agreement, (D) acts of war (whether or not declared), the commencement, continuation or escalation of a war, acts of armed hostility, sabotage or terrorism or other international or national calamity or any material worsening of such conditions, (E) changes in laws or generally accepted accounting principles ("*GAAP*") after date hereof or in interpretations thereof, or (F) any matter disclosed in this Subscription Agreement (including the schedules hereto).

(b) Authority. The Board of Directors of the Company has duly authorized the execution, delivery and performance of this Subscription Agreement by the Company, and the consummation of the transactions contemplated hereby. This Subscription Agreement has been (or upon delivery will be) duly executed by the Company when delivered in accordance with the terms hereof, and will constitute, assuming due authorization and execution and delivery by each of the parties thereto, a valid and binding obligation of the Company enforceable against the Company in accordance with its terms. The Securities, when issued, will be validly issued, fully-paid and non-assessable.

(c) No Conflicts. The execution and delivery of the Agreement and Securities and the consummation of the transactions contemplated by this Agreement and the Securities, will not (i) conflict with or result in a breach of or a default under any of the terms or provisions of, (A) the Company's certificate of incorporation or by-laws, or (B) of any material provision of any indenture, mortgage, deed of trust or other material agreement or instrument to which the Company is a party or by which it or any of its material properties or assets is bound, (ii) result in a violation of any provision of any law, statute, rule, regulation, or any existing applicable decree, judgment or order by any court, federal or state regulatory body, administrative agency, or other governmental body having jurisdiction over the Company, or any of its material properties or assets or (iii) result in the creation or imposition of any material lien, charge or encumbrance upon any material property or assets of the Company or any of its subsidiaries pursuant to the terms of any agreement or instrument to which any of them is a party or by which any of them may be bound or to which any of their property or any of them is subject except in the case of clauses (i)(B), (ii) or (iii) for any such conflicts, breaches, or defaults or any liens, charges, or encumbrances which would not have a Material Adverse Effect.

(d) No Solicitation. The Company represents that it has not paid, and shall not pay, any commissions or other remuneration, directly or indirectly, to any third party for the sale of the Securities. There are no brokers or other fees due with respect to the sale of the Securities.

(e) Material Disclosure. No representation, warranty or statement contained in this Section 3 or any disclosure furnished by the Company pursuant to this Agreement or pursuant to its filings with the Securities and Exchange Commission contains or will contain at closing hereunder any untrue statement of material fact or omits or will omit at such closing to state a material fact necessary to make the statements therein, in light of the circumstances under which they were made, not misleading.

5. Conditions to Closing.

(a) The Company's obligation to issue and sell the Units to Subscribers is subject to the fulfillment (or waiver by the Company) of the following conditions:

(i) Representations and Warranties. The representations and warranties made by Subscribers in this Subscription Agreement shall be true and correct in all material respects when made, and shall be true and correct in all material respects upon issuance of the Units;

(ii) Accredited Investor Questionnaire. All Subscribers shall have completed and delivered to the Company the Accredited Investor section of the Subscriber's signature page attached hereto; and

(iii) Approval of Subscribers. The Company, in its reasonable discretion, shall have approved the participation and amount of participation of any Subscribers who are either individuals that are non-United States citizens or are entities domiciled in any jurisdiction other than the United States.

(b) Each Subscriber's obligation to purchase the Units is subject to the fulfillment (or waiver by such Subscriber) of the following conditions:

(i) Representations and Warranties. The representations and warranties made by the Company in this Subscription Agreement shall be true and correct when made, and shall be true and correct in all material respects upon issuance of the Units; and

(ii) Compliance with Securities Laws. The Company shall have obtained all permits and qualifications required under federal and/or state law and/or foreign law for the offer and sale of the Units, or shall have the availability of exemptions therefrom. Upon sale of the Units, the Company shall file a Form D with the United States Securities and Exchange Commission in a timely manner as well as any "blue sky" filings required by the states in which Subscribers are located.

6. Legends. Subscriber understands and agrees that the Company will cause any necessary restrictive legends to be placed upon any instruments(s) evidencing ownership of the Units, together with any other legend that may be required by federal or state securities laws or deemed necessary or desirable by the Company.

7. General Provisions.

(a) Confidentiality. Subscriber covenants and agrees that it will keep confidential and will not disclose or divulge any confidential or proprietary information that such Subscriber may obtain from the Company pursuant to financial statements, reports, and other materials submitted by the Company to such Subscriber in connection with this Subscription Agreement, or as a result of discussions with or inquiry made to the Company, unless such information is known, or until such information becomes known, to the public through no action by Subscriber; *provided*, *however*, that a Subscriber may disclose such information to its attorneys, accountants, consultants, assignees or transferees and other professionals to the extent necessary in connection with his or her investment in the Company so long as any such professional to whom such information is disclosed is made aware of Subscriber's obligations hereunder and such professional agrees to be likewise bound as though such professional were a party hereto.

(b) Successors. The covenants, representations and warranties contained in this Subscription Agreement shall be binding on Subscriber's and the Company's heirs and legal representatives and shall inure to the benefit of the respective successors and assigns of the Company. The rights and obligations of this Subscription Agreement may not be assigned by any party without the prior written consent of the other party.

(c) Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original agreement**,** but all of which together shall constitute one and the same instrument.

(d) Execution by Facsimile**.** Execution and delivery of this Agreement by facsimile transmission (including the delivery of documents in Adobe PDF format) shall constitute execution and delivery of this Agreement for all purposes, with the same force and effect as execution and delivery of an original manually signed copy hereof.

(e) Governing Law and Jurisdiction. This Subscription Agreement shall be governed by and construed in accordance with the laws of the State of Nevada applicable to contracts to be wholly performed within such state and without regard to conflicts of laws provisions. THE PARTIES HERETO EACH HEREBY IRREVOCABLY AND UNCONDITIONALLY SUBMIT TO THE EXCLUSIVE JURISDICTION OF THE STATE AND FEDERAL COURTS SITTING IN THE CITY OF SOUTH SAN FRANCISCO, COUNTY OF SAN MATEO. THE PARTIES HERETO EACH AGREE THAT ALL ACTIONS OR PROCEEDINGS ARISING OUT OF OR RELATING TO THIS SUBSCRIPTION AGREEMENT AND/OR THE OFFERING DOCUMENTS OR THE TRANSACTIONS CONTEMPLATED THEREBY MUST BE LITIGATED EXCLUSIVELY IN ANY SUCH STATE OR FEDERAL COURT THAT SITS IN THE CITY OF SOUTH SAN FRANCISCO, COUNTY OF SAN MATEO, AND ACCORDINGLY, THE PARTIES EACH IRREVOCABLY WAIVE ANY OBJECTION WHICH IT MAY NOW OR HEREAFTER HAVE TO THE LAYING OF THE VENUE OF ANY SUCH LITIGATION IN ANY SUCH COURT. Each of Subscriber and Company hereby irrevocably waive and agree not to assert, by way of motion, as a defense, or otherwise, in every suit, action or other proceeding arising out of or based on this Subscription Agreement and brought in any such court, any claim that Subscriber or the Company is not subject personally to the jurisdiction of the above named courts, that Subscriber's or the Company's property, as applicable, is exempt or immune from attachment or execution, that the suit, action or proceeding is brought in an inconvenient forum or that the venue of the suit, action or proceeding is improper.

(f) Notices. All notices, requests, demands, claims and other communications hereunder shall be in writing and shall be delivered by certified or registered mail (first class postage pre-paid), guaranteed overnight delivery, or facsimile transmission if such transmission is confirmed by delivery by certified or registered mail (first class postage pre-paid) or guaranteed overnight delivery, to the following addresses and facsimile numbers (or to such other addresses or facsimile numbers which such party shall subsequently designate in writing to the other party):

(i) if to the Company, to the address first set forth above.

(ii) if to Subscriber to the address set forth next to its name on the signature page hereto.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

8. SUBSCRIPTION PARTICULARS

INFORMATION IN RESPONSE TO THIS SECTION WILL BE KEPT STRICTLY CONFIDENTIAL

BOX A

Particulars of Purchase of Units

Number of Units subscribed for:

Subscription Price ($1.05 X number of Units)

BOX B

Subscriber Information For individual subscribers this address should be Subscriber's primary legal residence. For entities other than individual subscribers, please provide address information for the entity's primary place of business. Information regarding a joint subscriber should also be included.

Name _____

Street Address _____

Street Address (2) _____

City and State _____

Zip Code _____

Contact Name _____

Alternate Contact _____

Phone No. _____

Fax No. / E-mail Address _____

Tax ID # or Social Security # _____

BOX C

Accredited Investor Status

The Subscriber represents and warrants that it is an "accredited investor", as defined in Rule 501(a) under the Securities Act, by virtue of satisfying one or more of the categories indicated below **(please write your initials on the line next to each applicable category)**:

☐	Category 1.	A bank, as defined in section 3(a)(2) of the Securities Act. A savings and loan association or other institution, as defined in section 3(a)(5)(A) of the Securities Act, whether acting in its individual or fiduciary capacity. A broker or dealer registered pursuant to section 15 of the Securities Exchange Act of 1934. An insurance company as defined in section 2(a)(13) of the Securities Act. An investment company registered under the Investment Corporation Act of 1940 or a business development company as defined in section 2(a)(48) of that Act. A Small Business Investment Corporation licensed by the U.S. Small Business Administration under section 301(c) or (d) of the Small Business Investment Act of 1958. A plan established and maintained by a state, its political subdivisions, or any agency or instrumentality of a state or its political subdivisions, for the benefit of its employees, if such plan has total assets in excess of $5,000,000. An employee benefit plan within the meaning of the Employee Retirement Income Security Act of 1974 if the investment decision is made by a plan fiduciary, as defined in section 3(21) of such Act, which is either a bank, savings and loan association, insurance company, or registered investment adviser, or if the employee benefit plan has total assets in excess of $5,000,000 or, if a self-directed plan, with investment decisions made solely by persons that are accredited investors.
☐	Category 2.	Any private business development company as defined in section 202(a)(22) of the Investment Advisers Act of 1940.
☐	Category 3.	An organization described in Section 501(c)(3) of the Internal Revenue Code, a corporation, a Massachusetts or similar business trust, or a partnership, not formed for the specific purpose of acquiring the Securities, with total assets in excess of $5,000,000.
☐	Category 4.	A director or executive officer of the Company.
☐	Category 5.	A natural person whose individual net worth, or joint net worth with that person's spouse, at the time of this purchase exceeds $1,000,000, excluding the value of the person's primary residence, if any.
☐	Category 6.	A natural person who had an individual income in excess of $200,000 in each of the two most recent years or joint income with that person's spouse in excess of $300,000 in each of those years and has a reasonable expectation of reaching the same income level in the current year.
☐	Category 7.	A trust, with total assets in excess of $5,000,000, not formed for the specific purpose of acquiring the Securities, whose purchase is directed by a sophisticated person as described in Rule 506(b)(2)(ii) of Regulation D under the U.S. Securities Act.
☐	Category 8.	An entity in which each of the equity owners is an accredited investor.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, **the Company has executed this Subscription Agreement as of the Closing Date.**

VISTAGEN THERAPEUTICS, INC.

By:
Name: Jerrold Dotson
Title: Chief Financial Officer

[SUBSCRIBER SIGNATURE PAGE FOLLOWS]

SUBSCRIBER SIGNATURE PAGE TO SUBSCRIPTION AGREEMENT

AGREED AND SUBSCRIBED

This __ day of _____, 2019

By:_____
Name:
Title (if any):

_____
Subscriber Name (Typed or Printed)

AGREED AND SUBSCRIBED
SIGNATURE OF JOINT SUBSCRIBER (if any)

This __ day of _____, 2019

By:_____
Name:
Title (if any):

_____
Additional Subscriber Name (Typed or Printed)

Exhibit 10.2

THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE BEEN ACQUIRED FOR INVESTMENT AND HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR ANY STATE SECURITIES LAWS. SUCH SECURITIES MAY NOT BE SOLD OR TRANSFERRED IN THE ABSENCE OF SUCH REGISTRATION OR AN EXEMPTION THEREFROM UNDER SAID ACT AND ANY APPLICABLE STATE SECURITIES LAWS.

THIS WARRANT AND THE SHARES PURCHASABLE HEREUNDER ARE SUBJECT TO RESTRICTIONS ON TRANSFER CONTAINED IN THAT CERTAIN SUBSCRIPTION AGREEMENT DATED _____ __, 2019, WHICH RESTRICTIONS ON TRANSFER ARE INCORPORATED HEREIN BY REFERENCE.

Dated: _____ __, 2019 ***Warrant Number: CSW-___***

WARRANT TO PURCHASE
COMMON STOCK
OF
VISTAGEN THERAPEUTICS, INC.

This certifies that _____, or its permitted assigns (each a "*Holder*"), for value received, is entitled to purchase, at an exercise price equal to Two dollars ($2.00) per share (the "*Exercise Price*") from VISTAGEN THERAPEUTICS, INC., a Nevada corporation (the "*Company*"), up to _____ (_____) shares of fully paid and nonassessable shares of the Company's Common Stock, $0.001 par value ("*Common Stock*").

This Warrant shall be exercisable at any time from time to time from and after May 2, 2020 (such date being referred to herein as the "Initial Exercise Date") up to and including 5:00 p.m. (Pacific Time) on November 2, 2023.

1. Method of Exercise. The Holder hereof may exercise this Warrant, in whole or in part, by the surrender of this Warrant (with the Form of Subscription attached hereto duly completed and executed) at the principal office of the Company, and by the payment to the Company of an amount of consideration therefor equal to the Exercise Price in effect on the date of such exercise multiplied by the number of shares of Common Stock with respect to which this Warrant is then being exercised, payable at such Holder's election by certified or official bank check or by wire transfer to an account designated by the Company.

2. Shares to be Fully Paid; Reservation of Shares. The Company covenants and agrees that all shares of Common Stock which may be issued upon the exercise of the rights represented by this Warrant will, upon issuance, be duly authorized, validly issued, fully paid and nonassessable and free from all preemptive rights of any shareholder and free of all taxes, liens and charges with respect to the issue thereof. The Company further covenants and agrees that during the period within which the rights represented by this Warrant may be exercised, the Company will at all times have authorized and reserved, for the purpose of issue or transfer upon exercise of the subscription rights evidenced by this Warrant, a sufficient number of shares of authorized but unissued shares of Common Stock.

3. Adjustment of Exercise Price and Number of Shares. The Exercise Price and the number of shares purchasable upon the exercise of this Warrant shall be subject to adjustment from time to time upon the occurrence of certain events described in this Section 3. Upon each adjustment of the Exercise Price, the Holder of this Warrant shall thereafter be entitled to purchase, at the Exercise Price resulting from such adjustment, the number of shares obtained by multiplying the Exercise Price in effect immediately prior to such adjustment by the number of shares purchasable pursuant hereto immediately prior to such adjustment, and dividing the product thereof by the Exercise Price resulting from such adjustment.

3.1 Subdivision or Combination of Stock. In case the Company shall at any time subdivide its outstanding shares of Common Stock into a greater number of shares, the Exercise Price in effect immediately prior to such subdivision shall be proportionately reduced, and conversely, in case the outstanding shares of the Common Stock of the Company shall be combined into a smaller number of shares, the Exercise Price in effect immediately prior to such combination shall be proportionately increased.

3.2 Reclassification. If any reclassification of the capital stock of the Company shall be effected in such a way that holders of Common Stock shall be entitled to receive stock, securities, or other assets or property, then, as a condition of such reclassification, lawful and adequate provisions shall be made whereby the Holder hereof shall thereafter have the right to purchase and receive (in lieu of the shares of the Common Stock immediately theretofore purchasable and receivable upon the exercise of the rights represented hereby) such shares of stock, securities or other assets or property as may be issued or payable with respect to or in exchange for a number of outstanding shares of such Common Stock equal to the number of shares of such Common Stock immediately theretofore purchasable and receivable upon the exercise of the rights represented hereby. In any reclassification described above, appropriate provision shall be made with respect to the rights and interests of the Holder of this Warrant to the end that the provisions hereof (including, without limitation, provisions for adjustments of the Exercise Price and of the number of shares purchasable and receivable upon the exercise of this Warrant) shall thereafter be applicable, as nearly as may be, in relation to any shares of stock, securities or assets thereafter deliverable upon the exercise hereof.

3.3 Notice of Adjustment. Upon any adjustment of the Exercise Price or any increase or decrease in the number of shares purchasable upon the exercise of this Warrant, the Company shall give written notice thereof, by first class mail postage prepaid, addressed to the registered Holder of this Warrant at the address of such Holder as shown on the books of the Company. The notice shall be signed by the Company's chief financial officer and shall state the Exercise Price resulting from such adjustment and the increase or decrease, if any, in the number of shares purchasable at such price upon the exercise of this Warrant, setting forth in reasonable detail the method of calculation and the facts upon which such calculation is based.

3.4 Other Notices. If at any time:

(1) the Company shall declare any cash dividend upon its Common Stock;

(2) there shall be a Change of Control; or

(3) there shall be a voluntary or involuntary dissolution, liquidation or winding-up of the Company;

then, in any one or more of said cases, the Company shall give, by first class mail, postage prepaid, addressed to the Holder of this Warrant at the address of such Holder as shown on the books of the Company, (a) at least twenty (20) days prior written notice of the date on which the books of the Company shall close or a record shall be taken for such dividend or for determining rights to vote in respect of any such Change of Control or dissolution, liquidation or winding-up, and (b) in the case of any such Change of Control or dissolution, liquidation, or winding-up, at least twenty (20) days prior written notice of the date when the same shall take place; provided, however, that the Holder shall make a best efforts attempt to respond to such notice as early as possible after the receipt thereof. Any notice given in accordance with the foregoing clause (a) shall also specify, in the case of any such dividend, the date on which the holders of Common Stock shall be entitled thereto. Any notice given in accordance with the foregoing clause (b) shall also specify the date on which the holders of Common Stock shall be entitled to exchange their Common Stock for securities or other property deliverable upon such Change of Control, dissolution, liquidation, winding-up, or conversion, as the case may be.

4. No Voting or Dividend Rights. Nothing contained in this Warrant shall be construed as conferring upon the Holder hereof the right to vote or to consent to receive notice as a shareholder of the Company or any other matters or any rights whatsoever as a shareholder of the Company. No dividends or interest shall be payable or accrued in respect of this Warrant or the interest represented hereby or the shares purchasable hereunder until, and only to the extent that, this Warrant shall have been exercised.

5. Warrants Transferable. Subject to compliance with applicable federal and state securities laws, this Warrant and all rights hereunder may be transferred, in whole or in part, without charge to the holder hereof (except for transfer taxes), upon the prior written consent of the Company and, thereafter, upon surrender of this Warrant properly endorsed and compliance with the provisions of this Warrant. Each taker and holder of this Warrant, by taking or holding the same, consents and agrees that this Warrant, when endorsed in blank, shall be deemed negotiable, and that the holder hereof, when this Warrant shall have been so endorsed, may be treated by the Company, at the Company's option, and all other persons dealing with this Warrant as the absolute owner hereof for any purpose and as the person entitled to exercise the rights represented by this Warrant, or to the transfer hereof on the books of the Company and notice to the contrary notwithstanding; but until such transfer on such books, the Company may treat the registered owner hereof as the owner for all purposes.

6. Lost Warrants. Upon receipt of evidence reasonably satisfactory to the Company of the loss, theft, destruction, or mutilation of this Warrant and, in the case of any such loss, theft or destruction, upon receipt of an indemnity reasonably satisfactory to the Company, or in the case of any such mutilation upon surrender and cancellation of such Warrant, the Company, at its expense, will make and deliver a new Warrant, of like tenor, in lieu of the lost, stolen, destroyed or mutilated Warrant.

7. Modification and Waiver. Any term of this Warrant may be amended and the observance of any term of this Warrant may be waived (either generally or in a particular instance and either retroactively or prospectively) only with the written consent of the Company and the Holder hereof. Any amendment or waiver affected in accordance with this Section 7 shall be binding upon the Company and the Holder.

8. Notices. All notices and other communications from the Company to the Holder, or vice versa, shall be deemed delivered and effective when given personally or mailed by first-class registered or certified mail, postage prepaid, at such address as may have been furnished to the Company or the Holder, as the case may be, in writing by the Company or such holder from time to time.

9. Titles and Subtitles; Governing Law; Venue. The titles and subtitles used in this Warrant are used for convenience only and are not to be considered in construing or interpreting this Warrant. This Warrant is to be construed in accordance with and governed by the internal laws of the State of Nevada without giving effect to any choice of law rule that would cause the application of the laws of any jurisdiction other than the internal laws of the State of Nevada to the rights and duties of the Company and the Holder. All disputes and controversies arising out of or in connection with this Warrant shall be resolved exclusively by the state and federal courts located in Carson City in the State of Nevada, and each of the Company and the Holder hereto agrees to submit to the jurisdiction of said courts and agrees that venue shall lie exclusively with such courts.

10. Definition of Warrant Shares. For purposes of this Warrant, "Warrant Shares" shall mean the number of shares of the Company's Common Stock issuable upon exercise of this Warrant.

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IN WITNESS WHEREOF, the Company has caused this Warrant to be duly executed by its officers, thereunto duly authorized as of the date first above written.

VistaGen Therapeutics, Inc.

By:
Jerrold D. Dotson
Chief Financial Officer

[Signature Page to Warrant]

FORM OF SUBSCRIPTION

(To be signed only upon exercise of Warrant)

To: VISTAGEN THERAPEUTICS, INC.

The undersigned, the holder of a right to purchase shares of Common Stock of VistaGen Therapeutics, Inc. (the "*Company*") pursuant to that certain Warrant to Purchase Common Stock of VistaGen Therapeutics, Inc. Number CSW-_____ (the "Warrant"), dated as of _____ __, 2019 hereby irrevocably elects to exercise the purchase right represented by such Warrant for, and to purchase thereunder, _____ (_____) shares of Common Stock of the Company and herewith makes payment of Two Dollars ($2.00) therefor in cash.

The undersigned represents that it is acquiring such securities for its own account for investment and not with a view to or for sale in connection with any distribution thereof and in order to induce the issuance of such securities makes to the Company, as of the date hereof, the representations and warranties set forth in the Unit Subscription Agreement, dated as of _____ ____, by and among the Company and the Holder.

DATED:

By:_____
Name: _____

Its: _____

ACKNOWLEDGMENT

To: **HOLDER**

The undersigned hereby acknowledges that as of the date hereof, _____ (_____) shares of Common Stock remain subject to the right of purchase in favor of _____ pursuant to that certain Warrant to Purchase Common Stock of VistaGen Therapeutics, Inc., number CSW-___ dated as of _____ __, 2019.

DATED: _____

VistaGen Therapeutics, Inc.

By:

Name:

Its:

Warrant Receipt

The undersigned, _____, does hereby acknowledge receipt of Warrant Number CSW-___ dated, _____ __, 2019, representing _____ (_____) shares of the Common Stock Warrants of VistaGen Therapeutics, Inc.

IN WITNESS WHEREOF, the undersigned has executed this Receipt as of the date set forth below.

Type:	Common Stock Warrants
Warrant Number:	CSW-___
Number of Shares:	_____

Name: _____
Date: _____

EXHIBIT 31.1

CERTIFICATION

I, Shawn K. Singh, certify that;

1. I have reviewed this quarterly report on Form 10-Q of VistaGen Therapeutics, Inc.;

2. Based on my knowledge, this report, does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by the report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

November 6, 2019

/s/ Shawn K. Singh
Shawn K. Singh
Principal Executive Officer

EXHIBIT 31.2

CERTIFICATION

I, Jerrold D. Dotson, certify that:

1. I have reviewed this quarterly report on Form 10-Q of VistaGen Therapeutics, Inc.;

2. Based on my knowledge, this report, does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by the report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

November 6, 2019

/s/ Jerrold D. Dotson
Jerrold D. Dotson
Principal Financial Officer

EXHIBIT 32

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of VistaGen Therapeutics, Inc. (the "*Company*") for the quarter ended September 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "*Report*"), Shawn K. Singh, JD, the Company's Principal Executive Officer, and Jerrold D. Dotson, the Company's Principal Financial Officer, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to the best of their knowledge:

1. The Report fully complies with the requirement of Section 13(a) or Section 15 (d) of the Securities Exchange Act of 1934, and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

November 6, 2019

/s/ Shawn K. Singh
Shawn K. Singh
Principal Executive Officer

/s/ Jerrold D. Dotson
Jerrold D. Dotson
Principal Financial Officer