UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended December 31, 2016
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: 000-54014

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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 (do not check if a smaller reporting company)	[ ]	Smaller reporting company	[X]

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

As of February 10, 2017, 8,581,471 shares of the registrant's common stock, $0.001 par value, were issued and outstanding.

VistaGen Therapeutics, Inc.
Quarterly Report on Form 10-Q
for the Quarter Ended December 31, 2016

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PART I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (Unaudited)

VISTAGEN THERAPEUTICS, INC.

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

	December 31 2016 (Unaudited)	March 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,372,000	$ 428,500
Sublicense fee receivable	1,250,000	-
Prepaid expenses and other current assets	146,400	426,800
Total current assets	5,768,400	855,300
Property and equipment, net	59,900	87,600
Security deposits and other assets	47,800	46,900
Total assets	$ 5,876,100	$ 989,800
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 874,400	$ 936,000
Accrued expenses	961,800	814,000
Current portion of notes payable and accrued interest	35,800	43,600
Capital lease obligations	300	1,100
Total current liabilities	1,872,300	1,794,700
Non-current liabilities:		
Notes payable	-	27,200
Accrued dividends on Series B Preferred Stock	1,339,300	2,089,600
Deferred rent liability	75,900	55,500
Total non-current liabilities	1,415,200	2,172,300
Total liabilities	3,287,500	3,967,000
Commitments and contingencies		
Stockholders' equity (deficit):		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at December 31, 2016 and March 31, 2016:		
Series A Preferred, 500,000 shares authorized and outstanding at December 31, 2016 and March 31, 2016	500	500
Series B Preferred; 4,000,000 shares authorized at December 31, 2016 and March 31, 2016; 1,160,240 shares and 3,663,077 shares issued and outstanding at December 31, 2016 and March 31, 2016, respectively	1,200	3,700
Series C Preferred; 3,000,000 shares authorized at December 31, 2016 and March 31, 2016; 2,318,012 shares issued and outstanding at December 31, 2016 and March 31, 2016	2,300	2,300
Common stock, $0.001 par value; 30,000,000 shares authorized at December 31, 2016 and March 31, 2016; 8,717,136 and 2,623,145 shares issued at December 31, 2016 and March 31, 2016, respectivtly	8,700	2,600
Additional paid-in capital	145,993,900	132,725,000
Treasury stock, at cost, 135,665 shares of common stock held at December 31, 2016 and March 31, 2016	(3,968,100)	(3,968,100)
Accumulated deficit	(139,449,900)	(131,743,200)
Total stockholders' equity (deficit)	2,588,600	(2,977,200)
Total liabilities and stockholders' equity (deficit)	$ 5,876,100	$ 989,800

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 December 31,		Nine Months Ended December 31,	
	2016	**2015**	**2016**	**2015**
Revenues:				
Sublicense fees	1,250,000	-	1,250,000	-
Total revenues	1,250,000	-	1,250,000	-
Operating expenses:				
Research and development	1,611,000	806,300	4,042,800	2,835,000
General and administrative	2,276,600	1,335,500	4,907,800	6,514,500
Total operating expenses	3,887,600	2,141,800	8,950,600	9,349,500
Loss from operations	(2,637,600)	(2,141,800)	(7,700,600)	(9,349,500)
Other expenses, net:				
Interest expense, net	(900)	(2,500)	(3,700)	(769,800)
Change in warrant liability	-	-	-	(1,894,700)
Loss on extinguishment of debt	-	-	-	(26,700,200)
Other income (expense)	-	(2,300)	-	(2,300)
Loss before income taxes	(2,638,500)	(2,146,600)	(7,704,300)	(38,716,500)
Income taxes	-	-	(2,400)	(2,300)
Net loss	$ (2,638,500)	$ (2,146,600)	$ (7,706,700)	$ (38,718,800)
Accrued dividend on Series B Preferred stock	(237,700)	(631,300)	(1,018,500)	(1,459,300)
Deemed dividend on Series B Preferred Units	-	(668,700)	(111,100)	(1,811,800)
Net loss attributable to common stockholders	$ (2,876,200)	$ (3,446,600)	$ (8,836,300)	$ (41,989,900)
Basic and diluted net loss attributable to common stockholders per common share	$ (0.34)	$ (1.95)	$ (1.23)	$ (25.45)
Weighted average shares used in computing basic and diluted net loss attributable to common stockholders per common share	8,381,824	1,765,641	7,181,307	1,650,160
Comprehensive loss	$ (2,638,500)	$ (2,146,600)	$ (7,706,700)	$ (38,718,800)

See accompanying notes to Condensed Consolidated Financial Statements.

VISTAGEN THERAPEUTICS, INC.

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

	Nine Months Ended December 31,	
	2016	**2015**
Cash flows from operating activities:		
Net loss	$ (7,706,700)	$ (38,718,800)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	37,600	40,800
Amortization of discounts on convertible and promissory notes	-	564,800
Change in warrant liability	-	1,894,700
Stock-based compensation	573,900	3,868,300
Expense related to modification of warrants, including exchange of warrants for Series C Preferred and common stock	427,500	614,900
Amortization of deferred rent	20,400	(19,500)
Fair value of common stock granted for services	1,217,500	606,300
Fair value of Series B Preferred stock granted for services	375,000	1,045,000
Fair value of warrants granted for services	240,300	111,200
Gain on currency fluctuation	-	(6,400)
Loss on disposition of fixed assets	-	2,300
Changes in operating assets and liabilities:		
Sublicense fee receivable	(1,250,000)	-
Prepaid expenses, security deposit and other current assets	22,000	61,800
Accounts payable and accrued expenses, including accrued interest	74,200	(264,500)
Net cash used in operating activities	(5,968,300)	(3,498,900)
Cash flows from investing activities:		
Purchases of equipment	(9,900)	(4,600)
Net cash used in investing activities	(9,900)	(4,600)
Cash flows from financing activities:		
Net proceeds from issuance of common stock and warrants, including Units	9,785,000	280,000
Net proceeds from issuance of Series B Preferred Units	278,000	4,397,800
Repayment of capital lease obligations	(800)	(700)
Repayment of notes	(140,500)	(85,200)
Net cash provided by financing activities	9,921,700	4,591,900
Net increase in cash and cash equivalents	3,943,500	1,088,400
Cash and cash equivalents at beginning of period	428,500	70,000
Cash and cash equivalents at end of period	$ 4,372,000	$ 1,158,400
Supplemental disclosure of noncash activities:		
Conversion of Senior Secured Notes, Subordinate Convertible Notes, Promissory Notes, Accounts payable and other debt into Series B Preferred	$ -	$ 18,891,400
Insurance premiums settled by issuing note payable	$ 117,500	$ 79,400
Accrued dividends on Series B Preferred	$ 1,018,500	$ 1,459,300
Accrued dividends on Series B Preferred settled upon conversion by issuance of common stock	$ 1,768,800	$ 43,500

See accompanying notes to Condensed Consolidated Financial Statements.

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

Note 1. Description of Business

Overview

VistaGen Therapeutics, Inc. (NASDAQ: VTGN), a Nevada corporation, is a clinical-stage biopharmaceutical company focused on developing new generation medicines for depression and other central nervous system (*CNS*) disorders. Our principal executive offices are located at 343 Allerton Avenue, South San Francisco, California 94080, and our telephone number is (650) 577-3600. Our website address is *www.vistagen.com*. Unless the context otherwise requires, the words "*VistaGen Therapeutics, Inc.*" "*VistaGen*," "*we*," "*the Company*," "*us*" and "*our*" refer to VistaGen Therapeutics, Inc., a Nevada corporation.

AV-101, our lead CNS product candidate, is a new generation oral antidepressant drug candidate in Phase 2 development, initially as an adjunctive treatment for Major Depressive Disorder (*MDD*) in patients with an inadequate response to standard antidepressants approved by the U.S. Food and Drug Administration (*FDA*). We believe AV-101 may also have the potential to treat additional CNS indications, including chronic neuropathic pain, epilepsy, Huntington's disease and Parkinson's disease.

AV-101's mechanism of action, as an N-methyl D aspartate receptor (*NMDAR*) antagonist binding selectively at the glycine binding (*GlyB*) co-agonist site of the NMDAR, is fundamentally differentiated from all FDA-approved antidepressants, as well as all atypical antipsychotics often used adjunctively with standard antidepressants.

A Phase 2a clinical study of AV-101 as a monotherapy in subjects with treatment-resistant MDD is being conducted and fully funded by the U.S. National Institute of Mental Health (*NIMH*), part of the U.S. National Institutes of Health (*NIH*), under our February 2015 Cooperative Research and Development Agreement (*CRADA*) with the NIMH (*Phase 2a Study*). The Principal Investigator of the Phase 2a Study is Dr. Carlos Zarate, Jr., Chief of the NIMH's Experimental Therapeutics & Pathophysiology Branch and its Section on Neurobiology and Treatment of Mood and Anxiety Disorders. Previous NIMH studies, including studies conducted by Dr. Zarate, have focused on the antidepressant effects of low dose, intravenous (*I.V.*) ketamine, a NMDAR antagonist, in patients with treatment-resistant MDD. These NIMH studies, as well as clinical research by Yale University and other academic institutions, have demonstrated robust antidepressant effects in MDD patients within twenty-four hours of a single low dose of I.V. ketamine. We believe orally-administered AV-101 may have potential to deliver ketamine-like fast-acting antidepressant effects without ketamine's serious side effects. We currently anticipate that the NIMH will complete the Phase 2a Study by the end of 2017.

We are preparing to launch our Phase 2b clinical study of AV-101 as a new generation adjunctive treatment of MDD in adult patients with an inadequate response to standard, FDA-approved antidepressants (*Phase 2b Study*). We currently anticipate commencement of this multi-center, multi-dose, double blind, placebo-controlled efficacy and safety study of AV-101 by the end of the second quarter of 2017. Dr. Maurizio Fava, Professor of Psychiatry at Harvard Medical School and Director, Division of Clinical Research, Massachusetts General Hospital (*MGH*) Research Institute, will be the Principal Investigator of the Phase 2b Study. Dr. Fava was the co-Principal Investigator with Dr. A. John Rush of the STAR*D study, the largest clinical trial conducted in depression to date, whose findings were published in journals such as the New England Journal of Medicine (*NEJM*) and the Journal of the American Medical Association (*JAMA*). We currently anticipate top line results of the Phase 2b Study by the end of 2018.

VistaStem Therapeutics (*VistaStem*) is our wholly owned subsidiary focused on applying human pluripotent stem cell (*hPSC*) technology, internally or with third-party collaborators, to discover, rescue, develop and commercialize (i) proprietary new chemical entities (*NCEs*), including small molecule NCEs with regenerative potential, for CNS and other diseases and (ii) cellular therapies involving stem cell-derived blood, cartilage, heart and liver cells. Our internal small molecule drug rescue programs utilize *CardioSafe 3D*, our customized cardiac bioassay system, to develop NCEs for our pipeline. In December 2016, we exclusively sublicensed to BlueRock Therapeutics LP, a next generation regenerative medicine company established in December 2016 by Bayer AG and Versant Ventures, rights to certain proprietary technologies relating to the production of cardiac stem cells for the treatment of heart disease (the *BlueRock Agreement*). VistaStem may also pursue additional potential regenerative medicine (*RM*) applications, including using blood, cartilage, and/or liver cells derived from hPSCs for (A) cell-based therapy, (B) cell repair therapy, and/or (C) tissue engineering. In a manner similar to our exclusive sublicense agreement with BlueRock Therapeutics, VistaStem may pursue these additional RM applications in collaboration with third-parties.

AV-101 and Major Depressive Disorder

Background

The World Health Organization (*WHO*) estimates that 350 million people worldwide are affected by depression. According to the NIH, major depression is one of the most common mental disorders in the U.S. The NIMH reports that, in 2014, an estimated 15.7 million adults aged 18 or older in the U.S. had at least one major depressive episode in the past year. This represented 6.7 percent of all U.S. adults. According to the U.S. Centers for Disease Control and Prevention (*CDC*) one in 10 Americans over the age of 12 takes a standard, FDA-approved antidepressant.

Most standard, FDA-approved antidepressants target neurotransmitter reuptake inhibition – either serotonin (antidepressants known as *SSRIs*) or serotonin/norepinephrine (antidepressants known as *SNRIs*). Even when effective, these standard depression medications take many weeks to achieve adequate antidepressant effects. Nearly two out of every three drug-treated depression patients, including an estimated 6.9 million drug-treated MDD patients in the U.S., obtain inadequate therapeutic benefit from initial treatment with a standard antidepressant. Unfortunately, even after treatment with as many as four different standard antidepressants, nearly one out of every three drug-treated depression patients still do not achieve adequate therapeutic benefits. Such patients with an inadequate response to standard antidepressants often seek to augment their treatment regimen by adding an atypical antipsychotic (such as, for example, aripiprazole), despite only modest potential therapeutic benefit and the risk of additional side effects from atypical antipsychotics.

All standard, FDA-approved antidepressants have risks of significant side effects, including, among others, potential anxiety, metabolic syndrome, sleep disturbance and sexual dysfunction. Adjunctive use of atypical antipsychotics to augment inadequately performing standard antidepressants increases the risk of serious side effects, including, potentially, tardive dyskinesia, significant weight gain, diabetes and heart disease, while offering only a modest potential increase in therapeutic benefit.

AV-101

AV-101, our oral new generation antidepressant prodrug candidate, is in Phase 2 clinical development for the adjunctive treatment of MDD patients with an inadequate response to standard antidepressants. As published in the October 2015 issue of the peer-reviewed, *Journal of Pharmacology and Experimental Therapeutics*, in an article entitled, *The prodrug 4-chlorokynurenine causes ketamine-like antidepressant effects, but not side effects, by NMDA/glycineB-site inhibition*, using well-established preclinical models of depression, AV-101 was shown to induce fast-acting, dose-dependent, persistent and statistically significant antidepressant-like responses following a single treatment. These responses were equivalent to those seen with a single sub-anesthetic control dose of ketamine, a NMDAR antagonist. In addition, these studies confirmed that the fast-acting antidepressant effects of AV-101 were mediated through the GlyB site and also involved the activation of another key neurological pathway, the alpha-amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid (*AMPA*) receptor pathway. We believe activation of the AMPA receptor pathway is a key final common pathway feature of new generation antidepressants.

Following the completion of our NIH-funded, randomized, double blind, placebo-controlled AV-101 Phase 1a and Phase 1b safety studies, the NIMH initiated and is fully funding the Phase 2a study of AV-101 as a monotherapy in subjects with treatment-resistant MDD under our February 2015 CRADA with the NIMH. Dr. Carlos Zarate Jr. of the NIMH is the Principal Investigator conducting the Phase 2a Study at the NIMH. The trial is expected to enroll up to 25 patients. We currently anticipate that the NIMH will complete the Phase 2a Study by the end of 2017.

We are preparing to launch our approximately 280-patient Phase 2b Study of AV-101 as an adjunctive treatment of MDD in patients with an inadequate response to standard, FDA-approved antidepressants. We currently anticipate the launch of the Phase 2b Study, with Dr. Maurizio Fava of Harvard Medical School serving as Principal Investigator, by the end of the second quarter of 2017. We currently anticipate top line results of the Phase 2b Study by the end of 2018.

We believe preclinical studies support the hypothesis that AV-101 may also have the potential to treat multiple CNS disorders and neurodegenerative diseases in addition to MDD, including chronic neuropathic pain, epilepsy, Parkinson's disease and Huntington's disease, where modulation of the NMDAR, AMPA pathway and/or key active metabolites of AV-101 may achieve therapeutic benefit. However, human clinical studies will be required before this therapeutic potential could be demonstrated. There is no guarantee that human clinical trials would be successful or that the FDA would approve the use of AV-101 for the treatment of one or more of these additional CNS indications.

CardioSafe 3D™; NCE Drug Rescue and Regenerative Medicine

VistaStem Therapeutics is our wholly owned subsidiary focused on applying hPSC technology to discover, rescue, develop and commercialize proprietary NCEs, including small molecule NCEs with regenerative potential, for CNS and other diseases, as well as potential cellular therapies involving stem cell-derived blood, cartilage, heart and liver cells. *CardioSafe* 3D™ is our customized *in vitro* cardiac bioassay system capable of predicting potential human heart toxicity of small molecule NCEs *in vitro*, long before they are ever tested in animal and human studies. We are currently focused on potential commercial applications of our stem cell technology platform involving (i) use of *CardioSafe* 3D for internal small molecule NCE drug discovery and drug rescue to expand our proprietary drug candidate pipeline, leveraging substantial prior research and development investments by pharmaceutical companies and others related to public domain NCEs terminated before FDA approval due to heart toxicity risks and (ii) RM. With respect to RM, in December 2016, we exclusively sublicensed to BlueRock Therapeutics LP, a next generation regenerative medicine company established in December 2016 by Bayer AG and Versant Ventures, rights to certain proprietary technologies relating to the production of cardiac stem cells for the treatment of heart disease (*BlueRock Therapeutics Agreement*). We may also pursue additional potential RM applications using blood, cartilage, and/or liver cells derived from hPSCs for (A) cell-based therapy (injection of stem cell-derived mature organ-specific cells obtained through directed differentiation), (B) cell repair therapy (induction of regeneration by biologically active molecules administered alone or produced by infused genetically engineered cells), or (C) tissue engineering (transplantation of *in vitro* grown complex tissues) using hPSC-derived blood, bone, cartilage, and/or liver cells. In a manner similar to the BlueRock Therapeutics Agreement, we may pursue these additional RM applications in collaboration with third-parties.

Subsidiaries

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

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, 2016 has been derived from our audited consolidated financial statements at that date but does not include all disclosures required by U.S. GAAP. The operating results for the three and nine months ended December 31, 2016 are not necessarily indicative of the operating results to be expected for our fiscal year ending March 31, 2017 or for any other interim period or any other future period.

The accompanying unaudited Condensed Consolidated Financial Statements and notes to Condensed Consolidated Financial Statements should be read in conjunction with our audited Consolidated Financial Statements for the fiscal year ended March 31, 2016 contained in our Annual Report on Form 10-K, as filed with the Securities and Exchange Commission (*SEC*) on June 24, 2016.

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared assuming we will continue as a going concern. As a developing-technology 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 $139.4 million accumulated from inception through December 31, 2016. We expect losses and negative cash flows from operations to continue for the foreseeable future as we engage in further potential development of AV-101, including conducting clinical trials, and pursue potential drug rescue, drug development and regenerative medicine opportunities.

Since our inception in May 1998 through December 31, 2016, we have financed our operations and technology acquisitions primarily through the issuance and sale of our equity and debt securities, including convertible promissory notes and short-term promissory notes, for cash proceeds of approximately $44.5 million, as well as from an aggregate of approximately $17.6 million of government research grant awards, strategic collaboration payments, intellectual property sublicensing and other revenues. Additionally, we have issued equity securities with an approximate value at issuance of $30.4 million in non-cash settlements of certain liabilities, including liabilities for professional services rendered to us or as compensation for such services.

Between April 1, 2016 and May 4, 2016, we sold to accredited investors Series B Preferred Units consisting of 39,714 unregistered shares of our Series B Preferred Stock, par value $0.001 per share (*Series B Preferred*), and five year warrants exercisable at $7.00 per share (*Series B Preferred Warrants*) to purchase 39,714 shares of our common stock, from which we received cash proceeds of $278,000. Further, on May 16, 2016 we consummated an underwritten public offering pursuant to which we issued an aggregate of 2,570,040 registered shares of our common stock at the public offering price of $4.24 per share and five-year warrants to purchase up to 2,705,883 registered shares of common stock, with an exercise price of $5.30 per share, at the public offering price of $0.01 per warrant, including shares and warrants issued pursuant to the exercise of the underwriters' over-allotment option (the *May 2016 Public Offering*). We received net cash proceeds of approximately $9.5 million from the May 2016 Public Offering after deducting fees and expenses. During the quarter ended December 31, 2016, we received aggregate cash proceeds of $247,900 from the sale of an aggregate of 67,000 shares of our unregistered common stock and warrants exercisable through November 30, 2019 to purchase 16,750 unregistered shares of our common stock to two accredited investors in private placement transactions. As described in greater detail in Note 5, *Sublicense Fee Receivable and Sublicense Revenue*, we received a cash payment of $1.25 million under the BlueRock Therapeutics Agreement in January 2017. We believe that we currently have sufficient financial resources to fund our expected operations at least through the first half of 2017, including preparation for and launch of the Phase 2b Study. Although our current financial resources are not yet sufficient to fully fund completion of the Phase 2b Study, we anticipate raising sufficient additional capital as and when necessary and advisable to satisfy our key corporate objectives, including conducting and completing the Phase 2b Study in an ordinary course manner. In furtherance of that objective, on January 23, 2017, we filed a Registration Statement on Form S-3 (Registration No. 333-215671) with the Securities and Exchange Commission (the *Commission*) covering the potential future sale of up to $100 million of our equity and/or debt securities or combinations thereof. There can be no assurance, however, that future financing will be available in sufficient amounts, in a timely manner, or on terms acceptable to us, if at all. We may also seek research and development collaborations that could generate revenue, funding for development of AV-101 and additional product candidates, as well as additional government grant awards and agreements similar to our current CRADA with the NIMH, which provides for the NIMH to fully fund the ongoing Phase 2a study of AV-101 as a monotherapy for MDD. 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. In a manner similar to the BlueRock Therapeutics Agreement, we may also pursue similar arrangements with third-parties covering other of our intellectual property. Although we may seek additional collaborations that could generate revenue and/or non-dilutive funding for development of AV-101 and other product candidates, as well as new government grant awards and/or agreements similar to our CRADA with NIMH, no assurance can be provided that any such collaborations, awards or agreements will occur in the future. Our future working capital requirements will depend on many factors, including, without limitation, the scope and nature of opportunities related to our success and the success of certain other companies in clinical trials, including our development and commercialization of AV-101 as an adjunctive treatment for MDD and other CNS conditions, 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 and 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, intellectual property, accounting, public company compliance and other professional services and working capital costs.

Notwithstanding the foregoing, substantial additional financing may not be available to us on a timely basis, on acceptable terms, or at all. If we are unable to obtain substantial additional financing on a timely basis when needed in 2017 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. These unaudited Condensed Consolidated Financial Statements do not include any adjustments that might result from the outcome of this uncertainty.

Note 3. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates include those relating to share-based compensation, and assumptions that have been used to value warrants, warrant modifications, warrant liabilities. With the exception of the $1.25 million of sublicense revenue recorded in the quarter ended December 31, 2016 under the BlueRock Therapeutics Agreement, which agreement is described in greater detail under Note 5, *Sublicense Fee Receivable and Sublicense Revenue* below, 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 of scientific personnel and direct project costs. External research and development expenses consist primarily of costs associated with nonclinical and clinical development of AV-101, now in Phase 2 clinical development, initially for Major Depressive Disorder, stem cell technology-related research and development costs, and costs related to the filing, maintenance and prosecution of patents and patent applications and technology licenses. All such costs are charged to expense as incurred.

Stock-Based Compensation

We recognize compensation cost for all stock-based awards to employees or consultants based on the grant date fair value of the award. Non-cash, stock-based compensation expense is recognized over the period during which the employee or consultant is required to perform services in exchange for the award, which generally represents the scheduled vesting period. We have no awards with market or performance conditions. For equity awards to non-employees, we re-measure the fair value of the awards as they vest and the resulting value is recognized as an expense during the period over which the services are performed.

The table below summarizes stock-based compensation expense included in the accompanying Condensed Consolidated Statements of Operations and Comprehensive Loss for the three and nine months ended December 31, 2016 and 2015.

	Three Months Ended December 31,		Nine Months Ended December 31,	
	2016	2015	2016	2015
Research and development expense:				
Stock option grants	$ 113,900	$ 71,300	$ 239,900	$ 118,700
Warrants granted to officer in March 2014	-	2,800	-	8,500
Warrants granted to officer in September 2015	-	-	-	852,200
	113,900	74,100	239,900	979,400
General and administrative expense:				
Stock option grants	153,300	20,400	334,000	36,500
Warrants granted to officers and directors in March 2014	-	3,900	-	11,700
Warrants granted to officers, directors and consultants in September 2015	-	-	-	2,840,700
	153,300	24,300	334,000	2,888,900
Total stock-based compensation expense	$ 267,200	$ 98,400	$ 573,900	$ 3,868,300

In June 2016, our Board of Directors (*the Board*) approved the grant of options to purchase an aggregate of 655,000 shares of our common stock at an exercise price of $3.49 per share to the independent members of our Board and to our officers, including our newly-hired Chief Medical Officer. In September 2016, the Board approved the grant of an option to purchase 125,000 shares of our common stock at an exercise price of $4.27 per share to another newly-hired officer. In November 2016, the Board authorized the grant of stock options to independent members of the Board and to our officers and employees to purchase an aggregate of 560,000 shares of our common stock at an exercise price of $3.80 per share. At December 31, 2016, there were stock options outstanding to purchase 1,659,324 shares of our common stock at a weighted average exercise price of $4.76 per share. We valued the options granted in June, September and November 2016 using the Black-Scholes Option Pricing Model and the following weighted average assumptions:

Assumption:	**June 2016**	**September 2016**	**November 2016**
Market price per share at grant date	$ 3.49	$ 4.27	$ 3.80
Exercise price per share	$ 3.49	$ 4.27	$ 3.80
Risk-free interest rate	1.34%	1.29%	1.76%
Contractual or estimated term in years	6.68	6.25	6.79
Volatility	81.69%	83.26%	84.38%
Dividend rate	0.0%	0.0%	0.0%
Shares	655,000	125,000	560,000
Fair Value per share	**$ 2.50**	**$ 3.05**	**$ 2.81**

During September 2015, the Board approved the grant of options to purchase an aggregate of 90,000 shares of our common stock at an exercise price of $9.25 per share to our non-officer employees and certain consultants. The Board also granted immediately vested warrants to purchase an aggregate of 650,000 shares of our common stock to our executive officers, independent members of the Board and certain consultants. We valued the warrants and options granted in September 2015 using the Black-Scholes Option Pricing Model and the following assumptions:

Assumption:	**Warrants**	**Employee Options**	**Non-employee Options**
Market price per share at grant date	$ 9.11	$ 9.11	$ 9.11
Exercise price per share	$ 9.25	$ 9.25	$ 9.25
Risk-free interest rate	1.52%	2.02%	2.20%
Contractual or estimated term in years	5.00	6.25	10.00
Volatility	77.19%	79.48%	103.42%
Dividend rate	0.0%	0.0%	0.0%
Shares	650,000	60,000	30,000
Fair Value per share	**$ 5.68**	**$ 6.35**	**$ 8.27**

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.

Income (Loss) per Common Share

Basic net income (loss) per share of common stock excludes the effect of dilution and is computed by dividing net income (loss) by the weighted-average number of shares of common stock outstanding for the period. Diluted net income (loss) 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 income (loss) per share, we have historically adjusted the numerator for the change in the fair value of the warrant liability attributable to outstanding warrants, only if dilutive, and increased the denominator to include the number of potentially dilutive common shares assumed to be outstanding during the period using the treasury stock method. The change in the fair value of the warrant liability, which was eliminated in May 2015, had no impact on the diluted net earnings per share calculation in any period included in these unaudited Condensed Consolidated Financial Statements.

As a result of our net loss for the periods presented, potentially dilutive securities were excluded from the computation of net loss per share, as their effect would be antidilutive. For the three and nine month periods ended December 31, 2016 and 2015, the accrual for dividends on our Series B Preferred and the deemed dividend attributable to the issuance of our Series B Preferred Units represent deductions from our net loss to arrive at net loss attributable to common stockholders for those periods.

Potentially dilutive securities excluded in determining diluted net loss attributable to common stockholders per common share are as follows:

	As of December 31,	
	2016	**2015**
Series A Preferred stock issued and outstanding [(1)]	750,000	750,000
Series B Preferred stock issued and outstanding [(2)]	1,160,240	3,588,863
Series C Preferred stock issued and outstanding [(3)]	2,318,012	-
Outstanding options under the 2016 (formerly 2008) and 1999 Stock Incentive Plans	1,659,324	296,738
Outstanding warrants to purchase common stock	4,550,370	4,971,497
Warrant shares issuable to PLTG upon exchange of Series A Preferred under the terms of the October 11, 2012 Note Exchange and Purchase Agreement, as subsequently amended	-	535,715
Total	10,437,946	10,142,813

(1) Assumes exchange under the terms of the October 11, 2012 Note Exchange and Purchase Agreement with PLTG, as amended
(2) Assumes exchange under the terms of the Certificate of Designation of the Relative Rights and Preferences of the Series B 10% Convertible Preferred Stock, effective May 5, 2015
(3) Assumes exchange under the terms of the Certificate of Designation of the Relative Rights and Preferences of the Series C Convertible Preferred Stock, effective January 25, 2016

Recent Accounting Pronouncements

Other than as identified below, there have been no recent accounting pronouncements or changes in accounting pronouncements during the nine months ended December 31, 2016, as compared to the recent accounting pronouncements described in the Company's Form 10-K for the fiscal year ended March 31, 2016, that are of significance or potential significance to the Company.

In August 2016, the Financial Accounting Standards Board issued guidance to reduce the diversity in the presentation of certain cash receipts and cash payments presented and classified in the statement of cash flows. The guidance addresses the following eight specific cash flow issues: (1) debt prepayment or debt extinguishment costs, (2) settlement of zero-coupon debt instruments or other debt instruments with coupon interest rates that are insignificant in relation to the effective interest rate of the borrowing, (3) contingent consideration payments made after a business combination, (4) proceeds from the settlement of insurance claims, (5) proceeds from settlement of corporate-owned life insurance policies, including bank-owned life insurance policies, (6) distributions received from equity method investees, (7) beneficial interests in securitization transitions and (8) separately identifiable cash flows and application of predominance principle. The guidance will be effective for fiscal years and interim periods beginning after December 15, 2017, and early adoption is permitted. The guidance requires retrospective adoption. We are evaluating the effect that ASU No. 2016-15 will have on our consolidated financial statements and related disclosures.

Note 4. Fair Value Measurements

We do not use derivative instruments for hedging of market risks or for trading or speculative purposes.

In conjunction with certain Senior Secured Convertible Promissory Notes that we issued to Platinum Long Term Growth VII, LLC (*PLTG*) between October 2012 and July 2013 and the related PLTG Warrants, and the contingently issuable Series A Exchange Warrant, we determined that the warrants included certain exercise price and other adjustment features requiring the warrants to be treated as liabilities, which were recorded at their issuance-date estimated fair values and marked to market at each subsequent reporting period. We determined the fair value of the warrant liabilities using Level 3 (unobservable) inputs, since there was minimal comparable external market data available. Inputs used to determine fair value included the remaining contractual term of the warrants, risk-free interest rates, expected volatility of the price of the underlying common stock, and the probability of a financing transaction that would trigger a reset in the warrant exercise price, and, in the case of the Series A Exchange Warrant, the probability of PLTG's exchange of the shares of Series A Preferred it holds into shares of common stock. The change in the fair value of these warrant liabilities between March 31, 2015 and their subsequent elimination (described below) was recognized as a non-cash expense in the Condensed Consolidated Statement of Operations and Comprehensive Loss for the three months ended June 30, 2015.

On May 12, 2015, we entered into an agreement with PLTG pursuant to which PLTG agreed to amend the PLTG Warrants to (i) fix the exercise price thereof at $7.00 per share, (ii) eliminate the exercise price reset features and (iii) fix the number of shares of our common stock issuable thereunder. This agreement and the related modification of the PLTG Warrants resulted in the elimination of the warrant liability with respect to the PLTG Warrants during the quarter ended June 30, 2015.

In January 2016, we entered into an Exchange Agreement with PLTG pursuant to which PLTG exchanged all outstanding PLTG Warrants plus the shares issuable pursuant to the Series A Preferred Exchange Warrant for unregistered shares of our Series C Convertible Preferred Stock (*Series C Preferred*) in the ratio of 0.75 share of Series C Preferred for each warrant share cancelled. As a result of the Exchange Agreement, all warrants previously issued to PLTG have been cancelled.

We carried no assets or liabilities at fair value at December 31, 2016 or March 31, 2016.

Note 5. Sublicense Fee Receivable and Sublicense Revenue

On December 9, 2016, we entered into an Exclusive License and Sublicense Agreement with BlueRock Therapeutics, LP, a next generation regenerative medicine company established in December 2016 by Bayer AG and Versant Ventures (*BlueRock Therapeutics*), pursuant to which BlueRock received exclusive rights to utilize certain technologies exclusively licensed by us from University Health Network (*UHN*) for the production of cardiac stem cells for the treatment of heart disease. We retained rights to cardiac stem cell technology licensed from UHN related to small molecule, protein and antibody drug discovery, drug rescue and drug development, including small molecules with cardiac regenerative potential, as well as small molecule, protein and antibody testing involving cardiac cells.

Under the BlueRock Therapeutics Agreement, we are entitled to receive an upfront payment of $1.25 million and we have the potential to receive additional milestone payments and royalties in the future, in the event certain performance-based milestones and commercial sales are achieved. At December 31, 2016, we had no further obligations under the BlueRock Therapeutics Agreement and, accordingly, we recorded a receivable for the $1.25 million upfront payment with a corresponding recognition of the sublicense revenue. We received the $1.25 million cash payment due under the BlueRock Therapeutics Agreement on January 5, 2017.

Also on December 9, 2016, we entered into a series of agreements with UHN pursuant to which we (i) executed two new exclusive patent license agreements related to certain cardiac stem cell technologies discovered by Dr. Gordon Keller, Director of UHN's McEwen Centre for Regenerative Medicine, under our Sponsored Research Agreement with Dr. Keller and UHN, originally executed on September 18, 2007 (the *SRA*); (ii) amended two exclusive cardiac stem cell technology patent license agreements previously entered into between us and UHN under the SRA; (iii) terminated the SRA to facilitate the BlueRock Therapeutics Agreement; and (iv) agreed to make a sublicense consideration payment to UHN with respect to the upfront payment we received under the BlueRock Therapeutics Agreement. All financial obligations related to the agreements with UHN, aggregating $233,400, were reflected in accounts payable at December 31, 2016.

Note 6. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets are composed of the following at December 31, 2016 and March 31, 2016:

	December 31, 2016	March 31, 2016
Insurance	$ 58,300	$ 27,000
Prepaid AV-101 development expenses	82,300	-
Prepaid compensation under financial advisory and other consulting agreements	-	337,500
Public offering expenses	-	57,400
All other	5,800	4,900
	$ 146,400	$ 426,800

Note 7. Accrued Expenses

Accrued expenses are composed of the following at December 31, 2016 and March 31, 2016:

	December 31, 2016	March 31, 2016
Accrued professional services	$ 34,700	$ 318,000
Accrued AV-101 development expenses	918,300	186,000
Accrued compensation	-	310,000
All other	8,800	-
	$ 961,800	$ 814,000

Note 8. Notes Payable

The following table summarizes our unsecured promissory notes at December 31, 2016 and March 31, 2016.

	December 31, 2016			March 31, 2016		
	Principal Balance	Accrued Interest	Total	Principal Balance	Accrued Interest	Total
5.75% Note payable to insurance premium financing company (current)	$ 35,800	$ -	$ 35,800	$ -	$ -	$ -
7.0% Note payable to Progressive Medical Research	$ -	$ -	$ -	$ 58,800	$ 12,000	$ 70,800
less: current portion	-	-	-	(31,600)	(12,000)	(43,600)
7.0% Notes payable - non-current portion	$ -	$ -	$ -	$ 27,200	$ -	$ 27,200
Total notes payable to unrelated parties	$ 35,800	$ -	$ 35,800	$ 58,800	$ 12,000	$ 70,800
less: current portion	(35,800)	-	(35,800)	(31,600)	(12,000)	(43,600)
Net non-current portion	$ -	$ -	$ -	$ 27,200	$ -	$ 27,200

Between May 2015 and August 2015, we extinguished the outstanding balances of approximately $17,200,000 of indebtedness, including all senior secured promissory notes and a substantial portion of other indebtedness that was either due and payable or would have become due and payable prior to March 31, 2016, by converting such indebtedness into shares of our Series B Preferred at a Conversion Price (or stated value) of $7.00 per share.

Evaluating each converted note or debt class separately, we determined that the conversion of each of such notes and other debt instruments into Series B Preferred should be accounted for as an extinguishment of debt. Because the fair value of the Series B Preferred into which the debt instruments were converted in all cases exceeded the carrying value of the debt, we recorded an aggregate, non-recurring, non-cash loss on extinguishment of debt of $26,700,200, in our fiscal year ended March 31, 2016, as reflected in the accompanying Condensed Consolidated Statement of Operations and Comprehensive Loss for the nine months ended December 31, 2015.

On January 5, 2016, we paid in full the $33,300 outstanding balance (principal and accrued but unpaid interest) of the promissory note previously issued to the University of California in connection with our collaborative research and development relationship with the University of California at Davis.

On June 13, 2016, we paid in full the $71,600 outstanding balance (principal and accrued but unpaid interest) of the promissory note we issued to Progressive Medical Research (*PMR*) in connection with our clinical development relationship with PMR.

In May 2016, we executed a promissory note in the face amount of $117,500 in connection with certain insurance policy premiums. The note is payable in monthly installments of $12,100, including principal and interest, through March 2017, and the remaining balance of such note as of December 31, 2016 was $35,800.

Note 9. Capital Stock

Series B Preferred Unit Offering

Prior to the consummation of our May 2016 Public Offering, we sold to accredited investors in self-placed private placement transactions an aggregate of $278,000 of units in our Series B Preferred Unit offering in April and May 2016, which units consisted of Series B Preferred and Series B Warrants (together *Series B Preferred Units*). We issued 39,714 shares of Series B Preferred and Series B Warrants to purchase 39,714 shares of our common stock. From May 2015 through the termination of the Series B Preferred Unit offering in May 2016, we received an aggregate of $5,303,800 in cash proceeds from our self-placed private placement and sale of the Series B Preferred Units.

We allocated the proceeds from the sale of the Series B Preferred Units during April and May 2016 to the Series B Preferred and the Series B Warrants based on their relative fair values on the dates of the sales. We determined that the fair value of a share of Series B Preferred was equal to the quoted market value of a share of our common stock on the date of a Series B Preferred Unit sale. We calculated the fair value of the Series B Warrants using the Black Scholes Option Pricing Model and the weighted average assumptions indicated in the table below. The table below also presents the aggregate allocation of the Series B Preferred Unit sales proceeds based on the relative fair values of the Series B Preferred and the Series B Warrants as of their respective Series B Preferred Unit sales dates. The difference between the relative fair value per share of the Series B Preferred, approximately $4.20 per share, and its Conversion Price (or stated value) of $7.00 per share represents a deemed dividend to the purchasers of the Series B Preferred Units. Accordingly, we have recognized a deemed dividend in the aggregate amount of $111,100 in arriving at net loss attributable to common stockholders in the accompanying Condensed Consolidated Statement of Operations and Comprehensive Loss for the nine months ended December 31, 2016.

Unit Warrants											
	Weighted Average Issuance Date Valuation Assumptions									Aggregate Allocation of Proceeds	
										Based on Relative Fair Value of:	
Warrant Shares Issued	Market Price	Exercise Price	Term (Years)	Risk free Interest Rate	Volatility	Dividend Rate	Per Share Fair Value of Warrant	Aggregate Fair Value of Unit Warrants	Aggregate Proceeds of Unit Sales	Unit Stock	Unit Warrant
39,714	$ 8.45	$ 7.00	5.00	1.27%	78.43%	0.0%	$ 5.63	$ 223,500	$ 278,000	$ 166,900	$ 61,100

May 2016 Public Offering and Listing of our Common Stock on The NASDAQ Capital Market

Effective on May 16, 2016, we consummated an underwritten public offering of our securities, pursuant to which we issued units consisting of an aggregate of 2,570,040 registered shares of our common stock at a public sales price of $4.24 per share and five-year warrants exercisable at $5.30 per share to purchase an aggregate of 2,705,883 shares of our common stock at a public sales price of $0.01 per warrant share, including shares and warrants issued in June 2016 pursuant to the exercise of the underwriters' over-allotment option. We received gross proceeds of approximately $10.9 million and net proceeds of approximately $9.5 million from the May 2016 Public Offering, after deducting underwriters' commissions and other offering expenses. The warrants issued in the May 2016 Public Offering have no anti-dilution or other exercise price or share reset features, except as is customary with respect to a change in our capital structure in the event of a stock split or dividend, and, accordingly, we have accounted for them as equity warrants.

The securities included in the May 2016 Public Offering Warrants were offered, issued and sold under a prospectus filed with the Commission pursuant to an effective registration statement (*Registration Statement*) filed with the Commission on Form S-1 (File No. 333-210152) pursuant to the Securities Act of 1933, as amended (*Securities Act*). The Registration Statement was first filed with the Commission on March 14, 2016, and was declared effective on May 10, 2016.

In connection with the completion of our May 2016 Public Offering, NASDAQ approved our common stock for listing on The NASDAQ Capital Market. Our common stock began trading on The NASDAQ Capital Market under the symbol "VTGN" on May 11, 2016.

Conversion of Series B Preferred into Common Stock

During April 2016, prior to the consummation of the May 2016 Public Offering, holders of an aggregate of 7,500 shares of Series B Preferred voluntarily converted such shares into an equivalent number of registered shares of our common stock. In connection with such conversions, we issued an aggregate of 510 shares of our unregistered common stock as payment in full of $4,000 in accrued dividends on the Series B Preferred that was voluntarily converted.

On May 19, 2016, upon the consummation of the May 2016 Public Offering, an aggregate of 2,403,051 shares of Series B Preferred were automatically converted into an aggregate of 2,192,847 registered shares of our common stock and an aggregate of 210,204 shares of our unregistered common stock. Additionally, we issued an aggregate of 416,806 shares of our unregistered common stock as payment in full of $1,642,100 in accrued dividends on the Series B Preferred that was automatically converted on May 19, 2016, at the rate of one share of common stock for each $3.94 of accrued Series B Preferred dividends. On June 15, 2016, pursuant to the underwriters' exercise of their over-allotment option, an additional 44,500 shares of Series B Preferred were converted into 44,500 shares of our registered common stock. We issued an additional 9,580 shares of our unregistered common stock as payment in full of $37,400 of accrued dividends on the Series B Preferred that was automatically converted on June 15, 2016, at the rate of one share of common stock for each $3.90 in accrued dividends.

In August 2016, one of the remaining holders of our Series B Preferred voluntarily converted 87,500 shares of Series B Preferred into an equivalent number of registered shares of our common stock. In connection with this conversion, we issued 26,258 shares of our unregistered common stock as payment in full of $85,300 in accrued dividends on the Series B Preferred that was voluntarily converted, at the rate of one share of common stock for each $3.25 in accrued dividends.

Common Stock and Warrants Issued in Private Placement

In December 2016, in self-placed private transactions, we accepted subscription agreements from two individual accredited investors, pursuant to which we sold to such investors units, at a purchase price of $3.70 per unit, consisting of an aggregate of 67,000 unregistered shares of our common stock and warrants, exercisable through November 30, 2019, to purchase an aggregate of 16,750 unregistered shares of our common stock at an exercise price of $6.00 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. We received aggregate cash proceeds of $247,900 in connection with this private placement of the units, of which the entire amount was credited to stockholders' equity.

Issuance of Common Stock to Professional Services Providers

In September 2016, we issued an aggregate of 170,000 shares of our unregistered common stock having an aggregate fair value on the date of issuance of $737,800 as compensation to certain entities previously engaged as professional services providers. Of that amount, we issued 120,000 shares having a fair value of $520,800 on the date of issuance for services to be rendered from October 2016 to December 2016. The value of these shares was recorded as a prepaid expense at September 30, 2016 and was fully expensed as a component of general and administrative expense during the quarter ended December 31, 2016. In November and December 2016, we issued an aggregate of 135,000 shares of our unregistered common stock having an aggregate fair value on the respective dates of issuance of $479,800 as compensation to professional services providers.

Warrant Exchanges and Other Warrant Modifications

During the nine months ended December 31, 2016, we entered into Warrant Exchange Agreements with certain holders of outstanding warrants to purchase an aggregate of 224,693 shares of our common stock pursuant to which the holders agreed to cancel such warrants in exchange for the issuance of an aggregate of 156,246 unregistered shares of common stock.

We accounted for the exchanges of these warrants as warrant modifications, comparing the fair value of the warrants immediately prior to the exchanges with the fair value of the unregistered common stock issued. We calculated the weighted average fair value of the warrants prior to the respective exchanges using the Black Scholes Option Pricing Model and the weighted average assumptions indicated in the table below. We determined the post-modification fair value based on the quoted market price of our common stock on the effective date of each exchange and the number of unregistered shares issued in the exchange, as also indicated in the table below. We recognized the amount of the incremental fair value of the unregistered common stock issued in excess of the fair value of the warrants cancelled, $293,300 and $350,700 for the three and nine months ended December 31, 2016, respectively, as warrant modification expense, which is included as a component of general and administrative expenses in our Condensed Consolidated Statement of Operations and Comprehensive Loss for the three and nine months ended December 31, 2016.

	April - May 2016		August 2016		October 2016		December 2016	
	Pre-modification	Post-modification	Pre-modification	Post-modification	Pre-modification	Post-modification	Pre-modification	Post-modification
Market Price per share	$ 8.44	$ 8.45	$ 3.33	$ 3.33	$ 4.05	$ 4.05	$ 3.73	$ 3.73
Exercise price per share	$ 7.37		$ 8.00		$ 8.15		$ 10.00	
Risk-free interest rate	1.23%		1.10%		0.77%		0.44%	
Contractual term (years)	4.77		4.58		2.4		0.003	
Volatility	79.0%		87.0%		93.0%		100.3%	
Dividend Rate	0%		0%		0%		0%	
Weighted average fair value per share	$ 5.37		$ 1.64		$ 1.27		$ -	
Warrant shares cancelled and exchanged	41,649		20,000		113,944		49,100	
Common shares issued in exchange		31,238		15,000		85,458		24,550
Fair Value	$ 223,700	$ 264,000	$ 32,900	$ 50,000	$ 144,400	$ 346,100	$ -	$ 91,600
Incremental fair value recognized		$ 40,300		$ 17,100		$ 201,700		$ 91,600

In December 2016, the Board authorized the modification of an outstanding warrant to both alter the exercise terms and increase the number of shares for which the warrant was exercisable. We calculated the fair value of the warrant immediately before and after the modification using the Black Scholes Option Pricing Model and the assumptions indicated in the table below. As indicated, we recognized the additional fair value, $76,900, as warrant modification expense, included as a component of general and administrative expenses, in our Condensed Consolidated Statement of Operations and Comprehensive Loss for the quarter ended December 31, 2016.

	Pre-modification	Post-modification
Market Price per share	$ 3.51	$ 3.51
Exercise price per share	$ 8.00	$ 3.51
Risk-free interest rate	1.88%	2.07%
Contractual term (years)	4.26	5.03
Volatility	87.1%	85.8%
Dividend Rate	0%	0%
Weighted average fair value per share	$ 1.71	$ 2.39
Number of warrant shares	25,000	50,000
Fair Value	$ 42,700	$ 119,600
Incremental fair value recognized		$ 76,900

Warrants Outstanding

Following the warrant issuances in the May 2016 Public Offering, the Series B Warrant issuances and the warrant exchanges and modification described above, at December 31, 2016, we had outstanding warrants to purchase shares of our common stock at a weighted average exercise price of $6.31 per share as follows:

Exercise Price per Share	Expiration Date	Shares Subject to Purchase at December 31, 2016
$ 3.51	12/31/2021	50,000
$ 4.50	9/26/2019	25,000
$ 5.30	5/16/2021	2,705,883
$ 6.00	9/26/2019 to 11/30/2019	97,750
$ 7.00	12/11/2018 to 3/3/2023	1,346,931
$ 8.00	3/25/2021	185,000
$ 10.00	2/28/2017 to 1/11/2020	25,758
$ 20.00	9/15/19	110,448
$ 30.00	11/20/2017	3,600
		4,550,370

With the exception of 2,705,883 shares of common stock underlying the warrants issued in the May 2016 Public Offering, all of the common shares issuable upon exercise of our outstanding warrants are unregistered.

Note 10. 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*) engaged by us for certain aspects of the development of AV-101. CBV is among our largest institutional stockholders at December 31, 2016, holding approximately 7.0% of our outstanding common stock. In October 2012 we issued certain unsecured promissory notes in the aggregate face amount of approximately $1.3 million to CBV and CRL (the *Cato Notes*) as payment in full for all contract research and development services and regulatory advice previously rendered to us by CRL. The Cato Notes and additional amounts payable to CRL for CRO services were extinguished in June 2015 in exchange for our issuance of an aggregate of 328,571 shares of Series B Preferred to CBV, which shares of Series B Preferred were automatically converted into an equal number of registered shares of our common stock in connection with the May 2016 Public Offering.

Under the terms of our CRO arrangement with CRL related to the development of AV-101, we incurred expenses of $101,900 and $19,400 for the quarters ended December 31, 2016 and 2015, respectively, and $180,100 and $41,500 in the nine month periods ended December 31, 2016 and 2015, respectively. Total interest expense, including amortization of note discount, on the Cato Notes was $28,200 for the three-month period ended June 30, 2015 during which the notes were extinguished.

University Health Network (*UHN*) holds approximately 2.0% of our outstanding common stock at December 31, 2016. As described more completely in Note 5, *Sublicense Fee Receivable and Sublicense Revenue*, in December 2016, we entered into certain agreements with UHN pursuant to which we acquired two exclusive patent licenses from UHN and became obligated to make a payment to UHN with respect to our sublicense to BlueRock Therapeutics of cardiac stem cell production technology licensed to us by UHN. At December 31, 2016, we had recorded a liability to UHN of $233,400 related to these agreements. In the nine months ended December 31, 2015, we had incurred approximately $153,000 related to the acquisition of three stem cell technology licenses from UHN.

Note 11. Lease Extension

Effective on November 10, 2016, we executed an amendment to the lease of our headquarters facility, pursuant to which the term of the lease was extended from July 31, 2017 to July 31, 2022 and the base rent for the five-year extension period was specified. The lease amendment also provides for a two-month period of rent abatement and an allowance for tenant improvements, which allowance may be disbursed between January 1, 2017 and August 1, 2018. We have recognized the effect of the amendment in the balance reported as Deferred Rent Liability in the accompanying Condensed Consolidated Balance Sheet at December 31, 2016 and in rent expense in the Condensed Consolidated Statement of Operations for the quarter ended December 31, 2016.

Note 12. Subsequent Events

We have evaluated subsequent events through February 10, 2017 and have identified no matters requiring disclosure.

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 (Quarterly Report) includes forward-looking statements. All statements contained in this Quarterly 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 additional financing, the results of our research and development efforts, the results of non-clinical and clinical testing, the effect of regulation by the United States 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 Quarterly 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 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 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 Quarterly 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 Quarterly 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.

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Business Overview

We are a clinical-stage biopharmaceutical company focused on developing new generation medicines for depression and other central nervous system (*CNS*) disorders. Unless the context otherwise requires, the words "*VistaGen Therapeutics, Inc.*" "*VistaGen*," "*we*," "*the Company*," "*us*" and "*our*" refer to VistaGen Therapeutics, Inc., a Nevada corporation. All references to future quarters and years in this Item 2 refer to calendar quarters and calendar years, unless reference is made otherwise.

AV-101, our lead CNS product candidate, is a new generation oral antidepressant drug candidate in Phase 2 development, initially as an adjunctive treatment for Major Depressive Disorder (*MDD*) in patients with an inadequate response to standard antidepressants approved by the U.S. Food and Drug Administration (*FDA*). We believe AV-101 may also have the potential to treat additional CNS indications, including chronic neuropathic pain, epilepsy, Huntington's disease and Parkinson's disease.

AV-101's mechanism of action, as an N-methyl D aspartate receptor (*NMDAR*) antagonist binding selectively at the glycine binding (*GlyB*) co-agonist site of the NMDAR, is fundamentally differentiated from all FDA-approved antidepressants, as well as all atypical antipsychotics often used adjunctively with standard antidepressants.

A Phase 2a clinical study of AV-101 as a monotherapy in subjects with treatment-resistant MDD is being conducted and fully funded by the U.S. National Institute of Mental Health (*NIMH*), part of the U.S. National Institutes of Health (*NIH*), under our February 2015 Cooperative Research and Development Agreement (*CRADA*) with the NIMH (*Phase 2a Study*). The Principal Investigator of the Phase 2a Study is Dr. Carlos Zarate, Jr., Chief of the NIMH's Experimental Therapeutics & Pathophysiology Branch and its Section on Neurobiology and Treatment of Mood and Anxiety Disorders. Previous NIMH studies, including studies conducted by Dr. Zarate, have focused on the antidepressant effects of low dose, intravenous (*I.V.*) ketamine, a NMDAR antagonist, in patients with treatment-resistant MDD. These NIMH studies, as well as clinical research by Yale University and other academic institutions, have demonstrated robust antidepressant effects in MDD patients within twenty-four hours of a single low dose of I.V. ketamine. We believe orally-administered AV-101 may have potential to deliver ketamine-like fast-acting antidepressant effects without ketamine's serious side effects. We currently anticipate that the NIMH will complete the Phase 2a Study by the end of 2017.

We are preparing to launch our Phase 2b clinical study of AV-101 as a new generation adjunctive treatment of MDD in adult patients with an inadequate response to standard, FDA-approved antidepressants (*Phase 2b Study*). We currently anticipate commencement of this multi-center, multi-dose, double blind, placebo-controlled efficacy and safety study of AV-101 by the end of the second quarter of 2017. Dr. Maurizio Fava, Professor of Psychiatry at Harvard Medical School and Director, Division of Clinical Research, Massachusetts General Hospital (*MGH*) Research Institute, will be the Principal Investigator of the Phase 2b Study. Dr. Fava was the co-Principal Investigator with Dr. A. John Rush of the STAR*D study, the largest clinical trial conducted in depression to date, whose findings were published in journals such as the New England Journal of Medicine (*NEJM*) and the Journal of the American Medical Association (*JAMA*). We currently anticipate top line results of the Phase 2b Study by the end of 2018.

VistaStem Therapeutics (*VistaStem*) is our wholly owned subsidiary focused on applying human pluripotent stem cell (*hPSC*) technology, internally or with third-party collaborators, to discover, rescue, develop and commercialize (i) proprietary new chemical entities (*NCEs*), including small molecule NCEs with regenerative potential, for CNS and other diseases and (ii) cellular therapies involving stem cell-derived blood, cartilage, heart and liver cells. Our internal small molecule drug rescue programs utilize *CardioSafe 3D*, our customized cardiac bioassay system, to develop NCEs for our pipeline. In December 2016, we exclusively sublicensed to BlueRock Therapeutics LP, a next generation regenerative medicine company established in December 2016 by Bayer AG and Versant Ventures, rights to certain proprietary technologies relating to the production of cardiac stem cells for the treatment of heart disease (the *BlueRock Agreement*). VistaStem may also pursue additional potential regenerative medicine (*RM*) applications, including using blood, cartilage, and/or liver cells derived from hPSCs for (A) cell-based therapy, (B) cell repair therapy, and/or (C) tissue engineering. In a manner similar to our exclusive sublicense agreement with BlueRock Therapeutics, VistaStem may pursue these additional RM applications in collaboration with third-parties.

AV-101 and Major Depressive Disorder

Background

The World Health Organization (*WHO*) estimates that 350 million people worldwide are affected by depression. According to the NIH, major depression is one of the most common mental disorders in the U.S. The NIMH reports that, in 2014, an estimated 15.7 million adults aged 18 or older in the U.S. had at least one major depressive episode in the past year. This represented 6.7 percent of all U.S. adults. According to the U.S. Centers for Disease Control and Prevention (*CDC*) one in 10 Americans over the age of 12 takes a standard, FDA-approved antidepressant.

Most standard, FDA-approved antidepressants target neurotransmitter reuptake inhibition – either serotonin (antidepressants known as *SSRIs*) or serotonin/norepinephrine (antidepressants known as *SNRIs*). Even when effective, these standard depression medications take many weeks to achieve adequate antidepressant effects. Nearly two out of every three drug-treated depression patients, including an estimated 6.9 million drug-treated MDD patients in the U.S., obtain inadequate therapeutic benefit from initial treatment with a standard antidepressant. Unfortunately, even after treatment with as many as four different standard antidepressants, nearly one out of every three drug-treated depression patients still do not achieve adequate therapeutic benefits. Such patients with an inadequate response to standard antidepressants often seek to augment their treatment regimen by adding an atypical antipsychotic (such as, for example, aripiprazole), despite only modest potential therapeutic benefit and the risk of additional side effects from atypical antipsychotics.

All standard, FDA-approved antidepressants have risks of significant side effects, including, among others, potential anxiety, metabolic syndrome, sleep disturbance and sexual dysfunction. Adjunctive use of atypical antipsychotics to augment inadequately performing standard antidepressants increases the risk of serious side effects, including, potentially, tardive dyskinesia, significant weight gain, diabetes and heart disease, while offering only a modest potential increase in therapeutic benefit.

AV-101

AV-101, our oral new generation antidepressant prodrug candidate, is in Phase 2 clinical development for the adjunctive treatment of MDD patients with an inadequate response to standard antidepressants. As published in the October 2015 issue of the peer-reviewed, *Journal of Pharmacology and Experimental Therapeutics*, in an article entitled, *The prodrug 4-chlorokynurenine causes ketamine-like antidepressant effects, but not side effects, by NMDA/glycineB-site inhibition*, using well-established preclinical models of depression, AV-101 was shown to induce fast-acting, dose-dependent, persistent and statistically significant antidepressant-like responses following a single treatment. These responses were equivalent to those seen with a single sub-anesthetic control dose of ketamine, a NMDAR antagonist. In addition, these studies confirmed that the fast-acting antidepressant effects of AV-101 were mediated through the GlyB site and also involved the activation of another key neurological pathway, the alpha-amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid (*AMPA*) receptor pathway. We believe activation of the AMPA receptor pathway is a key final common pathway feature of new generation antidepressants.

Following the completion of our NIH-funded, randomized, double blind, placebo-controlled AV-101 Phase 1a and Phase 1b safety studies, the NIMH initiated and is fully funding the Phase 2a study of AV-101 as a monotherapy in subjects with treatment-resistant MDD under our February 2015 CRADA with the NIMH. Dr. Carlos Zarate Jr. of the NIMH is the Principal Investigator conducting the Phase 2a Study at the NIMH. The trial is expected to enroll up to 25 patients. We currently anticipate that the NIMH will complete the Phase 2a Study by the end of 2017.

We are preparing to launch our approximately 280-patient Phase 2b Study of AV-101 as an adjunctive treatment of MDD in patients with an inadequate response to standard, FDA-approved antidepressants. We currently anticipate the launch of the Phase 2b Study, with Dr. Maurizio Fava of Harvard Medical School serving as Principal Investigator, by the end of the second quarter of 2017. We currently anticipate top line results of the Phase 2b Study by the end of 2018.

We believe preclinical studies support the hypothesis that AV-101 may also have the potential to treat multiple CNS disorders and neurodegenerative diseases in addition to MDD, including chronic neuropathic pain, epilepsy, Parkinson's disease and Huntington's disease, where modulation of the NMDAR, AMPA pathway and/or key active metabolites of AV-101 may achieve therapeutic benefit. However, human clinical studies will be required before this therapeutic potential could be demonstrated. There is no guarantee that human clinical trials would be successful or that the FDA would approve the use of AV-101 for the treatment of one or more of these additional CNS indications.

CardioSafe 3D™; NCE Drug Rescue and Regenerative Medicine

VistaStem Therapeutics is our wholly owned subsidiary focused on applying hPSC technology to discover, rescue, develop and commercialize proprietary NCEs, including small molecule NCEs with regenerative potential, for CNS and other diseases, as well as potential cellular therapies involving stem cell-derived blood, cartilage, heart and liver cells. *CardioSafe* 3D™ is our customized *in vitro* cardiac bioassay system capable of predicting potential human heart toxicity of small molecule NCEs *in vitro*, long before they are ever tested in animal and human studies. We are currently focused on potential commercial applications of our stem cell technology platform involving (i) use of *CardioSafe* 3D for internal small molecule NCE drug discovery and drug rescue to expand our proprietary drug candidate pipeline, leveraging substantial prior research and development investments by pharmaceutical companies and others related to public domain NCEs terminated before FDA approval due to heart toxicity risks and (ii) RM. With respect to RM, in December 2016, we exclusively sublicensed to BlueRock Therapeutics LP, a next generation regenerative medicine company established in December 2016 by Bayer AG and Versant Ventures, rights to certain proprietary technologies relating to the production of cardiac stem cells for the treatment of heart disease (*BlueRock Therapeutics Agreement*). We may also pursue additional potential RM applications using blood, cartilage, and/or liver cells derived from hPSCs for (A) cell-based therapy (injection of stem cell-derived mature organ-specific cells obtained through directed differentiation), (B) cell repair therapy (induction of regeneration by biologically active molecules administered alone or produced by infused genetically engineered cells), or (C) tissue engineering (transplantation of *in vitro* grown complex tissues) using hPSC-derived blood, bone, cartilage, and/or liver cells. In a manner similar to the BlueRock Therapeutics Agreement, we may pursue these additional RM applications in collaboration with third-parties.

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, 2016, as filed with the SEC on June 24, 2016, and in Note 3 to the accompanying unaudited Condensed Consolidated Financial Statements included in Part 1, Item 1 of this Quarterly Report on Form 10-Q.

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 lead CNS product candidate, AV-101, from early nonclinical studies to our ongoing Phase 2 clinical development program in MDD, as well as stem cell technology research and development, bioassay development, small molecule drug development, and creating, protecting and patenting intellectual property related to our product candidates and technologies, with the corollary initiatives of recruiting and retaining personnel and raising working capital. As of December 31, 2016, we had an accumulated deficit of approximately $139.4 million. Our net loss for the nine months ended December 31, 2016 was approximately $7.7 million. Our net loss for the nine months ended December 31, 2015 was approximately $38.7 million, which amount, however, included a non-recurring, non-cash loss of approximately $26.7 million attributable to extinguishment and conversion of approximately $17.2 million of prior indebtedness into equity securities between May and August 2015 at a Conversion Price (stated value) of $7.00 per share. We expect losses to continue for the foreseeable future, primarily related to our further clinical development of AV-101 for the adjunctive treatment of MDD, as well as a range of other CNS indications.

Summary of Nine Months Ended December 31, 2016

During the nine months ended December 31, 2016, we have continued to (i) advance nonclinical and clinical development of AV-101 as a potential new generation antidepressant, (ii) expand the regulatory foundation to support Phase 2 clinical development of AV-101 in the U.S., both as a new adjunctive treatment for patients with inadequate response to standard, FDA-approved antidepressants and as a new therapeutic alternative for several other CNS indications, and, (iii) on a limited basis, advance both (a) the predictive toxicology capabilities of *CardioSafe* 3D for drug rescue and development applications, including our ongoing participation in the FDA's Comprehensive in-vitro Proarrhythmia Assay (*CiPA*) initiative designed to change the landscape of preclinical drug development by providing a more complete and accurate assessment of potential drug effects on cardiac risk, and (b) regenerative medicine opportunities related to our stem cell technology platform.

Pursuant to our February 2015 Cooperative Research and Development Agreement (*CRADA*) with the NIH, the NIH continues to fund, and Dr. Carlos Zarate Jr. of the NIMH continues to conduct, a Phase 2a clinical study of AV-101 as a monotherapy for treatment-resistant MDD. We currently anticipate that the NIMH will complete the Phase 2a Study by the end of 2017. In addition, we continue to prepare for the Phase 2b Study. We currently anticipate the launch of the Phase 2b Study, with Dr. Maurizio Fava of Harvard Medical School serving as Principal Investigator, in the second quarter of 2017.

In May 2016, we consummated an underwritten public offering of our securities, pursuant to which we issued to institutional investors an aggregate of 2,570,040 registered shares of our common stock and five-year warrants exercisable at $5.30 per share to purchase an aggregate of 2,705,883 shares of our common stock and received net proceeds, after deducting underwriters' commissions and other expenses, of approximately $9.5 million (*May 2016 Public Offering*). In connection with the May 2016 Public Offering, our common stock was approved for listing on The NASDAQ Capital Market, where it has traded under the symbol "VTGN" since May 11, 2016. Please see the section titled "*Liquidity and Capital Resources*" below, for a discussion of our capital needs following the May 2016 Public Offering.

In addition to bolstering our Clinical and Regulatory Advisory Board with the appointment of Dr. Maurizio Fava as Chairman and the addition of members Dr. Sanjay Matthew and Dr. Thomas Laughren, all pre-eminent opinion leaders in the field of depression, and the addition of veteran healthcare executive Jerry Gin, Ph.D., MBA to our Board of Directors, we enhanced our management team with the addition of Mark A. Smith, MD, Ph.D., as our Chief Medical Officer in June 2016. Dr. Smith has over 20 years of pharmaceutical industry and CNS drug development experience. He has been a successful project leader in both drug discovery and development on projects resulting in approximately 20 investigational new drugs (INDs). Dr. Smith has directed clinical trials examining depression, bipolar disorder, anxiety, schizophrenia, Alzheimer's disease, ADHD and agitation in Phase 1 through Phase 2b. In addition, Dr. Smith has vast knowledge and expertise in translational neuroscience, clinical trial design and regulatory interactions. Further, in September 2016, we appointed Mark A. McPartland as our Vice President of Corporate Development. Mr. McPartland has over 20 years of experience in corporate development, capital markets, corporate communications and management consulting for companies at varying stage of their corporate evolution, including early- and mid-stage biopharmaceutical companies. Mr. McPartland is primarily concentrating his efforts in expanding awareness of VistaGen across a range of investors, researchers, patients, clinicians and potential partners.

In December 2016, we entered into an Exclusive License and Sublicense Agreement (the *BlueRock Therapeutics Agreement*) with BlueRock Therapeutics, LP, a next generation regenerative medicine company recently established by Bayer AG and Versant Ventures (*BlueRock*), pursuant to which BlueRock received exclusive rights to utilize certain technologies exclusively licensed by us from University Health Network (*UHN*) for the production of cardiac stem cells for the treatment of heart disease. We retained rights to technology licensed from UHN related to small molecule, protein and antibody drug discovery, drug rescue and drug development, including small molecules with cardiac regenerative potential, as well as small molecule, protein and antibody testing involving cardiac cells. In January 2017, we received an upfront cash payment of $1.25 million under the BlueRock Therapeutics Agreement and we have the potential to receive additional payments and royalties in the future, in the event certain performance-based milestones and commercial sales are achieved.

As a matter of course, we attempt 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 and our stem cell technology platform, as well as support our operating activities, we will 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, accounting, public company compliance and other professional services and working capital costs.

Results of Operations

Comparison of Three Months Ended December 31, 2016 and 2015

The following table summarizes the results of our operations for the three months ended December 31, 2016 and 2015 (amounts in thousands).

	Three Months Ended December 31,	
	2016	**2015**
Sublicense revenue	$ 1,250	$ -
Operating expenses:		
Research and development	$ 1,611	$ 806
General and administrative	2,276	1,336
Total operating expenses	3,887	2,142
Loss from operations	(2,637)	(2,142)
Interest expense, net	(1)	(3)
Change in warrant liabilities	-	-
Other expense	-	(2)
Loss before income taxes	(2,638)	(2,147)
Income taxes	-	-
Net loss	$ (2,638)	$ (2,147)
Accrued dividend on Series B Preferred Stock	(238)	(631)
Deemed dividend on Series B Preferred Stock	-	(669)
Net loss attributable to common stockholders	$ (2,876)	$ (3,447)

Revenue

We recognized $1.25 million in sublicense revenue pursuant to the BlueRock Therapeutics Agreement in the quarter ended December 31, 2016. While we have the potential to receive additional milestone payments and royalties under the BlueRock Therapeutics Agreement in the future, in the event certain performance-based milestones and commercial sales are achieved, the agreement might not provide additional revenue to us in the near term. We reported no other revenue for the quarter ended December 31, 2016 or 2015 and we presently have no revenue generating arrangements with respect to AV-101 or other potential product candidates. However, as indicated previously, our CRADA with the NIH provides for full NIH funding of the Phase 2a clinical study of AV-101 as a monotherapy for treatment resistant MDD.

Research and Development Expense

Research and development expense totaled $1,611,000 for the quarter ended December 31, 2016, approximately double the $806,300 reported for the quarter ended December 31, 2015. Current period costs reflect the increasing impact of our continued nonclinical and clinical development of AV-101, particularly preparations for launch of the Phase 2b Study of AV-101, which is currently anticipated in the second quarter of 2017. The following table indicates the primary components of research and development expense for each of the periods (amounts in thousands):

	Three Months Ended December 31,	
	2016	**2015**
Salaries and benefits	$ 302	$ 214
Stock-based compensation	114	74
Consulting and other professional services	(139)	5
Technology licenses and royalties, including UHN	293	159
Project-related research and supplies:		
AV-101	894	137
Stem cell and all other	50	19
	944	156
Rent	88	55
Depreciation	8	8
Warrant modification expense	-	135
All other	1	-
Total Research and Development Expense	$ 1,611	$ 806

The increase in salaries and benefits reflects the impact of the hiring of our Chief Medical Officer (*CMO*) in June 2016, and salary increases granted to our Chief Scientific Officer (*CSO*) and the four non-officer members of our scientific staff earlier this fiscal year.

Stock based compensation expense increased in the current period primarily as a result of the routine amortization of a new-hire option grant to our CMO and additional option grants made to our CSO, CMO and scientific staff in November 2016. Our stock options are generally amortized over a two-year to four-year vesting period. A substantial number of the option grants made in or prior to our fiscal year ended March 31, 2014 were fully-vested and fully-expensed prior to the quarter ended December 31, 2016.

Consulting services reflects fees paid or accrued for scientific, nonclinical and clinical development and regulatory advisory services rendered to us by third-parties, primarily by members of our scientific and CNS clinical and regulatory advisory boards. The reduction in expense in the current period primarily reflects the rationalization of our stem cell-related scientific advisory board and related accruals, including as a result of the BlueRock Therapeutics Agreement.

Technology license expense reflects both recurring annual fees as well as legal counsel and other costs related to patent prosecution and protection pursuant to our stem cell technology license agreements or have elected to pursue for commercial purposes. We recognize these costs as they are invoiced to us by the licensors and they do not occur ratably throughout the year or between years. In both periods, but to a greater extent in the quarter ended December 31, 2015, this expense includes legal counsel and other costs we have incurred to advance in the U.S. and numerous foreign countries numerous pending patent applications with respect to AV-101 and our stem cell technology platform. Technology license-related legal expense for the quarter ended December 31, 2016, also includes $55,000 representing the fair value of a warrant granted to intellectual property counsel as partial compensation for services. Current year expense further includes a net of $158,000 related to the sublicense consideration paid to University Health Network (*UHN*) pursuant to the BlueRock Therapeutics Agreement plus additional fees and expenses related to two new stem cell technology related licenses acquired from UHN, net of amounts previously accrued in connection with our prior Sponsored Research Collaboration Agreement (*SRCA*) with UHN.

AV-101 project expense for the quarter ended December 31, 2016 includes continuing costs incurred to develop more efficient and cost-effective production methods for AV-101 and for certain pre-production and nonclinical trial analyses and procedures to facilitate Phase 2 clinical development of AV-101, including the Phase 2b Study. AV-101 expense in both periods reflects the costs associated with monitoring for and responding to potential feedback related to the AV-101 Phase 1 clinical trials and addressing other matters required under the terms of our prior NIH grant awards, primarily through our Cato Research Ltd., our CRO for our Phase 1 safety studies. The increase in stem cell and other project related expenses for the quarter ended December 31, 2016 primarily reflects in-house costs associated with our participation in the FDA's *CiPA* project.

The increase in rent expense in the quarter ended December 31, 2016 reflects the impact of the scheduled rent increase effective August 2016 as well as the impact of accounting for the November 2016 lease amendment extending the lease of our headquarters facilities by five years from July 31, 2017 to July 31, 2022.

Warrant modification expense in the quarter ended December 31, 2015 reflects the increase in fair value resulting from the November 2015 modification of outstanding warrants to purchase an aggregate of 315,000 shares of our common stock held by our CSO and a key scientific advisor to reduce the exercise prices thereof from a range of $9.25 to $12.80 per share to $7.00 per share.

General and Administrative Expense

General and administrative expense increased to $2,276,600 from $1,335,500, for the quarters ended December 31, 2016 and 2015, respectively. This increase was primarily attributable to increased noncash stock compensation expense related to option and warrant grants and grants of equity securities as compensation for certain professional services. The following table indicates the primary components of general and administrative expenses, including noncash stock compensation expense, for each of the periods (amounts in thousands):

	Three Months Ended December 31,	
	2016	**2015**
Salaries and benefits	$ 257	$ 172
Stock-based compensation	153	24
Board fees	36	16
Legal, accounting and other professional fees	1,017	643
Investor relations	241	4
Insurance	38	33
Travel expenses	54	18
Rent and utilities	63	40
Warrant modification expense	370	358
All other expenses	48	28
Total General and Administrative Expense	$ 2,277	$ 1,336

The increase in salaries and benefits reflects the impact of the hiring of our Vice President of Corporate Development *(VP-Corporate Development*) in September 2016 and salary increases granted to our Chief Executive Officer (*CEO*), Chief Financial Officer (*CFO*) and a non-officer member of our administrative staff and the change in that employee's status from part-time to full-time earlier this fiscal year.

Stock based compensation expense increased in the current period primarily as a result of the routine amortization of a new-hire option grant to our VP-Corporate Development and additional option grants made to independent members of our Board of Directors, our CEO, CFO, VP of Corporate Development and other employees in November 2016. Our stock options are generally amortized over a two-year to four-year vesting period. A substantial number of the option grants made in or prior to our fiscal year ended March 31, 2014 were fully-vested and fully-expensed prior to the quarter ended December 31, 2016.

Board fees includes fees recognized for the services of independent members of our Board of Directors. We added an additional independent director to our Board in March 2016.

Legal, accounting and other professional fees for the quarter ended December 31, 2016 includes noncash expense related to grants of an aggregate of 220,000 unregistered shares of our common stock valued on the respective grant dates at an aggregate of $862,800 plus aggregate cash payments of $80,000 to investment professionals for financial advisory and corporate development services. Such expense for the quarter ended December 31, 2015, primarily included (i) $337,500 of noncash expense recognized during the quarter pursuant to the June 30, 2015 grant of an aggregate of 90,000 shares of our Series B Preferred having an aggregate fair value of $1,350,000 as compensation for financial advisory and corporate development service contracts with two service providers for services to be performed through June 30, 2016; and (ii) $138,000 of noncash expense attributable to the fair value of 15,750 shares of our unregistered common stock and a five-year warrant to purchase 7,500 unregistered shares of our common stock granted in connection with investment banking services. In both years, professional services fees also include expense related to routine legal fees and fees for preparation of our income tax returns for the prior fiscal year and the quarterly review of our current year financial statements.

Investor relations expense includes the fees of our external service providers for a significantly expanded and broad spectrum of investor relations and market awareness and support functions and, in the quarter ended December 31, 2016, initiatives that included numerous meetings in multiple U.S. markets and other communication activities focused on expanding market awareness of the Company, including among registered investment professionals and investment advisors, and individual and institutional investors. In the quarter ended December 31, 2016, in addition to cash fees and expenses we incurred, we granted an aggregate of 35,000 unregistered shares of our common stock to two investor relations and investor awareness service providers as partial compensation for their services and recognized noncash expense of $137,800, representing the fair value of the stock at the time of issuance.

In both periods, travel expense reflects costs associated with presentations to and meetings in multiple U.S. markets 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 initiatives, in the current year by both our CEO and our VP-Corporate Development.

The increase in rent expense in the quarter ended December 31, 2016 reflects the impact of the scheduled rent increase effective August 2016 as well as the impact of accounting for the November 2016 lease amendment extending the lease of our headquarters facilities by five years from July 31, 2017 to July 31, 2022.

In October and December 2016, we entered into warrant exchange agreements with certain warrant holders pursuant to which the warrant holders exchanged outstanding warrants to purchase an aggregate of 163,044 shares of our common stock for an aggregate of 110,008 shares of our unregistered common stock. As with similar transactions in fiscal year 2016 and in prior quarters of the current fiscal year, we accounted for these transactions as warrant modifications, resulting in our recognition of $293,300 in noncash expense in the quarter ended December 31, 2016. Further, in December 2016, we modified an outstanding warrant to reduce the exercise price from $8.00 per share to $3.51 per share and increase the number of shares exercisable under the warrant from 25,000 shares to 50,000 shares, recognizing $76,900 in expense in the quarter then ended as the incremental fair value attributable to the modification. During the quarter ended December 31, 2015, we modified outstanding warrants to purchase an aggregate of 808,553 shares of our common stock previously granted to our CEO, CFO, and independent members of our Board of Directors to reduce the exercise prices thereof from a range of $9.25 to $12.80 per share to $7.00 per share and recognized $357,500 of noncash expense in the quarter then ended as the incremental fair value attributable to the modifications.

Interest and Other Expenses, Net

Interest expense, net totaled $900 for the quarter ended December 31, 2016 compared to $2,500 reported for the quarter ended December 31, 2015. The following table summarizes the primary components of interest expense for each of the periods (amounts in thousands):

	Three Months Ended December 31,	
	2016	2015
Interest expense on promissory notes	$ -	$ 2
Other interest expense, including on capital leases and premium financing	1	1
Total interest expense	1	3
Interest income	-	-
Interest expense, net	$ 1	$ 3

Interest expense on promissory notes in the quarter ended December 31, 2015 represents the quarterly interest accrued on our outstanding note to University of California at Davis prior to our repayment of such note and accrued interest in January 2016 and our outstanding note to Progressive Medical Research prior to our repayment of such note and accrued interest in June 2016. Other interest expense in both periods relates to interest paid on insurance premium financing and one capital lease of office equipment.

We have recognized $237,700 and $631,300 for the quarters ended December 31, 2016 and 2015, respectively, representing the 10% cumulative dividend payable on our 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. The reduction in the quarterly dividend accrual results from the automatic conversion of an aggregate of 2,403,051 shares of Series B Preferred upon our completion of the May 2016 Public Offering and a subsequent voluntary conversion of 87,500 shares of our Series B Preferred in August 2016, as disclosed in Note 9, *Capital Stock*, to the accompanying Condensed Consolidated Financial Statements in Part I of this Report.

Comparison of Nine Months Ended December 31, 2016 and 2015

The following table summarizes the results of our operations for the nine months ended December 31, 2016 and 2015 (amounts in thousands).

	Nine Months Ended December 31,	
	2016	2015
Sublicense revenue	$ 1,250	$ -
Operating expenses:		
Research and development	$ 4,043	$ 2,835
General and administrative	4,908	6,515
Total operating expenses	8,951	9,350
Loss from operations	(7,701)	(9,350)
Interest expense (net)	(4)	(770)
Change in warrant liabilities	-	(1,895)
Loss on extinguishment of debt	-	(26,700)
Other expense	-	(2)
Loss before income taxes	(7,705)	(38,717)
Income taxes	(2)	(2)
Net loss	$ (7,707)	$ (38,719)
Accrued dividend on Series B Preferred Stock	(1,018)	(1,459)
Deemed dividend on Series B Preferred Stock	(111)	(1,812)
Net loss attributable to common stockholders	$ (8,836)	$ (41,990)

Revenue

We recognized $1.25 million in sublicense revenue pursuant to the BlueRock Therapeutics Agreement in the quarter ended December 31, 2016. While we may potentially receive additional payments and royalties under the BlueRock Therapeutics Agreement in the future, in the event certain performance-based milestones and commercial sales are achieved, the agreement might not provide recurring revenue to us in the near term. We reported no other revenue for the nine months ended December 31, 2016 or 2015 and we presently have no revenue generating arrangements with respect to AV-101 or other potential product candidates. However, as indicated previously, our CRADA with the NIH provides for the NIH to fully fund and conduct the Phase 2a Study.

Research and Development Expense

Research and development expense totaled $4,042,800 for the nine months ended December 31, 2016, an increase of approximately 43% compared with the $2,835,000 incurred for the nine months ended December 31 2015, demonstrating our increased focus on the continuing nonclinical and clinical development of AV-101 and our preparations to launch the Phase 2b Study of AV-101 as an adjunctive treatment for MDD patients with an inadequate response to standard antidepressants, which we currently anticipate to begin in the second quarter of 2017. The following table indicates the primary components of research and development expense for each of the periods (amounts in thousands):

	Nine Months Ended December 31,	
	2016	**2015**
Salaries and benefits	$ 1,013	$ 628
Stock-based compensation	240	979
Consulting and other professional services	(81)	51
Technology licenses and royalties, including UHN	547	646
Project-related research and supplies:		
AV-101	1,963	161
Stem cell and all other	129	42
	2,092	203
Rent	206	163
Depreciation	25	29
Warrant modification expense	-	135
All other	1	1
Total Research and Development Expense	$ 4,043	$ 2,835

The increase in salaries and benefits reflects the impact of the hiring of our Chief Medical Officer (*CMO*) in June 2016, as well as salary increases and bonus payments granted to our President and Chief Scientific Officer (*CSO*) and to the four non-officer members of our scientific staff.

The decrease in stock based compensation expense is primarily attributable to the $852,200 fair value, determined using the Black-Scholes Option Pricing Model and the assumptions indicated in Note 2, *Summary of Significant Accounting Policies*, to the accompanying Condensed Consolidated Financial Statements in Part I of this Report, of the September 2015 grant of immediately vested and expensed warrants to purchase 150,000 shares of our common stock granted to our CSO. Stock compensation expense in 2016 reflects the ratable amortization of option grants made to our CSO and CMO, scientific staff and consultants, in November 2016, June 2016 (CSO and CMO only) and September 2015. Our stock options are generally amortized over a two-year to four-year vesting period. A substantial number of the option grants made in or prior to our fiscal year ended March 31, 2014 were fully-vested and fully-expensed prior to December 31, 2016.

Consulting services reflects fees paid or accrued for scientific, nonclinical and clinical development and regulatory advisory services rendered to us by third-parties, primarily by members of our scientific and CNS clinical and regulatory advisory boards. The reduction in expense in the nine months ended December 31, 2016 primarily reflects the rationalization of our stem cell-related scientific advisory board and related accruals, including as a result of the BlueRock Therapeutics Agreement.

Technology license expense reflects both recurring annual fees as well as legal counsel and other costs related to patent prosecution and protection pursuant to certain of our stem cell technology license agreements or have elected to pursue for commercial purposes. We recognize these costs as they are invoiced to us by the licensors and they do not occur ratably throughout the year or between years. Additionally, in both periods, this expense includes legal counsel and other costs we have incurred to advance in the U.S. and numerous foreign countries several pending patent applications with respect to AV-101 and our stem cell technology platform. Technology license-related legal expense for the nine months ended December 31, 2016, also includes $55,000 representing the fair value of a warrant granted to intellectual property counsel as partial compensation for services. Current year expense further includes a net of $158,000 related to the sublicense consideration paid to University Health Network (*UHN*) related to the BlueRock Therapeutics Agreement plus additional fees and expenses related to two new stem cell technology related licenses acquired from UHN, net of amounts previously accrued in connection with our prior SRCA with UHN. Expense for the nine months ended December 31, 2015, included approximately $153,000 of fees and expenses related to additional stem cell technology related licenses acquired in connection with our SRCA with UHN as well as $120,000 of noncash expense resulting from the July 2015 grant of an aggregate of 10,000 shares of our Series B Preferred to two intellectual property legal service providers.

AV-101 expenses for the nine months ended December 31, 2016 include continuing costs incurred to develop more efficient and cost-effective production methods for AV-101 and for certain pre-production and preclinical trial analyses and procedures to facilitate Phase 2 clinical development of AV-101, including the Phase 2b Study. We expect these expenses to increase materially over the next several quarters as we initiate and conduct the Phase 2b Study. Additionally, AV-101 expense in both periods reflects the costs associated with monitoring for and responding to potential feedback related to our AV-101 Phase 1 clinical safety program and addressing other matters required under the terms of our prior NIH grant awards, primarily through our CRO for our Phase 1 safety studies, Cato Research Ltd. The increase in stem cell and other project related expenses in 2016 primarily reflects in-house costs associated with our participation in the FDA's CiPA project.

The increase in rent expense in the quarter ended December 31, 2016 reflects the impact of the scheduled rent increase effective August 2016 as well as the impact of accounting for the November 2016 lease amendment extending the lease of our headquarters facilities by five years from July 31, 2017 to July 31, 2022.

Warrant modification expense in the quarter ended December 31, 2015 reflects the increase in fair value resulting from the November 2015 modification of outstanding warrants to purchase an aggregate of 315,000 shares of our common stock held by our CSO and a key scientific advisor to reduce the exercise prices thereof from a range of $9.25 to $12.80 per share to $7.00 per share.

General and Administrative Expense

General and administrative expense decreased to $4,907,800 from $6,514,500, for the nine month periods ended December 31, 2016 and 2015, respectively, primarily as a result of the decrease in noncash stock compensation expense attributable to option and warrant grants to employees, officers and independent Board members in 2015, partially offset by an increase in noncash expense related to grants of equity securities in payment of certain professional services during 2016. The following table indicates the primary components of general and administrative expenses for each of the periods (amounts in thousands):

	Nine Months Ended December 31,	
	2016	**2015**
Salaries and benefits	$ 932	$ 520
Stock-based compensation	334	2,889
Board fees	105	72
Legal, accounting and other professional fees	1,766	2,113
Investor relations	820	60
Insurance	116	105
Travel and entertainment	126	73
Rent and utilities	148	116
Warrant modification expense	427	480
All other expenses	134	87
Total General and Administrative Expense	$ 4,908	$ 6,515

The increase in salaries and benefits reflects the impact of salary increases and bonus payments granted to our Chief Executive Officer (*CEO*), Chief Financial Officer (*CFO*), and a member of our administrative staff and the change in that employee's status from part-time to full-time, as well as the hiring of our VP-Corporate Development in September 2016.

The decrease in stock based compensation expense is primarily attributable to the $2,841,000 fair value, determined using the Black-Scholes Option Pricing Model and the assumptions indicated in Note 2, *Summary of Significant Accounting Policies*, to the accompanying Condensed Consolidated Financial Statements in Part I of this Report, of the September 2015 grant of immediately vested and expensed warrants to purchase 500,000 shares of our common stock granted to our CEO, CFO, independent members of our Board of Directors and certain consultants. Stock compensation expense in 2016 reflects the ratable amortization of option grants made to our CEO, CFO, independent members of our Board of Directors and administrative staff and consultants, in November 2016, June 2016 (CEO, CFO and independent Board members only) and September 2015, as well as to our VP-Corporate Development upon his commencement of employment in September 2016. Our stock options are generally amortized over a two-year to four-year vesting period. A substantial number of the option grants made in or prior to our fiscal year ended March 31, 2014 were fully-vested and fully-expensed prior to December 31, 2016.

Board fees includes fees recognized for the services of independent members of our Board of Directors. We added an additional independent director to our Board in March 2016.

Legal, accounting and other professional fees in the nine month periods ended December 31, 2016 and 2015, includes $337,500 and $675,000, respectively, of noncash expense recognized pursuant to the June 30, 2015 grant of an aggregate of 90,000 shares of our Series B Preferred having an aggregate fair value at the time of issuance of $1,350,000 as compensation for financial advisory and corporate development service contracts with two independent service providers for services performed between July 1, 2015 and June 30, 2016. During the nine-month period ended December 31, 2016, we granted an aggregate of 25,000 unregistered shares of our common stock having a fair value at the date of issuance of $108,500 to a legal services provider as partial compensation for services and an aggregate of 220,000 unregistered shares of our common stock having a fair value at the date of issuance of $862,800 as partial compensation for financial advisory, investment banking and business development services. During the nine-month period ended December 31, 2015, we granted (i) an aggregate of 50,000 shares of our common stock having an aggregate fair value of $500,000 pursuant to two corporate development contracts initiated during the quarter ended June 30, 2015; (ii) 25,000 shares of our Series B Preferred having a fair value of $250,000 to legal counsel as compensation for services in connection with our debt restructuring and other corporate finance matters, and (iii) 15,750 shares of our unregistered common stock and a five-year warrant to purchase 7,500 unregistered shares of our common stock having an aggregate fair value of $138,000 in connection with investment banking services. In both years, professional services fees also include routine legal fees and expenses and the expense related to the annual audit of the prior year financial statements, preparation of the prior year income tax returns, and quarterly reviews of current year financials statements.

Investor relations expense includes the fees of our external service providers for a significantly expanded broad spectrum of investor relations and market awareness and support functions and, particularly during the second half of 2016, initiatives that included numerous meetings in multiple U.S. markets and other communication activities focused on expanding market awareness of the Company, including among investment professionals and investment advisors, and individual and institutional investors. In the nine months ended December 31, 2016, in addition to cash fees and expenses we incurred, we granted an aggregate of 60,000 unregistered shares of our common stock to three investor relations and investor awareness service providers as partial compensation for their services and recognized noncash expense of $246,300, representing the fair value of the stock at the time of issuance. During the same period, we also granted three-year, immediately exercisable warrants to purchase an aggregate of 75,000 shares of our unregistered common stock at exercise prices ranging from $4.50 per share to $6.00 per share to three investor relations service providers and recognized non-cash expense of $172,300 representing the fair value of the warrants at the time of issuance.

In both periods, travel expense reflects costs associated with presentations to and meetings in numerous U.S. markets with existing and potential investors and investment professionals and advisors, media and securities analysts, as well as various investor relations, market awareness and corporate development initiatives, in 2016 by both our CEO and our VP-Corporate Development.

Between April 2016 and December 2016, we entered into warrant exchange agreements with certain warrant holders pursuant to which the warrant holders exchanged outstanding warrants to purchase an aggregate of 224,513 shares of our common stock for an aggregate of 156,246 shares of our unregistered common stock. As with similar transactions during our fiscal year ended March 31, 2016, we accounted for these transactions as warrant modifications, resulting in our recognition of an aggregate of $350,700 in noncash expense attributable to the increase in fair value related to the warrant exchanges during the nine-month period ended December 31, 2016. Further, in December 2016, we modified an outstanding warrant to reduce the exercise price from $8.00 per share to $3.51 per share and increase the number of shares exercisable under the warrant from 25,000 shares to 50,000 shares, recognizing $76,900 in expense in the quarter then ended as the incremental fair value attributable to the modification. Noncash warrant modification expense in 2015 includes (i) a $122,000 increase in the fair value attributable to the June 2015 strategic modification of outstanding warrants to purchase an aggregate of 54,576 shares of our common stock to reduce the exercise prices thereof, generally from $30.00 per share to $10.00 per share; and (ii) a $358,000 increase in the fair value attributable to the November 2015 modification of outstanding warrants to purchase an aggregate of 808,553 shares of our common stock previously granted to our CEO, CFO, and independent members of our Board of Directors to reduce the exercise prices thereof from a range of $9.25 to $12.80 per share to $7.00 per share

Interest and Other Expenses, Net

Interest expense, net, totaled $3,700 for the nine months ended December 31, 2016, a significant decrease compared to the $769,800 reported for the nine months ended December 31, 2015, resulting from the extinguishment of substantially all of our promissory notes, as well as other indebtedness, between May 2015 and August 2015 by conversion into our Series B Preferred or cash repayment and the related elimination of note interest and discount amortization. The following table summarizes the primary components of interest expense for each of the periods (amounts in thousands):

	Nine Months Ended December 31,	
	2016	**2015**
Interest expense on promissory notes	$ 1	$ 208
Amortization of discount on promissory notes	-	565
Other interest expense, including on capital leases and premium financing	3	3
Total interest expense	4	776
Effect of foreign currency fluctuations on notes payable	-	(6)
Interest income	-	-
Interest expense, net	$ 4	$ 770

Interest expense on promissory notes in the nine months ended December 31, 2016 represents only the interest accrued on our promissory note to Progressive Medical Research prior to its repayment in June 2016. The substantial overall decrease in interest expense on promissory notes and the related amortization of discounts on such notes between the periods reflects the cessation of interest accrual and discount amortization upon the extinguishment and conversion of all outstanding Senior Secured Convertible Notes, certain 10% convertible notes (*2014 Unit Notes*) and other outstanding promissory notes into shares of our Series B Preferred between May 2015 and August 2015.

Under the terms of our October 2012 Note Exchange and Purchase Agreement with Platinum Long Term Growth VII, LLC (*PLTG*), we issued certain Senior Secured Convertible Promissory Notes and a related Exchange Warrant and Investment Warrants between October 2012 and July 2013. Upon PLTG's exchange of the shares of our Series A Preferred Stock held by PLTG into shares of our common stock, we were also required to issue a Series A Exchange Warrant to PLTG. We determined that the various warrants included certain exercise price and other adjustment features requiring us to treat the warrants as liabilities. Accordingly, we recorded a noncash warrant liability at its estimated fair value as of the date of warrant issuance or contract execution. As described in Note 4, *Fair Value Measurements*, to the Condensed Consolidated Financial Statements included in Part 1, Item 1 of this Report, on May 12, 2015, we entered into an agreement with PLTG pursuant to which we amended the various warrants to fix the exercise price thereof and eliminate the anti-dilution reset features that had previously required the warrants to be treated as liabilities and carried at fair value. Accordingly, during the quarter ended June 30, 2015, we adjusted these warrants to their fair value, reflecting an increase of $1,894,700 since March 31, 2015, resulting primarily from the increase in the market price of our common stock in relation to the exercise price of the warrants, and then subsequently eliminated the entire warrant liability with respect to these warrants. In January 2016, the PLTG warrants were exchanged for shares of our Series C Preferred stock.

Between May 2015 and August 2015 we extinguished the outstanding balances of approximately $17,200,000 of promissory notes, including our Senior Secured Convertible Notes, our 2014 Unit Notes and other debt and certain adjustments thereto that were either already due and payable or would have otherwise matured prior to March 31, 2016 by converting such balances into shares of our Series B Preferred at a conversion price (stated value) of $7.00 per share. We treated the conversion of the indebtedness into Series B Preferred as extinguishments of debt for accounting purposes. Since the fair value of the Series B Preferred we negotiated in settlement of the promissory notes and other indebtedness exceeded the carrying value of the debts, we incurred non-recurring noncash losses on each of the extinguishments. Additionally, under the terms of our May 2015 agreement with PLTG in which PLTG agreed to, among other things, convert the Senior Secured Notes and certain other of our convertible promissory notes into Series B Preferred, we issued to PLTG 400,000 shares of Series B Preferred having an aggregate fair value of $4.0 million and Series B Warrants to purchase 1.2 million shares of our common stock having an aggregate of fair value of $8,270,900. We recognized this aggregate fair value as an additional non-recurring noncash component of loss on extinguishment of debt. Many of the 2014 Unit Notes that were converted into Series B Preferred contained a beneficial conversion feature at the time they were originally issued. We accounted for the repurchase of the beneficial conversion feature at the time the 2014 Unit Notes were extinguished and converted, an aggregate of $2,237,100, as a reduction to the loss on extinguishment of debt. We recorded an aggregate net non-recurring noncash loss of $26.7 million attributable to the extinguishment of the indebtedness converted into shares of Series B Preferred.

We allocated the proceeds from self-placed private placement sales of Series B Preferred Units to the Series B Preferred and the Series B Warrants based on their relative fair values on the dates of the sales. The difference between the relative fair value per share of the Series B Preferred, approximately $4.20 per share and $4.06 per share for the nine month periods ended December 31, 2016 and 2015, respectively, and its Conversion Price (or stated value) of $7.00 per share represents a deemed dividend to the purchasers of the Series B Preferred Units. Accordingly, we recognized a deemed dividend in the aggregate amount of $111,100 and $1,811,800 in arriving at net loss attributable to common stockholders for the nine months ended December 31, 2016 and 2015, respectively, in the accompanying Condensed Consolidated Statement of Operations and Comprehensive Loss included in Part I of this Report. Further, we recognized $1,018,500 and $1,459,300 for the nine months ended December 31, 2016 and 2015, respectively, representing the 10% cumulative dividend payable on our 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 elsewhere in this Report. The reduction in the dividend accrual results from the automatic conversion of an aggregate of 2,403,051 shares of Series B Preferred upon our completion of the May 2016 Public Offering and a subsequent voluntary conversion of 87,500 shares of our Series B Preferred in August 2016, as disclosed in Note 9, *Capital Stock*, to the accompanying Condensed Consolidated Financial Statements in Part I of this Report.

Liquidity and Capital Resources

Since our inception in May 1998 through December 31, 2016, we have financed our operations and technology acquisitions primarily through the issuance and sale of our equity and debt securities, including convertible promissory notes and short-term promissory notes, for cash proceeds of approximately $44.5 million, as well as from an aggregate of approximately $17.6 million of government research grant awards, strategic collaboration payments, intellectual property sublicensing and other revenues, but not including the fair market value of the NIH-funded AV-101 Phase 2a clinical study in MDD. Additionally, we have issued equity securities with an approximate aggregate value at issuance of $30.4 million in non-cash settlements of certain liabilities, including liabilities for professional services rendered to us or as compensation for such services.

During April and May 2016, prior to the consummation of our May 2016 Public Offering, we sold to accredited investors in self-placed private placement transactions Series B Preferred Units consisting of 39,714 unregistered shares of our Series B Preferred Stock, par value $0.001 per share (*Series B Preferred*), and five year warrants to purchase 39,714 shares of our common stock, and we received cash proceeds of $278,000. Further, on May 16, 2016, we consummated the May 2016 Public Offering, an underwritten public offering pursuant to which we issued an aggregate of 2,570,040 registered shares of our common stock at the public offering price of $4.24 per share and five-year warrants to purchase up to 2,705,883 registered shares of common stock, with an exercise price of $5.30 per share, at the public offering price of $0.01 per warrant, including shares and warrants issued pursuant to the exercise of the underwriters' over-allotment option. We received net cash proceeds of approximately $9.5 million from the May 2016 Public Offering after deducting fees and expenses. During the quarter ended December 31, 2016, we received aggregate cash proceeds of $247,900 from the sale of our common stock and warrants to two accredited investors in self-placed private placement transactions. As discussed earlier, we received a cash payment of $1.25 million pursuant to our grant of a sublicense under the BlueRock Therapeutics Agreement in early January 2017. We believe that we currently have sufficient financial resources to fund our expected operations at least through the first half of 2017, including preparation for and launch of the Phase 2b Study. Although our current financial resources are not yet sufficient to fully fund completion of the Phase 2b Study, we anticipate raising sufficient additional capital as and when necessary and advisable to satisfy our key corporate objectives, including conducting and completing the Phase 2b Study in an ordinary course manner. In furtherance of that objective, on January 23, 2017, we filed a Registration Statement on Form S-3 (Registration No. 333-215671) with the Commission covering the potential future sale of up to $100 million of our equity and/or debt securities or combinations thereof. There can be no assurance, however, that future financing will be available in sufficient amounts, in a timely manner, or on terms acceptable to us, if at all.

We may also seek research and development collaborations that could generate revenue, funding for development of AV-101 and additional product candidates, as well as additional government grant awards and agreements similar to our current CRADA with the NIMH, which provides for the NIMH to fully fund the NIMH's ongoing Phase 2a study of AV-101 as a monotherapy for MDD. 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. In a manner similar to the BlueRock Therapeutics Agreement, we may also pursue similar arrangements with third-parties covering other of our intellectual property. Although we may seek additional collaborations that could generate revenue and/or non-dilutive funding for development of AV-101 and other product candidates, as well as new government grant awards and/or agreements similar to our CRADA with NIMH, no assurance can be provided that any such collaborations, awards or agreements will occur in the future.

Our future working capital requirements will depend on many factors, including, without limitation, the scope and nature of opportunities related to our success and the success of certain other companies in clinical trials, including our development and commercialization of AV-101 as an adjunctive treatment for MDD and other potential CNS conditions, 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 and 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, accounting, public company compliance and other professional services and working capital costs.

Notwithstanding the foregoing, substantial additional financing may not be available to us on a timely basis, on acceptable terms, or at all. If we are unable to obtain substantial additional financing on a timely basis when needed in 2017 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.

Cash and Cash Equivalents

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

	Nine Months Ended December 31,	
	2016	**2015**
Net cash used in operating activities	$ (5,968)	$ (3,499)
Net cash used in investing activities	(10)	(5)
Net cash provided by financing activities	9,921	4,592
Net increase in cash and cash equivalents	3,943	1,088
Cash and cash equivalents at beginning of period	429	70
Cash and cash equivalents at end of period	$ 4,372	$ 1,158

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements.

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

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 and in our Annual Report on Form 10-K filed with the Securities and Exchange Commission for the fiscal year ended March 31, 2016 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 AV-101. We cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize AV-101, or any product candidate.

We currently have no drug products for sale and may never be able to develop and commercialize marketable drug products. Our business depends heavily on the successful development, regulatory approval and commercialization of AV-101 for depression, including for MDD, and various other diseases and disorders involving the CNS, as well as, but to a more limited extent, our ability to produce, develop and commercialize NCEs from our drug rescue programs. AV-101 will require substantial additional Phase 2 and Phase 3 clinical development, testing and regulatory approval before we are permitted to commence its commercialization and is unlikely to achieve regulatory approval until at least 2021, if at all. Each drug rescue NCE will require substantial nonclinical development, all phases of clinical development, and regulatory approval before we are permitted to commence its commercialization. The nonclinical studies and clinical trials of our product candidates are, and the manufacturing and marketing of our product candidates will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and, if approved, market any product candidate. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must demonstrate through nonclinical studies and clinical trials that the product candidate is safe and effective for use in each target indication. Drug development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our non-clinical studies or clinical trials. This process can take many years and may also include post-marketing studies and surveillance, which will require the expenditure of substantial resources beyond the proceeds we have raised to date. Of the large number of drugs in development in the United States, only a small percentage will successfully complete the FDA regulatory approval process and will be commercialized. Accordingly, even if we are able to obtain the requisite financing to continue to fund our non-clinical studies and clinical trials, we cannot assure you that AV-101, any drug rescue NCE, or any other product candidate will be successfully developed or commercialized.

We are not permitted to market our product candidates in the United States until we receive approval of a New Drug Application (*NDA*) from the FDA, or in any foreign countries until we receive the requisite approval from such countries. We expect the FDA to require us to complete the planned Phase 2b Study and at least two pivotal Phase 3 clinical trials in order to submit an NDA for AV-101 as an adjunctive treatment for MDD patients with an inadequate response to standard, FDA-approved antidepressants. Also, we anticipate that the FDA will require that we conduct additional toxicity studies, additional nonclinical and certain small clinical studies before submitting an NDA for AV-101. The results of all of these trials and studies are not known until after the studies are concluded.

Obtaining FDA approval of an NDA is a complex, lengthy, expensive and uncertain process, and the FDA may delay, limit or deny approval of AV-101 or any of our product candidates for many reasons, including, among others:

- if our NDA, if and when submitted, is reviewed by an 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 non-clinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;

- the FDA may require development of a Risk Evaluation and Mitigation Strategy (*REMS*) as a condition of approval or post-approval;

- 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 AV-101 or any other product candidate we may develop, including drug rescue NCEs. Any such setback in our pursuit of regulatory approval would have a material adverse effect on our business and prospects.

We intend to seek a Fast Track designation from the FDA for AV-101 for adjunctive treatment of MDD patients with an inadequate response to standard antidepressants. Even if the FDA approves Fast Track designation for AV-101 for this indication, it may not actually lead to a faster development or regulatory review or approval process.

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 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 approval or expedited approval of any application for the product.

We intend to seek FDA Fast Track designation for AV-101 for adjunctive treatment of MDD patients with an inadequate response to standard antidepressants, and we may do so for other product candidates as well. The FDA has broad discretion whether or not to grant this designation, and even if we believe AV-101 and other product candidates are eligible for this designation, we cannot be sure that the review or approval will compare to conventional FDA procedures. Even if granted, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development programs.

The number of patients suffering from MDD has not been established with precision. If the actual number of patients with MDD is smaller than we anticipate, we or our collaborators may encounter difficulties in enrolling patients in AV-101 clinical trials, including the Phase 2a Study and the planned Phase 2b Study, thereby delaying completion such studies or preventing additional clinical development. Further, if AV-101 is approved for adjunctive treatment of MDD patients with an inadequate response to standard antidepressants, and the market for this indication is smaller than we anticipate, our ability to achieve profitability could be limited.

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 and other product candidates may not be predictive of the results of later-stage clinical trials. AV-101 or other product candidates in later stages of clinical trials may fail to show the desired safety and efficacy results despite having progressed through preclinical 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.

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

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

If serious adverse events or other undesirable side effects are identified during the use of AV-101 in clinical trials, it may adversely affect our development of AV-101 for MDD and other CNS indications.

AV-101 as a monotherapy is currently being tested by the NIMH in an NIMH-investigator sponsored Phase 2a clinical trial for the treatment of MDD and may be subjected to testing in the future for other CNS indications in additional investigator sponsored clinical trials. If serious adverse events or other undesirable side effects, or unexpected characteristics of AV-101 are observed in investigator sponsored clinical trials of AV-101 or our clinical trials, it may adversely affect or delay our clinical development of AV-101, and the occurrence of these events would have a material adverse effect on our business.

Positive results from early preclinical studies and clinical trials of AV-101 or other product candidates are not necessarily predictive of the results of later preclinical studies and clinical trials of such product candidates. If we cannot replicate the positive results from our earlier preclinical studies and clinical trials of AV-101 or other product candidates in our later preclinical studies and clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize our product candidates.

Positive results from preclinical studies of our product candidates, and any positive results we may obtain from early clinical trials of our product candidates, may not necessarily be predictive of the results from required later preclinical studies and clinical trials. Similarly, even if we are able to complete our planned preclinical studies or clinical trials of our product candidates according to our current development timeline, the positive results from our preclinical studies and clinical trials of our product candidates may not be replicated in subsequent preclinical studies or clinical trial results. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA approval. We have not yet completed a Phase 2 clinical trial for AV-101, and if the NIMH fails to produce positive results in the Phase 2a Study, the development timeline and regulatory approval and commercialization prospects for AV-101 and, correspondingly, our business and financial prospects, could be materially adversely affected.

Failures or delays in the commencement or completion of our planned clinical trials and non-clinical studies of 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.

Under our CRADA, the NIMH is conducting and funding the Phase 2a Study. We will need to complete the planned Phase 2b Study, at least two additional large clinical trials, additional toxicity and nonclinical studies and certain smaller clinical studies prior to the submission of an NDA for AV-101 as a new generation adjunctive treatment for MDD. Successful completion of our clinical trials is a prerequisite to submitting an NDA to the FDA and, consequently, the ultimate approval and commercial marketing of AV-101 for MDD and any other product candidates we may develop. We do not know whether the NIMH-sponsored Phase 2a Study, the Phase 2b Study or any of our future-planned clinical trials will be completed on schedule, if at all, as the commencement and completion of clinical trials can be delayed or prevented for a number of reasons, including, among others:

- the FDA may deny permission to proceed with our planned clinical trials or any other clinical trials we may initiate, or may place a clinical trial on hold;
- delays in filing or receiving approvals of additional INDs that may be required;
- negative results from our ongoing nonclinical studies;
- delays in reaching or failing to reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- inadequate quantity or quality of a product candidate or other materials necessary to conduct clinical trials, for example delays in the manufacturing of sufficient supply of finished drug product;
- difficulties obtaining Institutional Review Board (*IRB*) approval to conduct a clinical trial at a prospective site or sites;
- challenges in recruiting and enrolling patients to participate in clinical trials, including the proximity of patients to trial sites;
- eligibility criteria for the clinical trial, the nature of the 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 drug-related side effects experienced by patients in a clinical trial;
- delays in validating any endpoints utilized in a clinical trial;
- the FDA may disagree with our clinical trial design and our interpretation of data from 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 non-clinical or clinical testing of other CNS 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 trials, 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 FDA, the IRBs at the sites where the IRBs are overseeing a clinical trial, a data and safety monitoring board (*DSMB*), overseeing the clinical trial at issue or other regulatory authorities due to a number of factors, including, among others:

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

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

Changes in regulatory requirements, FDA guidance or unanticipated events during our non-clinical studies and clinical trials may force us to amend non-clinical studies and clinical trial protocols or the FDA may impose additional non-clinical studies and clinical trial requirements. Amendments or changes to our clinical trial protocols would require resubmission to the FDA and IRBs for review and approval, which may adversely impact the cost, timing or successful completion of clinical trials. Similarly, amendments to our non-clinical studies may adversely impact the cost, timing, or successful completion of those non-clinical studies. If we experience delays completing, or if we terminate, any of our non-clinical studies or clinical trials, or if we are required to conduct additional non-clinical studies or clinical trials, the commercial prospects for our 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 clinical trials of AV-101 and any other product candidates. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, completion of clinical trials and development of AV-101 and other product candidates may be delayed and we may not be able to obtain regulatory approval for or commercialize AV-101 or other product candidates and our business could be substantially harmed.

We do not have the ability to independently conduct clinical trials. We rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct 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 parties for execution of clinical trials for our product candidates and control only certain aspects of their activities. As a result, we have less direct control over the conduct, timing and completion of these clinical trials and the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. 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 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 clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific requirements and standards, and our reliance on CROs or the NIH does not relieve us of our regulatory responsibilities. We and our CROs and the NIMH are required to comply with regulations and guidelines, including current 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 or our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials 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 regulations and will require a large number of test patients. Our failure or the failure of our CROs 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, we plan to have CROs, and in the case of the NIMH-sponsored AV-101 Phase 2a study in MDD, the NIMH, conduct the AV-101 Phase 2 and Phase 3 clinical trials. As a result, many important aspects of our drug development programs are outside of our direct control. In addition, the CROs or the NIMH, as the case may be, may not perform all of their obligations under arrangements with us or in compliance with regulatory requirements, but we remain responsible and are 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 our clinical trials. If the NIMH or CROs do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development and commercialization of AV-101 and other product candidates may be delayed or our development program materially and irreversibly harmed. We cannot control the amount and timing of resources these CROs or the NIMH devote to our program or our clinical products. If we are unable to rely on clinical data collected by our CROs or the NIMH, 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 any of our relationships with these third-party CROs or the NIMH terminate, we may not be able to enter into arrangements with alternative CROs or collaborators. If CROs or the NIMH 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 the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any clinical trials that such CROs or the NIMH are associated with may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully 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 could increase and our ability to generate revenue could be delayed.

We rely completely on third-parties to manufacture and prepare our clinical supplies of AV-101 and other product candidates, and we intend to rely on third parties to produce non-clinical, clinical and commercial supplies of AV-101 and any future product candidate.

We do not currently have, nor do we plan to acquire, the infrastructure or capability to internally manufacture our clinical drug supply of AV-101 or any other product candidates for use in the conduct of our nonclinical studies and clinical trials, and we lack the internal resources and the capability to manufacture any product candidates on a clinical or commercial scale. The facilities used by our contract manufacturers to manufacture the active pharmaceutical ingredient and final drug product must complete a pre-approval inspection by the FDA and other comparable foreign regulatory agencies to assess compliance with applicable requirements, including cGMPs, after we submit our NDA or relevant foreign regulatory submission to the applicable regulatory agency.

We do not control the manufacturing process of, and are completely dependent on, our contract manufacturers to comply with cGMPs for manufacture of both active drug substances and finished drug products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or applicable foreign regulatory agencies, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no direct control over our contract manufacturers' ability to maintain adequate quality control, quality assurance and qualified personnel. Furthermore, all of our contract manufacturers are engaged with other companies to supply and/or manufacture materials or products for such companies, which exposes our third-party contract manufacturers 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 contract manufacturers' facilities generally. If the FDA or an applicable foreign regulatory agency determines now or in the future that these facilities for the manufacture of our product candidates 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 contract manufacturers 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.

We do not yet have long-term supply agreements in place with our contract manufacturers and each batch of our product candidates are individually contracted under a quality and supply agreement. If we engage new contract manufacturers, such contractors must complete an inspection by the FDA and other applicable foreign regulatory agencies. We plan to continue to rely upon contract manufacturers and, potentially, collaboration partners, to manufacture commercial quantities of AV-101 and other product candidates, if approved. Our current scale of manufacturing for AV-101 is adequate to support our currently planned needs for additional non-clinical studies and clinical trial supplies.

Even if we receive marketing approval for our product candidates in the United States, we may never receive regulatory approval to market our product candidates outside of the United States.

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

If 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 an infrastructure for the sales, marketing and distribution of pharmaceutical products, nor do we intend to create such capabilities. Therefore, in order to market our product candidates globally, 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. 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, 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 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 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 the potential patient population. 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 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 could 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 FDA requirements governing the labeling, packaging, storage and promotion of the product and record keeping and submission of safety and other post-market information. The FDA has significant post-marketing authority, including, for example, the authority to require labeling changes based on new safety information and to require post-marketing studies or clinical trials to evaluate serious safety risks related to the use of a drug. The FDA also has the authority to require, as part of an NDA or post-approval, the submission of a REMS. Any REMS required by the FDA may lead to increased costs to assure compliance with new post-approval regulatory requirements and potential requirements or restrictions on the sale of approved products, all of which could lead to lower sales volume and revenue.

Manufacturers of drug 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 pharmaceuticals 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 products that may be similar to our product candidates or address similar markets. It is probable that the number of companies seeking to develop products and therapies similar to our products will increase.

Currently, management is unaware of any FDA-approved adjunctive therapy for MDD patients with an inadequate response to standard antidepressants having the same mechanism of action and safety profile as AV-101. However, new antidepressant products with other mechanisms of action or products approved for other indications, including the anesthetic ketamine, are being or may be used off-label for treatment of MDD, as well as other CNS indications for which AV-101 may have therapeutic potential. Additionally, other non-pharmaceutical treatment options, such psychotherapy and electroconvulsive therapy (*ECT*) are sometimes used before or instead of standard antidepressants to treat patients with MDD.

In the field of new generation antidepressants focused on modulation of the NMDA receptor at the glycine binding co-agonist site, we believe our principal competitor is Allergan, which recently acquired from and is now developing in Phase 3 clinical studies the intravenously-administered peptide, rapastinel (formerly GLYX-13).

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. We believe that a range of pharmaceutical and biotechnology companies have programs to develop small molecule drug candidates for the treatment of depression, including MDD, epilepsy, neuropathic pain, Parkinson's disease and other neurological conditions and diseases, including, but not limited to, Abbott Laboratories, Acadia, Allergan, Alkermes, Astra Zeneca, Eli Lilly, GlaxoSmithKline, IntraCellular, Johnson & Johnson/Janssen, Lundbeck, Merck, Novartis, Ono, Otsuka, Pfizer, Roche, Sage, Sumitomo Dainippon, and Takeda, as well as any affiliates of the foregoing companies. 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 clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market 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 depression, we may fail to pursue additional CNS-related Phase 2 development opportunities for AV-101, 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 have limited financial and management resources, we focus on a limited number of research programs and product candidates and are currently focused primarily on development of AV-101, with additional limited focus on NCE drug rescue and 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 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 programs to identify 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 products, we may be subject to additional healthcare statutory and regulatory requirements and enforcement by the federal government and the states and foreign governments in which we conduct our business. Healthcare providers, physicians and others will play a primary role in the recommendation and prescription of our product candidates, if approved. Our future arrangements with third-party payors will expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our product candidates, if we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

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

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

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

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

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

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

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

Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could be costly. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations, including anticipated activities to be conducted by our sales team, 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 is found not to be in 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, 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 marketing approval for AV-101 as an augmentation therapy for MDD, physicians may nevertheless prescribe AV-101 to their patients in a manner that is inconsistent with the approved label. 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 promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or 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 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 U.S. 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, including AV-101. Even if we have obtained FDA Orphan Drug designation for one or more of our product candidates, 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 product candidates, including AV-101. Even if we obtain Orphan Drug designation from the FDA for any one of our product candidates, there are limitations to the exclusivity afforded by such designation. In the United States, 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 exclusivity for a drug that shares the same active moiety as an already approved drug, it must be demonstrated to the FDA that the drug is safer or more effective than the approved orphan designated drug, or that it makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition or if another drug with the same active moiety is determined to be safer, more effective, or represents a major contribution to patient care.

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 in some foreign countries;
- 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 drug, biological and/or regenerative medicine 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 our lead drug candidate is in Phase 2 development, 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 strategic collaborators:

- produce product candidates;
- develop and obtain required regulatory approvals for commercialization of products we produce;
- 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 products; 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 AV-101 and discover, as well as produce, develop and commercialize proprietary drug rescue NCEs using our stem cell technology, and we cannot provide any assurance that we will successfully develop and commercialize AV-101 or drug rescue NCEs, or that, if produced, AV-101 or any drug rescue NCE will be successfully commercialized.

Research programs designed to identify and produce drug rescue NCEs require substantial technical, financial and human resources, whether or not any NCEs are ultimately identified and produced. In particular, our drug rescue programs may initially show promise in identifying potential NCEs, yet fail to yield a lead NCE suitable for preclinical, clinical development or commercialization for many reasons, including the following:

- our drug rescue research methodology may not be successful in identifying potential drug rescue NCEs;
- competitors may develop alternatives that render our drug rescue NCEs obsolete;
- a drug rescue NCE may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a drug rescue NCE may not be capable of being produced in commercial quantities at an acceptable cost, or at all; or
- a drug rescue NCE may not be accepted as safe and effective by regulatory authorities, patients, the medical community or third-party payors.

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, drug rescue NCEs and/or other product candidates if and when they are developed. 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 in entering into arrangements with third parties to sell, market and distribute AV-101, 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, 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 assessment of potential drug rescue NCEs and no operating history with respect to the production of drug rescue NCEs, and we may never be able to produce a drug rescue NCE.

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

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

- our ability to identify potential drug rescue candidates in the public domain, obtain sufficient quantities of them, and assess them using our bioassay systems;
- if we seek to rescue drug rescue candidates that are not available to us in the public domain, the extent to which third parties may be willing to out-license or sell certain drug rescue candidates to us on commercially reasonable terms;
- our medicinal chemistry collaborator's ability to design and produce proprietary drug rescue NCEs based on the novel biology and structure-function insight we provide using *CardioSafe* 3D; and
- financial resources available to us to develop and commercialize lead drug rescue NCEs internally, or, if we out-license them to strategic partners, the resources such partners choose to dedicate to development and commercialization of any drug rescue NCEs they license from us.

Even if we do produce proprietary drug rescue NCEs, we can give no assurance that we will be able to develop and commercialize them as a marketable drug, on our own or in collaboration with others. Before we generate any revenues from AV-101 and/or additional drug rescue NCEs we or our potential collaborators must complete preclinical and clinical developments, submit clinical and manufacturing data to the FDA, qualify a third party contract manufacturer, receive regulatory approval in one or more jurisdictions, satisfy the FDA that our contract manufacturer 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 drug rescue candidates and drug rescue NCEs, then our drug rescue programs will be adversely affected.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

To the extent that we pursue research and development activities involving iPSCs, we will be subject to a variety of laws and regulations in the United States and abroad that involve matters central to such research and development activities, including obligations to seek informed consent from donors for the use of their blood and other tissue to produce, or have produced for us, iPSCs, as well as state and federal laws that protect the privacy of such donors. United States federal and state and foreign laws and regulations are constantly evolving and can be subject to significant change. If we engage in iPSC-related research and development activities in countries other than the United States, we may become subject to foreign laws and regulations relating to human subjects research and other laws and regulations that are often more restrictive than those in the United States. In addition, both the application and interpretation of these laws and regulations are often uncertain, particularly in the rapidly evolving stem cell technology sector in which we operate. These laws and regulations can be costly to comply with and 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 regenerative medicine applications, such as tissue engineering or organ replacement, we would first need to obtain FDA pre-market clearance or approval. Obtaining such clearance or approval from the FDA is expensive, time-consuming and uncertain, generally requiring many years to obtain, and requiring detailed and comprehensive scientific and clinical data. Notwithstanding the time and expense, these efforts may not result in FDA approval or clearance. Even if we were to obtain regulatory approval or clearance, it may not be for the uses that we believe are important or commercially attractive.

Risks Related to Our Financial Position

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

We have incurred significant net losses in each fiscal year since our inception in 1998, including net losses of $47.2 million, which includes $26.7 million of non-cash expense related to the extinguishment of essentially all of our outstanding promissory notes and certain other indebtedness, and $13.9 million during the fiscal years ended March 31, 2016 and 2015, respectively, and a net loss of $7.7 million in the nine months ended December 31, 2016. As of December 31, 2016, we had an accumulated deficit of approximately $139.4 million. We do not know whether or when we will become profitable. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to incur increasing levels of operating losses over the next several years and for the foreseeable future. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' deficit and working capital. We expect our research and development expenses to significantly increase in connection with non-clinical 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 $16.4 million in revenues, primarily from the receipt of research and development grant awards from the NIH, not including the fair market value of the ongoing NIH-funded Phase 2a MDD study of AV-101. 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, or we enter into one or more development and commercialization agreements with respect to AV-101 or one or more other product candidates. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- initiate and successfully complete preclinical 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;
- commercialize our product candidates, if approved, by developing a sales force or entering into collaborations with third parties; and
- achieve market acceptance of our product candidates in the medical community and with third-party payors.

Unless we enter into a development and commercialization collaboration or partnership agreement, we expect to incur significant sales and marketing costs as we prepare to commercialize AV-101 or other product candidates. Even if we initiate and successfully complete pivotal clinical trials of AV-101 or other product candidates, and AV-101 or other product candidates are approved for commercial sale, and despite expending these costs, AV-101 or other 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.

Despite consummation of the May 2016 Public Offering (defined below), 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, 2016 and our condensed consolidated financial statements for the nine months ended December 31, 2016 have been prepared assuming we will continue to operate as a going concern. 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 the sale of our securities or 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 such funding on favorable terms or at all. If we are unable to obtain sufficient financing from the sale of our securities or from alternative sources, we may be required to reduce, defer, or discontinue certain or all of our research and development activities or we may not be able to continue as a going concern.

Since our inception, most of our resources have been dedicated to research and development of AV-101 and the drug rescue capabilities of our stem cell technology platform. In particular, we have expended substantial resources advancing AV-101 through preclinical development and Phase 1 clinical safety studies, and developing *CardioSafe* 3D for drug rescue applications, and we will continue to expend substantial resources for the foreseeable future developing and commercializing AV-101, and, potentially, developing drug rescue NCEs and RM therapies. These expenditures will include costs associated with general and administrative costs, facilities costs, research and development, acquiring new technologies, manufacturing product candidates, conducting preclinical experiments and clinical trials and obtaining regulatory approvals, as well as commercializing any products approved for sale.

At March 31, 2016, our existing cash and cash equivalents were not sufficient to fund our current operations for the next 12 months. However, as described in Note 9, *Capital Stock*, to the accompanying Condensed Consolidated Financial Statements for the nine months ended December 31, 2016 included elsewhere in this Quarterly Report, on May 16, 2016, we consummated an underwritten public offering, pursuant to which we issued an aggregate of 2,570,040 registered shares of our common stock at a public sales price of $4.24 per share and five-year warrants, exercisable at $5.30 per share, to purchase an aggregate of 2,705,883 shares of our common stock at a public sales price of $0.01 per warrant share, including shares and warrants issued pursuant to the exercise of the underwriters' over-allotment option, resulting in gross proceeds of approximately $10.9 million (*May 2016 Public Offering*). Our net proceeds from the May 2016 Public Offering were approximately $9.5 million after deducting underwriters' commissions and other expenses of the offering. During the quarter ended December 31, 2016, we received aggregate cash proceeds of $247,900 from the sale of our common stock and warrants to two accredited investors private placement transactions. Further, as described in greater detail in Note 5, *Sublicense Fee Receivable and Sublicense Revenue*, to the accompanying Condensed Consolidated Financial Statements for the nine months ended December 31, 2016 included elsewhere in this Quarterly Report, we received a cash payment of $1.25 million under the BlueRock Therapeutics Agreement in early January 2017. Additionally, in February 2015, we entered into the CRADA with the NIH, under which the NIMH is fully funding and conducting the Phase 2a Study. However, 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 AV-101, a drug rescue NCE, and/or another drug candidate unrelated to AV-101 to third-parties, (ii) enter into 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 compounds.

As the outcome of our AV-101 and NCE drug rescue activities and future anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates, on our own or in collaboration with others. In addition, other unanticipated costs may arise. As a result of these and other factors, we will need to seek additional capital in the near term to meet our future operating requirements, including capital necessary to 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 are considering a range of potential sources of funding, 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 in 2016. 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, including AV-101 and drug rescue NCEs;
- 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 arrangements and the financial terms of such agreements;
- market acceptance of our products;
- the effect of competing technological and market developments;
- our ability to obtain government funding for our programs;
- the costs involved in obtaining 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 acquire or invest in businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

Any additional fundraising efforts will divert certain members of our management team from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts, in a timely manner, or on terms acceptable to us, if at all, and the terms of any 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 or exchange 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 candidate 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.

Proceeds from recent financing activity, including the May 2016 Public Offering will not be sufficient to complete the planned Phase 2b MDD Study, resulting in the need for additional financing.

Although we anticipate that the net proceeds from the May 2016 Public Offering will provide sufficient funding for our operations through the launch and a portion of the planned Phase 2b Study, the proceeds received will not be sufficient to complete the planned Phase 2b Study. No assurances can be provided that sufficient additional capital will be available to us when necessary, on reasonable terms, or at all. In the event we are unable to raise such additional capital, our operations, including the conduct of the planned Phase 2b Study, will be negatively and materially affected.

Raising additional capital will cause 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, collaborations and licensing arrangements during 2017 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 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.

We currently have 30.0 million shares of common stock authorized for issuance. Based on the current number of shares of our common stock: (i) outstanding, (ii) reserved for conversion or exchange of our various series of outstanding preferred stock, including for payment of accrued dividends on our outstanding Series B Preferred, (iii) reserved for the exercise of outstanding warrants, and (iv) reserved for the exercise of options granted or available for grant pursuant to our equity incentive plans, we have approximately 8.5 million shares of common stock available for future financing or other activities. We may be required to seek stockholder approval to amend our Articles of Incorporation to increase the number of shares of common stock we are authorized to issue in order to achieve our near-term or longer-term financing objectives, including all or part of such financing as may be contemplated in the Registration Statement on Form S-3 filed with the Securities and Exchange Commission in January 2017 (Registration No. 333-215671).

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 and the NIH's National Institute of Mental Health, and the California Institute for Regenerative Medicine. 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, 2016, we had federal and state net operating loss carryforwards of $67.9 million and $60.1 million, respectively, which begin to expire in fiscal 2017. 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 AV-101, drug rescue NCEs, other potential product candidates and other commercial applications of our stem cell technology.

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 and Chief Financial Officer, as well as other employees, consultants and scientific collaborators. As of the date of this Quarterly Report, we have ten 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 AV-101, drug rescue NCEs, other product candidates, and other applications of our stem cell technology, including our production and assessment of potential drug recuse NCEs 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 as we 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 diverse range of strategic consultants and advisors, including manufacturing, scientific and clinical development, and regulatory advisors, to assist us in designing and implementing our research and development and regulatory strategies and plans, including our AV-101 development and drug rescue strategies and plans. 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 AV-101 for MDD and other CNS-related conditions, as well as drug rescue and stem cell technology-related RM programs, we will 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.

If we develop AV-101, drug rescue NCEs, other product candidates, or regenerative medicine 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, any drug rescue NCE, other product candidate, or regenerative medicine 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 products 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;
- 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 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. Furthermore, these laws, regulations and requirements require us to observe greater corporate governance practices than we have employed in the past, including, but not limited to maintaining a sufficient number of independent directors, increased frequency of board meetings, and holding annual stockholder meetings. 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 conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial and stock markets. Global financial 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 internal computer systems, or those of our third-party CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product candidates' development programs.

Despite the implementation of security measures, our internal computer systems and those of our third-party CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. 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 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 products, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions.

We may acquire additional businesses or products, 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 products resulting from a strategic alliance 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, we will achieve the expected synergies to justify the transaction.

Risks Related to Our Intellectual Property Rights

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

We strive to protect and enhance the proprietary technologies that we believe are important to our business, including seeking patents intended to cover our products and compositions, their methods of use and any other inventions we consider are 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, should they issue, 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 patent applications related to AV-101 and we own and have licensed patents and patent applications related to human pluripotent stem cell technology.

We do not yet have an issued patent covering AV-101. We cannot provide any assurances that any of our numerous pending U.S. and foreign patent applications relating to AV-101 will mature into issued patents and, if they do, that such patents will include claims with a scope sufficient to protect AV-101 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 applications, either by claiming the same methods or formulations or by claiming subject matter that could dominate our patent position. Such third-party patent positions may limit or even eliminate our ability to obtain patent protection.

The patent positions of biotechnology and pharmaceutical companies, including our patent position, involve complex legal and factual questions, and, therefore, the issuance, scope, validity and enforceability of any patent claims that we may obtain cannot be predicted with certainty. Patents, if issued, may be challenged, deemed unenforceable, invalidated, or circumvented. U.S. patents and patent applications may also be subject to interference proceedings, *ex parte* reexamination, or *inter partes* review proceedings, supplemental examination and challenges in district court. Patents may be subjected to opposition, post-grant review, or comparable proceedings lodged in various foreign, both national and regional, patent offices. These proceedings could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such proceedings may be costly. Thus, any patents, should they issue, that we may own or exclusively license may not provide any protection against competitors. Furthermore, an adverse decision in an interference proceeding can result in a third party receiving the patent right sought by us, which in turn could affect our ability to develop, market or otherwise commercialize our product candidates.

Furthermore, though a patent, if it were to issue, is presumed valid and enforceable, its issuance is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Even if a patent issues and is held to be valid and enforceable, competitors may be able to design around our patents, such as using pre-existing or newly developed technology. Other parties may develop and obtain patent protection for more effective technologies, designs or methods. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, vendors, former employees and 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 depends on our ability to detect infringement. It is difficult to detect infringers who do not advertise the components that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product. Any litigation to enforce or defend our patent rights, even if we were to prevail, could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

In addition, proceedings to enforce or defend our patents, if and when issued, 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 of our patents, if and when issued, covering our product candidates are invalidated or found unenforceable, our financial position and results of operations would be materially and adversely impacted. In addition, if a court found that valid, enforceable patents held by third parties covered our product candidates, our financial position and results of operations would also be materially and adversely impacted.

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

- any of our AV-101 or other pending patent applications, if issued, will include claims having a scope sufficient to protect AV-101 or any other products or product candidates, particularly considering that the compound patent to AV-101 has expired;
- any of our pending patent applications will issue as patents at all;
- we will be able to successfully commercialize our product candidates, if approved, before our relevant patents expire;
- we were the first to make the inventions covered by each of our patents and pending patent applications;
- we were the first to file patent applications for these inventions;
- others will not develop similar or alternative technologies that do not infringe our patents;
- others will not use pre-existing technology to effectively compete against us;
- any of our patents, if issued, will be found to ultimately be valid and enforceable;
- any patents issued to us 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
- that our commercial activities or products will not infringe upon the patents or proprietary rights of others.

We also rely upon unpatented trade secrets, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our employees and our collaborators and consultants. It is possible that technology relevant to our business will be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees and consultants who are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could otherwise become known or be independently discovered by our competitors.

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

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

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

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

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

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

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

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

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

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

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 U.S. Patent and Trademark Office (*USPTO*) and various 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.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

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

Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology 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 a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

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

If we or one of our licensing partners initiated legal proceedings against a third party to enforce a patent, if and when issued, covering one of our product candidates, 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 U.S. or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review and equivalent proceedings in foreign jurisdictions, e.g., opposition proceedings. Such proceedings could result in revocation or amendment of our patents in such a way that they no longer cover our product candidates or competitive products. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection would have a material adverse impact on our business.

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

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

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

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

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.

We are a party to a number of license agreements under which we are granted rights to intellectual property 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. See "*Business—Intellectual Property*" herein for a description of our license agreements, which includes a description of the termination provisions of these agreements.

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

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

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

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

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

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

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

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

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 if the active ingredient of AV-101 is used in another drug company's product candidate and that product candidate is the first to obtain FDA approval. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our ability to generate revenues could be materially adversely affected.

Changes in 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 biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation: the Leahy-Smith America Invents Act, referred to as the America Invents Act. The America Invents Act includes a number of significant changes to 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.

In addition to increasing uncertainty with regard to 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, 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.

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

Risks Related to our Securities

The limited public market for our securities may adversely affect an investor's ability to liquidate an investment in the Company.

Our common stock is currently quoted on The NASDAQ Capital Market, however, there is presently limited trading activity. We can give no assurance that an active market will develop, or if developed, that it will be sustained. If an investor acquires shares of our common stock, the investor may not be able to liquidate the shares should there be a need or desire to do so.

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 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 non-clinical studies and clinical trials of our product candidates;
- the failure of the FDA to approve our product candidates;
- announcements of new products, technologies, commercial relationships, acquisitions or other events by us or our competitors;
- the success or failure of other CNS therapies;
- regulatory or legal developments in the United States and other countries;
- failure of our product candidates, if approved, to achieve commercial success;
- fluctuations in stock market prices and trading volumes of similar companies;
- general market conditions and overall fluctuations in U.S. equity markets;
- variations in our quarterly operating results;
- changes in our financial guidance or securities analysts' estimates of our financial performance;
- changes in accounting principles;
- our ability to raise additional capital and the terms on which we can raise it;
- sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders;

- additions or departures of key personnel;
- discussion of us or our stock price by the press and by online investor communities; and
- other risks and uncertainties described in these risk factors.

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 these 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 biotechnology-based companies like ours in particular, has frequently experienced 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 operating performance. In certain recent situations in which the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against such 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 significant 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 highly 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.

Our principal institutional stockholders may continue to have substantial control over us and could limit your ability to influence the outcome of key transactions, including changes in control.

Certain of our current institutional stockholders own a substantial portion of our outstanding capital stock, including our common stock, Series A Preferred, Series B Preferred, and Series C Preferred, all of which preferred stock is convertible into a substantial number of shares of common stock. Accordingly, institutional stockholders may exert significant 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 us, even if such a change of control would benefit our other stockholders. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise. Furthermore, the interests of our principal institutional stockholders may not always coincide with your interests or the interests of other stockholders may act in a manner that advances its best interests and not necessarily those of other stockholders, including seeking a premium value for its common stock, which might affect the prevailing market price for our common stock.

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 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 Articles of Incorporation (the *Articles*) permit us to issue up to 10.0 million shares of preferred stock. Our Board of Directors has authorized the issuance of (i) 500,000 shares of Series A Preferred, all of which shares are currently issued and outstanding; (ii) 4.0 million shares of Series B 10% Convertible Preferred stock, of which approximately 1.2 million shares are issued and outstanding as of the date of this Report; and (iii) 3.0 million shares of Series C Convertible Preferred Stock, of which approximately 2.3 million shares are issued and outstanding as of the date of this Report. Our Board of Directors 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.

Since becoming a public company by means of a reverse merger in 2011, we have been 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 money 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

Sale of Units in Private Placement

In December 2016, in self-placed private transactions, we accepted subscription agreements from two individual accredited investors, pursuant to which we sold to such investors units, at a purchase price of $3.70 per unit, consisting of an aggregate of 67,000 unregistered shares of our common stock and warrants, exercisable through November 30, 2019, to purchase an aggregate of 16,750 unregistered shares of our common stock at an exercise price of $6.00 per share. The purchasers of the units have no registration rights with respect to the shares of common stock, warrants or shares of common stock issuable upon exercise of the warrants comprising the units sold. We received aggregate cash proceeds of $247,900 from the sales of the units, which we expect to use for general corporate purposes. The units were offered and sold in transactions exempt from registration under the Securities Act of 1933, as amended (the *Securities Act*), in reliance on Section 4(2) thereof and Rule 506 of Regulation D thereunder.

Issuance of Common Stock to Professional Services Providers

On November 14, 2016, we issued 10,000 shares of our unregistered common stock for services to be provided by a corporate investor relations provider. On December 19, 2016, we issued an aggregate of 100,000 shares of our unregistered common stock to certain investor relations, financial advisory and corporate development professionals who are also accredited investors for professional services provided and to be provided. In all instances, the shares were issued in a private placement transaction exempt from registration under the Securities Act, in reliance on Section 4(2) thereof and Rule 506 of Regulation D thereunder.

Warrants Exchanged for Common Stock

On December 30, 2016, we entered into warrant exchange agreements with accredited investors holding outstanding warrants to purchase an aggregate of 49,100 shares of our common stock pursuant to which the holders agreed to the cancellation of such warrants in exchange for an aggregate of 24,550 shares of our unregistered common stock. In all instances, the common stock was issued in private placement transactions exempt from registration under the Securities Act, in reliance on Section 3(a)(9) and/or 4(2) thereof.

Item 3. Defaults Upon Senior Securities

None.

Item 6. Exhibits

Exhibit Number	Description
10.1 +	Exclusive License and Sublicense Agreement by and between VistaGen Therapeutics, Inc. and Apollo Biologics LP, effective December 9, 2016, filed herewith.
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

+ Confidential treatment has been requested for certain confidential portions of this exhibit pursuant to Rule 24b-2 under the Securities Exchange Act of 1934. In accordance with Rule 24b-2, these confidential portions have been omitted from this exhibit and filed separately with the Securities and Exchange Commission.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned thereunto duly authorized.

VISTAGEN THERAPEUTICS, INC.

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

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

Dated: February 13, 2017

Exhibit 10.1

EXCLUSIVE LICENSE AND SUBLICENSE AGREEMENT

by and between

VISTAGEN THERAPEUTICS, INC.

and

APOLLO BIOLOGICS LP

EXCLUSIVE LICENSE AND SUBLICENSE AGREEMENT

This Agreement is effective as of December 9, 2016 (the "Effective Date"), by and between VistaGen Therapeutics, Inc., a California corporation located at 343 Allerton Avenue, South San Francisco, CA 94080 ("VistaGen"), and Apollo Biologics LP, a Delaware limited partnership located at c/o Versant Venture Management, LLC, One Sansome, Suite 3630, San Francisco, CA 94104 ("Apollo"). VistaGen and Apollo are each sometimes referred to herein as a "Party" or collectively as the "Parties."

RECITALS

WHEREAS, VistaGen and University Health Network ("UHN") entered into that certain (i) License Agreement, [*****] ("License Agreement Number One"), (ii) License Agreement, [*****] ("License Agreement Number Two"), (iii) License Agreement, [*****] ("License Agreement Number Three") and (iv) License Agreement, [*****] ("License Agreement Number Four" and together with License Agreement Number One, License Agreement Number Two, License Agreement Number Three and any additional license agreement entered into between UHN and VistaGen in accordance with Section 2.5 below, each a "License Agreement" and collectively, the "License Agreements");

WHEREAS, VistaGen and UHN have entered into that certain Patent License Amendment Agreement, dated as of December 9, 2016, pursuant to which each License Agreement is amended;

WHEREAS, pursuant to each License Agreement, VistaGen is the exclusive licensee, with the right to grant sublicenses (through multiple tiers), of all right, title and interest in the Licensed IP, subject only to a royalty-free, nonexclusive, non-transferable license to practice the Licensed IP granted by UHN to the United States Government for governmental purposes;

WHEREAS, Apollo desires to obtain, and VistaGen is willing to grant, (i) an exclusive sublicense under the Licensed IP in the Apollo Field of Use in accordance with each License Agreement, (ii) an exclusive license under the Present Improvements in the Apollo Field of Use under the terms of this Agreement and (iii) a non-exclusive license under the Future Improvements in the Apollo Field of Use, in each case of (i)-(iii), under the terms of this Agreement; and

WHEREAS, prior to entering into this Agreement, VistaGen has delivered sufficient evidence reasonably satisfactory to Apollo that (i) the Sponsored Research Collaboration Agreement by and between UHN and VistaGen, dated as of September 18, 2007, as amended from time to time (the "VistaGen SRA") has been terminated and (ii) the Strategic Consulting Agreement by and between VistaGen and Gordon Keller, Ph.D., dated as of August 1, 2014 has been appropriately amended to allow Dr. Keller to enter into a new consulting agreement with Apollo.

NOW, THEREFORE, in consideration of the promises and mutual covenants herein contained and for other good and valuable consideration, the adequacy and receipt of which are hereby acknowledged, VistaGen and Apollo hereby agree as follows:

ARTICLE 1

DEFINITIONS

1.1 "Affiliate" shall mean any entity which directly or indirectly controls, or is controlled by, or is under common control with, a Party. The term "control" as used herein means (a) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) of the stock or shares entitled to vote for the election of directors; or (b) with the power to direct the management and policies of such entities.

1.2 "Apollo Field of Use" shall mean [*****] cardiac cell therapy [*****], including for use in human medical or veterinary purposes [*****].

1.3 "Bankruptcy Code" means Title 7 or Title 11 U.S. Code, or any similar federal, state (or with respect to Canada, provincial) or foreign law for the relief of debtors.

***** **VISTAGEN THERAPEUTICS, INC. HAS REQUESTED THAT THE OMITTED PORTIONS OF THIS DOCUMENT, WHICH ARE INDICATED BY [*****], BE AFFORDED CONFIDENTIAL TREATMENT. VISTAGEN THERAPEUTICS, INC. HAS SEPARATELY FILED THE OMITTED PORTIONS OF THE DOCUMENT WITH THE SECURITIES AND EXCHANGE COMMISSION.**

1.4 "Biosimilar Product" shall mean, with respect to a Licensed Product and on a country-by-country basis, a product that (i) is marketed for sale in such country by a third party (not licensed, supplied or otherwise permitted by a Party or its Affiliates or Sublicensees); (ii) contains the corresponding Licensed Product or substantial equivalent as an active pharmaceutical ingredient in such country; and (iii) such product, as and to the extent required, is approved through an abbreviated process (similar, with respect to the United States, to an Abbreviated New Drug Applications under Section 505(j) of the FD&C Act (21 USC 355(j)) or is approved as a "Biosimilar Biologic Product" under Title VII, Subtitle A Biologics Price Competition and Innovation Act of 2009, Section 42 U.S.C. 262, Section 351 of the PHSA, or, outside the United States, in accordance with European Directive 2001/83/EC on the Community Code for medicinal products (Article 10(4) and Section 4, Part II of Annex I) and European Regulation EEC/2309/93 establishing the Community procedures for the authorization and evaluation of medicinal products, each as amended, and together with all associated guidance, and any counterparts thereof or equivalent process inside or outside of the United States or European Union to the foregoing.

1.5 "Calendar Year" means each successive period of twelve (12) months commencing on January 1 and ending on December 31.

1.6 "Combination Product" shall mean any Revenue Bearing Product sold or used in combination with one or more other products or components which are not Revenue Bearing Products.

1.7 "FDA" means the United States Food and Drug Administration or its successor.

1.8 "Field of Use" shall mean the Apollo Field of Use or the VistaGen Field of Use, as applicable.

1.9 "First Commercial Sale" shall mean, with respect to a Licensed Product and a country, the first sale to an independent third party in such country after all Regulatory Approvals, including any pricing or reimbursement approvals, as applicable, have been obtained in such country.

1.10 "Future Improvement" shall mean an Improvement created, conceived or reduced to practice after the Effective Date.

1.11 "Future Improvement Patent Rights" shall mean the patent rights within any Future Improvements.

1.12 "[*****] Transaction Agreement" shall mean an agreement pursuant to which Apollo or any of its Affiliates has [*****] either solely in [*****] or in [*****] and one or more of the following countries: [*****]. For clarity, an agreement pursuant to which Apollo or any of its Affiliates have [*****] in regions in addition to [*****] or one or more of the countries listed above (including globally) shall not be considered a "[*****] Transaction Agreement" hereunder.

1.13 "Licensed IP" shall mean all rights licensed or otherwise granted to VistaGen from UHN under each License Agreement, including the UHN Patent Rights.

1.14 "Licensed Product" shall mean [*****].

1.15 "Improvements" means any and all [*****].

1.16 "IND" means (a) an Investigational New Drug Application as defined in the United States Federal Food, Drug and Cosmetic Act, as amended, and applicable regulations promulgated thereunder by the FDA, or (b) the equivalent application to the equivalent regulatory authority in any other regulatory jurisdiction, the filing of which is necessary to initiate or conduct clinical testing of a biologic or pharmaceutical product candidate in humans in such jurisdiction.

***** **VISTAGEN THERAPEUTICS, INC. HAS REQUESTED THAT THE OMITTED PORTIONS OF THIS DOCUMENT, WHICH ARE INDICATED BY [*****], BE AFFORDED CONFIDENTIAL TREATMENT. VISTAGEN THERAPEUTICS, INC. HAS SEPARATELY FILED THE OMITTED PORTIONS OF THE DOCUMENT WITH THE SECURITIES AND EXCHANGE COMMISSION.**

1.17 "Net Sales" shall mean [*****]

(a) [*****]

(b) [*****]

(c) [*****]

(d) [*****]

[*****].

In the event that a Revenue Bearing Product is sold as a Combination Product, Net Sales, for the purposes of determining royalty payments on the Combination Product, shall mean [*****]:

(i) [*****]

(ii) [*****].

1.18 "Orphan Indication" means a disease or condition for which a product intended to treat such disease or condition has received orphan drug status from the FDA or European Medicines Agency (the "EMA").

1.19 "Phase 2 Clinical Trial" means a human clinical trial of a product, the principal purpose of which is a determination of safety and efficacy in the target patient population, as described in 21 C.F.R. 312.21(b) (as amended or any replacement thereof), or a similar clinical trial prescribed by the regulatory authority in a country other than the United States.

1.20 "Phase 3 Clinical Trial" means a human clinical trial of a product, the design of which is acknowledged by the FDA to be sufficient for such clinical trial to satisfy the requirements of 21 C.F.R. 312.21(c) (as amended or any replacement thereof), or a similar human clinical trial prescribed by the regulatory authority to be sufficient for such clinical trial to satisfy the requirements of a pivotal efficacy and safety clinical trial.

1.21 "Present Improvement" shall mean any Improvement in existence on the Effective Date.

1.22 "Regulatory Approval" means all approvals necessary for the manufacture, marketing, importation and sale of a product for one or more indications in a country or regulatory jurisdiction, which may include satisfaction of all applicable regulatory and notification requirements, including any pricing and reimbursement approvals. Regulatory Approvals include approvals by regulatory authorities of INDs, marketing authorization approvals, new drug applications or biologics license applications.

1.23 "Reporting Period" shall begin on the first day of each calendar quarter and end on the last day of such calendar quarter.

1.24 "Revenue Bearing Products" shall mean a Licensed Product [*****].

1.25 "Sublicensee" shall mean any non-Affiliate sub-sublicensee or sublicensee, as applicable, of the rights granted by Apollo pursuant to Section 2.2.

1.26 "Term" shall have the meaning set forth in Section 12.1.

1.27 "Territory" shall mean worldwide.

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1.28 "UHN Patent Rights" shall mean:

(a) the United States and international patents licensed to VistaGen from UHN pursuant to each License Agreement, including those listed on Exhibit A;

(b) the United States and international patent applications and provisional applications licensed to VistaGen from UHN pursuant to each License Agreement, including those listed on Exhibit A;

(c) any patent applications claiming priority from the patents, patent applications, or provisional applications licensed to VistaGen from UHN pursuant to each License Agreement, including those listed on Exhibit A, and any direct or indirect divisionals, continuations, continuation-in-part applications, and continued prosecution applications (and their relevant international equivalents) of the patent applications licensed to VistaGen from UHN pursuant to each License Agreement, including those listed on Exhibit A and of such patent applications claiming priority from the provisional applications licensed to VistaGen from UHN pursuant to each License Agreement, including those listed on Exhibit A, to the extent the claims are directed to subject matter specifically described in the patent applications licensed to VistaGen from UHN pursuant to each License Agreement, including those listed on Exhibit A, and the resulting patents;

(d) any patents resulting from reissues, reexaminations, or extensions (and their relevant international equivalents, including, without limitation supplementary protection certificates) of the patents described in clauses (a), (b) and (c) above; and

(e) international (non-United States) patent applications and provisional applications filed after the Effective Date and the relevant international equivalents to divisionals, continuations, continuation-in-part applications and continued prosecution applications of the patent applications to the extent the claims are directed to subject matter specifically described in the patents or patent applications referred to in clauses (a), (b), (c) and (d) above.

Notwithstanding the foregoing, to the extent there is a conflict between the content of Exhibit A and that listed in Exhibit B of each License Agreement, the content of Exhibit B of each License Agreement shall control.

1.29 "Valid Claim" shall mean [*****].

1.30 "VistaGen Field of Use" shall mean all fields other than the Apollo Field of Use. [*****].

ARTICLE 2

GRANT OF RIGHTS

2.1 License and Sublicense Grants.

(a) VistaGen hereby grants to Apollo and its Affiliates for the Term a royalty-bearing, exclusive (even as to VistaGen and its Affiliates, except as set forth in Section 2.3) sublicense, with the right to grant further sublicenses (as provided in Section 2.2 below) through multiple tiers, under the Licensed IP, to research, develop, commercialize, make, have made, use, have used, sell, have sold, offer to sell, have offered for sale, import, have imported and otherwise exploit, itself and through third parties, Licensed Products in the Apollo Field of Use in the Territory.

(b) VistaGen hereby grants to Apollo and its Affiliates for the Term a royalty-free, exclusive (even as to VistaGen and its Affiliates) license, with the right to grant sublicenses (as provided in Section 2.2 below) through multiple tiers, under the Present Improvements, to research, develop, commercialize, make, have made, use, have used, sell, have sold, offer to sell, have offered for sale, import, have imported and otherwise exploit, itself and through third parties, Licensed Products in the Apollo Field of Use in the Territory.

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(c) VistaGen hereby grants to Apollo and its Affiliates for the Term a royalty-free, non-exclusive license, with the right to grant sublicenses (as provided in Section 2.2 below) through multiple tiers, under the Future Improvements, to research, develop, commercialize, make, have made, use, have used, sell, have sold, offer to sell, have offered for sale, import, have imported and otherwise exploit, itself and through third parties, Licensed Products in the Apollo Field of Use in the Territory.

(d) VistaGen acknowledges and agrees that, during the Term, it shall not directly or indirectly grant any licenses, sublicenses or other rights inconsistent with this Section 2.1.

(e) Apollo acknowledges and agrees that, during the Term, it, its Affiliates and its Sublicensees under this Agreement will comply with any provision of the License Agreements if and to the extent such provision is applicable to a sublicensee under the License Agreements.

2.2 Sublicenses. Apollo shall have the right to grant further sublicenses of the rights and licenses granted to Apollo hereunder through multiple tiers. Apollo shall incorporate terms and conditions into its sublicense agreements sufficient to enable Apollo to comply with this Agreement. Apollo shall promptly furnish VistaGen with a fully signed photocopy of any sublicense agreement, which sublicense agreement may be redacted as necessary to protect commercially sensitive information. Upon termination of this Agreement for any reason, provided that a Sublicensee is not in material breach of its sublicense, VistaGen shall grant to such Sublicensee sublicense rights and terms equivalent to the sublicense rights and terms which Apollo previously granted to such Sublicensee.

2.3 Retained Rights.

(a) VistaGen shall retain the licenses granted to it by UHN pursuant to each License Agreement to use the Licensed IP in accordance with the terms of each License Agreement solely in the VistaGen Field of Use.

(b) Apollo acknowledges UHN's reserved right under each License Agreement to retain a non-exclusive, sublicensable right to use the Licensed IP for non-commercial research purposes and/or academic educational purposes, without any financial obligation to VistaGen or Apollo for so using the Licensed IP.

(c) Apollo acknowledges that, with respect to UHN, the U.S. federal government retains a royalty-free, non-exclusive, non-transferable license to practice any government-funded invention claimed in any UHN Patent Rights as set forth in 35 U.S.C. §§ 01-211, and the regulations promulgated thereunder, as amended, or any successor statutes or regulations.

2.4 No Additional Rights. Nothing in this Agreement shall be construed to confer any rights upon Apollo by implication, estoppel, or otherwise as to any patent rights or other intellectual property of VistaGen or UHN other than the Licensed IP and Improvements.

2.5 VistaGen SRA. VistaGen covenants and agrees to promptly notify Apollo (but in no event later than [*****] after receipt) in the event it receives any Invention Notice (as defined in the VistaGen SRA) applicable to [*****] the Apollo Field of Use from UHN following the Effective Date. For clarity, [*****]. In addition, VistaGen hereby assigns all right, title and interest in and to any unexercised or future option available to VistaGen pursuant to Section 4.3 of the VistaGen SRA, through which VistaGen may obtain an exclusive license to any Resulting IP (as defined in the VistaGen SRA) in the field set forth in [*****] Apollo Field of Use disclosed in such Invention Notice. To the extent Apollo, in its sole discretion, decides to exercise such option to obtain an exclusive license, it shall notify VistaGen of its decision within [*****] days of receipt of notice from VistaGen. VistaGen shall promptly (within the required time periods set forth in the VistaGen SRA) notify UHN of such decision on behalf of Apollo and acquire exclusive license rights to the applicable Resulting IP through the procedures set forth in Section 4.3 of the VistaGen SRA; provided that (i) the terms and conditions of each such exclusive license agreement shall be substantially identical to the terms and conditions set forth in the License Agreements and (ii) each such exclusive license agreement shall automatically be considered a License Agreement hereunder with all rights licensed or otherwise granted to VistaGen thereunder automatically considered Licensed IP hereunder with the field in clause (ii) of the Apollo Field of Use applying to such Licensed IP. Apollo and VistaGen shall endeavor to amend Exhibit A attached hereto to reflect such additional Licensed IP. Apollo shall reimburse VistaGen to the extent VistaGen pays an issue fee to UHN pursuant to each such exclusive license, which reimbursement shall not exceed [*****]. For the avoidance of doubt, in accordance with this Agreement, VistaGen shall retain the licenses granted to it by UHN solely within the VistaGen Field of Use under any such license agreement entered into pursuant to this Section 2.5.

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2.6 Future UHN SRA. During the Term and for a period of [*****] thereafter, neither VistaGen nor any of its Affiliates or sublicensees (other than Apollo and its Affiliates, licensees and Sublicensees), either alone, or with or through any third party (including by way of any assignment, license, covenant or other transaction regarding patent rights or other intellectual property, or by any research, development or other agreement), shall enter into any agreement with UHN in the field set forth in [*****] the Apollo Field of Use.

2.7 Section 365(n) of the Bankruptcy Code. All rights and licenses granted pursuant to any Section of this Agreement are, and shall be deemed to be, rights and licenses to "intellectual property" (as defined in Section 101(35A) of title 11 of the United States Code and of any similar provisions of applicable Bankruptcy Code under any other jurisdiction including the Bankruptcy and Insolvency Act, R.S.C. 1985, c. B-3 and Companies' Creditors Arrangement Act, R.S.C. 1985, c. C-36, as amended from time to time. VistaGen agrees that Apollo as a licensee and sublicensee of rights and licenses under this Agreement, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against VistaGen under the Bankruptcy Code or analogous provisions of applicable laws outside the United States, Apollo shall be entitled to a complete duplicate of (or complete access to, as appropriate) any patent rights or other intellectual property licensed or sublicensed to Apollo and all embodiments of such intellectual property, which, if not already in Apollo's possession, shall be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon Apollo's written request therefor, unless VistaGen in the bankruptcy proceeding elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under clause (a), following the rejection of this Agreement in the bankruptcy proceeding, upon written request therefor by Apollo.

ARTICLE 3

APOLLO DILIGENCE OBLIGATIONS AND REPORTING

3.1 Diligence Requirements. Apollo shall use commercially reasonable efforts, or shall cause one or more of its Affiliates and Sublicensees to use commercially reasonable efforts, to develop [*****]. In the event that VistaGen determines that Apollo (itself or through its Affiliates or Sublicensees) has failed to fulfill its obligations under this Section 3.1, then VistaGen may treat such failure as a material breach in accordance with Section 12.3(a).

3.2 R&D Plan. Within [*****] after the Effective Date, Apollo shall furnish to VistaGen a copy of Apollo's Research and Development Plan ("R&D Plan") for Licensed Products; and a status and progress report as to Apollo's implementation of the R&D Plan shall be furnished to VistaGen annually thereafter, in conjunction with submission to VistaGen of the annual report, together with an update for the R&D Plan for the next year. The Parties acknowledge that the R&D Plan will represent the optimal and desired goals and timeline for [*****], and that there is no guarantee of achieving the goals within said timeline.

3.3 Annual Report. [*****] each Calendar Year during the Term, Apollo shall prepare and deliver to VistaGen a written summary report which shall describe (a) the research performed to date employing the Licensed IP, (b) the progress of [*****] Licensed Products [*****] and (c) [*****].

ARTICLE 4

ROYALTIES AND PAYMENT TERMS

4.1 Consideration for Grant of Rights

(a) License and Sublicense Issue. Within [*****], Apollo shall pay to VistaGen a sublicense and license issue fee of One Million Two Hundred Fifty Thousand U.S. dollars (U.S.$1,250,000). [*****].

(b) Running Royalties. Beginning upon the First Commercial Sale of a Revenue Bearing Product, Apollo shall pay to VistaGen a [*****] royalty on a [*****] basis on [*****] Net Sales for [*****]. Running royalties shall be payable for each Reporting Period and shall be due to VistaGen within [*****] of the end of each Reporting Period.

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(c) Royalty Stacking. To the extent that Apollo or any of its Affiliates or Sublicensees obtains licenses to third party patent rights or other intellectual property in order to practice the Licensed IP or to develop or commercialize any Licensed Products, Apollo and its Affiliates and Sublicensees may deduct from any royalty due to VistaGen hereunder [*****] of the royalties due according to agreements between Apollo (and its Affiliates and Sublicensees, as applicable) and a third party(ies) on such patents or intellectual property up to an amount equal to [*****] of the running royalties owed in any Reporting Period hereunder, with any excess third party royalties carried over into next succeeding Reporting Periods until exhausted.

(d) Biosimilar Competition. Notwithstanding the foregoing, on a country-by-country basis in the Territory, the royalty rate for Net Sales of a Revenue Bearing Product set forth in Section 4.1(b) shall be reduced (A) by [*****], following a launch of a Biosimilar Product, if the unit sales of all Biosimilar Products in such country exceed [*****] of the sum of unit sales of Revenue Bearing Products plus unit sales of all Biosimilar Products in such country, (B) by [*****] following a launch of a Biosimilar Product, if the unit sales of all Biosimilar Products in such country exceed [*****] of the sum of unit sales of Revenue Bearing Products plus unit sales of all Biosimilar Products in such country, or (C) by [*****] to become [*****] following a launch of Biosimilar Product, if the unit sales of all Biosimilar Products in such country exceed [*****] of the sum of unit sales of Revenue Bearing Products plus unit sales of all Biosimilar Products in such country. Unless otherwise agreed by the Parties, the unit sales of each such Biosimilar Product sold during a Reporting Period shall be as reported by [*****] or any other independent sales auditing firm reasonably agreed upon by the Parties.

(e) No Multiple Royalties. If the commercial sale of any Revenue Bearing Product is covered by more than one of the [*****], multiple royalties shall not be due.

(f) Duration of Royalty Obligations. The royalty obligations of Apollo shall continue on a [*****] basis as to each Revenue Bearing Product, until the expiration or termination of the last to expire Valid Claim within [*****] in that country. Upon the expiration of Apollo's royalty obligations with respect to a Revenue Bearing Product in a country, the license grants contained in Sections 2.1 shall become fully paid-up, royalty-free, perpetual and irrevocable for such Revenue Bearing Product in such country.

(g) Development Milestone Payments. Subject to Section 4.1(h), Apollo shall pay to VistaGen the following development milestone payments listed in the tables below for [*****] Revenue Bearing Product to achieve each development milestone event. Apollo shall provide VistaGen with written notice and such milestone payment within [*****] after achieving each development milestone. Each such milestone payment shall be payable only once on the [*****] Revenue Bearing Product to achieve such development milestone event. For the avoidance of doubt, in no event shall Apollo be required to pay VistaGen more than an aggregate of [*****] in development milestone payments under this Section 4.1(g).

	Development Milestone Event	**Milestone Payment**
(A)	[*****]	[*****]
(B)	[*****]	[*****]
(C)	[*****]	[*****]
(D)	[*****]	[*****]

(h) [*****]

(i) [*****]

(ii) [*****]

(iii) [*****].

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(i) Commercial Milestone Payments. Apollo shall pay to VistaGen the following commercial milestone payments listed in the tables below after achievement of [*****] commercial milestone event. Apollo shall provide VistaGen with written notice and such milestone payment within [*****] after the end of the Calendar Year in which the applicable milestone event was achieved. Each such milestone payment shall be payable only once. For the avoidance of doubt, in no event shall Apollo be required to pay VistaGen more than an aggregate of [*****] in commercial milestone payments under this Section 4.1(i).

	Commercial Milestone Event	**Milestone Payment**
(A)	[*****]	[*****]
(B)	[*****]	[*****]
(C)	[*****]	[*****]
(D)	[*****]	[*****]

(j) [*****] Transaction Agreement Revenue.

(i) Subject to Sections 4.1(j)(ii), Apollo shall pay VistaGen the following percentage of all consideration allocable solely to [*****] received by Apollo pursuant to the [*****] Transaction Agreement:

(A) [*****]

(B) [*****]

(C) [*****].

Apollo shall provide VistaGen with written notice of [*****] Transaction Agreement and payment of the amount represented by the above percentages within [*****] after [*****]. [*****].

(ii) The following shall not be considered consideration and subject to the sharing percentages in Section 4.1(j)(i): [*****].

(iii) To the extent that patent rights, other intellectual property rights or other rights, products or obligations other than those applicable to Revenue Bearing Products are [*****] Transaction Agreement, that portion of the consideration received by Apollo and subject to Section 4.1(j)(i) shall be equitably apportioned between the Revenue Bearing Products and those other rights, products and obligations, and such apportionment shall be reasonable and in accordance with customary standards in the industry.

(iv) To the extent Apollo [*****] Transaction Agreement, that portion of the consideration received by Apollo and subject to Section 4.1(j)(i) shall be equitably apportioned between [*****] and any other such applicable country, and such apportionment shall be reasonable and in accordance with customary standards in the industry. [*****].

(v) With respect to each of Sections 4.1(j)(iii) and 4.1(j)(iv), Apollo shall promptly deliver to VistaGen a written report setting forth each such apportionment. In the event VistaGen disagrees with the determination made by Apollo, VistaGen shall so notify Apollo within [*****] of receipt of Apollo's report and the Parties shall meet to discuss and resolve such disagreement in good faith. If the Parties are unable to agree in good faith as to such fair market values within [*****], then (a) the matter shall be submitted in accordance with the dispute resolution process set forth in Article 13, and (b) VistaGen shall not be entitled to terminate this Agreement until such matter is fully determined by a court of competent jurisdiction.

(k) Method of Payment. All payments shall be made by wire transfer of immediately available funds into an account designated by VistaGen.

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(l) Payments in U.S. Dollars. All payments due under this Agreement shall be payable in United States dollars. Conversion of foreign currency to U.S. dollars shall be made at the conversion rate existing in the United States (as reported in the Wall Street Journal) on the last working day of the calendar quarter of the applicable Reporting Period. Such payments shall be without deduction of exchange, collection, or other charges, and, specifically, without deduction of withholding or similar taxes or other government imposed fees or taxes, except as permitted in the definition of Net Sales.

(m) Late Payments. Any payments by Apollo that are not paid on or before the date such payments are due under this Agreement shall bear interest, to the extent permitted by law, at [*****] above the Prime Rate of interest as reported in the Wall Street Journal on the date payment is due.

(n) Payments to UHN. VistaGen shall be solely responsible for any and all amounts payable to UHN pursuant to the terms of each License Agreement, including any amounts payable as a result of, or in connection with, entry by the Parties into this Agreement or any milestone achieved by, or royalties on Net Sales of, any Revenue Bearing Product. In no event shall Apollo be responsible or liable for any amounts due and payable to UHN under any License Agreement or the VistaGen SRA.

ARTICLE 5

REPORTS, RECORDS AND CONFIDENTIAL INFORMATION

5.1 Frequency of Reports.

(a) Upon First Commercial Sale of a Revenue Bearing Product. Apollo shall report to VistaGen the date of the First Commercial Sale of a Revenue Bearing Product within [*****] of occurrence in each country.

(b) After First Commercial Sale. After the First Commercial Sale of a Revenue Bearing Product, Apollo shall deliver reports to VistaGen within [*****] of the end of each Reporting Period, containing information concerning the immediately preceding Reporting Period, as further described in Section 5.2.

5.2 Content of Reports and Payments. Each report delivered by Apollo to VistaGen shall contain at least the following information for the immediately preceding Reporting Period:

(a) the number of Revenue Bearing Products sold by Apollo, its Affiliates and Sublicensees to independent third parties in each country;

(b) the gross price charged by Apollo, its Affiliates and Sublicensees for each Revenue Bearing Product in each country;

(c) calculation of Net Sales for the applicable Reporting Period in each country, including, without limitation, a listing of applicable deductions; and

(d) total royalty payable on Net Sales in U.S. dollars, together with the exchange rates used for conversion.

If no amounts are due to VistaGen for any Reporting Period, the report shall so state.

5.3 Records. Apollo shall maintain, and shall cause its Affiliates and Sublicensees to maintain, complete and accurate records relating to amounts payable to VistaGen in relation to this Agreement. The relevant entity shall retain such records for at least [*****] following the end of the Calendar Year to which they pertain, during which time a certified, independent public accountant selected by VistaGen and reasonably acceptable to Apollo shall have the right, at VistaGen's expense, to inspect such records during normal business hours to verify any reports and payments made or compliance in other respects under this Agreement. In the event that any audit performed under this Section 5.3 reveals an underpayment in excess of [*****], Apollo shall bear the full out-of-pocket cost of such audit and shall remit any amounts due to VistaGen within [*****] of receiving written notice thereof from VistaGen.

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5.4 Confidentiality of Reports and Records. The reports and records (including the R&D Plan) provided by Apollo hereunder shall be regarded as Apollo's Confidential Information (as defined below) and, notwithstanding Section 5.5 below, VistaGen hereby covenants that it shall not use or disclose any information included in such reports for any purpose other than determining whether Apollo, its Affiliates and Sublicensees have complied with their obligations under this Agreement; provided that VistaGen may disclose such reports to UHN solely to use for the same purpose. VistaGen further agrees that, notwithstanding Section 5.5 below, until such time as such information is no longer confidential through no fault of VistaGen, it shall maintain such reports and any information included therein in strict confidence and treat such information in a manner at least as restrictive as its manner of treating its own confidential information of similar nature and in any event not less than with a reasonable degree of care.

5.5 Confidentiality.

(a) *Confidential Information; Exceptions*. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, during the Term and for a period of [*****] thereafter, the Parties hereby agree to hold in strict confidence and not publish, disclose or transfer, directly or indirectly, or use for any purpose other than as provided for in this Agreement any information and materials furnished to it by or on behalf of the other Party or its Affiliates or generated pursuant to this Agreement (collectively, "Confidential Information"). For clarity, Confidential Information of a Party or its Affiliates will include, without limitation, all information and materials disclosed by such Party or its Affiliates or their respective designees that (a) is marked as "Confidential," "Proprietary" or with similar designation at the time of disclosure or (b) by its nature can reasonably be expected to be considered Confidential Information by the recipient. Information disclosed orally will not be required to be identified as such to be considered Confidential Information. The terms of this Agreement shall be deemed to be the Confidential Information of both Parties. Notwithstanding the foregoing, Confidential Information will not include any information to the extent that it can be established by written documentation by the receiving Party that such information: (a) was already known to the receiving Party, other than under an obligation of confidentiality (except to the extent such obligation has expired or an exception is applicable under the relevant agreement pursuant to which such obligation was established), at the time of disclosure, (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party, (c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement, (d) was independently developed by the receiving Party as demonstrated by written documentation prepared contemporaneously with such independent development; or (e) was disclosed to the receiving Party, other than under an obligation of confidentiality (except to the extent such obligation has expired or an exception is applicable under the relevant agreement pursuant to which such obligation was established), by a third party who had no obligation to the disclosing Party not to disclose such information to others.

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(b) *Authorized Disclosure*. Except as expressly provided otherwise in this Agreement, each Party may use and disclose Confidential Information of the other Party solely as follows: (a) under appropriate confidentiality provisions substantially equivalent to those in this Agreement: (i) in connection with the performance of its obligations or as reasonably necessary or useful in the exercise of its rights under this Agreement, including the right to grant licenses or sublicenses as permitted hereunder, or (ii) to actual or potential *bona fide* (sub)licensees, acquirers or assignees, collaborators, investment bankers, investors or lenders with whom a Party (or its Affiliates) has entered into good faith negotiations regarding a proposed transaction, or; (b) to the extent such disclosure is to a governmental authority as reasonably necessary in filing or prosecuting the UHN Patent Rights or Present Improvement Patent Rights, copyright and trademark applications in accordance with this Agreement, prosecuting or defending litigation related to this Agreement, complying with applicable governmental regulations with respect to performance under this Agreement, obtaining Regulatory Approval or fulfilling post-approval regulatory obligations for the Licensed Products, or otherwise required by applicable law; *provided, however*, that if a Party is required by applicable law or the rules of any securities exchange or automated quotation system to make any such disclosure of the other Party's Confidential Information it will, except where impracticable for necessary disclosures (for example, in the event of medical emergency), give reasonable advance notice to the other Party of such disclosure requirement and, in each of the foregoing, will use its reasonable efforts to secure confidential treatment of such Confidential Information required to be disclosed and will only disclosed that Confidential Information that is required to be disclosed; (c) to advisors (including lawyers and accountants) on a need to know basis, in each case under appropriate confidentiality provisions or professional standards of confidentiality substantially equivalent to those of this Agreement, or (d) to the extent mutually agreed to by the Parties. Each Party acknowledges and agrees that the other Party may submit this Agreement to the SEC and if a Party does submit this Agreement to the SEC, such Party agrees to consult with the other Party with respect to the preparation and submission of, a confidential treatment request for this Agreement. If a Party is required by applicable law to make a disclosure of the terms of this Agreement in a filing with or other submission to the SEC, and [*****], then such Party will have the right to make such public disclosure at the time and in the manner reasonably determined by its counsel to be required by applicable law. Notwithstanding anything to the contrary herein, it is hereby understood and agreed that if a Party seeking to make a disclosure to the SEC as set forth in this Section 5.5(b), [*****] such comments, limit disclosure or obtain confidential treatment to the extent reasonably requested by the other Party.

(c) *Press Releases*. Neither Party may issue any press release or make any other public announcement or statement concerning this Agreement, the transactions contemplated hereby or the terms hereof, without the prior written approval of the other Party, except as may be required by applicable law. In the event either Party (the "Issuing Party") desires to issue a press release or other public statement disclosing information relating to this Agreement, the transactions contemplated hereby or the terms hereof, the Issuing Party will provide the other Party (the "Reviewing Party") with a copy of the proposed press release or public statement (the "Release") and seek the Reviewing Party's prior written consent. The Issuing Party will specify with each such Release, taking into account the urgency of the matter being disclosed, a reasonable period of time within which the Receiving Party may provide any comments on such Release and if the Receiving Party fails to provide any comments during the response period called for by the Issuing Party, the Reviewing Party will be deemed to have consented to the issuance of such Release. If the Receiving Party provides any comments, the Parties will consult on such Release and work in good faith to prepare a mutually acceptable Release. Either Party may subsequently publicly disclose any information previously contained in any Release so consented to.

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ARTICLE 6

PATENT PROSECUTION

6.1 Responsibility for UHN Patent Rights. Pursuant to each License Agreement, VistaGen has the right to control the preparation, filing, prosecution, defense in post-grant or post-issuance administrative proceedings, and maintenance of all patents and patent applications in respect of the UHN Patent Rights in the Territory. VistaGen hereby grants to Apollo the sole and exclusive right to exercise all of its rights regarding patent prosecution, maintenance and enforcement under each License Agreement, and VistaGen hereby appoints Apollo to act as its agent, to prepare, file, prosecute, maintain and defend in all agency proceedings (e.g., reissues, reexaminations, oppositions and interferences) all of the UHN Patent Rights during the Term. Likewise, VistaGen hereby grants to Apollo the sole and exclusive right to prepare, file, prosecute, maintain and defend in all agency proceedings (e.g., reissues, reexaminations, oppositions and interferences) any and all patent rights within the Present Improvements (the "Present Improvement Patent Rights" and together with Future Improvement Patent Rights, "Improvement Patent Rights") during the Term. With respect to the foregoing, Apollo shall copy VistaGen on all patent prosecution documents and give VistaGen reasonable opportunities to advise Apollo on such filing, prosecution and maintenance. In the event Apollo desires to abandon any patent or patent application within the UHN Patent Rights or Present Improvement Patent Rights, Apollo shall provide VistaGen with reasonable prior written notice of such intended abandonment or decline of responsibility. If VistaGen elects to continue such patent or patent application, the Parties shall consult and Apollo may elect to retain responsibility therefor. Otherwise, the right to prepare, file, prosecute, maintain and defend the relevant UHN Patent Rights or Present Improvement Patent Rights, at VistaGen's expense, shall revert to VistaGen and with respect to the UHN Patent Rights shall be subject to the terms and conditions of the applicable License Agreement.

6.2 Payment of Expenses. The Parties acknowledge and agree that pursuant to each License Agreement, payment of all fees and costs, including, without limitation, attorney's fees, for the filing, prosecution and maintenance of the UHN Patent Rights incurred by UHN before the Effective Date shall be the responsibility of VistaGen. Apollo shall be responsible for all such fees and costs incurred after the Effective Date. For the avoidance of doubt, Apollo shall not be responsible for payment of any fees and costs associated with the prosecution and maintenance of the UHN Patent Rights or Present Improvement Patent Rights incurred prior to the Effective Date.

6.3 Patent Extensions and Orange or Purple Book Listings. If elections with respect to obtaining patent term extensions (including, without limitation, any available pediatric extensions) or supplemental protection certificates or their equivalents in any country with respect to UHN Patent Rights or Present Improvement Patent Rights are available, Apollo shall have the sole and exclusive right to make any such elections based on Licensed Products. With respect to data exclusivity periods (such as those periods listed in the FDA's Orange or Purple Book (including, without limitation, any available pediatric extensions) or periods under national implementations of Article 10.1(a)(iii) of Directive 2001/EC/83 or orphan exclusivity periods, and all equivalents in any country), Apollo shall have the sole and exclusive right to seek and maintain all such data exclusivity periods available for the Licensed Products. With respect to all of the rights and activities identified in this Section 6.3, VistaGen hereby appoints Apollo as its agent for such purposes with the authority to act on VistaGen's behalf with respect to the UHN Patent Rights or Present Improvement Patent Rights in a manner consistent with this Agreement.

ARTICLE 7

INFRINGEMENT

7.1 Notification of Infringement of Licensed IP or Improvements. Each Party agrees to provide written notice to the other Party promptly after becoming aware of any infringement of the Licensed IP or Improvements by a third party and of any available evidence thereof, including to the extent VistaGen receives notice from UHN of any infringement of the Licensed IP by a third party and of any available evidence thereof.

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7.2 Right to Prosecute Infringements. Pursuant to each License Agreement, VistaGen has the right to determine the appropriate course of action to enforce the Licensed IP or otherwise abate the infringement thereof, to take (or refrain from taking) appropriate action to enforce the Licensed IP, to defend any declaratory judgments seeking to invalidate or hold the Licensed IP unenforceable, to control any litigation or other enforcement action and to enter into, or permit, the settlement of any such litigation, declaratory judgments or other enforcement action with respect to Licensed IP.

(a) Apollo Right to Prosecute. VistaGen hereby assigns to Apollo the first and exclusive right, but not the obligation, under its own control and at its own expense, to prosecute any third party infringement of the Licensed IP or Present Improvements, subject to Sections 7.4 and 7.5. The total cost of any such infringement action commenced or defended solely by Apollo shall be borne by Apollo.

(b) VistaGen Right to Prosecute. If within [*****] after having been notified of any alleged infringement that is material and competitive in the marketplace Apollo is unsuccessful in persuading the alleged infringer to desist and shall not have brought and shall not be diligently prosecuting an infringement action, then VistaGen shall have the right, but shall not be obligated, under its own control and at its own expense, to prosecute any infringement of the Licensed IP or Present Improvements, and, with respect to the Licensed IP, the terms and conditions of the applicable License Agreement shall govern.

7.3 Declaratory Judgment Actions. If a declaratory judgment action is brought naming UHN, VistaGen or Apollo or any of its Affiliates or Sublicensees as a defendant and alleging invalidity, unenforceability or non-infringement of any UHN Patent Rights or Improvement Patent Rights, Apollo or VistaGen, as the case may be, shall promptly notify the other Party in writing and Apollo may elect, upon written notice to VistaGen within [*****] after receiving or giving notice of the commencement of such action, to take over the sole control of such action at its own expense solely with respect to UHN Patent Rights or Present Improvement Patent Rights. If Apollo does not defend any such action, then VistaGen shall have the right, but shall not be obligated, to defend such action at VistaGen's expense and, with respect to the UHN Patent Rights, the terms of the applicable License Agreement shall govern.

7.4 Offsets. Apollo may offset a total of [*****] of any expenses incurred under Sections 7.2 and 7.3 against any payments due to VistaGen under Article 4, provided that in no event shall such payments under Article 4, when aggregated with any other offsets and credits allowed under this Agreement, be reduced by more than [*****] in any Reporting Period.

7.5 Recovery. In the event that either Party exercises the rights conferred in this Article 7 and recovers any damages or other sums in such action, such damages or other sums recovered shall first be applied to all out-of-pocket costs and expenses incurred by the Parties in connection therewith (including, without limitation, attorneys' fees). If such recovery is insufficient to cover all such costs and expenses of both Parties, the controlling Party's costs shall be paid in full first before any of the other Party's costs. If after such reimbursement any funds shall remain from such damages or other sums recovered, such funds shall be retained by the Party that controlled the action or proceeding under this Article 7; provided, however, that (a) if Apollo is the Party that controlled such action or proceeding, VistaGen shall receive out of any such remaining recovery received by Apollo an amount equal to royalties payable hereunder by treating such remaining recovery as "Net Sales" hereunder and (b) if VistaGen is the Party that controlled such action or proceeding, the remaining recovery received by VistaGen shall be shared equally between Apollo and VistaGen.

7.6 Cooperation. Each Party agrees to cooperate in any action under this Article 7 which is controlled by the other Party, including, without limitation, joining such action as a party plaintiff if necessary or desirable for initiation or continuation of such action; provided that the controlling Party reimburses the cooperating Party promptly for any reasonable costs and expenses incurred by the cooperating Party in connection with providing such assistance.

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ARTICLE 8

INDEMNIFICATION AND INSURANCE

8.1 Indemnification of VistaGen. Apollo hereby agrees to indemnify, defend and hold harmless each of VistaGen and its Affiliates and its and their trustees, directors, officers, employees, scientists, agents, successors, assigns and other representatives (collectively, the "VistaGen Indemnitees") from and against all damages, liabilities, losses and other expenses, including, without limitation, reasonable attorney's fees, expert witness fees and costs (collectively, "Losses"), regarding any claims, suits or proceedings brought by a third party, whether or not a lawsuit or other proceeding is filed (collectively "Claim"), that arise out of or relate to (a) any product, process, or service that is made, used, sold, imported, or performed by or on behalf of Apollo pursuant to any right or license granted under this Agreement, (b) Apollo's failure to comply with any applicable laws, rules or regulations in connection with this Agreement and (c) the [*****] of Apollo, except that Apollo's liability for damages under its indemnity shall be reduced or apportioned to the extent any claim is proximately caused by VistaGen's [*****]. [*****].

8.2 Indemnification of Apollo. VistaGen hereby agrees to indemnify, defend and hold harmless Apollo and its Affiliates and its and their trustees, directors, officers, employees, scientists, agents, successors, assigns and other representatives (collectively, the "Apollo Indemnitees") from and against all Losses regarding any Claims that arise out of or relate to (a) any product, process, or service that is made, used, sold, imported, or performed by or on behalf of VistaGen using or incorporating the Licensed IP, (b) VistaGen's failure to comply with any applicable laws, rules or regulations in connection with this Agreement, (c) any Claims brought by UHN with respect to any payments due and payable to UHN under any License Agreement and (d) the [*****] of VistaGen, except that VistaGen's liability for damages under its indemnity shall be reduced or apportioned to the extent any claim is proximately caused by Apollo's [*****].

8.3 Indemnification Procedure. A party entitled to indemnification hereunder shall provide the indemnifying Party with prompt written notice of any claim, suit, action, demand, or judgment for which indemnification is sought under this Agreement. The indemnifying Party shall, at its own expense, provide attorneys reasonably acceptable to the other Party to defend against any such claim. The indemnified Party shall cooperate fully with the indemnifying Party in such defense and shall permit the indemnifying Party to conduct and control such defense and the disposition of such claim, suit, or action (including all decisions relative to litigation, appeal, and settlement).

8.4 Insurance. Within [*****] after the Effective Date, Apollo shall obtain and carry in full force and effect commercial general liability insurance, including, without limitation, product liability and errors and omissions insurance which shall protect Apollo and VistaGen Indemnitees with respect to events covered by Section 8.1. The limits of such insurance shall be customary and reasonable in Apollo's industry. At the request of VistaGen, Apollo shall provide VistaGen with Certificates of Insurance evidencing compliance with this Section 8.4. Apollo shall continue to maintain such insurance after the expiration or termination of this Agreement during any period in which Apollo or any Affiliate or Sublicensee continues to make, use, or sell a product that was a Licensed Product under this Agreement, [*****].

ARTICLE 9

REPRESENTATIONS OR WARRANTIES

9.1 Mutual Representations. Each Party represents and warrants to the other that (i) such Party is a company or corporation duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is organized; (ii) such Party has the legal power and authority to execute, deliver and perform this Agreement; (iii) the execution, delivery and performance by such Party of this Agreement has been duly authorized by all necessary corporate action; (iv) this Agreement constitutes the legal, valid and binding obligation of such Party, enforceable against such Party in accordance with its terms; and (v) the execution, delivery and performance of this Agreement shall not cause or result in a violation of any law, of such Party's charter documents, or of any contract by which such Party is bound.

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9.2 VistaGen Representations, Warranties and Covenants. VistaGen represents, warrants and covenants that:

(a) it has, or will have (with respect to Future Improvements), the power and authority to grant the licenses and sublicenses provided for herein to Apollo, and that it has not earlier granted, or assumed any obligation to grant, any rights in the Licensed IP or Improvements to any third party that would conflict with the rights granted to Apollo herein;

(b) it has obtained from UHN the exclusive right to grant sublicenses (including exclusive sublicenses) under the Licensed IP;

(c) as of the Effective Date, neither UHN nor VistaGen is in breach of any License Agreement, nor has VistaGen received any notification from UHN alleging it is in breach of any License Agreement;

(d) during the Term, in the event that it (i) receives formal written notice from UHN of a material breach of its obligations under any License Agreement or (ii) sends formal written notice to UHN of a material breach of UHN's obligations under any License Agreement, in each of (i) and (ii), it shall promptly provide Apollo a copy of any such written notice;

(e) as of the Effective Date, to its knowledge, there are no actions, suits, investigations, claims or proceedings pending or threatened in writing relating to the Licensed IP or Improvements;

(f) as of the Effective Date, VistaGen has not received any written notice from UHN or any third party with respect to any actions, suits, investigations, claims or proceedings pending or threatened in writing relating to the Licensed IP or Improvements;

(g) other than the License Agreements and the VistaGen SRA, it does not license or does not have the right to license from UHN any other patent rights or other intellectual property applicable to the Apollo Field of Use;

(h) during the Term, VistaGen shall not breach or default under any provision of each License Agreement; and

(i) during the Term and thereafter, VistaGen shall not amend or modify any License Agreement in any manner without the prior written consent of Apollo.

9.3 Disclaimer of Warranties. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY OTHER WARRANTIES CONCERNING LICENSED IP, IMPROVEMENTS OR ANY OTHER MATTER WHATSOEVER, INCLUDING, WITHOUT LIMITATION, ANY EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OF THIRD PARTY RIGHTS OR ARISING OUT OF COURSE OF CONDUCT OR TRADE CUSTOM OR USAGE, AND EACH PARTY DISCLAIMS ALL SUCH EXPRESS OR IMPLIED WARRANTIES. VISTAGEN MAKES NO WARRANTY OR REPRESENTATION AS TO THE VALIDITY OR SCOPE OF UHN PATENT RIGHTS OR IMPROVEMENT PATENT RIGHTS, OR THAT ANY LICENSED PRODUCT SHALL BE FREE FROM AN INFRINGEMENT ON PATENTS OR OTHER INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES. FURTHER, VISTAGEN HAS MADE NO INVESTIGATION AND MAKES NO REPRESENTATION THAT THE UHN PATENT RIGHTS OR IMPROVEMENT PATENT RIGHTS ARE SUITABLE FOR APOLLO'S PURPOSES.

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9.4 Limitation of Liability. EXCEPT FOR [*****], IN NO EVENT SHALL EITHER PARTY BE LIABLE FOR ANY INDIRECT, SPECIAL, INCIDENTAL, EXEMPLARY OR CONSEQUENTIAL DAMAGES (INCLUDING, WITHOUT LIMITATION, DAMAGES FOR LOSS OF PROFITS OR EXPECTED SAVINGS OR OTHER ECONOMIC LOSSES) ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT OR ITS SUBJECT MATTER. EACH PARTY'S AGGREGATE LIABILITY, IF ANY, FOR ALL DAMAGES OF ANY KIND RELATING TO THIS AGREEMENT OR ITS SUBJECT MATTER SHALL NOT EXCEED THE AMOUNT PAID BY APOLLO TO VISTAGEN UNDER THIS AGREEMENT. THE FOREGOING EXCLUSIONS AND LIMITATIONS SHALL APPLY TO ALL CLAIMS AND ACTIONS OF ANY KIND AND ON ANY THEORY OF LIABILITY, WHETHER BASED ON CONTRACT, TORT (INCLUDING, WITHOUT LIMITATION, NEGLIGENCE OR STRICT LIABILITY), OR ANY OTHER GROUNDS, AND REGARDLESS OF WHETHER THE PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, AND NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OF ANY LIMITED REMEDY. THE PARTIES FURTHER AGREE THAT EACH WARRANTY DISCLAIMER, EXCLUSION OF DAMAGES OR OTHER LIMITATION OF LIABILITY HEREIN IS INTENDED TO BE SEVERABLE AND INDEPENDENT OF THE OTHER PROVISIONS SINCE THEY EACH REPRESENT SEPARATE ELEMENTS OF RISK ALLOCATION BETWEEN THE PARTIES.

9.5 Breach by VistaGen. In the event that VistaGen commits a breach of any License Agreement and Apollo receives notice of such breach, within [*****] of the receipt of any such notice of breach, subject to any cure period permitted under the applicable License Agreement, Apollo may request to meet with UHN and VistaGen and representatives of the Parties shall meet and discuss in good faith a potential cure of such breach in accordance with the terms of the applicable License Agreement. In the event VistaGen is unable to cure such breach, VistaGen hereby provides Apollo (or any of its Affiliates or Sublicensees) the right, but not the obligation, to cure such breach directly with UHN on VistaGen's behalf in accordance with the terms of the applicable License Agreement. VistaGen shall reimburse Apollo (or any of its Affiliates or Sublicensees) for any and all costs and expenses incurred in attempting to cure, or curing, such breach. In the event such breach is unable to be cured or is not cured (including because Apollo does not elect to cure such breach), at Apollo's request, VistaGen shall use all reasonable efforts to assist Apollo in entering into a direct license with UHN equal in scope to the sublicense set forth in Article 2, [*****]. VistaGen further agrees not to impede, restrict or otherwise interfere with the entrance of Apollo and UHN into such direct license.

9.6 Breach by UHN. In the event that UHN commits a material breach of any License Agreement and such License Agreement is terminated as a result of such breach, VistaGen shall delegate to Apollo, or pursue at Apollo's written request and expense, any cause of action that VistaGen may have pursuant to the terms of the applicable License Agreement.

ARTICLE 10

ASSIGNMENT

This Agreement, and the rights and obligations hereunder, may not be assigned or transferred, in whole or in part, by either Party without the prior written consent of the other Party, except that no consent shall be required for either Party to assign this Agreement to (i) any entity acquiring it or all or substantially all of the assets of such Party as to which this Agreement relates whether by sale, merger, operation of law or otherwise (including, for clarity, with respect to VistaGen all of the License Agreements), or (ii) any of its Affiliates; provided that upon any such assignment with respect to VistaGen, VistaGen shall similarly assign each License Agreement and that certain letter agreement by and among UHN, Apollo and VistaGen effective as of the date hereof (the "Letter Agreement") such that the VistaGen contracting party in each License Agreement and the Letter Agreement is the same VistaGen contracting party as in this Agreement. Each Party shall notify the other Party no later than **[*****]** after any assignment of this Agreement. Any assignment in circumvention of the foregoing shall be void. Subject to the foregoing, this Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective permitted successors and assigns.

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ARTICLE 11

GENERAL COMPLIANCE WITH LAW

11.1 Compliance with Laws. Apollo shall use reasonable commercial efforts to comply with all commercially material local, state, federal, and international laws and regulations relating to the development, manufacture, use, and sale of Licensed Products.

11.2 Export Control. Apollo and its Affiliates and Sublicensees shall comply with all United States laws and regulations controlling the export of certain commodities and technical data, including, without limitation, all Export Administration Regulations of the United States Department of Commerce. Among other things, these laws and regulations prohibit or require a license for the export of certain types of commodities and technical data to specified countries. Apollo hereby gives written assurance that it shall comply with, and shall cause its Affiliates and Sublicensees to comply with, all United States export control laws and regulations, that it bears sole responsibility for any violation of such laws and regulations by itself or its Affiliates or Sublicensees, and that it shall indemnify, defend, and hold VistaGen harmless (in accordance with Section 8.1) for the consequences of any such violation.

11.3 Marking of Licensed Products. To the extent commercially feasible and consistent with prevailing business practices, Apollo shall mark, and shall cause its Affiliates and Sublicensees to mark, all Licensed Products that are manufactured or sold under this Agreement with the number of each issued patent under the UHN Patent Rights or Improvement Patent Rights that applies to such Licensed Product.

ARTICLE 12

TERMINATION

12.1 Term. Unless earlier terminated in accordance with the provisions of this Article 12, this Agreement shall continue in force on a country-by-country and Licensed Product-by-Licensed Product basis until the expiration of the last to expire patent within the UHN Patent Rights or Improvement Patent Rights (the "Term"). Following the end of the Term for any such Licensed Product in such country by expiration (but not termination), the licenses granted to Apollo under Sections 2.1(a)-(c) will become perpetual, irrevocable, non-terminable, fully paid-up and royalty-free.

12.2 Voluntary Termination by Apollo.

(a) Apollo shall have the right to terminate this Agreement, for any reason, upon at least [*****] prior written notice to VistaGen, such notice to state the date at least [*****] in the future upon which termination is to be effective.

(b) Apollo shall have the right to terminate this Agreement immediately upon written notice to VistaGen on a Licensed IP-by-Licensed IP, UHN Patent Right-by-UHN Patent Right, Improvement-by-Improvement or Improvement Patent Right-by-Improvement Patent Right basis, such notice to state the Licensed IP, UHN Patent Right, Improvement or Improvement Patent Right for which such termination shall be applicable (such terminated patent right or other intellectual property, the "Terminated IP"). In the event Apollo provides such notice, the Terminated IP will no longer be subject to this Agreement, all licenses or sublicenses to such Terminated IP will terminate and Apollo shall have no further rights or obligations with respect to such Terminated IP as of the date of VistaGen's receipt of such written notice.

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12.3 Termination for Breach.

(a) In the event Apollo commits a material breach of its obligations under this Agreement, and fails to cure that breach within [*****] after receiving written notice thereof, VistaGen may terminate this Agreement immediately upon written notice to Apollo, subject to completion of the dispute resolution process set forth in Article 13 and subsequent cure. Notwithstanding the foregoing, if VistaGen terminates this Agreement due to Apollo's failure to timely pay the sublicense and license issue fee required in Section 4.1(a), the termination is effective upon notice and the dispute resolution process set forth in Article 13 shall not apply to such termination.

(b) In the event VistaGen commits a material breach of its obligations under this Agreement, Apollo may, in its discretion, either (i) terminate this Agreement if VistaGen has not cured such breach within [*****] after receipt of written notice thereof or (ii) continue this Agreement and seek arbitration pursuant to Article 13 confirming that such breach has in fact occurred and/or seeking specific performance, and if such arbitration finds that such breach indeed has occurred, then any future payments to VistaGen pursuant to Article 4 of this Agreement shall be reduced by [*****] as of the termination date.

12.4 Other Grounds for Bankruptcy. A Party may terminate this Agreement immediately if the other Party hereto is declared insolvent or commits an act of bankruptcy.

12.5 Effect of Expiration or Termination.

(a) Survival. The following provisions shall survive the expiration or termination of this Agreement: Article 1, Article 8, Article 9, Article 13 and Article 14, and Sections 4.1(f), 5.2 (but only with respect to obligation to provide final report and payment), 5.3, 11.1, 11.2, 12.1 (but only with respect to the second sentence) and 12.5.

(b) Inventory. Upon the early termination of this Agreement, Apollo and its Affiliates and Sublicensees may complete and sell any work-in-progress and inventory of Licensed Products that exist as of the effective date of termination, provided that (i) Apollo pays VistaGen the applicable running royalty or other amounts due on Net Sales of any Revenue Bearing Products in accordance with the terms and conditions of this Agreement, and (ii) Apollo and its Affiliates and Sublicensees shall complete and sell all work-in-progress and inventory of Licensed Products after the effective date of termination.

(c) Expiration or termination of this Agreement for any reason shall not relieve either Party of any liability or obligation which accrued hereunder prior to the effective date of such termination or expiration.

ARTICLE 13

DISPUTE RESOLUTION

13.1 Mandatory Procedures. The Parties agree that any dispute arising out of or relating to this Agreement shall be resolved solely by means of the procedures set forth in this Article 13, and that such procedures constitute legally binding obligations that are an essential provision of this Agreement. If either Party fails to observe the procedures of this Article 13, as may be modified by their written agreement, the other Party may bring an action for specific performance of these procedures in any court of competent jurisdiction.

13.2 Equitable Remedies. Although the procedures specified in this Article 13 are the sole and exclusive procedures for the resolution of disputes arising out of or relating to this Agreement, either Party may seek a preliminary injunction or other provisional equitable relief if, in its reasonable judgment, such action is necessary to avoid irreparable harm to itself or to preserve its rights under this Agreement.

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13.3 Dispute Resolution Procedures. Any controversy or claim arising out of or relating to this Agreement, or the breach thereof, shall be settled by binding confidential arbitration in accordance with the Commercial Arbitration Rules (the "Rules") of the American Arbitration Association ("AAA"), and the procedures set forth below. In the event of any inconsistency between the Rules of AAA and the procedures set forth below, the procedures set forth below shall control. Judgment upon the award rendered by the arbitrators may be enforced in any court having jurisdiction thereof.

(a) The location of the arbitration shall be in the County of New York. VistaGen and Apollo hereby irrevocably submit to the exclusive jurisdiction and venue of the AAA arbitration panel selected by the Parties and located in New York, New York for any dispute regarding this Agreement, and to the exclusive jurisdiction and venue of the federal and state courts located in New York, New York for any action or proceeding to enforce an arbitration award or as otherwise provided in Section 13.3(e), and waive any right to contest or otherwise object to such jurisdiction or venue.

(b) The arbitration shall be conducted by a panel of three neutral arbitrators who are independent and disinterested with respect to the Parties, this Agreement, and the outcome of the arbitration. Each Party shall appoint one neutral arbitrator, and these two arbitrators so selected by the Parties shall then select the third arbitrator, and all arbitrators must have at least ten (10) years' experience in mediating or arbitrating cases regarding the same or substantially similar subject matter as the dispute between VistaGen and Apollo. If one Party has given written notice to the other Party as to the identity of the arbitrator appointed by the Party, and the Party thereafter makes a written demand on the other Party to appoint its designated arbitrator within the next ten days, and the other Party fails to appoint its designated arbitrator within ten days after receiving said written demand, then the arbitrator who has already been designated shall appoint the other two arbitrators.

(c) The arbitrators shall decide any disputes and shall control the process concerning these pre-hearing discovery matters. Pursuant to the Rules of AAA, the Parties may subpoena witnesses and documents for presentation at the hearing.

(d) Prompt resolution of any dispute is important to both Parties; and the Parties agree that the arbitration of any dispute shall be conducted expeditiously. The arbitrators are instructed and directed to assume case management initiative and control over the arbitration process (including, without limitation, scheduling of events, pre-hearing discovery and activities, and the conduct of the hearing), in order to complete the arbitration as expeditiously as is reasonably practical for obtaining a just resolution of the dispute.

(e) The arbitrators may grant any legal or equitable remedy or relief that the arbitrators deem just and equitable, to the same extent that remedies or relief could be granted by a state or federal court, provided however, that no punitive damages may be awarded. No court action shall be maintained seeking punitive damages. The decision of any two of the three arbitrators appointed shall be binding upon the Parties. Notwithstanding anything to the contrary in this Agreement, prior to or while an arbitration proceeding is pending, either Party has the right to seek and obtain injunctive and other equitable relief from a court of competent jurisdiction to enforce that Party's rights hereunder.

(f) The expenses of the arbitration, including, without limitation, the arbitrators' fees, expert witness fees, and attorney's fees, may be awarded to the prevailing Party, in the discretion of the arbitrators, or may be apportioned between the Parties in any manner deemed appropriate by the arbitrators. Unless and until the arbitrators decide that one Party is to pay for all (or a share) of such expenses, both Parties shall share equally in the payment of the arbitrators' fees as and when billed by the arbitrators.

(g) Notwithstanding the foregoing, any disputes arising hereunder with respect to the inventorship, validity, enforceability or other aspect of intellectual property rights shall be resolved by a court of competent jurisdiction and not by arbitration.

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(h) Except as set forth below and as necessary to obtain or enforce a judgment upon any arbitration award, the Parties shall keep confidential the fact of the arbitration, the dispute being arbitrated, and the decision of the arbitrators. Notwithstanding the foregoing, the Parties may disclose information about the arbitration to persons who have a need to know, such as directors, trustees, management employees, witnesses, experts, investors, attorneys, lenders, insurers, actual or potential collaborators or corporate partners of Apollo, actual or potential acquirors of Apollo, and others who may be directly affected provided that such persons are bound to keep such information confidential. Additionally, if a Party has stock which is publicly traded, the Party may make such disclosures as are required by applicable securities laws, but shall use commercially reasonably efforts to seek confidential treatment for such disclosure.

13.4 Performance to Continue. Each Party shall continue to perform its undisputed obligations under this Agreement pending final resolution of any dispute arising out of or relating to this Agreement; provided, however, that a Party may suspend performance of its undisputed obligations during any period in which the other Party fails or refuses to perform its undisputed obligations.

13.5 Statute of Limitations. The Parties agree that all applicable statutes of limitation and time-based defenses (such as estoppel and laches) shall be tolled while the procedures set forth in Section 13.5 are pending. The Parties shall cooperate in taking any actions necessary to achieve this result.

ARTICLE 14

MISCELLANEOUS

14.1 Notice. Any notices required or permitted under this Agreement shall be in writing, shall specifically refer to this Agreement, and shall be sent by hand, recognized national overnight courier, confirmed facsimile transmission, confirmed electronic mail, or registered or certified mail, postage prepaid, return receipt requested, to the following addresses or facsimile numbers of the Parties:

If to VistaGen:

VistaGen Therapeutics, Inc.
343 Allerton Ave
South San Francisco, CA 94080
Attention: Shawn K. Singh, CEO

If to Apollo:

Apollo Biologics LP
c/o Versant Venture Management, LLC
One Sansome
Suite 3630
San Francisco, CA 94104
Attention: Jerel Davis, Authorized Representative

All notices under this Agreement shall be deemed effective upon receipt. A Party may change its contact information immediately upon written notice to the other Party in the manner provided in this Section 14.1.

14.2 Governing Law. This Agreement and all disputes arising out of or related to this Agreement, or the performance, enforcement, breach or termination hereof, and any remedies relating thereto, shall be construed, governed, interpreted and applied in accordance with the laws of the State of Delaware, without regard to conflict of laws principles, except that questions affecting the construction and effect of any patent shall be determined by the law of the country in which the patent shall have been granted.

***** **VISTAGEN THERAPEUTICS, INC. HAS REQUESTED THAT THE OMITTED PORTIONS OF THIS DOCUMENT, WHICH ARE INDICATED BY [*****], BE AFFORDED CONFIDENTIAL TREATMENT. VISTAGEN THERAPEUTICS, INC. HAS SEPARATELY FILED THE OMITTED PORTIONS OF THE DOCUMENT WITH THE SECURITIES AND EXCHANGE COMMISSION.**

14.3 Force Majeure. Neither Party shall be responsible for delays resulting from causes beyond the reasonable control of such Party, including, without limitation fire, explosion, flood, war, strike, or riot, provided that the nonperforming Party uses commercially reasonable efforts to avoid or remove such causes of nonperformance and continues performance under this Agreement with reasonable dispatch whenever such causes are removed.

14.4 Amendment and Waiver. This Agreement may be amended, supplemented, or otherwise modified only by means of a written instrument signed by both Parties. Any waiver of any rights or failure to act in a specific instance shall relate only to such instance and shall not be construed as an agreement to waive any rights or fail to act in any other instance, whether or not similar.

14.5 Severability. In the event that any provision of this Agreement shall be held invalid or unenforceable for any reason, such invalidity or unenforceability shall not affect any other provision of this Agreement, and the Parties shall negotiate in good faith to modify this Agreement to preserve (to the extent possible) their original intent. If the Parties fail to reach a modified agreement within thirty (30) days after the relevant provision is held invalid or unenforceable, then the dispute shall be resolved in accordance with the procedures set forth in Article 13. While the dispute is pending resolution, this Agreement shall be construed as if such provision were deleted by agreement of the Parties.

14.6 Binding Effect. This Agreement shall be binding upon and inure to the benefit of the Parties and their respective legal representatives, successors and assigns.

14.7 Headings. All headings are for convenience only and shall not affect the meaning of any provision of this Agreement.

14.8 Entire Agreement. This Agreement constitutes the entire agreement between the Parties with respect to its subject matter and supersedes all prior agreements or understandings between the parties relating to its subject matter.

14.9 Construction. The use of words in the singular or plural, or with a particular gender, shall not limit the scope or exclude the application of any provision of this Agreement to such person or persons or circumstances as the context otherwise permits. The words “will” and “shall” shall have the same meaning and, unless the context otherwise requires, the use of the word “or” is used in the inclusive sense (and/or). The term “including, “include,” or “includes” as used herein shall mean including, without limiting the generality of any description preceding such term, irrespective of whether such term is used “without limitation” or “without limiting” throughout this Agreement.

14.10 Counterparts. This Agreement may be executed in counterparts signed separately by the Parties, each of which together shall constitute one and the same instrument. Execution of this Agreement may be concluded by signing and delivery by electronic transmission to a Party of the other Party’s signed copy.

[*remainder of this page intentionally left blank*]

***** **VISTAGEN THERAPEUTICS, INC. HAS REQUESTED THAT THE OMITTED PORTIONS OF THIS DOCUMENT, WHICH ARE INDICATED BY [*****], BE AFFORDED CONFIDENTIAL TREATMENT. VISTAGEN THERAPEUTICS, INC. HAS SEPARATELY FILED THE OMITTED PORTIONS OF THE DOCUMENT WITH THE SECURITIES AND EXCHANGE COMMISSION.**

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives.

VISTAGEN THERAPEUTICS, INC.

By: /s/ Shawn K. Singh

Name: Shawn K. Singh

Title: Chief Executive Officer

APOLLO BIOLOGICS LP

By: BJD Newco, LLC, its general partner

By: /s/ Jerel Davis
Name: Jerel Davis
Title: Authorized Representative

EXHIBIT A

LICENSED IP

[*****]

[*****]

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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.

February 13, 2017

/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.

February 13, 2017

/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 December 31, 2016 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.

February 13, 2017

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

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