

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

Form 10-K

Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the fiscal year ended: March 31, 2017

or

Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Commission file number: 001-37761

VistaGen Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Nevada

(State or other jurisdiction of
incorporation or organization)

20-5093315

(I.R.S. Employer
Identification No.)

**343 Allerton Avenue
South San Francisco, California 94080
(650) 577-3600**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive office)

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

Title of each class
Common Stock, par value \$0.001 per share

Name of each exchange on which registered
The NASDAQ Capital Market

Securities registered pursuant to Section 12(g) of the Act

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes No

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company Emerging Growth Company

(Do not check if a smaller
reporting company)

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

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

The aggregate market value of the common stock of the registrant held by non-affiliates of the registrant on September 30, 2016, the last business day of the registrant's second fiscal quarter, was: \$34,033,497.

As of June 27, 2017, there were 9,301,472 shares of the registrant's common stock, \$0.001 par value per share, outstanding.

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Forward-Looking Statements

This Annual Report on Form 10-K (*Annual Report*) contains forward-looking statements that involve substantial risks and uncertainties. All statements contained in this Annual Report other than statements of historical facts, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

The words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “target,” “potential,” “will,” “would,” “could,” “should,” “continue,” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among other things, statements about:

- the availability of capital to satisfy our working capital requirements, including our clinical and non-clinical development objectives;
- the accuracy of our estimates regarding expenses, future revenues and capital requirements;
- our plans to develop and commercialize our lead product candidate, AV-101, initially as a treatment for Major Depressive Disorder (*MDD*), and subsequently as a treatment for additional diseases and disorders involving the Central Nervous System (*CNS*);
- our ability to initiate and complete our clinical trials, including our proposed Phase 2 clinical study of AV-101 for MDD, and to advance AV-101 and other product candidates into additional clinical trials, including pivotal clinical trials, and successfully complete such clinical trials;
- regulatory developments in the U.S. and foreign countries;
- the performance of the U.S. National Institute of Mental Health, our third-party contract manufacturer(s), contract research organization(s) and other third-party non-clinical and clinical drug development collaborators and regulatory service providers;
- our ability to obtain and maintain intellectual property protection for our core assets, including our product candidates;
- the size of the potential markets for our product candidates and our ability to serve those markets;
- the rate and degree of market acceptance of our product candidates for any indication once approved;
- the success of competing products and product candidates in development by others that are or become available for the indications that we are pursuing;
- the loss of key scientific, clinical or non-clinical development, regulatory, and/or management personnel, internally or from one of our third-party collaborators; and
- other risks and uncertainties, including those listed under Part I, Item 1A of this Annual Report titled “*Risk Factors*.”

These forward-looking statements are only predictions and we may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, so you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. 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 business, financial condition and operating results. We have included important factors in the cautionary statements included in this Annual Report, particularly in Part I, Item 1A, titled “*Risk Factors*,” that could cause actual future results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this Annual Report and the documents that we have filed as exhibits to the Annual Report with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

PART I

All brand names or trademarks appearing in this report are the property of their respective holders. Unless the context requires otherwise, references in this report to “VistaGen,” the “Company,” “we,” “us,” and “our” refer to VistaGen Therapeutics, Inc., a Nevada corporation.

Item 1. Business

Company Overview

We are a clinical-stage biopharmaceutical company focused on developing new generation medicines for depression and other central nervous system (CNS) disorders.

AV-101 is our oral CNS product candidate in Phase 2 clinical development in the United States, initially as a new generation 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). AV-101’s mechanism of action (MOA) involves both NMDA (N-methyl-D-aspartate) and AMPA (alpha-amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid) receptors in the brain responsible for fast excitatory synaptic activity throughout the CNS. AV-101’s MOA is fundamentally differentiated from all FDA-approved antidepressants, as well as all atypical antipsychotics often used adjunctively to augment them. We believe AV-101 also has potential as a new treatment alternative for several additional indications involving the CNS, including epilepsy, Huntington’s disease, L-DOPA-induced dyskinesia associated with Parkinson’s disease, and neuropathic pain.

Clinical studies conducted at the U.S. National Institute of Mental Health (NIMH), part of the U.S. National Institutes of Health (NIH), by 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, have focused on the antidepressant effects of low dose ketamine hydrochloride injection (ketamine), an NMDA receptor antagonist, in MDD patients with inadequate responses to multiple standard antidepressants. These NIMH studies, as well as clinical research at Yale University and other academic institutions, have demonstrated robust antidepressant effects in these MDD patients within twenty-four hours of a single sub-anesthetic dose of ketamine administered by intravenous (IV) injection.

We believe orally-administered AV-101 may have potential to deliver ketamine-like antidepressant effects without ketamine’s psychological and other negative side effects. As published in the October 2015 issue of the peer-reviewed, *Journal of Pharmacology and Experimental Therapeutics*, in an article titled, *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. In addition, these studies confirmed that the fast-acting antidepressant effects of AV-101 were mediated through both inhibiting the GlyB site of the NMDA receptor and activating the AMPA receptor pathway in the brain.

Pursuant to our Cooperative Research and Development Agreement (CRADA) with the NIMH, the NIMH is funding, and Dr. Zarate, as Principal Investigator, and his team are conducting, a small Phase 2 clinical study of AV-101 monotherapy in subjects with treatment-resistant MDD (the *NIMH AV-101 MDD Phase 2 Monotherapy Study*). We are preparing to launch our 180-patient Phase 2 multi-center, multi-dose, double blind, placebo-controlled efficacy and safety study of AV-101 as a new generation adjunctive treatment of MDD in adult patients with an inadequate response to standard, FDA-approved antidepressants (the *AV-101 MDD Phase 2 Adjunctive Treatment Study*). 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 our AV-101 MDD Phase 2 Adjunctive Treatment 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 completing our AV-101 MDD Phase 2 Adjunctive Treatment Study by the end of 2018 with top line results available in the first quarter of 2019.

VistaStem Therapeutics (VistaStem) is our wholly owned subsidiary focused on applying human pluripotent stem cell (hPSC) technology, internally and with collaborators, to discover, rescue, develop and commercialize (i) proprietary new chemical entities (NCEs) for CNS and other diseases and (ii) regenerative medicine (RM) involving hPSC-derived blood, cartilage, heart and liver cells. Our internal drug rescue programs are designed to utilize *CardioSafe 3D*, our customized cardiac bioassay system, to develop small molecule NCEs for our pipeline. In December 2016, we exclusively sublicensed to BlueRock Therapeutics LP, a next generation RM company established 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*). In a manner similar to our exclusive sublicense agreement with BlueRock Therapeutics, VistaStem may pursue additional RM collaborations or licensing transactions involving blood, cartilage, and/or liver cells derived from hPSCs for (A) cell-based therapy, (B) cell repair therapy, and/or (C) tissue engineering.

AV-101 and Major Depressive Disorder

Background

The World Health Organization (WHO) estimates that 300 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, approximately 16 million adults in the U.S. had at least one major depressive episode in the past year. 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 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 do not obtain adequate therapeutic benefit from initial treatment with a standard antidepressant. Even after treatment with many different standard antidepressants, nearly one out of every three drug-treated depression patients still do not achieve adequate therapeutic benefits from their antidepressant medication. Such patients with an inadequate response to standard antidepressants often seek to augment their treatment regimen by adding an atypical antipsychotic (drugs such as aripiprazole), despite only modest potential therapeutic benefit and the risk of additional side effects.

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

AV-101

AV-101 is our oral CNS drug candidate in Phase 2 development in the United States, initially focused as a new generation antidepressant for the adjunctive treatment of MDD patients with an inadequate response to standard, FDA-approved antidepressants. As published in the October 2015 issue of the peer-reviewed, *Journal of Pharmacology and Experimental Therapeutics*, in an article titled, *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 ketamine-like antidepressant effects following a single treatment, responses equivalent to those seen with a single sub-anesthetic control dose of ketamine, without the negative side effects seen with ketamine. In addition, these studies confirmed that the antidepressant effects of AV-101 were mediated through both inhibition of the GlyB site of NMDA receptors and activation of the AMPA receptor pathway in the brain, a key final common pathway feature of certain new generation antidepressants such as ketamine and AV-101, each with a MOA that is fundamentally different from all standard antidepressants and atypical antipsychotics used adjunctively to augment them.

We have completed two NIH-funded, randomized, double blind, placebo-controlled AV-101 Phase 1 safety studies. Currently, pursuant to our CRADA with Dr. Carlos Zarate, Jr., the NIMH is funding, and Dr. Zarate, as Principal Investigator, and his team are conducting, the 20 patient NIMH AV-101 MDD Phase 2 Monotherapy Study. We currently anticipate that the NIMH will complete the NIMH AV-101 MDD Phase 2 Monotherapy Study in 2017, with top line results during the first half of 2018.

We are currently preparing to launch our 180-patient AV-101 MDD Phase 2 Adjunctive Treatment Study as an adjunctive treatment of MDD in patients with an inadequate response to standard, FDA-approved antidepressants. We currently anticipate the launch of the AV-101 MDD Phase 2 Adjunctive Treatment Study, with Dr. Maurizio Fava of Harvard Medical School serving as Principal Investigator, in the first quarter of 2018. Subject to securing adequate financing, we currently anticipate completing our AV-101 MDD Phase 2 Adjunctive Treatment Study by the end of 2018 with top line results available in the first quarter of 2019.

We believe preclinical studies and Phase 1 safety studies support our hypothesis that AV-101 may also have potential to treat multiple CNS disorders and diseases beyond MDD, including epilepsy, neuropathic pain, Huntington's disease, L-DOPA-induced dyskinesia associated with Parkinson's disease, and several other CNS indications where modulation of the NMDA receptor, activation of AMPA pathways and/or key active metabolites of AV-101 may achieve therapeutic benefit. We are beginning to plan additional Phase 2 clinical studies of AV-101 to further evaluate its therapeutic potential beyond MDD.

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 small molecule NCEs 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. Potential commercial applications of our stem cell technology platform involve (i) using *CardioSafe 3D* internally for NCE drug discovery and drug rescue to expand our proprietary drug candidate pipeline. Drug rescue involves leveraging substantial prior research and development investments by pharmaceutical companies and others related to public domain NCE programs terminated before FDA approval due to heart toxicity risks and (ii) RM and cellular therapies. In December 2016, we exclusively sublicensed to BlueRock Therapeutics LP, a next generation regenerative medicine company established 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. 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 Agreement, we may pursue these additional RM and cellular therapy applications in collaboration with third-parties.

Subsidiaries

VistaGen Therapeutics, Inc., a California corporation dba VistaStem Therapeutics (*VistaStem*), is our wholly-owned subsidiary. Our 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.

Our Strategy

Our core strategy is to develop and commercialize innovative small molecule drugs that address significant unmet medical needs related to CNS diseases and disorders. We have assembled a management team and a team of scientific, clinical, and regulatory advisors, including recognized experts in the fields of depression and other CNS disorders, with significant industry and regulatory experience to lead and execute the development and commercialization of our CNS product candidate opportunities. Key elements of our strategy are to:

- **Develop and commercialize our lead CNS product candidate, AV-101, initially as a new generation adjunctive treatment for MDD patients with an inadequate response to standard, FDA-approved antidepressants.** We are currently pursuing adjunctive treatment of MDD as our lead indication for AV-101. We are preparing to launch our approximately 180-patient AV-101 MDD Phase 2 Adjunctive Treatment Study of AV-101 for the adjunctive treatment of MDD in patients with an inadequate response to standard antidepressants. We intend to develop AV-101 internally, through a pivotal Phase 3 clinical program focused on adjunctive treatment of MDD, accompanied by submission of our New Drug Application (NDA) for AV-101 to the FDA. If our NDA is approved by the FDA, we plan to commercialize AV-101 for this indication in the U.S. either by (A) collaborating with a large pharmaceutical company with a strong commercial presence in global depression and other CNS markets and/or (B) contracting for specialty sales force support focused primarily on psychiatrists and long-term care physicians who prescribe standard antidepressants and atypical antipsychotics for treatment of their MDD patients.
- **Leverage the commercial potential of AV-101 by expanding Phase 2 development to include additional CNS-related disorders and diseases.** We intend to pursue broad clinical development and commercialization of AV-101 across a range of CNS-related indications that are underserved by currently available medicines and represent significant unmet medical needs. Based on AV-101 preclinical studies, our successful NIH-funded AV-101 Phase 1a and 1b clinical safety studies, and regulatory submissions related to the AV-101 MDD Phase 2 Adjunctive Treatment Study, we expect to have opportunities to expand Phase 2 development of AV-101 beyond MDD to include other CNS indications, such as neuropathic pain, epilepsy, Huntington's disease and L-DOPA-induced dyskinesia associated with Parkinson's disease, where modulation of the NMDA receptors, the AMPA receptor pathway and/or key active metabolites of AV-101 may achieve therapeutic benefit.
- **Capitalize on our drug rescue and RM opportunities using our stem cell technology platform.** We are focused on using our cardiac stem cell technology to screen and develop proprietary NCEs through drug rescue programs intended to produce proprietary NCEs for our internal drug development pipeline, without incurring many of the substantial costs and risks typically inherent in new drug discovery and non-clinical drug development. In order to capitalize on our existing stem cell technology, we may establish additional strategic collaborations similar to the BlueRock Agreement, as well as investigating potential spin-off opportunities. As most of our resources are currently focused on the non-clinical and clinical development activities we believe are necessary to advance AV-101 through Phase 2 and into pivotal Phase 3 development, a strategic collaboration or spin-off involving our stem cell technology could allow us to capitalize on our existing stem cell technology and shift our focus exclusively to developing our CNS pipeline.
- **Pursue in-licensing and acquisition of additional CNS product candidates.** While our resources are currently focused primarily on development of AV-101 for MDD and additional CNS indications, we anticipate pursuing acquisition of additional CNS-related product candidates in the future. We believe that a diversified CNS product candidate portfolio will mitigate risks inherent in drug development and increase the likelihood of our success.
- **Grow our internal development pipeline through drug rescue using our cardiac stem cell technology platform.** We have developed our cardiac bioassay system, *CardioSafe* 3D, for drug rescue applications intended to produce proprietary small molecule NCEs for our internal drug development pipeline, without incurring many of the substantial costs and risks typically inherent in new drug discovery and non-clinical drug development.

AV-101 (L-4-cholorkyurenine or 4-Cl-KYN)

Overview and Mechanism of Action

AV-101 is an orally available, clinical-stage prodrug candidate that readily gains access to the CNS after systemic administration and is rapidly converted *in vivo* into its active metabolite, 7-chlorokynurenic acid (*7-Cl-KYNA*), a well-characterized, potent and highly selective antagonist of the NMDA receptor at its GlyB co-agonist site.

Current evidence suggests that AV-101's antagonism of NMDA receptor signaling may provide faster-acting antidepressant effects in the treatment of MDD than standard antidepressants. In addition, as confirmed in our AV-101 Phase 1 clinical studies, targeting the GlyB site of the NMDA receptor does not have the negative side effects typically associated with standard antidepressants and channel-blocking NMDA receptor antagonists, such as ketamine.

Major Depressive Disorder

Depression is a serious medical illness and a global public health concern. The WHO estimates that depression is the leading cause of disability worldwide, and is a major contributor to the global burden of disease, affecting 300 million people globally. According to the CDC, approximately one in every 10 Americans aged 12 and over takes antidepressant medication.

While most people will experience depressed mood at some point during their lifetime, MDD is different. MDD is the chronic, pervasive feeling of utter unhappiness and suffering, which impairs daily functioning. Symptoms of MDD include diminished pleasure in activities, changes in appetite that result in weight changes, insomnia or oversleeping, psychomotor agitation, loss of energy or increased fatigue, feelings of worthlessness or inappropriate guilt, difficulty thinking, concentrating or making decisions, and thoughts of death or suicide and attempts at suicide. Suicide is estimated to be the cause of death in up to 15% individuals with MDD.

Standard Antidepressants

For many people, depression cannot be controlled for any length of time without treatment. Standard antidepressant medications available in the multi-billion dollar global depression market, including commonly-prescribed SSRIs and SNRIs, have limited effectiveness, and, because of their mechanism of action, must be taken for several weeks or months before patients experience any significant therapeutic benefit. About two out of every three depression sufferers, including over an estimated 6.0 million drug-treated MDD patients in the U.S., do not receive adequate therapeutic benefits from their initial treatment with a standard antidepressant, and the likelihood of achieving remission of depressive symptoms declines with each successive treatment attempt. Even after multiple treatment attempts, approximately one out of every three depression sufferers still fails to find an adequately effective standard antidepressant. In addition, this trial and error process and the systemic effects of the various antidepressants involved may increase the risk of patient tolerability issues and serious side effects, including suicidal thoughts and behaviors in certain groups.

Ketamine and NIH Clinical Studies in Major Depressive Disorder

Ketamine hydrochloride (*ketamine*) is an FDA-approved, rapid-acting general anesthetic currently administered only by intravenous (*IV*) or intramuscular (*IM*) injection. The use of ketamine (an NMDA receptor antagonist which acts as an NMDA channel blocker) to treat MDD has been studied in several clinical trials conducted by depression experts at Yale University and other academic institutions and at the NIMH, including Dr. Carlos Zarate, Jr., the NIMH's Chief of Experimental Therapeutics & Pathophysiology Branch and of the Section on Neurobiology and Treatment of Mood and Anxiety Disorders. In randomized, placebo-controlled, double blind clinical trials reported by Dr. Zarate and others at the NIMH, a single low dose of ketamine (0.5 mg/kg over 40 minutes) produced robust and rapid antidepressant effects in MDD patients who had not responded to standard antidepressants. These results were in contrast to the very slow onset of SSRIs and SNRIs that usually require many weeks or months of chronic usage to achieve similar antidepressant effects. The potential for widespread therapeutic use of current FDA-approved ketamine, a Schedule III drug, for MDD is limited by its potential for abuse, dissociative and psychosis-like side effects and by practical challenges associated with the necessity of I.V. administration in a medical center. Notwithstanding these limitations, however, the discovery of ketamine's fast-acting antidepressant effects revolutionized thinking about the current MDD treatment paradigm and catalyzed development of a new generation of antidepressants with faster-acting mechanisms of action similar to ketamine's. Our orally available AV-101 is among the next generation of antidepressants with potential to deliver faster-onset antidepressant effects than standard antidepressants, without the side effects typically associated with standard antidepressants or ketamine.

AV-101 and Major Depressive Disorder

AV-101 is an orally available prodrug candidate that produces, in the brain, 7-Cl-KYNA, one of the most potent and selective antagonists of the GlyB site of the NMDA receptor, resulting in the down-regulation of NMDA receptor signaling. Growing evidence suggests that glutamatergic activation involving AMPA receptors is central to the neurobiology and treatment of MDD and other mood disorders.

AV-101's mechanism of action is fundamentally differentiated from all standard, FDA-approved antidepressants and all atypical antipsychotics often used adjunctively to augment inadequate response to standard antidepressants, placing AV-101 among a new generation of antidepressants with potential to treat millions of MDD sufferers worldwide who are poorly served by SSRIs, SNRIs and other current depression therapies. AV-101 is functionally similar to ketamine in that both induce final common pathway antidepressant activity via glutamatergic activation involving AMPA receptors. However, AV-101 inhibits NMDA receptor channel activity, whereas ketamine blocks the ion channel of the NMDA receptor. AV-101, as a prodrug, produces in the brain an antagonist that inhibits the NMDA receptor by selectively binding to its functionally required GlyB site. Experimental evidence confirms that inhibiting the NMDA receptor by targeting the GlyB site can produce potent antidepressive effects and bypass adverse effects that result when ketamine blocks the NMDA receptor ion channel. Experimental evidence also supports the conclusion that this NMDA receptor inhibition by AV-101 may then result in a glutamatergic activation that depends on the AMPA receptor pathway, resulting in an increase in neuronal connections that has been associated with the faster-acting antidepressant effects than those achieved by standard antidepressants, similar to those seen with ketamine.

In peer-reviewed published preclinical studies, AV-101 caused ketamine-like antidepressant effects, including rapid onset and long duration of effect following a single treatment, without causing ketamine's negative side effects. In two NIH-funded randomized, double blind, placebo-controlled Phase 1 safety studies, AV-101 was safe, well-tolerated and not associated with any severe adverse events. There were no signs of sedation, hallucinations or psychological side effects often associated with ketamine and other channel-blocking NMDA receptor antagonists.

Building on over \$8.8 million of prior grant award funding from the NIH for preclinical and Phase 1 clinical development of AV-101, under our CRADA, we are collaborating with Dr. Carlos Zarate, Jr. and his team at the NIMH on the small NIMH AV-101 MDD Phase 2 Monotherapy Study. Pursuant to the CRADA, this ongoing study is being conducted at the NIMH by Dr. Zarate as Principal Investigator, and is being fully-funded by the NIMH. The primary objective of the NIMH AV-101 MDD Phase 2 Monotherapy Study will be to evaluate the ability of AV-101 to improve overall depressive symptomatology in subjects with MDD, specifically whether subjects with MDD have a greater and more rapid decrease in depressive symptoms when treated with AV-101 than with placebo. We currently anticipate that the NIMH will complete the NIMH AV-101 MDD Phase 2 Monotherapy Study in 2017, with top line results available during the first half of 2018.

We are currently preparing to launch our AV-101 MDD Phase 2 Adjunctive Treatment Study in patients with an inadequate response to standard, FDA-approved antidepressants. We currently anticipate completing this proposed 180-patient multi-center, multi-dose, double blind, placebo-controlled Phase 2 efficacy and safety study by the end of 2018 with top line results available in the first quarter of 2019. The Principal Investigator of the AV-101 MDD Phase 2 Adjunctive Treatment Study will be Dr. Maurizio Fava of Harvard Medical School. Dr. Fava was the co-Principal Investigator with Dr. A. John Rush of the largest clinical trial ever conducted in depression, STAR*D, whose findings were published in journals such as the *New England Journal of Medicine* and the *Journal of the American Medical Association*.

AV-101 and Neuropathic Pain

Neuropathic pain is a complex, chronic pain state that results from problems with signals from nerves. There are various causes of neuropathic pain, including tissue injury, nerve damage or disease, diabetes, infection, toxins, certain types of drugs, such as antivirals and chemotherapeutic agents, certain cancers, and even chronic alcohol intake. With neuropathic pain, damaged, dysfunctional or injured nerve fibers send incorrect signals to other pain centers and impact nerve function both at the site of injury and areas around the injury. Many neuropathic pain treatments on the market today, including gabapentin, have side effects such as anxiety, depression, mild cognitive impairment and/or sedation.

The effects of AV-101 were assessed in published peer-reviewed studies involving four well-established non-clinical models of pain, both hyperalgesia and allodynia, to examine its analgesic and behavioral profile. The publication, titled: “*Characterization of the effects of L-4-chlorokynurenine on nociception in rodents*,” by lead author, Tony L. Yaksh, Ph.D., Professor in Anesthesiology at the University of California, San Diego, was published in *The Journal of Pain* in April 2017 (DOI: 10.1016/j.jpain.2017.03.014). In these studies, systemic delivery of AV-101 yielded brain concentrations of AV-101's active metabolite, 7-Cl-KYNA. The high CNS levels of 7-Cl-KYNA were calculated to exceed its IC50 at the NMDA receptor GlyB site and resulted in robust, dose-dependent anti-nociceptive effects, similar to gabapentin, but with no discernable negative side effects. Gabapentin, a commonly used drug for neuropathic pain, causes sedation and mild cognitive impairment. Therefore, a drug that is equally effective on pain, but is better tolerated than gabapentin, could be quite important for the millions of patients battling chronic neuropathic pain. Taken together with our successful AV-101 Phase 1a and 1b clinical safety studies, we believe the published results of these non-clinical studies support further clinical development of AV-101 in a Phase 2 clinical study to assess its potential as a new generation treatment alternative to gabapentin to reduce debilitating neuropathic pain effectively, without causing gabapentin-like side effects.

AV-101 and Epilepsy

AV-101 has been shown to protect against seizures and neuronal damage in animal models of epilepsy, providing preclinical support for its potential as a novel treatment alternative for epilepsy. Epilepsy is one of the most prevalent neurological disorders, affecting almost 1% of the worldwide population. According to the Epilepsy Foundation, as many as three million Americans have epilepsy, and one-third of those suffering from epilepsy are not effectively treated with currently available medications. In addition, standard anticonvulsants can cause significant side effects, which frequently interfere with compliance.

Glutamate is a neurotransmitter that is critically involved in the pathophysiology of epilepsy. Through its stimulation of the NMDA receptor subtype, glutamate has been implicated in the neuropathology and clinical symptoms of the disease. In support of this, NMDA receptor antagonists are potent anticonvulsants. However, classic NMDA receptor antagonists are limited by adverse effects, such as neurotoxicity, declining mental status, and the onset of psychotic symptoms following administration of the drug. The endogenous amino acid glycine modulates glutamatergic neurotransmission by stimulating the GlyB co-agonist site of the NMDA receptor. GlyB site antagonists inhibit NMDA receptor function and are therefore anticonvulsant and neuroprotective. Importantly, GlyB site antagonists have fewer and less severe side effects than classic channel-blocking NMDA receptor antagonists and other antiepileptic agents, making them a safer potential alternative to, and one expected to be associated with greater patient compliance than, available anticonvulsant medications.

AV-101 has two additional therapeutically important properties as a drug candidate for treatment of epilepsy:

1. AV-101 is preferentially converted to 7-Cl-KYNA in brain areas related to neuronal injury. This is because astrocytes, which are responsible for the enzymatic transamination of 4-Cl-KYN prodrug to active 7-Cl-KYNA, are focally activated at sites of neuronal injury. Due to AV-101's highly focused site of conversion, local concentrations of newly formed 7-Cl-KYNA are greatest at the site of therapeutic need. In addition to delivering the drug where it is needed, this reduces the chance of systemic and dangerous side effects with long-term use of the drug; and
2. An active metabolite of AV-101, 4-Cl-3-hydroxyanthranilic acid, inhibits the synthesis of quinolinic acid, an endogenous NMDAR agonist that causes convulsions and excitotoxic neuronal damage.

AV-101's ability to activate astrocytes for focal delivery of an anti-epileptic principle, and its dual action as a NMDAR GlyB antagonist and quinolinic acid synthesis inhibitor, make AV-101 a potential Phase 2 development candidate for treatment of epilepsy.

AV-101 and Parkinson's Disease and L-DOPA-Induced Dyskinesia

Parkinson's disease (PD) is a chronic and progressive movement disorder, meaning that symptoms continue and worsen over time. According to the Parkinson's Disease Foundation, as many as one million Americans live with PD and more than 10 million people worldwide are living with PD. The cause of PD is unknown, and there is presently no cure.

PD involves the malfunction and death of certain nerve cells in the brain that produce dopamine, a key chemical that sends messages to the part of the brain that controls movement and coordination. As PD progresses, the amount of dopamine produced in the brain decreases, leaving a person unable to control movement normally.

Levodopa (L-DOPA) therapy increases brain levels of dopamine and is the gold standard for treating symptoms of PD in nearly all phases of the disease. Currently, it is considered the most effective drug for controlling the symptoms of PD. However, L-DOPA-induced dyskinesia (LID) is a common, and generally disabling, complication of long-term L-DOPA treatment in PD patients. Studies published in the *New England Journal of Medicine* and *Movement Disorders* have shown that LID develops in approximately 45% of L-DOPA-treated PD patients after five years and 80% after 10 years of L-DOPA treatment. This dyskinesia, or uncontrollable muscle movement, induced by L-DOPA therapy, is not part of PD, but instead a complication of L-DOPA therapy. LID interferes not only with L-DOPA treatment of PD, but also negatively impacts the quality of life of PD patients and is a major contributor to disability later in the ordinary course of the disease. While amantadine, a low-affinity NMDA receptor antagonist, has been shown to offer some relief for certain PD patients suffering from LID, more effective and better tolerated pharmacologic management of LID remains a significant unmet medical need.

In a monkey model of PD, AV-101 (250 mg/kg and 450 mg/kg) reduced by 30% the mean dyskinesia score associated with L-DOPA treatment of PD. Maximum dyskinesia scores were also reduced by 17%. Importantly, AV-101 did not reduce the anti-parkinsonian therapeutic benefit of L-DOPA. Moreover, the duration of L-DOPA response and delay to L-DOPA effect were not affected by treatment with AV-101. We believe these monkey data warrant the Phase 2 clinical testing of AV-101 in L-DOPA-treated PD patients suffering from LID.

AV-101 and Huntington's Disease

Working together with metabotropic glutamate receptors, the NMDA receptor ensures the establishment of long-term potentiation (LTP), a process believed to be responsible for the acquisition of information. These functions are mediated by calcium entry through the NMDA receptor-associated channel, which in turn influences a wide variety of cellular components, like cytoskeletal proteins or second-messenger synthases. However, over activation at the NMDA receptor triggers an excessive entry of calcium ions, initiating a series of cytoplasmic and nuclear processes that promote neuronal cell death through necrosis as well as apoptosis, and these mechanisms have been implicated in several neurodegenerative diseases.

Huntington's disease (HD) is an inherited disorder that causes degeneration of brain cells, called neurons, in motor control regions of the brain, as well as other areas. Symptoms of the disease, which gets progressively worse, include uncontrolled movements (called chorea), abnormal body postures, and changes in behavior, emotion, judgment, and cognition. HD is caused by an expansion in the number of glutamine repeats beyond 35 at the amino terminal end of a protein termed "huntingtin." Such a mutation in huntingtin leads to a sequence of progressive cellular changes in the brain that result in neuronal loss and other characteristic neuropathological features of HD. These are most prominent in the neostriatum and in the cerebral cortex, but also observed in other brain areas.

The tissue levels of two neurotoxic metabolites of the kynurenine pathway of tryptophan degradation, quinolinic acid (QUIN) and 3-hydroxykynurenine (3-HK) are increased in the striatum and neocortex, but not in the cerebellum, in early stage HD. QUIN and 3-HK and especially the joint action of these two metabolites, have long been associated with the neurodegenerative and other features of the pathophysiology of HD. The neuronal death caused by QUIN and 3-HK is due to both free radical formation and NMDA receptor overstimulation (excitotoxicity).

Based on the hypothesis that 3-HK and QUIN are involved in the progression of HD, early intervention aimed at affecting the kynurenine pathway in the brain may present a promising treatment strategy. We believe the ability of AV-101 to reduce the brain levels of neurotoxic QUIN and to potentially produce significant local concentrations of 7-Cl-KYNA on chronic administration, presents an exciting opportunity for Phase 2 clinical investigation of AV-101 as a potential chronic treatment alternative for certain symptoms of HD.

AV-101 Phase 1 Clinical Safety Studies

The safety data from two NIH-funded AV-101 Phase 1 clinical safety studies indicate that AV-101 was safe and well tolerated in healthy subjects at all doses tested. There were no Adverse Effects (AEs) reported by subjects that received AV-101 that were graded as probably related to study drug. The type and distribution of AEs reported by subjects in the studies were considered to be typical for studies in healthy volunteers. All AEs were completely resolved. Further, no Serious Adverse Events (SAEs) were reported.

The Pharmacokinetics (PK) of AV-101 were fully characterized across the range of doses in these Phase 1a and 1b studies. Plasma concentration-time profiles obtained for 4-Cl-KYN (AV-101) and 7-Cl-KYNA after administration of a single escalating dose (Phase 1a) and multiple, once daily oral doses of 360, 1,080, or 1,440 mg for 14 days (Phase 1b) were consistent with rapid absorption of the oral dose and first-order elimination of both analytes, with evidence of multi-compartment kinetics, particularly for the AV-101's active metabolite, 7-Cl-KYNA.

Although the Phase 1 safety and PK studies were not designed to measure or evaluate the potential antidepressant effects of AV-101, approximately 9% (5/54) of the subjects receiving AV-101 and 0% of the 30 subjects receiving placebo reported "feelings of well-being" (coded as euphoric mood), similar to the fast-acting antidepressant effects reported in the literature with ketamine.

Phase 1a Study

A phase 1a, randomized, double blind, placebo-controlled study to evaluate the safety and PK of single doses of AV-101 in healthy volunteers was conducted. Seven cohorts (30, 120, 360, 720, 1,080, 1,440, and 1,800 mg) with six subjects per cohort (1:1, AV-101: placebo) were to be enrolled in the study. Nine subjects experienced 10 AEs, with four of the AEs occurring in subjects in the placebo group and two of the AEs occurring for one subject receiving 30 mg AV-101. For the AEs occurring in the AV-101-treated subjects, there were no meaningful differences in the number of AEs observed at the 30-mg dose (two AEs) when compared with that at the 120-mg dose (one AE), 360-mg dose (one AE), 720-mg dose (zero AEs), 1,080-mg dose (zero AEs), or 1,440-mg dose (two AEs). Eight of 10 AEs (80%) were considered mild, and two (20%, headache and gastroenteritis) were considered moderate. Four subjects on AV-101, one each in Cohorts 1 through 4 and two subjects on placebo in Cohort 5 reported AEs of headaches. Five headaches were mild with no concomitant treatment, and one was moderate with concomitant drug therapy administered. Most completely resolved the same day as onset and were considered not serious. One headache started the day after dosing and resolved approximately one week later on the same day as the concomitant drug therapy was administered. One case of contact dermatitis bilateral lower extremities was reported in Cohort 2 on placebo that was ongoing. One of the subjects with the headache also reported an AE of gastroenteritis that was unrelated to AV-101. This AE was considered moderate but did not require any drug therapy and was completely resolved within two days of onset. This AE was also considered not serious.

The PK of AV-101 was fully characterized across the range of doses in this Phase 1a study following a single oral administration. Plasma concentration-time profiles obtained for 4-Cl-KYN (AV-101) and 7-Cl-KYNA were consistent with rapid absorption of the oral dose and first-order elimination of both analytes, with evidence of multi-compartment kinetics, particularly for the metabolite 7-Cl-KYNA.

Even though this Phase 1a safety study was not designed to quantitatively assess effects on mood, during the interviews, two out of three subjects who received the highest dose (1440 mg) of AV-101 voluntarily acknowledged positive effects on their mood. Similar comments were not made by any of the 18 placebo group subjects.

Phase 1b Study

A Phase 1b clinical study was conducted as a single-site, dose-escalating study to evaluate the safety, tolerability, and PK of multiple doses of AV-101 administered daily in healthy volunteers. The antihyperalgesic effect of AV-101 on capsaicin-induced hyperalgesia was also assessed. Subjects were sequentially enrolled into one of three cohorts (360 mg, 1,080 mg, and 1,440 mg) and were randomized to AV-101 or placebo at a 12:4 (AV-101 to placebo) ratio. Subjects were dosed for 14 consecutive days. Each subject was given a paper diary and instructed to record daily dose administration, concomitant medications, and AEs during the 14-day treatment period.

For this study, the minimum toxic dose was to be (i) the dose at which a drug-related SAE occurred in an AV-101-treated subject, or (ii) the dose at which a severe AE that warranted stopping the study, as determined by the investigator and medical monitor, occurred in an AV-101-treated subject within a cohort. The minimum toxic dose was not reached in this study.

A total of 40 AEs were reported by 24 of 37 (64.9%) subjects receiving AV-101, and 17 AEs were reported by 10 of 13 (76.9%) subject receiving placebo. The frequency of AEs was similar among the treatment groups. Thirty-four subjects experienced a total of 57 AEs, with 16 (28.1% of the total AEs) in the 360-mg group, 14 (24.6% of the total AEs) in the 1,040-mg group, 10 (17.5% of the total AEs) in the 1,440-mg group, and 17 (29.8% of the total AEs) in the placebo group. All of the AEs were completely resolved, and no SAEs were reported.

The majority of the reported AEs were nervous system disorders (23 subjects, 46% of subjects) and gastrointestinal disorders (seven subjects, 14.0%). The remaining AEs were classified as eye disorders (three subjects, 6.0%); psychiatric disorders (three subjects, 6.0%); respiratory, thoracic, and mediastinal disorders (three subjects, 6.0%); skin and subcutaneous tissue disorders (three subjects, 6.0%); general disorders and administration site conditions (two subjects, 4.0%); cardiac disorders one subject, 2.0%); infections and infestations (one subject, 2.0%); musculoskeletal and connective tissue disorders (one subject, 2.0%); and renal disorders (one subject, 2.0%).

The distribution of AEs by System Organ Class was similar among the cohorts with the exception of headaches and gastrointestinal disorders. Eight of the 18 (44.4%) reported headaches were in the placebo group, 6 (33.3%) were in the 1,080-mg group, three (16.7%) were in the 1,440-mg group, and one (5.6%) was in the 360-mg group. Three (42.9%) of the seven reported gastrointestinal disorders were in the 360-mg group, two (28.6%) were in the placebo group, one (14.3%) was in the 1,080-mg group, and one (14.3%) was in the 1,440-mg group.

The determination of the relationship of the AE to the study drug was made when the data were unblinded. Ten of the 15 AEs (66.7%) that occurred in the 360-mg AV-101 group, 10 of the 14 AEs (71.4%) that occurred in the 1,040-mg AV-101 group, seven of the 10 AEs (70.0%) that occurred in the 1,440-mg AV-101 group, and 13 of the 17 AEs (76.5%) that occurred in the placebo group were determined to be possibly related to study drug. One (5.9%) AE in the placebo group was probably related to study drug (rash around neck). Of the 57 reported AEs, 49 (85.9%) were of mild intensity and eight (14.0%) were of moderate intensity. There were two moderate intensity AEs in the 360-mg AV-101 group; one was unrelated pain in the right foot, and one was a possibly related headache. All other moderate AEs occurred in the placebo group and included nausea or vomiting (two AEs), headache (two AEs), and rash around the neck (one AE). No SAEs were reported.

Even though this Phase 1b safety study was not designed to quantitatively assess effects on mood, during the interviews certain subjects who received 360, 1080, and 1440 mg of AV-101, voluntarily acknowledged positive effects on mood. Similar comments were not made by any of the placebo-group subjects.

The PK of AV-101 was fully characterized across the range of doses in this Phase 1b study. Plasma concentration-time profiles obtained for 4-Cl-KYN (AV-101) and 7-Cl-KYNA following 14 daily oral administrations of 360, 1,080, or 1,440 mg were consistent with rapid absorption of the oral dose and first-order elimination of both analytes, with evidence of multi-compartment kinetics, particularly for the metabolite 7-Cl-KYNA.

VistaStem Therapeutics

VistaStem Therapeutics (*VistaStem*) is our wholly owned subsidiary focused on applying human pluripotent stem cell (*hPSC*) technology, internally and with collaborators, to discover, rescue, develop and commercialize (i) proprietary new chemical entities (*NCEs*) for CNS and other diseases and (ii) regenerative medicine (*RM*) involving *hPSC*-derived blood, cartilage, heart and liver cells. We used our *hPSC*-derived cardiomyocytes (human heart cells) to develop *CardioSafe 3D*[™], our customized *in vitro* bioassay system for predicting heart toxicity of drug rescue *NCEs*. We believe *CardioSafe 3D* is more comprehensive and clinically predictive than the hERG assay, which currently is the only *in vitro* cardiac safety assay required by FDA guidelines, and provides us with new generation human cell-based technology to identify and evaluate drug rescue candidates and develop drug rescue *NCEs*.

Scientific Background

Stem cells are the building blocks of all cells of the human body. They have the potential to develop into many different mature cell types. Stem cells are defined by a minimum of two key characteristics: (i) their capacity to self-renew, or divide in a way that results in more stem cells; and (ii) their capacity to differentiate, or turn into mature, specialized cells that make up tissues and organs. There are many different types of stem cells that come from different places in the body or are formed at different times throughout our lives, including pluripotent stem cells and adult or tissue-specific stem cells, which are limited to differentiating into the specific cell types of the tissues in which they reside. We focus exclusively on human pluripotent stem cells.

Human pluripotent stem cells can be differentiated into all of the more than 200 types of cells in the human body, can be expanded readily, and have diverse medical research, drug discovery, drug rescue, drug development and therapeutic applications. We believe *hPSCs* can be used to develop numerous cell types, tissues and customized assays that can mimic complex human biology, including heart and liver biology for drug rescue.

Human pluripotent stem cells are either embryonic stem cells (*hESCs*) or induced pluripotent stem cells (*iPSCs*). Both *hESCs* and *iPSCs* have the capacity to be maintained and expanded in an undifferentiated state indefinitely. We believe these features make them highly useful research and development tools and as a source of normal, functionally mature cell populations. We use multiple types of these mature cells as the foundation to design and develop novel, customized bioassay systems to test the safety and efficacy of *NCEs in vitro*. These cells also have potential for diverse regenerative medicine applications.

Human Embryonic Stem Cells

According to the NIH, hESCs are derived from excess embryos that develop from eggs that have been fertilized in an *in vitro* fertilization (IVF) clinic and then donated for research purposes with the informed consent of the parental donors after a successful IVF procedure. Human embryonic stem cells are not derived from eggs fertilized in a woman's body. Human ESCs are isolated when the embryo is approximately 100 cells, well before organs, tissues or nerves have developed.

Human ESCs have the potential to both self-renew and differentiate. They undergo increasingly tissue-restrictive developmental decisions during their differentiation. These "fate decisions" commit the hESCs to becoming only a certain type of mature, functional cells and ultimately tissues. At one of the first fate decision points, hESCs differentiate into epiblasts. Although epiblasts cannot self-renew, they can differentiate into the major tissues of the body. This epiblast stage can be used, for example, as the starting population of cells that develop into millions of blood, heart, muscle, liver and insulin-producing pancreatic beta-islet cells, as well as neurons. In the next step, the presence or absence of certain growth factors, together with the differentiation signals resulting from the physical attributes of the cell culture techniques, induce the epiblasts to differentiate into neuroectoderm or mesendoderm cells. Neuroectoderm cells are committed to developing into cells of the skin and nervous systems. Mesendoderm cells are precursor cells that differentiate into mesoderm and endoderm. Mesoderm cells develop into muscle, bone and blood, among other cell types. Endoderm cells develop into the internal organs such as the heart, liver, pancreas and intestines, among other cell types.

Induced Pluripotent Stem Cells

It is also possible to obtain hPSC lines from individuals without the use of embryos. Induced PSCs are adult cells, typically human skin or fat cells that have been genetically reprogrammed to behave like hESCs by being forced to express genes necessary for maintaining the pluripotential properties of hESCs. Although researchers are exploring non-viral methods, most early iPSCs were produced by using various viruses to express three or four genes required for the immature pluripotential property similar to hESCs. It is not yet precisely known, however, how each gene actually functions to induce cellular pluripotency, nor whether each of the three or four genes is essential for this reprogramming. Although hESCs and iPSCs are believed to be similar in many respects, including their pluripotential ability to form all cells in the body and to self-renew, scientists do not yet know whether they differ in clinically significant ways or have the same ability to self-renew.

We believe the biology and differentiation capabilities of hESCs and iPSCs are likely to be comparable for most if not all purposes. There are, however, specific situations in which we may prefer to use one or the other type of hPSC. For example, we may prefer to use iPSCs for potential drug discovery applications based on the relative ease of generating iPSCs from:

- individuals with specific inheritable diseases and conditions that predispose the individual to respond differently to drugs; or
- individuals with specific variations in genes that directly affect drug levels in the body or alter the manner or efficiency of their metabolism, breakdown and/or elimination of drugs.

Because they can significantly affect the therapeutic and/or toxic effects of drugs, these genetic variations have an impact on drug discovery and development. We believe iPSC technologies may allow the rapid and efficient generation of hPSCs from individuals with specific genetic variations. These hPSCs might then be used to produce cells to model specific diseases and genetic conditions for drug discovery and drug rescue purposes.

CardioSafe 3D

The limitations of current preclinical drug testing systems used by pharmaceutical companies and others contribute to the high failure rate of NCEs. Incorporating novel *in vitro* assays using hPSC-derived cardiomyocytes (*hPSC-CMs*) early in preclinical development offers the potential to improve clinical predictability, decrease development costs, and avoid adverse patient effects, late-stage clinical termination, and product recall from the market.

We produce fully functional, non-transformed hPSC-CMs at a high level of purity and with normal ratios of all important cardiac cell types. Importantly, our hPSC-CM differentiation protocols do not involve either genetic modification or antibiotic selection. This is important because genetic modification and antibiotic selection can distort the ratio of cardiac cell types and have a direct impact on the ultimate results and clinical predictivity of assays that incorporate hPSC-CMs produced in such a manner. In addition to normal expression all of the key ion channels of the human heart (calcium, potassium and sodium) and various cardiomyocytic markers of the human heart, our *CardioSafe 3D* cardiac toxicity assays screening for both direct cardiomyocyte cytotoxicity and arrhythmogenesis (or development of irregular beating patterns). We believe *CardioSafe 3D* is sensitive, stable, reproducible and capable of generating data enabling a more accurate prediction of the *in vivo* cardiac effects of NCEs than is possible with existing preclinical testing systems, particularly the hERG assay.

Limited Clinical Predictivity of the FDA-Required hERG Assay vs. Broad Clinical Predictivity of CardioSafe 3D

The hERG assay, which uses either transformed hamster ovary cells or human kidney cells, is currently the only *in vitro* cardiac safety assay required by FDA Guidelines (ICH57B). We believe the clinical predictivity of the hERG assay is limited because it assesses only a single cardiac ion channel - the hERG potassium ion channel. It does not assess any other clinically relevant cardiac ion channels, including calcium, non-hERG potassium and sodium ion channels. Also, importantly, the hERG assay does not assess the normal interaction between these ion channels and their regulators. In addition, the hERG assay does not assess clinically relevant cardiac biological effects associated with cardiomyocyte viability, including apoptosis and other forms of cytotoxicity, as well as energy, mitochondria and oxidative stress. As a result of its limitations, results of the hERG assay can lead to false negative and false positive predictions regarding the cardiac safety of new drug candidates.

We have developed and validated two clinically relevant functional components of our *CardioSafe* 3D screening system to assess multiple categories of cardiac toxicities, including both direct cardiomyocyte cytotoxicity and arrhythmogenesis (or development of irregular beating patterns). The first functional component of *CardioSafe* 3D consists of a suite of five fluorescence or luminescence based high-throughput hPSC-CM assays. These five *CardioSafe* 3D assays measure the following important drug-induced cardiac biological effects:

1. cell viability;
2. apoptosis;
3. mitochondrial membrane depolarization;
4. oxidative stress; and
5. energy metabolism disruption.

These five *CardioSafe* 3D biological assays were correlated to reported clinical results using reference compounds known to be cardiotoxic in humans versus compounds known to be safe in humans. These reference compounds were representative of eight different drug classes, including:

1. ion channel blockers: amiodarone, nifedipine;
2. hERG trafficking blockers: pentamidine, amoxapine;
3. α -1 adrenoreceptors: doxazosin;
4. protein and DNA synthesis inhibitors: emetine;
5. DNA intercalating agents: doxorubicin;
6. antibiotics: ampicillin, cefazolin;
7. NSAID: aspirin; and
8. kinase inhibitors: staurosporine.

This suite of five *CardioSafe* 3D cytotoxicity assays provided measurement of cardiac drug effects with high sensitivity that are consistent with the expected cardiac responses to each of these compounds. Based on our results, we believe *CardioSafe* 3D provides valuable and more comprehensive bioanalytical tools for both assessing the effects of pharmaceutical compounds on cardiac cytotoxicity than the hERG assay and can elucidate for us and our strategic partners specific mechanisms of cardiac toxicity, thereby laying what we believe is a novel and advantageous foundation for our *CardioSafe* 3D drug rescue NCE programs.

The other component of our *CardioSafe* 3D assay system is a sensitive and reliable medium throughput multi-electrode array (MEA) assay developed to predict drug-induced alterations of electrophysiological function of the human heart, representing an integrated assessment of not only hERG potassium ion channel activity analogous to the FDA-mandated hERG assay but, in addition, non-hERG potassium channels, and calcium channels and sodium channels, which are well beyond the scope of the hERG assay. Functional electrophysiological assessment is a key component of *CardioSafe* 3D, and has been validated with reported clinical results involving drugs with known toxic or non-toxic cardiac effects in humans.

We have validated that *CardioSafe* 3D is capable of assessing important electrophysiological activity of drug rescue NCEs, including spike amplitude, beat period and field potential duration. Our *CardioSafe* 3D MEA assay, which we refer to as *ECG in a test tube*TM, was reproducible and consistent with the known human cardiac effects of all compounds studied, based on the mechanisms of action and dosage of the compounds. For instance, by using *CardioSafe* 3D, we were able to distinguish between the arrhythmogenic cardiac effects of terfenadine (SeldaneTM), withdrawn by the FDA due to cardiotoxicity, and the cardiac effects of the closely structurally-related compound, fexofenadine (AllegraTM), a safe variant of terfenadine, which remains on the market. We believe our correlation data demonstrate that *CardioSafe* 3D provides valuable and more comprehensive bioanalytical tools for *in vitro* cardiac safety screening than the hERG assay. We believe *CardioSafe* 3D will contribute to our efficient and rapid identification of novel, potentially safer proprietary NCEs in our drug rescue programs.

Using CardioSafe 3D to Develop Drug Rescue NCEs

Our drug rescue activities are focused on producing for our internal pipeline proprietary, safer variants of still-promising NCEs previously discovered, optimized and tested for efficacy by pharmaceutical companies and others but terminated before FDA approval due to unexpected heart toxicity or liver toxicity. Our current drug rescue strategy involves using *CardioSafe* 3D to assess the toxicity that caused certain NCEs available in the public to be terminated, and use that biological insight to produce and develop a new, potentially safer, and proprietary NCEs for our pipeline. We believe the pre-existing public domain knowledge base supporting the therapeutic and commercial potential of NCEs we target for our drug rescue programs will provide us with a valuable head start as we launch each of our drug rescue programs. Leveraging the substantial prior investments by global pharmaceutical companies and others in discovery, optimization and efficacy validation of the NCEs we identify in the public domain is an essential component of our drug rescue strategy.

By using *CardioSafe 3D* to enhance our understanding of the cardiac liability profile of NCEs, biological insight not previously available when the NCEs were originally discovered, optimized for efficacy and developed, we believe we can demonstrate preclinical proof-of-concept (POC) as to the efficacy and safety of new, safer drug rescue NCEs in standard *in vitro* and *in vivo* models, as well as in *CardioSafe 3D*, earlier in development and with substantially less investment in discovery and preclinical development than was required of pharmaceutical companies and others prior to their decision to terminate the original NCE.

Our goal in each drug rescue program will be to produce a proprietary drug rescue NCE and establish its preclinical POC, using standard preclinical *in vitro* and *in vivo* efficacy and safety models, as well as *CardioSafe 3D*. In this context, POC means that the lead drug rescue NCE, as compared to the original, previously-terminated NCE, demonstrates both (i) equal or superior efficacy in the same, or a similar, *in vitro* and *in vivo* preclinical efficacy models used by the initial developer of the previously-terminated NCE before it was terminated for safety reasons, and (ii) significant reduction of concentration dependent cardiotoxicity in *CardioSafe 3D*.

Regenerative Medicine (RM)

Although we believe the best and most valuable near term commercial application of our stem cell technology platform is for small molecule drug rescue, we also believe stem cell technology-based RM has the potential to transform healthcare in the U.S. over the next decade by providing new approaches for treating the fundamental mechanisms of disease. We currently intend to establish strategic collaborations to leverage our stem cell technology platform, our expertise in human biology, differentiation of human pluripotent stem cells to develop functional adult human cells and tissues involved in human disease, including blood, bone, cartilage, heart and liver cells, and our expertise in designing and developing novel, customized biological assay systems with the cells we produce, for RM purposes. In December 2016, we exclusively sublicensed to BlueRock Therapeutics LP, a next generation RM company established 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. In a manner similar to our exclusive sublicense agreement with BlueRock Therapeutics, VistaStem may pursue additional RM collaborations or licensing transactions involving blood, cartilage, and/or liver cells derived from hPSCs for (A) cell-based therapy, (B) cell repair therapy, and/or (C) tissue engineering.

Strategic Transactions and Relationships

Strategic collaborations are an important cornerstone of our corporate development strategy. We believe that our highly selective outsourcing of certain research and development activities gives us flexible access to chemistry broad range of research and development capabilities, manufacturing, clinical development and regulatory expertise at a lower overall cost than developing and maintaining such expertise internally on a full-time basis. In particular, we contract with third parties for certain manufacturing, non-clinical development, clinical development and regulatory affairs support. The following are among our current third-party collaborators:

Cato Research Ltd.

Cato Research Ltd. is a CRO with international resources dedicated to helping biotechnology and pharmaceutical companies navigate the regulatory approval process in order to bring new biologics, drugs and medical devices to markets throughout the world. Cato Research is one of our CROs for development of AV-101, currently focused on all chemistry, manufacturing and controls (CMC) aspects of our Phase 2 development program in MDD. Cato Research's senior management team, including co-founders Allen Cato, M.D., Ph.D. and Lynda Sutton, have over 30 years of experience interacting with the FDA and international regulatory agencies and a successful track record of product approvals.

Cardiac Safety Research Consortium

We have joined the Cardiac Safety Research Consortium (CSRC) as an Associate Member. The CSRC, which is sponsored in part by the FDA, was launched in 2006 through an FDA Critical Path Initiative Memorandum of Understanding with Duke University to support research into the evaluation of cardiac safety of medical products. CSRC supports research by engaging stakeholders from industry, academia, and government to share data and expertise regarding several areas of cardiac safety evaluation, including novel stem cell-based approaches, from preclinical through post-market periods.

Cardiac Safety Technical Committee of the Health and Environmental Sciences Institute – FDA's CIPA Initiative

We have also joined the Cardiac Safety Technical Committee, Cardiac Stem Cell Working Group, and Proarrhythmia Working Group of the Health and Environmental Sciences Institute (HESI) to help advance, among other goals, the FDA's Comprehensive In Vitro Proarrhythmia Assay (CIPA) initiative, which is focused on developing innovative preclinical systems for cardiac safety assessment during drug development. HESI is a global branch of the International Life Sciences Institute (ILSI), whose members include most of the world's largest pharmaceutical and biotechnology companies.

The goal of the FDA's CIPA initiative is to develop a new paradigm for cardiac safety evaluation of new drugs that provides a more comprehensive assessment of proarrhythmic potential by (i) evaluating effects of multiple cardiac ionic currents beyond hERG and ICH S7B Guidelines (inward and outward currents), (ii) providing more complete, accurate assessment of proarrhythmic effects on human cardiac electrophysiology, and (iii) focusing on Torsades de Pointes proarrhythmia rather than surrogate QT prolongation alone.

Centre for Commercialization of Regenerative Medicine

The Toronto-based Centre for Commercialization of Regenerative Medicine (CCRM) is a not-for-profit, public-private consortium funded by the Government of Canada, six Ontario-based institutional partners and more than 20 companies representing the key sectors of the regenerative medicine industry. CCRM supports the development of foundational technologies that accelerate the commercialization of stem cell- and biomaterials-based products and therapies.

We are a member of the CCRM's Industry Consortium. Other members of CCRM's Industry Consortium include Pfizer and GE Healthcare. The industry leaders that comprise the CCRM consortium benefit from proprietary access to certain licensing opportunities, academic rates on fee-for-service contracts at CCRM and opportunities to participate in large collaborative projects, among other advantages. Our CCRM membership reflects our strong association with CCRM and its core programs and objectives, both directly and through our strategic relationships with Dr. Gordon Keller and UHN. We believe our long-term sponsored research agreement with Dr. Keller, UHN and UHN's McEwen Centre offers unique opportunities for expanding the commercial applications of our stem cell technology platform by building multi-party collaborations with CCRM and members of its Industry Consortium. We believe these collaborations have the potential to transform medicine and accelerate significant advances in human health and wellness that stem cell technologies and regenerative medicine promise.

Massachusetts General Hospital Clinical Trials Network and Institute

Massachusetts General Hospital Clinical Trials Network and Institute (CTNI) is an academic CRO, part of the Department of Psychiatry of the Massachusetts General Hospital (MGH), a leader in academic scientific and clinical research in psychiatry. By exploring the brain science, genetics, and neurobiology of psychiatric disorders, the MGH CTNI has been instrumental in the development of novel treatments and surrogate markers of illness and therapeutic response. Its scientific and clinical research has been instrumental in defining the standards for the state-of-the-art practice of psychiatry. We are working with MGH CTNI, including its principals, Dr. Maurizio Fava and Dr. Thomas Laughren, in connection with the planning and execution of our AV-101 MDD Adjunctive Treatment Study. Dr. Fava is acknowledged as a world-renowned expert in depressive disorders and psychopharmacology. He is Director of the Division of Clinical Research of the MGH Research Institute, Executive Vice Chair, Department of Psychiatry, at MGH, and Executive Director of MGH CTNI. He will serve as Principal Investigator of the AV-101 MDD Phase 2 Adjunctive Treatment Study. Dr. Laughren is the former FDA Division Director, Division of Psychiatry Products, Center for Drug Evaluation and Research (CDER).

United States National Institutes of Health

Since our inception in 1998, the NIH has awarded us \$11.3 million in non-dilutive research and development grants, including \$2.3 million to support research and development of our stem cell technology and \$8.8 million for non-clinical and Phase 1a and 1b clinical development of AV-101.

United States National Institute of Mental Health

The NIMH, part of the NIH, is the largest scientific organization in the world dedicated to mental health research. NIMH is one of 27 Institutes and Centers of the NIH, the world's leading biomedical research organization. The mission of NIMH is to transform the understanding and treatment of mental illnesses through basic and clinical research, paving the way for prevention, recovery and cure. Our CRADA with the NIH provides for NIMH sponsorship of the ongoing NIMH AV-101 MDD Phase 2 Monotherapy Study, a study being fully funded by the NIH and is being conducted at the NIMH by Dr. Carlos Zarate, the NIMH's Chief of Experimental Therapeutics & Pathophysiology Branch and Section on Neurobiology and Treatment of Mood and Anxiety Disorders.

Intellectual Property

We rely upon patents as a major component of our intellectual property portfolio, as is typical for development-stage, biopharmaceutical companies. In addition, from time to time, we enter into patent license agreements to acquire rights to intellectual property. We also rely, in part, on trade secrets for protection of some of our discoveries. We attempt to protect our trade secrets by entering into confidentiality agreements with employees, consultants, collaborators and third parties. We also own several registered and common-law trademarks.

To help protect our intellectual property rights, our employees and consultants also sign agreements in which they assign to us, for example, their interests in patents, trade secrets and copyrights arising from their work for us.

From time to time, we sponsor research with key scientists in academic institutions to advance or supplement our internal research and development activities and objectives. These sponsored research agreements generally provide us with an opportunity to negotiate a new license, or acquire a substantially prescribed license, to acquire intellectual property rights in the results of the sponsored research.

AV-101

As discussed elsewhere in this Annual Report, AV-101 (4-Cl-KYN) is our oral CNS product candidate presently being investigated in the NIMH AV-101 MDD Phase 2 Monotherapy Study. Further, we are preparing to launch our AV-101 MDD Phase 2 Adjunctive Treatment Study to assess the safety and efficacy of AV-101 as a new generation adjunctive treatment of MDD in adult patients with an inadequate response to standard, FDA-approved antidepressants. We have developed a portfolio of intellectual property assets around AV-101, which involves both patent applications and trade secrets. In addition, we will seek regulatory exclusivity to supplement our intellectual property rights.

AV-101 itself is no longer patented. We obtained a patent license from the University of Maryland to certain pharmaceutical formulations and associated methods of using AV-101 when we acquired the original licensee, Artemis Neuroscience, Inc. However, patent rights included in that license that were relevant to AV-101 have expired. Although the license agreement contains royalty obligations that nominally remain in force until 10 years after the first commercial sale of the first product even after relevant patent rights have expired, the U.S. Supreme Court's decision in *Kimble v. Marvel Entertainment, LLC* (2015) determined that patent license royalties that extend beyond a patent's expiration are not enforceable.

Even though the compound 4-Cl-KYN per se, and certain of its formulations are in the public domain and thus are no longer protectable, we have filed several of our own patent applications on certain other formulations and novel therapeutic methods of use of AV-101 as part of our strategy to seek and secure broad commercial exclusivity for AV-101.

Presently, we are prosecuting one family of patent applications in the USPTO, European Patent Office (EPO) and selected major markets related to specific dosage formulations of AV-101, as well as to methods of treating depression, hyperalgesia pain and several other neurological conditions. For reference, these are based on PCT patent application WO2014/116739. Our claims to the treatment of depression have been granted by the EPO. We are prosecuting formulation claims in one application, and we filed a continuation application in this family in the U.S., focused on the treatment of depression. There is no guarantee, however, that the USPTO will allow or grant any of the pending claims.

We are also prosecuting another patent family related to novel methods of synthesizing AV-101, based on extensive research involving a range of synthetic routes that was conducted on our behalf by a contract research organization. For reference, this is based on PCT patent application WO2014/152835, which is presently being pursued at the national phase in the U.S. and selected other countries. This patent application also includes pharmaceutical composition claims to certain precursors and variants of AV-101, which may be useful and patentable as synthesis intermediates.

Another patent application related to additional and expanded clinical uses of AV-101 to treat depression and other medical conditions is pending as PCT patent application WO 2016/191351. We plan to seek patent protection at the national phase in appropriate global markets in due course.

Additionally, we are presently developing potentially improved synthesis routes through another contract research organization. If we determine that these routes may be patentable, then we intend to file patent applications relating to this developmental activity in the second half of 2017.

As noted, we are currently involved with the NIMH AV-101 MDD Phase 2 Monotherapy Study being conducted by the NIMH. As part of our analysis of the study results, we will be evaluating the possibility of seeking additional patent protection based on the clinical data and on clinical observations.

As another major component of our plans to obtain market exclusivity for approved therapeutic indications for AV-101, we intend to utilize New Drug Product Exclusivity provided by the FDA under section 505(c)(3)(E) and 505(j)(5)(F) of the Federal Food, Drug, and Cosmetic Act (FDCA). The FDA's New Drug Product Exclusivity is available for NCEs such as AV-101, which are innovative and have not been previously approved by the FDA, either alone or in combination with other drugs. The FDA's New Drug Product Exclusivity protection provides the holder of an FDA-approved NDA with up to five years of protection from competition in the U.S. marketplace for the innovation represented by its approved new drug product. This protection precludes FDA approval of certain generic drug applications under section 505(b)(2) of the FDCA, as well as certain abbreviated new drug applications (ANDAs), during the up to five-year exclusivity period, except that such applications may be submitted after four years if they contain a certification of patent invalidity or non-infringement. As and if applicable, we will pursue similar types of regulatory exclusivity in other regions, such as Europe, and in certain other countries.

There is no guarantee that we will be successful in obtaining patents related to AV-101 in the U.S. or other countries, or that if we are successful in obtaining such patents that we would also be successful in protecting those patents against challengers or in enforcing them to stop infringement. We are pursuing patent rights in a limited number of countries that we believe are the few major markets where having patent rights will substantially facilitate commercialization of AV-101. There are many other countries in which we are not pursuing such patent rights. There is no guarantee that we will successfully obtain patents in the countries in which we are pursuing patent rights.

Stem Cell Technology

We have obtained and are pursuing intellectual property rights to several stem cell technologies through a combination of our own patent properties, exclusive and non-exclusive patent and technology licenses, and participation in sponsored research relationships. Generally, our stem cell intellectual property portfolio relates to drug rescue, toxicity testing and drug discovery. It also relates to novel production systems and the use of various cell types that have been differentiated from pluripotent stem cells for those and other purposes. Additionally, our intellectual property includes enriched populations of certain cell types, such as cardiomyocytes and hepatocytes, and some related aspects of cell-based therapy. We also maintain certain trade secrets regarding stem cell technology, several of which are discussed below.

Overall, our stem cell patent portfolio includes nine patent families, which collectively include several issued U.S. patents as well as several foreign counterpart patents in countries of commercial interest to VistaGen. The portfolio also includes several patent applications pending in the U.S. and in various foreign countries.

The patent properties in these families are based on discoveries from our internal research and development activities, research that it has sponsored at various academic institutions, as well as from patent license agreements signed with the University Health Network (Toronto) and the Mount Sinai School of Medicine.

These license agreements generally require us to pay annual license fees, patent prosecution and maintenance fees, and royalty payments that vary based on product sales and services that are covered by the licensed patent rights, as well as fees for sublicensing. As noted above in the context of AV-101 intellectual property, there is no guarantee that we will successfully obtain patents in the countries in which we are pursuing patent rights or that we would be successful in enforcing granted patent rights against infringers.

In December 2016, we exclusively sublicensed to BlueRock Therapeutics, a stem cell research company recently established 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.

Trademarks

We have a federal trademark registration for the trademark "VISTAGEN". Corresponding trademarks have been registered in the European Union and in Switzerland. We also use certain other trademarks in connection with our customized in vitro bioassay systems, such as CardioSafe 3D™ and LiverSafe 3D™.

U.S. Government Rights

We have received federal funding from both the NIH and the NIMH to support research and development of inventions disclosed in our patent applications relating to AV-101 and certain of our stem cell technology. Under the Bayh-Dole Act of 1980, if we do not take adequate steps to commercialize certain intellectual property rights, or certain other exigent circumstances relating to public health and safety prescribed under federal law become applicable, the U.S. government may acquire certain rights with respect to inventions made during programs funded by NIH or other federal grants.

Competition

The biopharmaceutical industry is highly competitive. There are many public and private biopharmaceutical companies, universities, governmental agencies, including the NIH and NIMH, 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, there are no FDA-approved therapies for MDD with the mechanism of action of AV-101. However, products approved for other indications, for example, 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 treatment options, such as psychotherapy and electroconvulsive therapy, are sometimes used instead of and before standard antidepressant medications to treat patients with MDD.

In the field of new generation, orally available, adjunctive treatments of adult MDD patients with an inadequate response to standard antidepressants, we believe our principal competitor is Alkermes' orally available drug candidate in Phase 3 development, ALKS-5461, an opioid modulator.

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, Alkermes, Allergan, AstraZeneca, Eli Lilly, GlaxoSmithKline, Johnson & Johnson, Lundbeck, Merck, Novartis, Minerva, Otsuka, Pfizer, Roche, Sage, Sanofi, Shire, Sumitomo Dainippon, and Takeda. 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 expect that AV-101 will have to compete with a variety of therapeutic products and procedures.

We believe that VistaStem's human pluripotent stem cell (*hPSC*) technology platform, the *hPSC*-derived human cells we produce, and the customized human cell-based assay systems we have formulated and developed are capable of being competitive in the diverse and growing global stem cell and regenerative medicine markets, including markets involving the sale of *hPSC*-derived cells to third-parties for their *in vitro* drug discovery and safety testing, contract predictive toxicology drug screening services for third parties, internal drug discovery, drug development and drug rescue of new NCEs, and regenerative medicine, including *in vivo* cell therapy research and development. A representative list of such biopharmaceutical companies pursuing one or more of these potential applications of adult and/or *hPSC* technology includes the following: Acea Biosciences, Astellas, Athersys, BioCardia, BioTime, Caladrius Biosciences, Cellectis Bioresearch, Cellerant Therapeutics, Cytori Therapeutics, Fujifilm Holdings, HemoGenix, International Stem Cell, Neuralstem, Organovo Holdings, PluriStem Therapeutics, and Stemina BioMarker Discovery. Pharmaceutical companies and other established corporations such as Bristol-Myers Squibb, Charles River, GE Healthcare Life Sciences, GlaxoSmithKline, Novartis, Pfizer, Roche Holdings, Thermo Fisher Scientific and others have been and are expected to continue pursuing internally various stem cell-related research and development programs. Many of the foregoing companies have greater resources and capital availability and as a result, may be more successful in their research and development programs than us. We anticipate that acceptance and use of *hPSC* technology for drug development and regenerative medicine will continue to occur and increase at pharmaceutical and biotechnology companies in the future.

Government Regulation

Our business activities, including the manufacturing, research, development and marketing of our product candidates, are subject to extensive regulation by numerous governmental authorities in the United States and other countries. Before marketing in the United States, any new drug developed by us or our collaborators must undergo rigorous preclinical testing, clinical trials and an extensive regulatory clearance process implemented by the United States Food and Drug Administration (*FDA*) under the Federal Food, Drug, and Cosmetic Act, as amended. The *FDA* regulates, among other things, the development, testing, manufacture, safety, efficacy, record keeping, labeling, storage, approval, advertising, promotion, import, export, sale and distribution of biopharmaceutical products. The regulatory review and approval process, which includes preclinical testing and clinical trials of each product candidate, is lengthy, expensive and uncertain. Moreover, government coverage and reimbursement policies will both directly and indirectly impact our ability to successfully commercialize any future approved products, and such coverage and reimbursement policies will be impacted by enacted and any applicable future healthcare reform and drug pricing measures. In addition, we are subject to state and federal laws, including, among others, anti-kickback laws, false claims laws, data privacy and security laws, and transparency laws that restrict certain business practices in the pharmaceutical industry.

In the United States, drug product candidates intended for human use undergo laboratory and animal testing until adequate proof of safety is established. Clinical trials for new product candidates are then typically conducted in humans in three sequential phases that may overlap. Phase 1 trials involve the initial introduction of the product candidate into healthy human volunteers. The emphasis of Phase 1 trials is on testing for safety or adverse effects, dosage, tolerance, metabolism, distribution, excretion and clinical pharmacology. Phase 2 involves studies in a limited patient population to determine the initial efficacy of the compound for specific targeted indications, to determine dosage tolerance and optimal dosage, and to identify possible adverse side effects and safety risks. Once a compound shows evidence of effectiveness and is found to have an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to more fully evaluate clinical outcomes. Before commencing clinical investigations in humans, we or our collaborators must submit an Investigational New Drug Application (*IND*) to the *FDA*.

Regulatory authorities, Institutional Review Boards and Data Monitoring Committees may require additional data before allowing clinical studies to commence, continue or proceed from one phase to another, and could demand that studies be discontinued or suspended at any time if there are significant safety issues. We have in the past and may in the future rely on assistance from our third-party collaborators and contract service providers to file our *INDs* and generally support our development and regulatory activities approval process for our potential products. Clinical testing must also meet requirements for clinical trial registration, institutional review board oversight, informed consent, health information privacy, and good clinical practices, or *GCPs*. Additionally, the manufacture of our drug product, must be done in accordance with current good manufacturing practices (*GMPs*).

To establish a new product candidate's safety and efficacy, the *FDA* requires companies seeking approval to market a drug product to submit extensive preclinical and clinical data, along with other information, for each indication for which the product will be labeled. The data and information are submitted to the *FDA* in the form of a New Drug Application (*NDA*), which must be accompanied by payment of a significant user fee unless a waiver or exemption applies. Generating the required data and information for an *NDA* takes many years and requires the expenditure of substantial resources. Information generated in this process is susceptible to varying interpretations that could delay, limit or prevent regulatory approval at any stage of the process. The failure to demonstrate adequately the quality, safety and efficacy of a product candidate under development would delay or prevent regulatory approval of the product candidate. Under applicable laws and *FDA* regulations, each *NDA* submitted for *FDA* approval is given an internal administrative review within 60 days following submission of the *NDA*. If deemed sufficiently complete to permit a substantive review, the *FDA* will "file" the *NDA*. The *FDA* can refuse to file any *NDA* that it deems incomplete or not properly reviewable. The *FDA* has established internal goals of eight months from submission for priority review of *NDAs* that cover product candidates that offer major advances in treatment or provide a treatment where no adequate therapy exists, and 12 months from submission for the standard review of *NDAs*. However, the *FDA* is not legally required to complete its review within these periods, these performance goals may change over time and the review is often extended by *FDA* requests for additional information or clarification. Moreover, the outcome of the review, even if generally favorable, may not be an actual approval but a "complete response letter" that describes additional work that must be done before the *NDA* can be approved. Before approving an *NDA*, the *FDA* can choose to inspect the facilities at which the product is manufactured and will not approve the product unless the manufacturing facility complies with *GMPs*. The *FDA* may also audit sites at which clinical trials have been conducted to determine compliance with *GCPs* and data integrity. The *FDA's* review of an *NDA* may also involve review and recommendations by an independent *FDA* advisory committee, particularly for novel indications. The *FDA* is not bound by the recommendation of an advisory committee.

In addition, delays or rejections may be encountered based upon changes in regulatory policy, regulations or statutes governing product approval during the period of product development and regulatory agency review.

Before receiving FDA approval to market a potential product, we or our collaborators must demonstrate through adequate and well-controlled clinical studies that the potential product is safe and effective in the patient population that will be treated. In addition, under the Pediatric Research Equity Act, or PREA, an NDA or supplement to an NDA must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective, unless a waiver applies. If regulatory approval of a potential product is granted, this approval will be limited to those disease states and conditions for which the product is approved. Marketing or promoting a drug for an unapproved indication is generally prohibited. Furthermore, FDA approval may entail ongoing requirements for risk management, including post-marketing, or Phase 4, studies. Even if approval is obtained, a marketed product, its manufacturer and its manufacturing facilities are subject to payment of significant annual fees and continuing review and periodic inspections by the FDA. Discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions on the product or manufacturer, including labeling changes, warning letters, costly recalls or withdrawal of the product from the market.

Any drug is likely to produce some toxicities or undesirable side effects in animals and in humans when administered at sufficiently high doses and/or for sufficiently long periods of time. Unacceptable toxicities or side effects may occur at any dose level at any time in the course of studies in animals designed to identify unacceptable effects of a product candidate, known as toxicological studies, or during clinical trials of our potential products. The appearance of any unacceptable toxicity or side effect could cause us or regulatory authorities to interrupt, limit, delay or abort the development of any of our product candidates. Further, such unacceptable toxicity or side effects could ultimately prevent a potential product's approval by the FDA or foreign regulatory authorities for any or all targeted indications or limit any labeling claims and market acceptance, even if the product is approved.

In addition, as a condition of approval, the FDA may require an applicant to develop a Risk Evaluation and Mitigation Strategy, or REMS. A REMS uses risk minimization strategies beyond the professional labeling to ensure that the benefits of the product outweigh the potential risks. To determine whether a REMS is needed, the FDA will consider the size of the population likely to use the product, seriousness of the disease, expected benefit of the product, expected duration of treatment, seriousness of known or potential adverse events, and whether the product is a new molecular entity. REMS can include medication guides, physician communication plans for healthcare professionals, and elements to assure safe use (ETASU). ETASU may include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The FDA may require a REMS before approval or post-approval if it becomes aware of a serious risk associated with use of the product. The requirement for a REMS can materially affect the potential market and profitability of a product.

Any trade name that we intend to use for a potential product must be approved by the FDA irrespective of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office. The FDA conducts a rigorous review of proposed product names, and may reject a product name if it believes that the name inappropriately implies medical claims or if it poses the potential for confusion with other product names. The FDA will not approve a trade name until the NDA for a product is approved. If the FDA determines that the trade names of other products that are approved prior to the approval of our potential products may present a risk of confusion with our proposed trade name, the FDA may elect to not approve our proposed trade name. If our trade name is rejected, we will lose the benefit of any brand equity that may already have been developed for this trade name, as well as the benefit of our existing trademark applications for this trade name.

We and our collaborators and contract manufacturers also are required to comply with the applicable FDA GMP regulations. GMP regulations include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Manufacturing facilities are subject to inspection by the FDA. These facilities must be approved before we can use them in commercial manufacturing of our potential products and must maintain ongoing compliance for commercial product manufacture. The FDA may conclude that we or our collaborators or contract manufacturers are not in compliance with applicable GMP requirements and other FDA regulatory requirements, which may result in delay or failure to approve applications, warning letters, product recalls and/or imposition of fines or penalties.

If a product is approved, we must also comply with post-marketing requirements, including, but not limited to, compliance with advertising and promotion laws enforced by various government agencies, including the FDA's Office of Prescription Drug Promotion, through such laws as the Prescription Drug Marketing Act, federal and state anti-fraud and abuse laws, including anti-kickback and false claims laws, healthcare information privacy and security laws, post-marketing safety surveillance, and disclosure of payments or other transfers of value to healthcare professionals and entities. In addition, we are subject to other federal and state regulation including, for example, the implementation of corporate compliance programs.

If we elect to distribute our products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of pharmaceutical products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain.

Outside of the United States, our ability to market a product is contingent upon receiving a marketing authorization from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. At present, foreign marketing authorizations are applied for at a national level, although within the European Community (EC), centralized registration procedures are available to companies wishing to market a product in more than one EC member state. If the regulatory authority is satisfied that adequate evidence of safety, quality and efficacy has been presented, marketing authorization will be granted. This foreign regulatory development and approval process involves all of the risks associated with achieving FDA marketing approval in the U.S. as discussed above. In addition, foreign regulations may include applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or other transfers of value to healthcare professionals and entities.

Reimbursement

Potential sales of AV-101 or any other future product candidate, if approved, will depend, at least in part, on the extent to which such products will be covered by third-party payors, such as government health care programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly limiting coverage and/or reducing reimbursements for medical products and services. A third-party payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our future revenues and results of operations. Decreases in third-party reimbursement or a decision by a third-party payor to not cover AV-101, if approved, or any future approved products could reduce physician usage of our products, and have a material adverse effect on our sales, results of operations and financial condition.

In the United States, the Medicare Part D program provides a voluntary outpatient drug benefit to Medicare beneficiaries for certain products. We do not know whether AV-101, if approved, or any other future product candidate will be eligible for coverage under Medicare Part D, but individual Medicare Part D plans offer coverage subject to various factors such as those described above. In addition, while Medicare Part D plans have historically included "all or substantially all" drugs in the following designated classes of "clinical concern" on their formularies: anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants, the Centers for Medicare and Medicaid Services (CMS) has in the past proposed, but not adopted, changes to this policy. If this policy is changed in the future and if CMS no longer considers the antidepressant class to be of "clinical concern", Medicare Part D plans would have significantly more discretion to reduce the number of products covered in that class. Furthermore, private payors often follow Medicare coverage policies and payment limitations in setting their own coverage policies.

Healthcare Laws and Regulations

Sales of AV-101, if approved, or any other future product candidate will be subject to healthcare regulation and enforcement by the federal government and the states and foreign governments in which we might conduct our business. The healthcare laws and regulations that may affect our ability to operate include the following:

- The federal Anti-Kickback Statute makes it illegal for any person or entity to knowingly and willfully, directly or indirectly, solicit, receive, offer, or pay any remuneration that is in exchange for or to induce the referral of business, including the purchase, order, lease of any good, facility, item or service for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. The term "remuneration" has been broadly interpreted to include anything of value.
- Federal false claims and false statement laws, including the federal civil False Claims Act, prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, for payment to, or approval by, federal programs, including Medicare and Medicaid, claims for items or services, including drugs, that are false or fraudulent.
- The U.S. federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) created additional federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors or making any false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH) and their implementing regulations, impose obligations on certain types of individuals and entities regarding the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information.
- The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to CMS information related to payments or other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

Also, many states have similar laws and regulations, such as anti-kickback and false claims laws that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Additionally, we may be subject to state laws that require pharmaceutical companies to comply with the federal government's and/or pharmaceutical industry's voluntary compliance guidelines, state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, as well as state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA.

Additionally, to the extent that our product is sold in a foreign country, we may be subject to similar foreign laws.

Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. By way of example, in March 2010, the Patient Protection and Affordable Care Act (ACA) was signed into law, which intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose taxes and fees on the health industry and impose additional health policy reforms. There have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. In early 2017, the U.S. House of Representatives and Senate passed legislation which, if signed into law by President Trump, would repeal certain aspects of the ACA. Congress also could consider subsequent legislation to replace elements of the ACA that are repealed. At this time, the full effect that the ACA will have on our business in the future remains unclear.

Among the provisions of the ACA that may be of importance to AV-101, if approved, and any of our future product candidates are:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities based on their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts to negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- a requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Other legislative changes have been proposed and adopted in the United States since the ACA. Through the process created by the Budget Control Act of 2011, there are automatic reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and, following passage of the Bipartisan Budget Act of 2015, will remain in effect through 2025 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to certain providers. Moreover, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products. We expect that healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and potentially lower reimbursement levels. We cannot predict what healthcare reform initiatives may be adopted in the future.

Stem Cell Technology - United States

With respect to our stem cell research and development in the U.S., the U.S. government has established requirements and procedures relating to the isolation and derivation of certain stem cell lines and the availability of federal funds for research and development programs involving those lines. All of the stem cell lines that we are using were either isolated under procedures that meet U.S. government requirements and are approved for funding from the U.S. government, or were isolated under procedures that meet U.S. government requirements.

All procedures we use to obtain clinical samples, and the procedures we use to isolate hESCs, are consistent with the informed consent and ethical guidelines promulgated by the U.S. National Academy of Science, the International Society of Stem Cell Research (ISSCR), or the NIH. These procedures and documentation have been reviewed by an external Stem Cell Research Oversight Committee, and all cell lines we use have been approved under one or more of these guidelines.

The U.S. government and its agencies on July 7, 2009 published guidelines for the ethical derivation of hESCs required for receiving federal funding for hESC research. Should we seek further NIH funding for our stem cell research and development, our request would involve the use of hESC lines that meet the NIH guidelines for NIH funding. In the U.S., the President's Council on Bioethics monitors stem cell research, and may make recommendations from time to time that could place restrictions on the scope of research using human embryonic or fetal tissue. Although numerous states in the U.S. are considering, or have in place, legislation relating to stem cell research, including California whose voters approved Proposition 71 to provide up to \$3 billion of state funding for stem cell research in California, it is not yet clear what affect, if any, state actions may have on our ability to commercialize stem cell technologies.

Stem Cell Technology - Canada

In Canada, stem cell research and development is governed by two policy documents and by one legislative statute: the Guidelines for Human Pluripotent Stem Cell Research (the *Guidelines*) issued by the Canadian Institutes of Health Research; the Tri-Council Statement: Ethical Conduct for Research Involving Humans (TCPS); and the Assisted Human Reproduction Act (*Act*). The Guidelines and the TCPS govern stem cell research conducted by, or under the auspices of, institutions funded by the federal government. Should we seek funding from Canadian government agencies or should we conduct research under the auspices of an institution so funded, we may have to ensure the compliance of such research with the ethical rules prescribed by the Guidelines and the TCPS.

The Act subjects all research conducted in Canada involving the human embryo, including hESC derivation (but not the stem cells once derived), to a licensing process overseen by a federal licensing agency. However, as of the date of this Annual Report, the provisions of the Act regarding the licensing of hESC derivation were not in force.

We are not currently conducting stem cell research in Canada. We have, however, sponsored pluripotent stem cell research in Canada by Dr. Gordon Keller at UHN's McEwen Centre. Should the provisions of the Act come into force, we may have to apply for a license for all hESC research we may sponsor or conduct in Canada and ensure compliance of such research with the provisions of the Act.

Subsidiaries and Inter-Corporate Relationships

VistaGen Therapeutics, Inc., a California corporation, dba VistaStem (*VistaStem*), is our wholly-owned subsidiary and has two wholly-owned subsidiaries: VistaStem Canada Inc., a corporation incorporated pursuant to the laws of the Province of Ontario, and Artemis Neuroscience, Inc., a corporation incorporated pursuant to the laws of the State of Maryland. The operations of VistaStem, and each of its wholly owned subsidiaries are managed by our senior management team based in South San Francisco, California.

Employees

As of June 27, 2017, we employed nine full-time employees, four of whom have doctorate degrees. Five full-time employees work in research and development and laboratory support services and four full-time employees work in general and administrative roles. Staffing for all other functional areas is achieved through strategic relationships with service providers and consultants, each of whom provides services on a real-time, as-needed basis, including human resources and payroll, information technology, facilities, legal, investor relations and website maintenance, regulatory affairs, and FDA program management.

We have never had a work stoppage, and none of our employees is represented by a labor organization or under any collective bargaining agreement. We consider our employee relations to be good.

Facilities

We lease our office and laboratory space, which consists of approximately 10,900 square feet located in South San Francisco, California, under a lease expiring on July 31, 2022.

Legal Proceedings

None.

Environmental Regulation

Our business does not require us to comply with any extraordinary environmental regulations.

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 other information in this Annual Report 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/or operating results 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, potentially, 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 non-clinical and clinical development, testing and regulatory approval before it may be commercialized. It is unlikely to achieve regulatory approval, if at all, until at least 2021. Each drug rescue NCE will require substantial non-clinical development, all phases of clinical development, and regulatory approval before it may be commercialized. The non-clinical and clinical development of our product candidates are, and the manufacturing and marketing of our product candidates will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and, if approved, market any product candidate. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must demonstrate through non-clinical 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 or clinical studies. 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 and clinical studies, we cannot assure you that AV-101, any drug rescue NCE, or any other future 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 AV-101 MDD Phase 2 Adjunctive Treatment 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 non-clinical and certain small clinical studies before submitting an NDA for AV-101. The results of all of these 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 we submit an NDA and it 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 or clinical studies, 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 for any product candidate 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, initially 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, initially for adjunctive treatment of MDD patients with an inadequate response to standard antidepressants, and we may do so for other CNS indications, as well as for other product candidates. The FDA has broad discretion whether or not to grant a Fast Track designation, and even if we believe AV-101 and other product candidates 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 NIMH AV-101 MDD Phase 2 Monotherapy Study and our planned AV-101 MDD Phase 2 Adjunctive Treatment 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 timing or nature of clinical trials compared to completed clinical trials. As product candidates are developed through preclinical to early and late stage clinical trials towards 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 non-clinical 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 2 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 NIMH AV-101 MDD Phase 2 Monotherapy 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 NIMH AV-101 MDD Phase 2 Monotherapy Study. We will need to complete the planned AV-101 MDD Phase 2 Adjunctive Treatment Study, at least two additional large Phase 2b/3 clinical trials, additional toxicity and non-clinical 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 AV-101 MDD Phase 2 Monotherapy Study, the AV-101 MDD Phase 2 Adjunctive Treatment Study or any of our future-planned non-clinical and clinical trials will be completed on schedule, if at all, as the commencement and completion of non-clinical and 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 planned or ongoing clinical trial on hold;
- delays in filing or receiving approvals of additional INDs that may be required;
- negative results from our ongoing non-clinical 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 non-clinical or 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 clinical 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 prior non-clinical studies or clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials;
- reports from non-clinical or clinical testing of other CNS indications or therapies that raise safety or efficacy concerns; and
- difficulties retaining patients who have enrolled in a clinical trial but may be prone to withdraw due to rigors of the clinical 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 non-clinical and 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 non-clinical and 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 internal staff resources to independently conduct non-clinical and clinical trials completely on our own. We rely on our strategic relationships with various medical institutions, non-clinical and clinical investigators, contract laboratories and other third parties, such as contract research and development organizations (CROs), to conduct non-clinical and clinical trials of our product candidates. We enter into agreements with third-party CROs to provide monitors for and to manage data for our clinical trials, as well as provide other services necessary to prepare for, conduct and complete clinical trials. We rely heavily on these and other third-parties for execution of non-clinical and 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 non-clinical and clinical trials and the management of data developed through non-clinical and 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 non-clinical and clinical trials and may subject us to unexpected cost increases that are beyond our control. Nevertheless, we are responsible for ensuring that each of our non-clinical studies and 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 any of 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 AV-101 MDD Phase 2 Monotherapy Study, 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 non-clinical and 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 develop and commercialize our product candidates. As a result, we believe that our financial results and the commercial prospects for our product candidates in the subject indication would be harmed, our costs would increase and our ability to generate revenue would be delayed.

We rely completely on third-parties to manufacture 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 drug supply of AV-101 or any other product candidates for use in the conduct of our non-clinical studies and clinical trials, and we lack the internal resources and the capability to manufacture any product candidates on a research, development 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 directly 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 other 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 research, development and 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 trials.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval for and commercialize AV-101 and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system, including the ACA, that could, among other things, prevent or delay marketing approval of AV-101, restrict or regulate post-approval activities, and affect our ability to profitably sell any products for which we obtain marketing approval.

In March 2010, the ACA was enacted to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry, and impose additional health policy reforms. The law has continued the downward pressure on pharmaceutical pricing, especially under the Medicare program, and increased the industry's regulatory burdens and operating costs. We cannot predict the full impact of the ACA on pharmaceutical companies, as many of the reforms require the promulgation of detailed regulations implementing the statutory provisions, some of which have not yet fully occurred.

Further, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. In January 2017, the President of the United States signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. In May 2017, the United States House of Representatives passed legislation known as the American Health Care Act, which, if enacted, would amend or repeal significant portions of the ACA. The United States Senate could adopt the American Health Care Act as passed by the United States House of Representatives or other legislation to amend or replace elements of the ACA. Thus, it is uncertain when or if the American Health Care Act will become law. We continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business.

Other legislative changes have been proposed and adopted since the ACA was enacted. For example, in August 2011, the President of the United States signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This included further reductions to Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2025 unless additional Congressional action is taken. Additionally, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several types of providers and increased the statute of limitations period in which the government may recover overpayments to providers from three to five years. Further, there have been several recent United States Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the out-of-pocket cost of prescription drugs, and reform government reimbursement methodologies for drugs.

Moreover, the Drug Supply Chain Security Act, which was enacted in 2012 as part of the Food and Drug Administration Safety and Innovation Act, imposes new obligations on manufacturers of pharmaceutical products related to product tracking and tracing. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We are not sure whether additional legislative changes will be enacted, or whether the current regulations, guidance or interpretations will be changed, or what the impact of such changes on our business, if any, may be. In addition, increased scrutiny by the United States Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

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 sale, marketing and distribution of pharmaceutical products, nor do we intend to create such capabilities. Therefore, in order to market our product candidates, if approved by the FDA or any other regulatory body, we must make contractual arrangements with third parties to perform services related to sales, marketing, managerial and other non-technical capabilities relating to the commercialization of our product candidates. 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 safety concerns and side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

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

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

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

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

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

Even if we receive marketing approval for our product candidates, regulatory authorities may still impose significant restrictions on our product candidates, indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies. Our product candidates will also be subject to ongoing regulatory requirements governing the labeling, packaging, storage and promotion of the product and record keeping and submission of safety and other post-market information. The FDA 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 product candidates that may be similar to our product candidates or address similar markets. It is probable that the number of companies seeking to develop product candidates similar to our product candidates will increase.

Currently, management is unaware of any FDA-approved oral adjunctive therapy for MDD patients with an inadequate response to standard antidepressants having the same mechanism of action and safety profile as AV-101. However, new antidepressant products with other mechanisms of action or products approved for other indications, including the anesthetic ketamine hydrochloride, 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 as psychotherapy and electroconvulsive therapy (ECT) are sometimes used before or instead of standard antidepressant medications to treat patients with MDD.

In the field of new generation, orally available, adjunctive treatments of adult MDD patients with an inadequate response to standard antidepressants, we believe our principal competitor is Alkermes' orally available drug candidate in Phase 3 development, ALKS-5461.

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, dyskinesia associated with L-DOPA therapy for 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 markets for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for our product candidate. The terms of any collaboration or other arrangements that we may establish may not be favorable to us.

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

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

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

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

The success of our business depends primarily upon our ability to identify, develop and commercialize product candidates with commercial and therapeutic potential. Although AV-101 is in Phase 2 clinical development for treatment of 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 currently have limited financial and management resources, we necessarily focus on a limited number of research and development programs and product candidates and are currently focused primarily on development of AV-101, 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 and development programs to identify and advance new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful.

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

Although we do not currently have any products on the market, once we begin commercializing our 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 adjunctive treatment of 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 heavily on reimbursement policies and may be affected by healthcare reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels for those medications. Cost containment is a primary concern in the 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 AV-101 of other 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 AV-101 or any other 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 status for a drug that shares the same active moiety as an already approved drug, it must be demonstrated to the FDA that the drug is safer or more effective than the approved orphan designated drug, or that it makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition or if another drug with the same active moiety is determined to be safer, more effective, or represents a major contribution to patient care.

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 product candidates 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 and development methodology may not be successful in identifying and developing 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 non-clinical 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 non-clinical regenerative medicine studies. In the past, our stem cell research and development projects have been significantly delayed when we encountered unanticipated difficulties in differentiating human pluripotent stem cells into heart and liver cells. Although we have overcome such difficulties in the past, we may have similar delays in the future, and we may not be able to overcome them or obtain any benefits from our future stem cell technology research and development activities. Any delay or failure by us, for example, to produce functional, mature blood, bone, cartilage, and liver cells could have a substantial and material adverse effect on our potential drug discovery, drug rescue and regenerative medicine business opportunities and results of operations.

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

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

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 \$10.3 million and \$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, during the fiscal years ended March 31, 2017 and 2016, respectively. As of March 31, 2017, we had an accumulated deficit of approximately \$142.0 million. We do not know whether or when we will become profitable. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to incur increasing levels of operating losses over the next several years and for the foreseeable future. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity (deficit) and working capital. We expect our research and development expenses to significantly increase in connection with 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 \$17.7 million in revenues, including receipt of non-dilutive cash payments from collaborators, sublicense revenue, and research and development grant awards from the NIH, not including the fair market value of the ongoing NIMH AV-101 MDD Phase 2 Monotherapy Study under our NIMH CRADA. 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 non-clinical 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.

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, 2017 have been prepared assuming we will continue to operate as a going concern, although our auditors have indicated that our continuing losses and negative cash flows from operations raise substantial doubt about our ability to continue as such. Because we continue to experience net operating losses, our ability to continue as a going concern is subject to our ability to obtain necessary funding from outside sources, including obtaining additional funding from 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 and our cardiac stem cell technology for drug rescue and potential regenerative medicine applications, and we will continue to expend substantial resources for the foreseeable future developing and commercializing AV-101 for multiple CNS indications, and, potentially, developing drug rescue NCEs and RM therapies, on our own or in collaborations similar to the BlueRock Agreement. 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, 2017, our existing cash and cash equivalents were not sufficient to fund our current operations for the next 12 months or to complete our proposed AV-101 MDD Phase 2 Adjunctive Treatment Study of AV-101. However, as described in Note 16, *Subsequent Events*, to the accompanying Consolidated Financial Statements for the fiscal year ended March 31, 2017, included in Item 8 of this Annual Report, between April 1, and June 27, 2017, in self-placed private placement transactions, we sold to accredited investors units consisting of (i) an aggregate of 437,751 shares of our unregistered common stock and (ii) warrants to purchase an aggregate of 218,875 shares of our common stock, pursuant to which we received cash proceeds of \$837,300, bringing proceeds for the Spring 2017 Private Placement to approximately \$1.0 million. 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 Consolidated Financial Statements for the fiscal year ended March 31, 2017, we received a cash payment of \$1.25 million under the BlueRock Agreement in January 2017. Additionally, in February 2015, we entered into the CRADA with the NIH, under which the NIMH is fully funding and conducting the NIMH AV-101 MDD Phase 2 Monotherapy 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 develop, obtain regulatory approval for, and to commercialize our product candidates, and may seek additional capital in the event there exists favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. We 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 2017 and beyond. 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.

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

We have identified material weaknesses in our internal control over financial reporting. In particular, we concluded that (i) the size and capabilities of our staff does not permit appropriate segregation of duties to prevent one individual from overriding the internal control system by initiating, authorizing and completing all transactions, and (ii) we utilize accounting software that does not prevent erroneous or unauthorized changes to previous reporting periods and/or can be adjusted so as to not provide an adequate auditing trail of entries made in the accounting software (See Item 9A. *Controls and Procedures* contained in this Annual Report).

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

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

We intend to pursue private and public equity offerings, debt financings, strategic collaborations and licensing arrangements during 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, at March 31, 2017, we have approximately 8.9 million shares of common stock available for future financing or other activities. We anticipate seeking 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.

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

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

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

As of March 31, 2017, we had federal and state net operating loss carryforwards of \$77.1 million and \$67.6 million, respectively, which begin to expire in fiscal 2018. 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 Annual Report, we have nine full-time employees, which may make us more reliant on our individual employees than companies with a greater number of employees. The loss of services of any of these individuals could delay or prevent the successful development of AV-101, drug rescue NCEs, other product candidates, and other applications of our stem cell technology, including our production and assessment of potential drug rescue 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 stem cell technology-related drug rescue and 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 or political conditions could adversely affect our business, financial condition or results of operations.

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

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

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

Our 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.

Although we have an issued patent relating to AV-101 in the European Union, we cannot yet provide any assurances that any of our numerous pending U.S. and additional 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 additional 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 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 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 could put our patents at risk of being invalidated, held unenforceable, or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. If any patents covering our product candidates are invalidated or found unenforceable, our financial position and results of operations would be materially and adversely impacted. In addition, if a court found that valid, enforceable patents held by third parties covered our product candidates, our financial position and results of operations would also be materially and adversely impacted.

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

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

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 or European Union.

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 EPO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review and equivalent proceedings in foreign jurisdictions, e.g., opposition proceedings. Such proceedings could result in revocation or amendment of our patents in such a way that they no longer cover our product candidates or competitive products. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection would have a material adverse impact on our business.

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 and clinical development activities related to our product candidates;
- the failure of the FDA to approve our product candidates;
- announcements of new products, technologies, commercial relationships, acquisitions or other events by us or our competitors;
- the success or failure of other CNS therapies;
- regulatory or legal developments in the United States and other countries;
- 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 small biopharmaceutical companies like ours in particular, have 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 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 Restated 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 issued and outstanding at March 31, 2017; (ii) 4.0 million shares of Series B 10% Convertible Preferred stock, of which approximately 1.2 million shares remain issued and outstanding at March 31, 2017; and (iii) 3.0 million shares of Series C Convertible Preferred Stock, of which approximately 2.3 million shares are issued and outstanding at March 31, 2017. 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 1B. Unresolved Staff Comments

The disclosures in this section are not required since we qualify as a smaller reporting company.

Item 2. Properties

Our corporate headquarters and laboratories are located at 343 Allerton Avenue, South San Francisco, California 94080, where we occupy approximately 10,900 square feet of office and lab space under a lease expiring on July 31, 2022. We believe that our facilities are suitable and adequate for our current and foreseeable needs.

Item 3. Legal Proceedings

None.

Item 4. Mine Safety Disclosures

Not applicable.

PART II**Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities****Market Information**

Our common stock was approved for listing and has traded since May 11, 2016 on The NASDAQ Capital Market under the symbol “VTGN”. From June 21, 2011 through May 10, 2016, our common stock traded on the OTC Marketplace (OTCQB), under the symbol “VSTA”. There was no established trading market for our common stock prior to June 21, 2011.

Shown below is the range of high and low sales prices for our common stock for the periods indicated as reported by the NASDAQ Capital Market or the OTCQB. The market quotations reflect inter-dealer prices, without retail mark-up, mark-down or commissions and may not necessarily represent actual transactions.

	High	Low
Year Ending March 31, 2017		
First quarter ending June 30, 2016	\$ 9.00	\$ 3.40
Second quarter ended September 30, 2016	\$ 4.69	\$ 2.81
Third quarter ended December 31, 2016	\$ 4.50	\$ 3.11
Fourth quarter ended March 31, 2017	\$ 3.90	\$ 1.74
Year Ending March 31, 2016		
First quarter ending June 30, 2015	\$ 16.50	\$ 8.00
Second quarter ending September 30, 2015	\$ 14.90	\$ 6.50
Third quarter ending December 31, 2015	\$ 10.25	\$ 4.00
Fourth quarter ending March 31, 2016	\$ 9.97	\$ 6.50

On June 27, 2017 the closing price of our common stock on The NASDAQ Capital Market was \$1.83 per share.

As of June 27, 2017, we had 9,301,472 shares of common stock outstanding and approximately 700 stockholders of record. On the same date, two stockholders held all 500,000 outstanding restricted shares of our Series A Preferred Stock, which shares are convertible into 750,000 shares of common stock; two stockholders held 1,160,240 outstanding shares of our Series B 10% Convertible Preferred Stock, which shares are convertible into 1,160,240 shares of common stock; and one stockholder held all 2,318,012 outstanding shares of our Series C Preferred stock, which shares are convertible into 2,318,012 shares of common stock.

Dividend Policy

We have never paid or declared any cash dividends on our common stock, and we do not anticipate paying any cash dividends on our common stock in the foreseeable future. Covenants in certain of our debt agreements prohibit us from paying dividends while the debt remains outstanding. Our Series B Preferred accrues dividends at a rate of 10% per annum, which dividends are payable solely in unregistered shares of our common stock at the time the Series B Preferred is converted into common stock.

Issuer Purchases of Equity Securities

We did not purchase any of our registered equity securities during the period covered by this Annual Report.

Recent Sales of Unregistered Securities

We have issued the following securities in private placement transactions which were not registered under the Securities Act of 1933, as amended (*Securities Act*) and that have not been previously reported in a Quarterly Report on Form 10-Q or a Current Report on Form 8-K.

Sale of Units of Common Stock and Warrants in Private Placement

Between March 30, 2017 and June 27, 2017, we entered into self-placed private placement transactions involving securities purchase agreements with accredited investors, pursuant to which we sold units consisting of an aggregate of (i) 495,001 shares of our unregistered common stock; and (ii) warrants exercisable six months following issuance and through April 30, 2021 to purchase an aggregate of 247,500 shares of our common stock at a fixed exercise price of \$4.00 per share, subject to adjustment only for customary stock dividends, reclassifications, splits and similar transactions. We received cash proceeds of \$987,800, which we expect to use for general corporate purposes. The units were offered and sold in a self-placed private placement transaction exempt from registration under the Securities Act in reliance on Section 4(2) thereof and Rule 506 of Regulation D thereunder.

Securities Issued for Professional Services

During December 2016, we granted an aggregate of 200,000 unregistered shares of our common stock, including 100,000 unregistered shares from our Amended and Restated 2016 Stock Incentive Plan, to five accredited investors as full or partial compensation for various investor relations, corporate development, and other professional services. The shares of common stock were issued in private placement transactions exempt from registration under the Securities Act, in reliance on Section 4(2) thereof and Rule 506 of Regulation D thereunder.

Item 6. Selected Financial Data

The disclosures in this section are not required because we qualify as a smaller reporting company under federal securities laws.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

Cautionary Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K (Annual Report) includes forward-looking statements. All statements contained in this Annual 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 Annual 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 Annual 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 Annual Report or to conform these statements to actual results or revised expectations. If we do update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements.

Business Overview

We are a clinical-stage biopharmaceutical company focused on developing new generation medicines for depression and other central nervous system (CNS) disorders.

AV-101 is our oral CNS product candidate in Phase 2 clinical development in the United States, initially as a new generation 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). AV-101's mechanism of action (MOA) involves both NMDA (N-methyl-D-aspartate) and AMPA (alpha-amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid) receptors in the brain responsible for fast excitatory synaptic activity throughout the CNS. AV-101's MOA is fundamentally differentiated from all FDA-approved antidepressants, as well as all atypical antipsychotics often used adjunctively to augment them. We believe AV-101 also has potential as a new treatment alternative for several additional indications involving the CNS, including epilepsy, Huntington's disease, L-DOPA-induced dyskinesia associated with Parkinson's disease, and neuropathic pain.

Clinical studies conducted at the U.S. National Institute of Mental Health (NIMH), part of the U.S. National Institutes of Health (NIH), by 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, have focused on the antidepressant effects of low dose ketamine hydrochloride injection (ketamine), an NMDA receptor antagonist, in MDD patients with inadequate responses to multiple standard antidepressants. These NIMH studies, as well as clinical research at Yale University and other academic institutions, have demonstrated robust antidepressant effects in these MDD patients within twenty-four hours of a single sub-anesthetic dose of ketamine administered by intravenous (IV) injection.

We believe orally-administered AV-101 may have potential to deliver ketamine-like antidepressant effects without ketamine's psychological and other negative side effects. As published in the October 2015 issue of the peer-reviewed, *Journal of Pharmacology and Experimental Therapeutics*, in an article titled, *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. In addition, these studies confirmed that the fast-acting antidepressant effects of AV-101 were mediated through both inhibiting the GlyB site of the NMDA receptor and activating the AMPA receptor pathway in the brain.

Pursuant to our Cooperative Research and Development Agreement (CRADA) with the NIMH, the NIMH is funding, and Dr. Zarate, as Principal Investigator, and his team are conducting, a small Phase 2 clinical study of AV-101 monotherapy in subjects with treatment-resistant MDD (the *NIMH AV-101 MDD Phase 2 Monotherapy Study*). We are preparing to launch our 180-patient Phase 2 multi-center, multi-dose, double blind, placebo-controlled efficacy and safety study of AV-101 as a new generation adjunctive treatment of MDD in adult patients with an inadequate response to standard, FDA-approved antidepressants (the *AV-101 MDD Phase 2 Adjunctive Treatment Study*). 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 our AV-101 MDD Phase 2 Adjunctive Treatment 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 completing our AV-101 MDD Phase 2 Adjunctive Treatment Study by the end of 2018 with top line results available in the first quarter of 2019.

VistaStem Therapeutics (*VistaStem*) is our wholly owned subsidiary focused on applying human pluripotent stem cell (hPSC) technology, internally and with collaborators, to discover, rescue, develop and commercialize (i) proprietary new chemical entities (NCEs) for CNS and other diseases and (ii) regenerative medicine (RM) involving hPSC-derived blood, cartilage, heart and liver cells. Our internal drug rescue programs are designed to utilize *CardioSafe 3D*, our customized cardiac bioassay system, to develop small molecule NCEs for our pipeline. In December 2016, we exclusively sublicensed to BlueRock Therapeutics LP, a next generation RM company established 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*). In a manner similar to our exclusive sublicense agreement with BlueRock Therapeutics, VistaStem may pursue additional RM collaborations or licensing transactions involving blood, cartilage, and/or liver cells derived from hPSCs for (A) cell-based therapy, (B) cell repair therapy, and/or (C) tissue engineering.

The Merger

VistaGen Therapeutics, Inc., a California corporation incorporated on May 26, 1998, dba VistaStem, is our wholly-owned subsidiary. Excaliber Enterprises, Ltd. (*Excaliber*), a publicly-held company (formerly OTCBB: EXCA) was incorporated under the laws of the State of Nevada on October 6, 2005. Pursuant to a strategic merger transaction on May 11, 2011, Excaliber acquired all outstanding shares of VistaStem in exchange for 341,823 shares of our common stock and assumed all of VistaStem's pre-Merger obligations (the *Merger*). Shortly after the Merger, Excaliber's name was changed to "VistaGen Therapeutics, Inc." (a Nevada corporation).

VistaStem, as the accounting acquirer in the Merger, recorded the Merger as the issuance of common stock for the net monetary assets of Excaliber, accompanied by a recapitalization. The accounting treatment for the Merger was identical to that resulting from a reverse acquisition, except that we recorded no goodwill or other intangible assets. A total of 78,450 shares of our common stock, representing the shares held by stockholders of Excaliber immediately prior to the Merger are reflected as outstanding for all periods presented in the Consolidated Financial Statements of the Company included in Item 8 of this Annual Report on Form 10-K. Additionally, the Consolidated Balance Sheets reflect the \$0.001 par value of Excaliber's common stock.

The Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K represent the activity of VistaStem from May 26, 1998, and the consolidated activity of VistaStem and Excaliber (now VistaGen Therapeutics, Inc., a Nevada corporation), from May 11, 2011 (the date of the Merger). The Consolidated Financial Statements also include the accounts of VistaStem's two inactive wholly-owned subsidiaries, Artemis Neuroscience, Inc., a Maryland corporation (*Artemis*), and VistaStem Canada, Inc., a corporation organized under the laws of Ontario, Canada (*VistaStem Canada*).

Critical Accounting Policies and Estimates

We consider certain accounting policies related to revenue recognition, impairment of long-lived assets, research and development, stock-based compensation, warrant liability and income taxes to be critical accounting policies that require the use of significant judgments and estimates relating to matters that are inherently uncertain and may result in materially different results under different assumptions and conditions. The preparation of financial statements in conformity with United States generally accepted accounting principles (GAAP) requires us to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes to the consolidated financial statements. These estimates include useful lives for property and equipment and related depreciation calculations, and assumptions for valuing options, warrants and other stock-based compensation. Our actual results could differ from these estimates.

Revenue Recognition

We have historically generated revenue principally from collaborative research and development arrangements, licensing and technology access fees and government grants. We recognize revenue under the provisions of the SEC issued Staff Accounting Bulletin 104, Topic 13, *Revenue Recognition Revised and Updated (SAB 104)* and Accounting Standards Codification (ASC) 605-25, *Revenue Arrangements-Multiple Element Arrangements (ASC 605-25)*. Revenue for arrangements not having multiple deliverables, as outlined in ASC 605-25, is recognized once costs are incurred and collectability is reasonably assured.

Revenue arrangements with multiple components are divided into separate units of accounting if certain criteria are met, including whether the delivered component has stand-alone value to the customer. Consideration received is allocated among the separate units of accounting based on their respective selling prices. The selling price for each unit is based on vendor-specific objective evidence, or *VSOE*, if available, third party evidence if *VSOE* is not available, or estimated selling price if neither *VSOE* nor third party evidence is available. The applicable revenue recognition criteria are then applied to each of the units.

We recognize revenue when the four basic criteria of revenue recognition are met: (i) a contractual agreement exists; (ii) the transfer of technology has been completed or services have been rendered; (iii) the fee is fixed or determinable; and (iv) collectability is reasonably assured. For each source of revenue, we comply with the above revenue recognition criteria in the following manner:

- Collaborative arrangements typically consist of non-refundable and/or exclusive technology access fees, cost reimbursements for specific research and development spending, and various future product development milestone and royalty payments. If the delivered technology does not have stand-alone value, the amount of revenue allocable to the delivered technology is deferred. Non-refundable upfront fees with stand-alone value that are not dependent on future performance under these agreements are recognized as revenue when received, and are deferred if we have continuing performance obligations and have no objective and reliable evidence of the fair value of those obligations. We recognize non-refundable upfront technology access fees under agreements in which we have a continuing performance obligation ratably, on a straight-line basis, over the period in which we are obligated to provide services. Cost reimbursements for research and development spending are recognized when the related costs are incurred and when collectability is reasonably assured. Payments received related to substantive, performance-based “at-risk” milestones are recognized as revenue upon achievement of the milestone event specified in the underlying contracts, which represent the culmination of the earnings process. Amounts received in advance are recorded as deferred revenue until the technology is transferred, costs are incurred, or a milestone is reached.
- Technology license agreements typically consist of non-refundable upfront license fees, annual minimum access fees and/or royalty payments. Non-refundable upfront license fees and annual minimum payments received with separable stand-alone values are recognized when the technology is transferred or accessed, provided that the technology transferred or accessed is not dependent on the outcome of the continuing research and development efforts. Otherwise, revenue is recognized over the period of our continuing involvement.
- Government grant awards, which support our research efforts on specific projects, generally provide for reimbursement of approved costs as defined in the terms of grant awards. We recognize grant revenue when associated project costs are incurred.

As described more completely in Note 3, *Summary of Significant Accounting Policies*, to the accompanying Consolidated Financial Statements contained in Item 8 of this Annual Report, the Financial Accounting Standards Board (the *FASB*) has recently issued new guidance regarding revenue recognition. This new guidance will be effective for our fiscal year beginning April 1, 2018, with earlier adoption permitted. We have completed our initial assessment of the new guidance and will be developing an implementation plan to evaluate the accounting and disclosure requirements under the new guidance. Based on our assessment to date, we do not believe that adoption of the new guidance will have a material impact on our consolidated financial statements. We have not yet finalized our transition method for adoption of the new guidance.

Impairment of Long-Lived Assets

In accordance with ASC 360-10, *Property, Plant & Equipment—Overall*, we review for impairment whenever events or changes in circumstances indicate that the carrying amount of property and equipment may not be recoverable. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, we write down the assets to their estimated fair values and recognize the loss in the Consolidated Statements of Operations and Comprehensive Loss.

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 clinical and non-clinical development of AV-101, our oral CNS prodrug candidate in Phase 2 clinical development for Major Depressive Disorder, sponsored stem cell research and development costs, and costs related to the application and prosecution of patents related to AV-101 and our stem cell technology platform. All such costs are charged to expense as incurred.

Stock-Based Compensation

We recognize non-cash compensation expense for all stock-based awards to employees based on the grant date fair value of the award. We record this expense over the period during which the employee is required to perform services in exchange for the award, which generally represents the scheduled vesting period. We have granted no restricted stock awards nor do we have any 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.

We use the Black-Scholes option pricing model to estimate the fair value of stock-based awards as of the grant date. The Black-Scholes model is complex and dependent upon key data input estimates. The primary data inputs with the greatest degree of judgment are the expected term of the stock options and the estimated volatility of our stock price. The Black-Scholes model is highly sensitive to changes in these two inputs. The expected term of the options represents the period of time that options granted are expected to be outstanding. We use the simplified method to estimate the expected term as an input into the Black-Scholes option pricing model. We determine expected volatility using the historical method, which, because of the limited period during which our stock has been publicly traded and its historically limited trading volume, is based on the historical daily trading data of the common stock of a peer group of public companies over the expected term of the option.

Warrant Liability

Although we did not have a warrant liability at March 31, 2017 or 2016, 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 warrants, and the contingently issuable Series A Exchange Warrant (collectively, the *PLTG Warrants*), we determined that the *PLTG Warrants* included certain exercise price and other adjustment features requiring them to be treated as noncash liabilities. Accordingly, the *PLTG Warrants* were recorded at their issuance-date estimated fair values and marked to market at each subsequent reporting period, recording the change in the fair value as non-cash expense or non-cash income. The key component in determining the fair value of the *PLTG Warrants* and the related liability was the market price of our common stock, which is subject to significant fluctuation and is not under our control. The resulting change in the fair value of the warrant liability on our net income or loss was therefore also subject to significant fluctuation and would have continued to be so until all of the *PLTG Warrants* were issued and exercised, amended, cancelled or expired. Assuming all other fair value inputs remained generally constant, we recorded an increase in the warrant liability and non-cash losses when our stock price increased and a decrease in the warrant liability and non-cash income when our stock price decreased.

Notwithstanding the foregoing, and as described in Note 9, *Capital Stock*, to the Consolidated Financial Statements included in Item 8 of this Annual Report, on May 12, 2015, we entered into an agreement with *PLTG* pursuant to which we (i) fixed the exercise price of the *PLTG Warrants* at \$7.00 per share, (ii) eliminated the exercise price reset features and (iii) fixed the number of shares of our common stock issuable thereunder. This agreement and the related amendments to the *PLTG Warrants* resulted in the elimination of the warrant liability with respect to the *PLTG Warrants* during the quarter ending June 30, 2015. As further described in Note 9, *Capital Stock*, the *PLTG Warrants*, including the right to receive the Series A Exchange Warrant, were cancelled in exchange for our issuance of shares of our Series C Preferred stock to *PLTG* in January 2016.

Income Taxes

We account for income taxes using the asset and liability approach for financial reporting purposes. We recognize deferred tax assets and liabilities for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Valuation allowances are established, when necessary, to reduce the deferred tax assets to an amount expected to be realized.

Recent Accounting Pronouncements

See Note 3 to the Consolidated Financial Statements included in Item 8 in this Annual Report on Form 10-K for information on recent accounting pronouncements.

Results of Operations

Financial Operations Overview and Results of Operations

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 non-clinical 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 March 31, 2017, we had an accumulated deficit of approximately \$142.0 million. Our net loss for the fiscal years ended March 31, 2017 and 2016 was approximately \$10.3 million and \$47.2 million, respectively, the latter amount including a non-recurring, non-cash loss of approximately \$26.7 million attributable to the extinguishment and conversion of approximately \$15.9 million carrying value of prior indebtedness into our equity securities between May and September 2015 at a Conversion Price (the stated value of the equity received) 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 Our Fiscal Year Ended March 31, 2017

During Fiscal 2017, we have continued to (i) advance non-clinical and clinical development of AV-101 as a potential new generation antidepressant and as a new therapeutic alternative for several other CNS indications with significant unmet medical need, (ii) expand the regulatory foundation to support broad Phase 2 clinical development of AV-101 in the U.S. and, (iii) on a limited basis, advance (a) the predictive toxicology capabilities of *CardioSafe* 3D for small molecule NCE drug rescue and development applications, (b) our 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 in vitro assessment of potential drug effects on cardiac risk, and (c) collaborative regenerative medicine opportunities related to our cardiac stem cell technology platform.

Pursuant to our Cooperative Research and Development Agreement (*CRADA*) with the NIH, the NIH is funding, and Dr. Carlos Zarate Jr. of the NIMH is conducting the NIMH AV-101 MDD Phase 2 Monotherapy Study. We currently anticipate that the NIMH will complete the NIMH AV-101 MDD Phase 2 Monotherapy Study in 2017, with top line results during the first half of 2018. In addition, we continue to prepare for our AV-101 Phase 2 Adjunctive Treatment Study. We currently anticipate completing our AV-101 MDD Phase 2 Adjunctive Treatment Study by the end of 2018 with top line results available in the first quarter of 2019.

In May 2016, we consummated an underwritten public offering of our securities pursuant to which we received net proceeds of approximately \$9.54 million and 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 (*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 expected future capital requirements.

In addition to bolstering our Clinical and Regulatory Advisory Board with the appointment of Dr. Maurizio Fava (Harvard University) as Chairman and the addition of members Dr. Sanjay Matthew (Baylor University) and Dr. Thomas Laughren (former director, FDA's Division of Psychiatry), 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 the BlueRock 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 Agreement and we may potentially receive additional cash milestones and royalty payments in the future upon BlueRock's achievement of certain development objectives and commercial sales.

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 non-clinical 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 internal costs.

Comparison of Fiscal Years Ended March 31, 2017 and 2016

The following table summarizes the results of our operations for the fiscal years ended March 31, 2017 and 2016 (amounts in thousands).

	Fiscal Years Ended March 31,	
	2017	2016
Sublicense revenue	\$ 1,250	\$ -
Operating expenses:		
Research and development	5,204	3,932
General and administrative	6,295	13,919
Total operating expenses	<u>11,499</u>	<u>17,851</u>
Loss from operations	(10,249)	(17,851)
Interest expense (net)	(5)	(771)
Change in warrant liabilities	-	(1,895)
Loss on extinguishment of debt	-	(26,700)
Other expense	-	(2)
Loss before income taxes	(10,254)	(47,219)
Income taxes	(2)	(2)
Net loss	(10,256)	(47,221)
Accrued dividend on Series B Preferred Stock	(1,257)	(2,140)
Deemed dividend on Series B Preferred Stock	(111)	(2,058)
Net loss attributable to common stockholders	<u>\$ (11,624)</u>	<u>\$ (51,419)</u>

Revenue

We recognized \$1.25 million in sublicense revenue pursuant to the BlueRock Agreement in the quarter ended December 31, 2016. While we may potentially receive additional payments and royalties under the BlueRock 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 fiscal years ended March 31, 2017 or 2016 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 NIMH AV-101 MDD Phase 2 Monotherapy Study.

Research and Development Expense

Research and development expense totaled \$5,203,700 for the fiscal year ended March 31, 2017 (*Fiscal 2017*), an increase of approximately 33% compared with the \$3,931,600 incurred for the fiscal year ended March 31, 2016 (*Fiscal 2016*), demonstrating our increased focus on the continuing non-clinical and clinical development of AV-101 and our preparations to launch our AV-101 MDD Phase 2 Adjunctive Treatment Study, which we currently anticipate to begin in the first quarter of 2018. Of the amounts reported, non-cash expenses, related primarily to grants or modifications of our equity securities, totaled approximately \$534,000 in Fiscal 2017 and \$1,749,000 in Fiscal 2016. The following table indicates the primary components of research and development expense for each of the periods (amounts in thousands):

	Fiscal Years Ended March 31,	
	2017	2016
Salaries and benefits	\$ 1,331	\$ 818
Stock-based compensation	375	1,093
Consulting and other professional services	(75)	112
Technology licenses and royalties, including UHN	746	1,010
Project-related research and supplies:		
AV-101	2,292	406
Stem cell and all other	185	100
	<u>2,477</u>	<u>506</u>
Rent	310	219
Depreciation	37	37
Warrant modification expense	-	135
All other	3	2
Total Research and Development Expense	<u>\$ 5,204</u>	<u>\$ 3,932</u>

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 13, *Stock Option Plans and 401(k) Plan*, to the accompanying Consolidated Financial Statements in Part 8 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 Fiscal 2017 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 became fully-vested and were fully-expensed by March 31, 2017.

Consulting services reflects fees paid or accrued for scientific, non-clinical and clinical development and regulatory advisory and consulting services rendered to us by third-parties, primarily by members of our scientific and CNS clinical and regulatory advisory boards. The reduction in expense for Fiscal 2017 primarily reflects the rationalization of our stem cell-related scientific advisory board and related accruals, including as a result of the BlueRock 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 for other potential 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 Fiscal 2017 also includes \$55,000 representing the fair value of a warrant granted to intellectual property counsel as partial compensation for services. Fiscal 2017 expense further includes a net of \$158,000 related to the sublicense consideration paid to University Health Network (UHN) related to the BlueRock Agreement plus additional fees and expenses related to two new cardiac stem cell technology related licenses that we acquired from UHN, net of amounts previously accrued in connection with our prior sponsored research collaboration with UHN. Technology license expense for Fiscal 2016 included (i) approximately \$153,000 of fees and expenses incurred for additional stem cell technology related licenses acquired in connection with our agreement with UHN; (ii) \$120,000 of noncash expense resulting from the grants to two intellectual property legal service providers in July 2015 of an aggregate of 10,000 shares of our Series B Preferred, and (iii) \$254,000 of noncash expense resulting from the March 2016 grant of immediately-vested warrants to purchase an aggregate of 50,000 shares of our common stock to two intellectual property legal service providers.

AV-101 expenses for Fiscal 2017 include continuing costs incurred to develop more efficient and cost-effective proprietary 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 in the U.S., including our AV-101 MDD Phase 2 Adjunctive Treatment Study. We expect these expenses to increase significantly during fiscal 2018 as we continue preparations for, initiate and conduct our AV-101 MDD Phase 2 Adjunctive Treatment 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 Fiscal 2017 primarily reflects in-house costs associated with our participation in the FDA's CiPA project.

The increase in rent expense in Fiscal 2017 reflects both the impact of the scheduled rent increase for our South San Francisco headquarters and laboratory facilities effective August 2016 as well as the impact of accounting for the November 2016 lease amendment extending the lease of those facilities by five years from July 31, 2017 to July 31, 2022.

Warrant modification expense in Fiscal 2016 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. No similar modifications occurred in Fiscal 2017.

General and Administrative Expense

General and administrative expense decreased to \$6,294,800 in Fiscal 2017 from \$13,918,600 in Fiscal 2016 primarily as a result of the decrease in non-cash stock compensation expense attributable to option and warrant grants to employees, officers and independent Board members in Fiscal 2016, partially offset by an increase in non-cash expense related to grants of equity securities in payment of certain professional services during Fiscal 2017. Of the amounts reported, non-cash expenses, related primarily to grants or modifications of our equity securities, totaled approximately \$3,100,000 in Fiscal 2017 and \$11,939,000 in Fiscal 2016. The following table indicates the primary components of general and administrative expenses for each of the periods (amounts in thousands):

	Fiscal Years Ended March 31,	
	2017	2016
Salaries and benefits	\$ 1,206	\$ 694
Stock-based compensation	476	2,949
Board fees	140	98
Legal, accounting and other professional fees	2,093	3,405
Investor relations	1,219	172
Insurance	165	140
Travel and entertainment	179	96
Rent and utilities	220	157
Warrant modification expense	427	6,083
All other expenses	170	125
Total General and Administrative Expense	\$ 6,295	\$ 13,919

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 13, *Stock Option Plans and 401(k) Plan*, to the accompanying Consolidated Financial Statements in Item 8 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 Fiscal 2017 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 the commencement of his 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 became fully-vested and were fully-expensed by March 31, 2017.

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

Legal, accounting and other professional fees in Fiscal 2017 and Fiscal 2016 includes \$337,500 and \$1,012,500, respectively, of non-cash expense recognized pursuant to the June 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 2015 and June 2016. During Fiscal 2017, in addition to the expense noted above attributable to the June 2015 Series B Preferred grant, 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 320,000 unregistered shares of our common stock having a fair value at the date of issuance of \$1,058,800 as partial compensation for financial advisory, investment banking and business development services. During Fiscal 2016, in addition to the expense noted above attributable to the June 2015 Series B Preferred grant, we also 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 first quarter of Fiscal 2016; (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 expense also includes cash payments for 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 financial statements.

Investor relations expense includes the fees of our external service providers for a significantly expanded broad spectrum of institutional investor relations and market awareness and support functions and, particularly during Fiscal 2017, 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. During Fiscal 2017, in addition to cash fees and expenses we incurred, we granted an aggregate of 160,000 unregistered shares of our common stock to six investor relations and market awareness service providers as full or partial compensation for their services and recognized non-cash expense of \$472,800, representing the fair value of the stock at the time of issuance. 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 Fiscal 2017 by our CEO, CMO and VP, Corporate Development.

As described more completely in Note 9, *Capital Stock*, to the accompanying Consolidated Financial Statements for the years ended March 31, 2017 and 2016 in Item 8 of this Report, between January 2016 and December 2016, we entered into various warrant exchange agreements with certain warrant holders pursuant to which those holders exchanged outstanding warrants to purchase shares of our common stock for a lesser number of unregistered shares of our common stock. In both periods, we accounted for these transactions as warrant modifications. Between April 2016 and December 2016, certain warrant holders agreed to exchange an aggregate of 224,513 shares of our common stock for an aggregate of 156,246 shares of our unregistered common stock, resulting in our recognition of an aggregate of \$350,700 in noncash expense attributable to the increase in fair value related to Fiscal 2017 warrant exchanges. 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 as the incremental fair value attributable to the modification. Noncash warrant modification expense in Fiscal 2016 includes (i) \$122,000 representing the increase in the fair value attributable to the June 2015 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; (ii) \$358,000 representing the 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; and (iii) \$5,603,200 representing the aggregate increase in the fair value of certain warrant exchange transactions conducted during the fourth quarter of Fiscal 2016. In January 2016, we entered into an Exchange Agreement with PLTG pursuant to which PLTG exchanged warrants, including all outstanding PLTG Warrants and the shares issuable pursuant to the Series A Preferred Exchange Warrant, to purchase an aggregate of 2,824,016 shares of our common stock for 2,118,012 unregistered shares of our Series C Convertible Preferred Stock (*Series C Preferred*) at the ratio of 0.75 share of Series C Preferred for each warrant share cancelled. We recognized related noncash warrant modification expense of \$3,195,000. In February and March 2016, we entered into similar agreements with certain other warrant holders pursuant to which such warrant holders exchanged outstanding warrants to purchase an aggregate of 1,086,611 shares of our common stock for an aggregate of 814,989 shares of our unregistered common stock. We recognized an additional \$2,362,000 in non-cash warrant modification expense. In February 2016, we also extended the term of certain outstanding warrants to purchase an aggregate of 91,230 shares of our common stock and recognized \$46,000 of non-cash expense as a result of such modifications.

Interest and Other Expenses, Net

Interest expense, net, totaled \$4,600 for Fiscal 2017, a significant decrease compared to the \$70,800 reported for Fiscal 2016, resulting from the extinguishment of substantially all of our promissory notes, as well as other indebtedness, having an aggregate carrying value at the time of extinguishment of approximately \$15,900,000, between May 2015 and August 2015 by conversion into our shares of our Series B Preferred at a conversion price of \$7.00 per share 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):

	Fiscal Years Ended March 31,	
	2017	2016
Interest expense on promissory notes	\$ 1	\$ 209
Amortization of discount on promissory notes	-	565
Other interest expense, including on capital leases and premium financing	4	3
Total interest expense	<u>5</u>	<u>777</u>
Effect of foreign currency fluctuations on notes payable	-	(6)
Interest income	-	-
Interest expense, net	<u>\$ 5</u>	<u>\$ 771</u>

Interest expense on promissory notes in Fiscal 2017 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 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 resets 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 9, *Capital Stock*, to the Consolidated Financial Statements included in Item 8 of this Annual Report, in May 2015, we entered into an agreement with PLTG pursuant to which we amended the various warrants and fixed the exercise price thereof and eliminated the anti-dilution reset features that had previously required the warrants to be treated as liabilities and carried at fair value. Accordingly, during the first quarter of Fiscal 2016, we adjusted these warrants to their fair value, reflecting an increase in the fair value in the amount 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 cancelled and exchanged for shares of our Series C Preferred stock.

Between May 2015 and August 2015 we extinguished outstanding promissory notes and other indebtedness having a carrying value of approximately \$15,900,000, 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 (the stated value of the Series B Preferred issued) 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 \$4,000,000 and Series B Warrants to purchase 1,200,000 shares of our common stock having an aggregate of fair value of \$8,270,900. We recognized this aggregate fair value as a further 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 \$2,237,200, as a reduction to the loss on extinguishment of debt. We recorded an aggregate net non-recurring non-cash loss of approximately \$26,700,000 million attributable to the extinguishment of substantially all of our indebtedness as a result of the conversion of such indebtedness into shares of our Series B Preferred at a conversion price (stated value) of \$7.00 per share.

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 \$4.13 per share for Fiscal 2017 and Fiscal 2016, respectively, and its conversion price (or stated value) of \$7.00 per share represented 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 \$2,058,000 in arriving at net loss attributable to common stockholders for Fiscal 2017 and Fiscal 2016 in the accompanying Consolidated Statement of Operations and Comprehensive Loss included in Item 8 of this Annual Report. Further, we recognized \$1,257,000 and \$2,140,500 for Fiscal 2017 and Fiscal 2016, 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 Consolidated Statement of Operations and Comprehensive Loss, included in this Annual 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 Consolidated Financial Statements in Item 8 of this Annual Report.

Liquidity and Capital Resources

Since our inception in May 1998 through March 31, 2017, 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 \$44.7 million, as well as from an aggregate of approximately \$17.6 million of strategic collaboration payments, intellectual property sublicensing, government research grant awards and other revenues, but not including the fair market value of the NIMH AV-101 MDD Phase 2 Monotherapy Study being fully funded and conducted by the NIMH pursuant to our CRADA. Additionally, we have issued equity securities with an approximate aggregate value at issuance of \$30.8 million in non-cash settlements of certain liabilities, including liabilities for professional services rendered to us or as compensation for such services.

During the first quarter of Fiscal 2017, 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.

On May 16, 2016, we consummated the May 2016 Public Offering, an underwritten public offering pursuant to which we received net cash proceeds of approximately \$9.5 million and 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.

During the last two quarters of Fiscal 2017, we sold to accredited investors units consisting of an aggregate of 124,250 unregistered shares of our common stock and three-year and five-year warrants to purchase an aggregate of 45,375 shares of our unregistered common stock. We received cash proceeds of \$342,400 from this self-placed private placement.

Additionally, in January 2017, we received a cash payment of \$1.25 million pursuant to our grant of a sublicense under the BlueRock Agreement.

At March 31, 2017, we had a cash and cash equivalents balance of \$2.9 million. This amount was not sufficient to enable us to fund our planned operations, including expected cash expenditures of approximately \$12 million for the twelve months following the issuance of these financial statements, including expenditures required to further prepare for, launch and satisfy a significant portion of the projected expenses associated with our proposed AV-101 MDD Phase 2 Adjunctive Treatment Study. However, during the first quarter of our fiscal year ending March 31, 2018 (*Fiscal 2018*), we sold to accredited investors in a self-placed private placement units consisting of an aggregate of 437,751 unregistered shares of our common stock and warrants to purchase an aggregate of 218,875 unregistered shares of our common stock pursuant to which we received \$837,300 in cash proceeds, bringing total proceeds for the Spring 2017 Private Placement to approximately \$1.0 million (the *Spring 2017 Private Placement*).

Further, although our current financial resources are not yet sufficient to fully fund completion of the AV-101 MDD Phase 2 Adjunctive Treatment Study, we anticipate raising sufficient additional capital as and when necessary and advisable to sustain our operations and achieve our key corporate objectives through at least the next twelve months, including initiating and conducting the AV-101 MDD Phase 2 Adjunctive Treatment Study in an ordinary course manner. In furtherance of that objective, on January 23, 2017, we filed with the U.S. Securities and Exchange Commission (*SEC*) our Registration Statement on Form S-3 (Registration No. 333-215671) covering the potential future sale of our equity securities from time to time in the future. The SEC declared this Registration Statement effective in May 2017. However, there can be no assurance 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 NIMH AV-101 MDD Phase 2 Monotherapy Study. Such strategic collaborations may provide non-dilutive resources to advance our strategic initiatives while reducing a portion of our future cash outlays and working capital requirements. In a manner similar to the BlueRock 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 the timing of and projected costs relating to key research and development projects, including our expenses associated with our proposed AV-101 MDD Phase 2 Adjunctive Treatment Study, regulatory consulting, CRO services, 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):

	Fiscal Years Ended March 31,	
	2017	2016
Net cash used in operating activities	\$ (7,263)	\$ (4,808)
Net cash used in investing activities	(239)	(26)
Net cash provided by financing activities	<u>9,994</u>	<u>5,193</u>
Net increase in cash and cash equivalents	2,492	359
Cash and cash equivalents at beginning of period	<u>429</u>	<u>70</u>
Cash and cash equivalents at end of period	<u>\$ 2,921</u>	<u>\$ 429</u>

Off-Balance Sheet Arrangements

Other than contractual obligations incurred in the normal course of business, we do not have any off-balance sheet financing arrangements or liabilities, guarantee contracts, retained or contingent interests in transferred assets or any obligation arising out of a material variable interest in an unconsolidated entity. VistaStem has two inactive, wholly owned subsidiaries, Artemis Neuroscience, Inc., a Maryland corporation, and VistaStem Canada, Inc., an Ontario corporation.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

The disclosures in this section are not required because we qualify as a smaller reporting company under federal securities laws.

Item 8. Financial Statements and Supplementary Data

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
VistaGen Therapeutics, Inc.

We have audited the accompanying consolidated balance sheets of VistaGen Therapeutics, Inc. as of March 31, 2017 and 2016 and the related consolidated statements of operations and comprehensive loss, cash flows, and stockholders' equity (deficit) for each of the two fiscal years in the period ended March 31, 2017. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of VistaGen Therapeutics, Inc. at March 31, 2017 and 2016, and the consolidated results of its operations and its cash flows for each of the two fiscal years in the period ended March 31, 2017, in conformity with U.S. generally accepted accounting principles.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has not yet generated sustainable revenues, has suffered recurring losses and negative cash flows from operations and has minimal stockholders' equity, all of which raise substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ OUM & Co. LLP

San Francisco, California
June 28, 2017

VISTAGEN THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(Amounts in dollars, except share amounts)

	<u>March 31,</u> <u>2017</u>	<u>March 31,</u> <u>2016</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 2,921,300	\$ 428,500
Prepaid expenses and other current assets	456,600	426,800
Total current assets	<u>3,377,900</u>	<u>855,300</u>
Property and equipment, net	286,500	87,600
Security deposits and other assets	47,800	46,900
Total assets	<u>\$ 3,712,200</u>	<u>\$ 989,800</u>
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	\$ 867,300	\$ 936,000
Accrued expenses	443,000	814,000
Current portion of notes payable and accrued interest	54,800	43,600
Capital lease obligations	2,400	1,100
Total current liabilities	<u>1,367,500</u>	<u>1,794,700</u>
Non-current liabilities:		
Notes payable	-	27,200
Accrued dividends on Series B Preferred Stock	1,577,800	2,089,600
Deferred rent liability	139,200	55,500
Capital lease obligations	11,900	-
Total non-current liabilities	<u>1,728,900</u>	<u>2,172,300</u>
Total liabilities	<u>3,096,400</u>	<u>3,967,000</u>
Commitments and contingencies		
Stockholders' equity (deficit):		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized at March 31, 2017 and March 31, 2016:		
Series A Preferred, 500,000 shares authorized and outstanding at March 31, 2017 and March 31, 2016	500	500
Series B Preferred; 4,000,000 shares authorized at March 31, 2017 and March 31, 2016; 1,160,240 shares and 3,663,077 shares issued and outstanding at March 31, 2017 and March 31, 2016, respectively	1,200	3,700
Series C Preferred: 3,000,000 shares authorized at March 31, 2017 and March 31, 2017; 2,318,012 shares issued and outstanding at March 31, 2017 and March 31, 2016	2,300	2,300
Common stock, \$0.001 par value; 30,000,000 shares authorized at March 31, 2017 and March 31, 2016; 8,974,386 and 2,623,145 shares issued at March 31, 2017 and March 31, 2016, respectively		
Additional paid-in capital	146,569,600	132,725,000
Treasury stock, at cost, 135,665 shares of common stock held at March 31, 2017 and March 31, 2016	(3,968,100)	(3,968,100)
Accumulated deficit	(141,998,700)	(131,743,200)
Total stockholders' equity (deficit)	<u>615,800</u>	<u>(2,977,200)</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 3,712,200</u>	<u>\$ 989,800</u>

See accompanying notes to consolidated financial statements.

VISTAGEN THERAPEUTICS, INC.

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

	Fiscal Years Ended	
	March 31,	
	2017	2016
Revenues:		
Sublicense fees	\$ 1,250,000	\$ -
Total revenues	<u>1,250,000</u>	<u>-</u>
Operating expenses:		
Research and development	5,203,700	3,931,600
General and administrative	6,294,800	13,918,600
Total operating expenses	<u>11,498,500</u>	<u>17,850,200</u>
Loss from operations	(10,248,500)	(17,850,200)
Other expenses, net:		
Interest expense, net	(4,600)	(770,800)
Change in warrant liability	-	(1,894,700)
Loss on extinguishment of debt	-	(26,700,200)
Other expense	-	(2,300)
Loss before income taxes	(10,253,100)	(47,218,200)
Income taxes	(2,400)	(2,300)
Net loss and comprehensive loss	<u>(10,255,500)</u>	<u>(47,220,500)</u>
Accrued dividend on Series B Preferred stock	(1,257,000)	(2,140,500)
Deemed dividend on Series B Preferred Units	(111,100)	(2,058,000)
Net loss attributable to common stockholders	<u>\$ (11,623,600)</u>	<u>\$ (51,419,000)</u>
Basic and diluted net loss attributable to common stockholders per common share	<u>\$ (1.54)</u>	<u>\$ (29.08)</u>
Weighted average shares used in computing basic and diluted net loss attributable to common stockholders per common share	<u>7,531,642</u>	<u>1,767,957</u>

See accompanying notes to consolidated financial statements.

VISTAGEN THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(Amounts in dollars)

	Fiscal Years Ended March 31,	
	2017	2016
Cash flows from operating activities:		
Net loss	\$ (10,255,500)	\$ (47,220,500)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	54,900	53,500
Amortization of discounts on convertible and promissory notes	-	564,800
Change in warrant liability	-	1,894,700
Stock-based compensation	851,300	4,041,400
Expense related to modification of warrants, including exchange of warrants for Series C Preferred and common stock	427,500	6,218,000
Amortization of deferred rent	83,700	(27,500)
Fair value of common stock granted for services	1,640,100	829,200
Fair value of Series B Preferred stock granted for services	375,000	1,382,500
Fair value of warrants granted for services	240,300	1,280,800
Gain on currency fluctuation	-	(6,400)
Loss on extinguishment of debt	-	26,700,200
Loss on disposition of fixed assets	-	2,300
Changes in operating assets and liabilities:		
Prepaid expenses, security deposit and other current assets	(227,700)	25,700
Accounts payable and accrued expenses, including accrued interest	(451,700)	(547,200)
Net cash used in operating activities	<u>(7,262,100)</u>	<u>(4,808,500)</u>
Cash flows from investing activities:		
Purchases of equipment	(239,100)	(26,300)
Net cash used in investing activities	<u>(239,100)</u>	<u>(26,300)</u>
Cash flows from financing activities:		
Net proceeds from issuance of common stock and warrants, including Units	9,899,500	280,000
Net proceeds from issuance of Series B Preferred Units	278,000	5,025,800
Repayment of capital lease obligations	(1,300)	(1,000)
Repayment of notes	(182,200)	(111,500)
Net cash provided by financing activities	<u>9,994,000</u>	<u>5,193,300</u>
Net increase in cash and cash equivalents	2,492,800	358,500
Cash and cash equivalents at beginning of period	428,500	70,000
Cash and cash equivalents at end of period	<u>\$ 2,921,300</u>	<u>\$ 428,500</u>
Supplemental disclosure of cash flow activities:		
Cash paid for interest	\$ 16,600	\$ 12,700
Cash paid for income taxes	\$ 2,400	\$ 2,400
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	\$ 178,200	\$ 79,400
Accrued dividends on Series B Preferred	\$ 1,257,000	\$ 2,140,500
Accrued dividends on Series B Preferred settled upon conversion by issuance of common stock	\$ 1,768,800	\$ 50,900
Acquisition of equipment under capital lease	\$ 14,700	\$ -

See accompanying notes to consolidated financial statements.

VISTAGEN THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

Fiscal Years Ended March 31, 2017 and 2016
(Amounts in dollars, except share amounts)

	Series A Preferred Stock		Series B Preferred Stock		Series C Preferred Stock		Common Stock		Additional Paid-in Capital	Treasury Stock	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balances at March 31, 2015	500,000	\$ 500	-	\$ -	-	\$ -	1,677,126	\$ 1,700	\$67,945,800	\$3,968,100	\$(84,522,700)	\$(20,542,800)
Allocated proceeds from sale of common stock												
Units for cash under 2014 Unit Private Placement, including beneficial conversion feature	-	-	-	-	-	-	33,000	-	277,200	-	-	277,200
Proceeds from sale of Series B Preferred Units for cash under Series B Preferred Unit Private Placement	-	-	717,978	700	-	-	-	-	5,025,100	-	-	5,025,800
Share-based compensation expense	-	-	-	-	-	-	-	-	4,041,400	-	-	4,041,400
Conversion of Senior Secured and subordinate promissory notes into Series B Preferred stock, including recapture of beneficial conversion feature upon conversion	-	-	3,018,917	3,100	-	-	-	-	42,577,100	-	-	42,580,200
Elimination of warrant liability resulting from modification of PLTG Warrants	-	-	-	-	-	-	-	-	4,903,100	-	-	4,903,100
Exchange of common stock for Series B Preferred stock	-	-	30,000	-	-	-	(30,000)	-	-	-	-	-
Accrued dividends on Series B Preferred stock	-	-	-	-	-	-	-	-	(2,140,500)	-	-	(2,140,500)
Conversion of Series B Preferred stock into common stock, including common stock issued in payment of accrued dividends			(228,818)	(200)	-	-	235,655	200	50,900	-	-	50,900
Exchange of common stock for Series C Preferred stock	-	-	-	-	200,000	200	(200,000)	(200)	-	-	-	-
Exchange of outstanding warrants for Series C Preferred stock	-	-	-	-	2,118,012	2,100	-	-	3,192,800	-	-	3,194,900
Exchange of outstanding warrants for common stock and other warrant modifications	-	-	-	-	-	-	814,989	800	3,022,300	-	-	3,023,100
Fair value of common stock, Series B Preferred stock and warrants granted for services	-	-	125,000	100	-	-	92,375	100	3,829,800	-	-	3,830,000
Net loss for fiscal year ended March 31, 2016	-	-	-	-	-	-	-	-	-	-	(47,220,500)	(47,220,500)
Balances at March 31, 2016	500,000	\$ 500	3,663,077	\$ 3,700	2,318,012	\$ 2,300	2,623,145	\$ 2,600	\$132,725,000	\$3,968,100	\$(131,743,200)	\$(2,977,200)
Proceeds from sale of Series B Preferred Units for cash under Series B Preferred Unit Private Placement	-	-	39,714	-	-	-	-	-	278,000	-	-	278,000
	-	-	-	-	-	-	2,570,040	2,600	9,534,500	-	-	9,537,100

Proceeds from sale of common stock and warrants for cash in May 2016 Public Offering													
Proceeds from sale of common stock and warrants for cash in private placement offerings	-	-	-	-	-	-	124,250	100	362,300	-	-	-	362,400
Series B Preferred converted to common stock automatically upon consummation of May 2016 Public Offering and voluntarily	-	-	(2,542,551)	(2,500)	-	-	2,542,551	2,500	-	-	-	-	-
Common stock issued for dividends upon conversion of Series B Preferred	-	-	-	-	-	-	453,154	500	1,768,300	-	-	-	1,768,800
Accrued dividends on Series B Preferred stock	-	-	-	-	-	-	-	-	(1,257,000)	-	-	-	(1,257,000)
Share-based compensation expense	-	-	-	-	-	-	-	-	851,300	-	-	-	851,300
Exchange of outstanding warrants for common stock and other warrant modifications	-	-	-	-	-	-	156,246	200	427,300	-	-	-	427,500
Fair value of common stock and warrants granted for services	-	-	-	-	-	-	505,000	500	1,879,900	-	-	-	1,880,400
Net loss for fiscal year ended March 31, 2017	-	-	-	-	-	-	-	-	-	-	-	(10,255,500)	(10,255,500)
Balances at March 31, 2017	<u>500,000</u>	<u>\$ 500</u>	<u>1,160,240</u>	<u>\$ 1,200</u>	<u>2,318,012</u>	<u>\$ 2,300</u>	<u>8,974,386</u>	<u>\$ 9,000</u>	<u>\$146,569,600</u>	<u>\$3,968,100</u>	<u>\$(141,998,700)</u>	<u>\$ 615,800</u>	

See accompanying notes to consolidated financial statements.

VISTAGEN THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Description of Business

We are a clinical-stage biopharmaceutical company focused on developing new generation medicines for depression and other central nervous system (CNS) disorders.

AV-101 is our oral CNS product candidate in Phase 2 clinical development in the United States, initially as a new generation 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). AV-101's mechanism of action (MOA) involves both NMDA (N-methyl-D-aspartate) and AMPA (alpha-amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid) receptors in the brain responsible for fast excitatory synaptic activity throughout the CNS. AV-101's MOA is fundamentally differentiated from all FDA-approved antidepressants, as well as all atypical antipsychotics often used adjunctively to augment them. We believe AV-101 also has potential as a new treatment alternative for several additional indications involving the CNS, including epilepsy, Huntington's disease, L-DOPA-induced dyskinesia associated with Parkinson's disease, and neuropathic pain.

Clinical studies conducted at the U.S. National Institute of Mental Health (NIMH), part of the U.S. National Institutes of Health (NIH), by 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, have focused on the antidepressant effects of low dose ketamine hydrochloride injection (ketamine), an NMDA receptor antagonist, in MDD patients with inadequate responses to multiple standard antidepressants. These NIMH studies, as well as clinical research at Yale University and other academic institutions, have demonstrated robust antidepressant effects in these MDD patients within twenty-four hours of a single sub-anesthetic dose of ketamine administered by intravenous (IV) injection.

We believe orally-administered AV-101 may have potential to deliver ketamine-like antidepressant effects without ketamine's psychological and other negative side effects. As published in the October 2015 issue of the peer-reviewed, *Journal of Pharmacology and Experimental Therapeutics*, in an article titled, *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. In addition, these studies confirmed that the fast-acting antidepressant effects of AV-101 were mediated through both inhibiting the GlyB site of the NMDA receptor and activating the AMPA receptor pathway in the brain.

Pursuant to our Cooperative Research and Development Agreement (CRADA) with the NIMH, the NIMH is funding, and Dr. Zarate, as Principal Investigator, and his team are conducting, a small Phase 2 clinical study of AV-101 monotherapy in subjects with treatment-resistant MDD (the *NIMH AV-101 MDD Phase 2 Monotherapy Study*). We are preparing to launch our 180-patient Phase 2 multi-center, multi-dose, double blind, placebo-controlled efficacy and safety study of AV-101 as a new generation adjunctive treatment of MDD in adult patients with an inadequate response to standard, FDA-approved antidepressants (the *AV-101 MDD Phase 2 Adjunctive Treatment Study*). 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 our AV-101 MDD Phase 2 Adjunctive Treatment 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 completing our AV-101 MDD Phase 2 Adjunctive Treatment Study by the end of 2018 with top line results available in the first quarter of 2019.

VistaGen Therapeutics, Inc., a California corporation dba VistaStem Therapeutics (VistaStem), is our wholly owned subsidiary focused on applying human pluripotent stem cell (hPSC) technology, internally and 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 drug rescue programs are designed to utilize *CardioSafe 3D*, our customized cardiac bioassay system, to develop small molecule NCEs for our pipeline. In December 2016, we exclusively sublicensed to BlueRock Therapeutics LP, a next generation regenerative medicine company established 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.

2. Basis of Presentation and Going Concern

The accompanying Consolidated Financial Statements have been prepared assuming that we will continue as a going concern. As a clinical-stage biopharmaceutical company having not yet developed commercial products or achieved sustainable revenues, we have experienced recurring losses and negative cash flows from operations resulting in a deficit of \$142.0 million accumulated from inception through March 31, 2017. 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, initially as an adjunctive treatment for MDD, and subsequently as a new treatment alternative for other CNS conditions, execute our drug rescue programs, and pursue potential drug development and regenerative medicine opportunities.

Since our inception in May 1998 through March 31, 2017, we have financed our operations and technology acquisitions primarily through the issuance and sale of equity and debt securities, including convertible promissory notes and short-term promissory notes, for cash proceeds of approximately \$44.7 million, as well as from an aggregate of approximately \$17.6 million of government research grant awards (excluding the fair market value of the NIMH AV-101 MDD Phase 2 Monotherapy Study), strategic collaboration payments, intellectual property sublicensing and other revenues. Additionally, we have issued equity securities with an approximate value at issuance of \$30.8 million in non-cash settlements of certain liabilities, including liabilities for professional services rendered to us or as compensation for such services.

During the first quarter of our fiscal year ended March 31, 2017, we sold to accredited investors Series B Preferred Units consisting of 39,714 unregistered shares of our Series B 10% Convertible 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.

In May 2016, we consummated an underwritten public offering pursuant to which we received net cash proceeds of approximately \$9.5 million, after deducting fees and expenses, and 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*).

During the last two quarters of our fiscal year ended March 31, 2017, we sold to accredited investors units consisting of an aggregate of 124,250 unregistered shares of our common stock and three-year and five-year warrants to purchase an aggregate of 45,375 shares of our unregistered common stock. We received cash proceeds of \$342,400 from this self-placed private placement.

At March 31, 2017, we had a cash and cash equivalents balance of \$2.9 million. This amount was not sufficient to enable us to fund our planned operations, including expected cash expenditures of approximately \$12 million for the twelve months following the issuance of these financial statements, including expenditures required to further prepare for, launch and satisfy a significant portion of the projected expenses associated with our proposed AV-101 MDD Phase 2 Adjunctive Treatment Study. However, during the first quarter of our fiscal year ending March 31, 2018 (*Fiscal 2018*), we sold to accredited investors in a self-placed private placement units consisting of an aggregate of 437,751 unregistered shares of our common stock and warrants to purchase an aggregate of 218,875 unregistered shares of our common stock pursuant to which we received \$837,300 in cash proceeds, bringing total proceeds for the Spring 2017 Private Placement to approximately \$1.0 million (the *Spring 2017 Private Placement*).

Our limited cash position at March 31, 2017 plus subsequent proceeds from the Spring 2017 Private Placement considered with our recurring and anticipated losses and negative cash flows from operations make it probable, in the absence of additional financing, that we will not be able to meet our obligations as they come due within one year from the date of this Report, raising substantial doubt that we can continue as a going concern. However, to alleviate that doubt, we plan, as we have in the past, to raise additional financing when needed, primarily through the sale of our equity securities in one or more public offerings or private placements. 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 our equity securities. The Commission declared such Registration Statement effective on May 12, 2017 (the *S-3 Registration Statement*). As of the date of this Report, we have not yet sold any securities under the S-3 Registration Statement, nor do we have an obligation to do so. At March 31, 2017, we had a limited number of unallocated or unreserved shares of our common stock available for issuance in future offerings or for other purposes. To facilitate a substantial offering of our equity securities to sustain our operations and enable the launch and completion of our AV-101 MDD Phase 2 Adjunctive Treatment Study, our Board of Directors has approved an amendment to our Restated Articles of Incorporation to increase the number of shares of common stock available for issuance thereunder to 100 million shares. Before taking effect, this amendment must be approved by a majority of our stockholders. We plan to present this amendment to our stockholders at our 2017 annual meeting of stockholders to be held in the fall of 2017.

In addition to the sale of our equity securities, we may also seek to enter research and development collaborations that could generate revenue or provide funding for development of AV-101 and additional product candidates. We may also seek additional government grant awards or agreements similar to our current CRADA with the NIMH, which provides for the NIMH to fully fund the NIMH AV-101 MDD Phase 2 Monotherapy Study. Such strategic collaborations may provide non-dilutive resources to advance our strategic initiatives while reducing a portion of our future cash outlays and working capital requirements. In a manner similar to the BlueRock 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, public company compliance and other professional services and operating costs.

Notwithstanding the foregoing, there can be no assurance that our stockholders will authorize the issuance of additional shares of our common stock to facilitate further financing opportunities and for other purposes, or that future financing will be available in sufficient amounts, in a timely manner, or on terms acceptable to us, if at all. If we are unable to obtain substantial additional financing on a timely basis when needed later 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. As noted above, these Consolidated Financial Statements do not include any adjustments that might result from the negative outcome of this uncertainty.

3. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles (*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, but are not limited to, those relating to stock-based compensation, revenue recognition, and the assumptions used to value warrants, warrant modifications and warrant liabilities.

Principles of Consolidation

The accompanying consolidated financial statements include the Company's accounts, VistaStem's accounts and the accounts of VistaStem's two wholly-owned inactive subsidiaries, Artemis Neurosciences and VistaStem Canada.

Cash and Cash Equivalents

Cash and cash equivalents are considered to be highly liquid investments with maturities of three months or less at the date of purchase.

Property and Equipment

Property and equipment is stated at cost. Repairs and maintenance costs are expensed in the period incurred. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets. The estimated useful lives of property and equipment range from five to seven years.

Impairment of Long-Lived Assets

Our long-lived assets consist of property and equipment. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that we consider in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in our use of the assets. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset over its fair value, determined based on discounted cash flows. To date, we have not recorded any impairment losses on long-lived assets.

Revenue Recognition

We have historically generated revenue principally from collaborative research and development arrangements, licensing and technology transfer agreements, including strategic licenses or sublicenses, and government grants. Revenue arrangements with multiple components are divided into separate units of accounting if certain criteria are met, including whether the delivered component has stand-alone value to the customer. Consideration received is allocated among the separate units of accounting based on their respective selling prices. The selling price for each unit is based on vendor-specific objective evidence, or VSOE, if available, third party evidence if VSOE is not available, or estimated selling price if neither VSOE nor third party evidence is available. The applicable revenue recognition criteria are then applied to each of the units.

We recognize revenue when four basic criteria of revenue recognition are met: (i) a contractual agreement exists; (ii) the transfer of technology has been completed or services have been rendered; (iii) the fee is fixed or determinable; and (iv) collectability is reasonably assured. For each source of revenue, we comply with the above revenue recognition criteria in the following manner:

- Collaborative arrangements typically consist of non-refundable and/or exclusive up front technology access fees, cost reimbursements for specific research and development spending, and future product development milestone and royalty payments. If the delivered technology does not have stand-alone value, the amount of revenue allocable to the delivered technology is deferred. Non-refundable upfront fees with stand-alone value that are not dependent on future performance under these agreements are recognized as revenue when received, and are deferred if we have continuing performance obligations and have no objective and reliable evidence of the fair value of those obligations. We recognize non-refundable upfront technology access fees under agreements in which we have a continuing performance obligation ratably, on a straight-line basis, over the period during which we are obligated to provide services. Cost reimbursements for research and development spending are recognized when the related costs are incurred and when collectability is reasonably assured. Payments received related to substantive, performance-based “at-risk” milestones are recognized as revenue upon achievement of the milestone event specified in the underlying contracts, which represent the culmination of the earnings process. Amounts received in advance are recorded as deferred revenue until the technology is transferred, costs are incurred, or a milestone is reached.
- Technology license agreements typically consist of non-refundable upfront license fees, annual minimum access fees, development and/or regulatory milestone payments and/or royalty payments. Non-refundable upfront license fees and annual minimum payments received with separable stand-alone values are recognized when the technology is transferred or accessed, provided that the technology transferred or accessed is not dependent on the outcome of the continuing research and development efforts. Otherwise, revenue is recognized over the period of our continuing involvement, and, in the case of development and/or regulatory milestone payments, when the applicable event triggering such a payment has occurred.
- Government grants, which support our research efforts on specific projects, generally provide for reimbursement of approved costs as defined in the terms of grant awards. Grant revenue is recognized when associated project costs are incurred.

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 clinical and non-clinical development of AV-101, our prodrug candidate in clinical development for MDD, sponsored stem cell research and development costs, and costs related to the application and prosecution of patents related to AV-101 and our stem cell technology platform. All such costs are charged to expense as incurred.

Stock-Based Compensation

We recognize compensation cost for all stock-based awards to employees based on the grant date fair value of the award. We record non-cash, stock-based compensation expense over the period during which the employee is required to perform services in exchange for the award, which generally represents the scheduled vesting period. We have granted no restricted stock awards to employees nor do we have any awards with market or performance conditions. For option grants to non-employees, we re-measure the fair value of the awards as they vest and the resulting value is recognized as an expense during the period over which the services are performed. Compensatory grants of stock to non-employees are generally treated as fully-earned at the time of the grant and the non-cash expense recognized is based on the quoted market price of the stock on the date of grant.

Income Taxes

We account for income taxes using the asset and liability approach for financial reporting purposes. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Valuation allowances are established, when necessary, to reduce the deferred tax assets to an amount expected to be realized.

Concentrations of Credit Risk

Financial instruments, which potentially subject us to concentrations of credit risk, consist of cash and cash equivalents. Our investment policies limit any such investments to short-term, low-risk investments. We deposit cash and cash equivalents with quality financial institutions and are insured to the maximum of federal limitations. Balances in these accounts may exceed federally insured limits at times.

Warrant Liability

Although we did not have a warrant liability at March 31, 2017 or 2016, 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 warrants, and the contingently issuable Series A Exchange Warrant (collectively, the *PLTG Warrants*), we determined that the *PLTG Warrants* included certain exercise price and other adjustment features requiring them to be treated as liabilities. Accordingly, the *PLTG Warrants* were recorded at their issuance-date estimated fair values and marked to market at each subsequent reporting period, recording the change in the fair value as non-cash expense or non-cash income. The key component in determining the fair value of the *PLTG Warrants* and the related liability was the market price of our common stock, which is subject to significant fluctuation and is not under our control. The resulting change in the fair value of the warrant liability on our net loss was therefore also subject to significant fluctuation and would have continued to be so until all of the *PLTG Warrants* were issued and exercised, amended or expired. Assuming all other fair value inputs remained generally constant, we recorded an increase in the warrant liability and non-cash losses when our stock price increased and a decrease in the warrant liability and non-cash income when our stock price decreased.

Notwithstanding the foregoing, and as disclosed in Note 9, *Capital Stock*, in May 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 amendments to the *PLTG Warrants* resulted in the elimination of the warrant liability with respect to the *PLTG Warrants* during the quarter ended June 30, 2015 and the recognition of a non-cash loss of \$1,874,700 in that quarter, reflecting the change in the fair value of the *PLTG Warrants* between March 31, 2015 and the date of their amendment. As further disclosed in Note 9, *Capital Stock*, the *PLTG Warrants*, including the right to receive the Series A Exchange Warrant, were cancelled in exchange for our issuance of shares of our Series C Preferred stock to *PLTG* in January 2016.

Comprehensive Loss

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

Loss per Common Share Attributable to Common Stockholders

Basic net income (loss) attributable to common stockholders per share of common stock excludes the effect of dilution and is computed by dividing net income (loss) less the accrual for dividends on our Series B Preferred and the deemed dividend attributable to the issuance of our Series B Preferred Units by the weighted-average number of shares of common stock outstanding for the period. Diluted net income (loss) attributable to common stockholders per share of common stock reflects the potential dilution that could occur if securities or other contracts to issue shares of common stock were exercised or converted into shares of common stock. In calculating diluted net income (loss) attributable to common stockholders per share, we have historically adjusted the numerator for the change in the fair value of the warrant liability attributable to any outstanding *PLTG 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 last recognized in the first quarter of our fiscal year ended March 31, 2016, had no impact on the diluted net loss per share calculation for that fiscal year.

As a result of our net loss for both years presented, potentially dilutive securities were excluded from the computation of diluted loss per share, as their effect would be antidilutive.

Basic and diluted net loss attributable to common stockholders per share was computed as follows:

	Fiscal Years Ended March 31,	
	2017	2016
Numerator:		
Net loss attributable to common stockholders for basic and diluted earnings per share	<u>\$ (11,623,600)</u>	<u>\$ (51,419,000)</u>
Denominator:		
Weighted average basic and diluted common shares outstanding	<u>7,531,642</u>	<u>1,767,957</u>
Basic and diluted net loss attributable to common stockholders per common share	<u>\$ (1.54)</u>	<u>\$ (29.08)</u>

Potentially dilutive securities excluded in determining diluted net loss per common share for the fiscal years ended March 31, 2017 and 2016 are as follows:

	<u>As of March 31,</u>	
	<u>2017</u>	<u>2016</u>
Series A Preferred stock issued and outstanding ⁽¹⁾	750,000	750,000
Series B Preferred stock issued and outstanding ⁽²⁾	1,160,240	3,663,077
Series C Preferred stock issued and outstanding ⁽³⁾	2,318,012	2,318,012
Outstanding options under the 2016 (formerly 2008) and 1999 Stock Incentive Plans	1,659,324	336,987
Outstanding warrants to purchase common stock	<u>4,577,631</u>	<u>1,907,221</u>
Total	<u>10,465,207</u>	<u>8,975,297</u>

(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

We believe the following recent accounting pronouncements or changes in accounting pronouncements are of significance or potential significance to the Company.

In May 2014, the Financial Accounting Standards Board (the FASB) issued ASU No. 2014-09, *Revenue from Contracts with Customers* (Topic 606), which supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. The standard creates a five-step model that requires entities to exercise judgment when considering the recognition of revenue, including (1) identifying the contract(s) with the customer, (2) identifying the separate performance obligations in the contract, (3) determining the transaction price, (4) allocating the transaction price to the separate performance obligations, and (5) recognizing revenue as each performance obligation is satisfied. The standard also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including qualitative and quantitative information about contracts with customers, significant judgments and changes in judgments and assets recognized with respect to costs incurred to obtain or fulfill a contract. The FASB has continued to issue accounting standards updates to clarify and provide implementation guidance related to Revenue from Contracts with Customers, including ASU 2016-08, *Revenue from Contract with Customers: Principal versus Agent Considerations*, ASU 2016-10, *Revenue from Contracts with Customers: Identifying Performance Obligations and Licensing*, and ASU 2016-12, *Revenue from Contracts with Customers: Narrow-Scope Improvements and Practical Expedients*. These amendments address a number of areas, including a company's identification of its performance obligations in a contract, collectability, non-cash consideration, presentation of sales tax and a company's evaluation of the nature of its promise to grant a license of intellectual property and whether or not that revenue is recognized over time or at a point in time. These new standards will be effective for our fiscal year beginning April 1, 2018, with earlier adoption permitted. We have completed our initial assessment of the new guidance and will be developing an implementation plan to evaluate the accounting and disclosure requirements under the new standards. Based on our assessment to date, we do not believe that adoption of Topic 606 and the related standards will have a material impact on our consolidated financial statements. We have not yet finalized our transition method for adoption of the new standards.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements—Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (ASU 2014-15)*. The ASU sets forth a requirement for management to evaluate whether there are conditions or events that raise substantial doubt about an entity's ability to continue as a going concern by incorporating and expanding upon certain principles that are currently in U.S. auditing standards. Specifically, the amendments (1) provide a definition of the term substantial doubt; (2) require an evaluation every reporting period, including interim periods; (3) provide principles for considering the mitigating effect of management's plans; (4) require certain disclosures when substantial doubt is alleviated as a result of consideration of management's plans; (5) require an express statement or other disclosures when substantial doubt is not alleviated; and (6) require an assessment for a period of one year after the date the financial statements are issued or available to be issued. Substantial doubt about an entity's ability to continue as a going concern exists when relevant conditions and events, considered in the aggregate, indicate that it is probable (as defined under ASC 450, *Contingencies*) that the entity will be unable to meet its obligations as they become due within one year after the date that the financial statements are issued or are available to be issued. If substantial doubt exists, the extent of the required disclosures depends on an evaluation of management's plans (if any) to mitigate the going concern uncertainty. This evaluation should include consideration of conditions and events that are either known or are reasonably knowable at the date the financial statements are issued or are available to be issued, as well as whether it is probable that management's plans to address the substantial doubt will be implemented and, if so, whether it is probable that the plans will alleviate the substantial doubt. We adopted ASU 2014-15 for our fiscal year ended March 31, 2017 and Note 2, *Basis of Presentation and Going Concern*, includes our disclosures regarding substantial doubt about our ability to continue as a going concern and the steps we have planned to alleviate such doubt for the twelve months following the date of the issuance of these Consolidated Financial Statements.

In April 2015, the FASB issued ASU No. 2015-03, *Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*. The amendments in this ASU require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The amendments in this update are effective for financial statements issued for fiscal years ending after December 31, 2015, and interim periods within those fiscal years. We have adopted this ASU effective with our fiscal year beginning April 1, 2016, but have incurred no debt issuance costs since that date.

In November 2015, the FASB issued ASU No. 2015-17, *Balance Sheet Classification of Deferred Taxes*, which amends existing guidance on income taxes to require the classification of all deferred tax assets and liabilities as non-current on the balance sheet. We have adopted this ASU effective with our fiscal year beginning April 1, 2017 on a prospective basis. We do not expect this ASU to have a material impact on our consolidated financial statements

In January 2016, the FASB issued ASU No. 2016-01, *Financial Instruments - Overall: Recognition and Measurement of Financial Assets and Financial Liabilities*. The updated guidance enhances the reporting model for financial instruments, which includes amendments to address aspects of recognition, measurement, presentation and disclosure. The amendment to the standard is effective for financial statements issued for our fiscal year beginning April 1, 2018. We do not believe that this ASU will have a material impact on our consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases (ASC 842)*, which will replace the existing guidance in ASC 840, *Leases*, and which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e. lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less will be accounted for similar to the current guidance for operating leases. The standard is effective for financial statements issued for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years, with early adoption permitted. We are in the process of evaluating the impact that this new guidance will have on our consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting* which includes multiple provisions intended to simplify several aspects of accounting for share-based payment transactions, including income tax consequences, classification of awards as either equity or liabilities, an option to recognize gross stock compensation expense with actual forfeitures recognized as they occur, as well as certain classifications on the statement of cash flows. The standard is effective for our fiscal year beginning April 1, 2017. We are evaluating the impact of this ASU on our consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*. The standard reduces the diversity in practice of how certain cash receipts and cash payments are 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 our fiscal year beginning April 1, 2018, and early adoption is permitted. The guidance requires retrospective adoption. We are evaluating the impact of this ASU on our consolidated financial statements and related disclosures.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash* that changes the presentation of restricted cash and cash equivalents on the statement of cash flows. Restricted cash and restricted cash equivalents must be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. This standard is effective for our fiscal year beginning April 1, 2018, but early adoption is permissible. As we do not currently have nor have we historically had restricted cash or restricted cash equivalents, we do not believe that this ASU will have a material impact on our consolidated financial statements.

4. Fair Value Measurements

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

We follow the principles of fair value accounting as they relate to our financial assets and financial liabilities. Fair value is defined as the estimated exit price received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, rather than an entry price that represents the purchase price of an asset or liability. Where available, fair value is based on observable market prices or parameters, or derived from such prices or parameters. Where observable prices or inputs are not available, valuation models are applied. These valuation techniques involve some level of management estimation and judgment, the degree of which is dependent on several factors, including the instrument's complexity. The required fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels is described as follows:

- *Level 1* — Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.
- *Level 2* — Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- *Level 3* — Unobservable inputs (*i.e.*, inputs that reflect the reporting entity's own assumptions about the assumptions that market participants would use in estimating the fair value of an asset or liability) are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

A financial instrument's categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement. Where quoted prices are available in an active market, securities are classified as Level 1 of the valuation hierarchy. If quoted market prices are not available for the specific financial instrument, then we estimate fair value by using pricing models, quoted prices of financial instruments with similar characteristics or discounted cash flows. In certain cases where there is limited activity or less transparency around inputs to valuation, financial assets or liabilities are classified as Level 3 within the valuation hierarchy.

In conjunction with certain Senior Secured Convertible Promissory Notes that we issued to 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 Consolidated Statement of Operations and Comprehensive Loss for the fiscal year ended March 31, 2016.

In May 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 March 31, 2017 or 2016.

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	March 31,	
	2017	2016
Insurance	\$ 85,800	\$ 27,000
AV-101 materials and services	352,800	-
Prepaid compensation under financial advisory and other consulting agreements	-	337,500
Public offering expenses	11,600	57,400
All other	6,400	4,900
	<u>\$ 456,600</u>	<u>\$ 426,800</u>

6. Property and Equipment

Property and equipment consists of the following:

	March 31,	
	2017	2016
Laboratory equipment	\$ 888,300	\$ 659,000
Tenant improvements	26,900	26,900
Computers and network equipment	53,000	43,200
Office furniture and equipment	79,700	69,500
	<u>1,047,900</u>	<u>798,600</u>
Accumulated depreciation and amortization	<u>(761,400)</u>	<u>(711,000)</u>
Property and equipment, net	<u>\$ 286,500</u>	<u>\$ 87,600</u>

Other than certain leased office equipment, none of our assets were subject to third party security interests at March 31, 2017 or 2016.

7. Accrued Expenses

Accrued expenses consist of:

	March 31,	
	2017	2016
Accrued professional services	\$ 37,000	\$ 318,000
Accrued AV-101 development and related expenses	402,400	186,000
Accrued compensation	-	310,000
All other	3,600	-
	<u>\$ 443,000</u>	<u>\$ 814,000</u>

8. Notes Payable

The following table summarizes our notes payable:

	March 31, 2017			March 31, 2016		
	Principal Balance	Accrued Interest	Total	Principal Balance	Accrued Interest	Total
8.25% Note payable to insurance premium financing company (current)	\$ 54,800	\$ -	\$ 54,800	\$ -	\$ -	\$ -
7.0% Note payable to Progressive Medical	\$ -	\$ -	\$ -	\$ 58,800	\$ 12,000	\$ 70,800
less: current portion	-	-	-	(31,600)	(12,000)	(43,600)
7.0% Note payable - non-current portion	\$ -	\$ -	\$ -	\$ 27,200	\$ -	\$ 27,200
Total notes payable to unrelated parties	\$ 54,800	\$ -	\$ 54,800	\$ 58,800	\$ 12,000	\$ 70,800
less: current portion	(54,800)	-	(54,800)	(31,600)	(12,000)	(43,600)
Net non-current portion	\$ -	\$ -	\$ -	\$ 27,200	\$ -	\$ 27,200

In June 2016, we paid in full the \$71,600 then-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 was payable in monthly installments of \$12,100, including principal and interest, through March 2017. In February 2017, we executed a promissory note in the face amount of \$60,700 in connection with other insurance policy premiums. The note is payable in monthly installments of \$6,300, including principal and interest, and has an outstanding balance of \$54,800 at March 31, 2017.

Convertible and Promissory Notes and Other Indebtedness Converted into Series B Preferred

Between May 2015 and September 2015, we extinguished outstanding indebtedness having a carrying value of approximately \$15.9 million (principal plus unpaid accrued interest less unamortized debt discount), including all of our senior secured promissory notes, all except \$58,800 principal of our unsecured promissory notes, and a substantial portion of other indebtedness, and certain adjustments thereto, that were either due and payable or would have become due and payable prior to March 31, 2016, by converting all such indebtedness into shares of our Series B Preferred (as described more completely in Note 9, *Capital Stock*, under the caption *Series B Preferred Stock*). Evaluating each note or debt class separately, we determined that the conversion of each of the notes or other debt instruments into Series B Preferred should be accounted for as an extinguishment of debt. Further, considering the direct exchangeability of the Series B Preferred shares into shares of our common stock, the 10% dividend applicable to the Series B Preferred prior to such exchange, and other factors, we determined that the fair value of a share of Series B Preferred issued pursuant to the conversion of each of the notes or other debt instruments was equal to the market value of a share of our common stock on the conversion date. 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 loss on extinguishment of debt of \$26,700,200, in the first and second quarters of the fiscal year ended March 31, 2016, as reflected in the accompanying Consolidated Statement of Operations and Comprehensive Loss for that period. The carrying values and components of the loss on extinguishment of our notes and other indebtedness converted into Series B Preferred during our fiscal year ended March 31, 2016 are summarized in a table presented in Note 9, *Capital Stock*, under the caption *Conversion of Debt Securities into Series B Preferred and Loss on Extinguishment of Debt*.

9. Capital Stock

Series A Preferred Stock

In December 2011, our Board of Directors authorized the creation of a series of up to 500,000 shares of Series A Preferred, par value \$0.001 (*Series A Preferred*). Each restricted share of Series A Preferred was initially convertible at the option of the holder into one-half of one restricted share of our common stock. The Series A Preferred ranks prior to the common stock for purposes of liquidation preference.

The Series A Preferred has no separate dividend rights, however, whenever the Board of Directors declares a dividend on the common stock, each holder of record of a share of Series A Preferred shall be entitled to receive an amount equal to such dividend declared on one share of common stock multiplied by the number of shares of common stock into which such share of Series A Preferred could be converted on the Record Date.

Except with respect to transactions upon which the Series A Preferred shall be entitled to vote separately as a class, the Series A Preferred has no voting rights. The restricted common stock into which the Series A Preferred is convertible shall, upon issuance, have all of the same voting rights as other issued and outstanding shares of our common stock.

In the event of the liquidation, dissolution or winding up of the affairs of the Company, after payment or provision for payment of our debts and other liabilities, the holders of Series A Preferred then outstanding shall be entitled to receive an amount per share of Series A Preferred calculated by taking the total amount available for distribution to holders of all of our outstanding common stock before deduction of any preference payments for the Series A Preferred, divided by the total of (x), all of the then outstanding shares of our common stock, plus (y) all of the shares of our common stock into which all of the outstanding shares of the Series A Preferred can be converted before any payment shall be made or any assets distributed to the holders of the common stock or any other junior stock.

At March 31, 2017 and 2016, there were 500,000 restricted shares of Series A Preferred outstanding, convertible into 750,000 shares of our common stock at the option of the holder, all held by PLTG or its affiliates and a third party to whom PLTG transferred certain of the shares. PLTG initially acquired the Series A Preferred pursuant to certain transactions with us that occurred between December 2011 and June 2012, the latter of which involved, among other considerations, the exchange of common stock then owned by PLTG for shares of Series A Preferred. The common shares exchanged for shares of Series A Preferred are treated as treasury stock in the accompanying Consolidated Balance Sheets at March 31, 2017 and 2016.

Series B Preferred Stock

In July 2014, our Board of Directors authorized the creation of a class of Series B Preferred Stock. In May 2015, we filed a Certificate of Designation of the Relative Rights and Preferences of the Series B 10% Preferred Stock of VistaGen Therapeutics, Inc. (*Certificate of Designation*) with the Nevada Secretary of State to designate 4.0 million shares of our authorized preferred stock as Series B Preferred.

Each share of Series B Preferred is convertible, at the option of the holder (*Voluntary Conversion*), into one (1) share of our Common Stock, subject to adjustment only for customary stock dividends, reclassifications, splits and similar transactions set forth in the Certificate of Designation. All outstanding shares of Series B Preferred are also convertible automatically on a one-to-one basis into shares of our Common Stock (*Automatic Conversion*) upon the closing or effective date of any of the following transactions or events: (i) a strategic transaction involving AV-101 with an initial up-front cash payment to us of at least \$10.0 million; (ii) a registered public offering of our common stock with aggregate gross proceeds to us of at least \$10.0 million; or (iii) for 20 consecutive trading days, our common stock trades at least 20,000 shares per day with a daily closing price of at least \$12.00 per share; provided, however, that Automatic Conversion and Voluntary Conversion (collectively, *Conversion*) are subject to certain beneficial ownership blockers as set forth in the Certificate of Designation and/or securities purchase agreements.

Prior to Conversion, shares of Series B Preferred accrue in-kind dividends (payable only in unregistered shares of our common stock) at a rate of 10% per annum (*Accrued Dividends*). The Accrued Dividends are payable on the date of either a Voluntary Conversion or Automatic Conversion solely in that number of shares of common stock equal to the Accrued Dividends. At March 31, 2017, we have recognized a liability in the amount of \$1,577,800 for Accrued Dividends in the accompanying Consolidated Balance Sheet at March 31, 2017, based on the Series B Preferred issued and outstanding, net of conversions to common stock, through that date. We have recognized a deduction from net loss of \$1,257,000 and \$2,140,500 related to dividends on Series B Preferred in arriving at net loss attributable to common stockholders in the accompanying Consolidated Statement of Operations and Comprehensive Loss for the fiscal years ended March 31, 2017 and 2016, respectively. The liquidation value of the Series B Preferred at March 31, 2017 is approximately \$9,699,500.

Following the completion of the May 2016 Public Offering, which occurred concurrently with and facilitated the listing of our common stock on the NASDAQ Capital Market, approximately 2.4 million shares of Series B Preferred were converted automatically into approximately 2.4 million shares of our common stock pursuant to the Automatic Conversion provision. At March 31, 2017, there were 1,160,240 shares of Series B Preferred outstanding, which shares are currently subject to beneficial ownership blockers and are exchangeable at the option of the respective holders by Voluntary Conversion, or pursuant to Automatic Conversion to the extent not otherwise subject to beneficial ownership blockers, into an aggregate of 1,160,240 shares of our common stock.

Series C Preferred Stock

In January 2016, our Board authorized the creation of and, accordingly, we filed a Certificate of Designation of the Relative Rights and Preferences of the Series C Convertible Preferred Stock of VistaGen Therapeutics, Inc. (the *Series C Preferred Certificate of Designation*) with the Nevada Secretary of State to designate 3.0 million shares of our preferred stock, par value \$0.001 per share, as Series C Convertible Preferred Stock (*Series C Preferred*). Upon liquidation, each share of Series C Preferred ranks pari-passu with our Series B Preferred and our Series A Preferred, and is convertible, at the option of the holder into one share of our common stock, subject to certain beneficial ownership limitations as set forth in the Series C Preferred Certificate of Designation. Shares of the Series C Preferred do not accrue dividends, and holders of the Series C Preferred have no voting rights. Each share of Series C Preferred is convertible into one (1) share of our common stock. At March 31, 2017, PLTG or its affiliates held all 2,318,012 outstanding shares of Series C Preferred.

2014 Unit Private Placement

Between late-March 2014 and May 14, 2015, we entered into securities purchase agreements with accredited investors for the self-placed 2014 Unit Private Placement pursuant to which we sold 2014 Units consisting of (i) promissory notes (*2014 Unit Notes*) in the aggregate face amount of \$3,413,500 due between March 31, 2015 and May 15, 2015 or automatically convertible into securities issuable upon our consummation of a Qualified Financing, as defined in the note; (ii) an aggregate of 315,850 restricted shares of our common stock; and (iii) warrants exercisable through December 31, 2016 to purchase an aggregate of 307,100 restricted shares of our common stock at an exercise price of \$10.00 per share. We received aggregate cash proceeds of \$3,413,500 from the 2014 Unit Private Placement. We sold 2014 Units resulting in \$280,000 of cash proceeds during our fiscal year ended March 31, 2016.

May 2015 Agreement with PLTG

In May 2015, we entered into an Agreement with PLTG (the *PLTG Agreement*) pursuant to which PLTG:

- Converted into 641,335 shares of Series B Preferred all of the approximately \$4.5 million outstanding balance (principal and accrued but unpaid interest) of the Senior Secured Notes we had previously issued to PLTG;
- Released in their entirety its security interests in our assets and those of our subsidiaries by terminating the Amended and Restated Security Agreement, IP Security Agreement and Negative Covenant, each of which had been executed in October 2012;
- Converted into 240,305 shares of Series B Preferred and five-year warrants to purchase 240,305 shares of our common stock at a fixed exercise price of \$7.00 per share (*Series B Warrants*) all of the approximately \$1.3 million outstanding balance (principal and accrued but unpaid interest) of the 2014 Unit Notes that we issued to PLTG;
- Purchased approximately \$1.5 million (including accrued but unpaid interest thereon) of outstanding 2014 Unit Notes we had previously issued to various accredited investors from the respective holders thereof (*Acquired Unit Notes*) and converted the entire approximately \$1.5 million outstanding balance of the Acquired Unit Notes into 265,699 shares of Series B Preferred and Series B Warrants to purchase 265,699 shares of our common stock;
- Entered into a Securities Purchase Agreement (*SPA*) to purchase from us, in our self-placed private placement, for \$1.0 million, a total of 142,857 shares of Series B Preferred and a Series B Warrant to purchase 142,857 shares of our common stock, which purchase was consummated and the shares and warrants issued;
- Amended the PLTG Warrants previously issued to PLTG in connection with the Senior Secured Notes and the Series A Exchange Warrant to (i) fix the exercise price thereof, (ii) eliminate the exercise price reset features; (iii) fix the number of shares of our common stock issuable thereunder, and (iv) eliminate the cashless exercise provisions from the PLTG Warrants, as described in Note 4. *Fair Value Measurements*; and
- Agreed to refrain from the sale of any shares of our common stock held by PLTG or its affiliates until the earlier to occur of an effective registration statement under the Securities Act of 1933, as amended, relating to resale of certain shares of common stock issuable upon conversion of shares of Series B Preferred held by PLTG, or the closing price of our common stock is at least \$15.00 per share.

As additional consideration under the PLTG Agreement, we issued to PLTG 400,000 shares of Series B Preferred (*Additional Consideration Shares*) and Series B Warrants (*Additional Consideration Warrants*) to purchase 1.2 million shares of our common stock, and exchanged 30,000 shares of our common stock then beneficially owned or controlled by PLTG for 30,000 shares of Series B Preferred. Considering the exchangeability of the Series B Preferred into our common stock, the dividend applicable to the Series B Preferred prior to such exchange, and other factors, we determined that the fair value of a share of Series B Preferred issued to PLTG pursuant to the PLTG Agreement was equal to the market value of a share of our common stock on the effective date of the PLTG Agreement. Based on the \$10.00 per share fair value of the Series B Preferred at the effective date of the PLTG Agreement, we issued Additional Consideration Shares having an aggregate fair value of \$4.0 million to PLTG. We valued the Additional Consideration Warrants at an aggregate of \$8,270,900 using the Black Scholes option pricing model and the following assumptions: market price per share: \$10.00; exercise price per share: \$7.00; risk-free interest rate: 1.58%; contractual term: 5.00 years; volatility: 76.5%; expected dividend rate: 0%. We recognized the aggregate fair value of the Additional Consideration Shares and Additional Consideration Warrants, \$12,270,900, as a component of loss on debt extinguishment in the second quarter of our fiscal year ended March 31, 2016.

Conversion of Debt Securities into Series B Preferred and Loss on Extinguishment of Debt

As described in Note 8, *Notes Payable*, during the first and second quarters of our fiscal year ended March 31, 2016, we extinguished a substantial portion of our outstanding indebtedness, including all of our senior secured promissory notes issued to PLTG, all except \$58,800 principal of our unsecured promissory notes, and a significant portion of outstanding accounts payable and accrued expenses, by converting such indebtedness into shares of our Series B Preferred. In most instances, the consideration given upon conversion was limited to shares of Series B Preferred. In certain instances, as in the case of the Additional Consideration Warrants noted previously, we agreed to issue new warrants or modify outstanding warrants as additional incentive provided to our counterparty to accept the equity for debt settlement offer. Further, with respect to the 2014 Unit Notes, we determined that the Series B Preferred Unit Offering (described below) would be treated as a Qualified Financing with respect to such notes, entitling the 2014 Unit Note holders at the time of conversion to the 25% Qualified Financing conversion premium under the terms of the 2014 Unit Notes. Evaluating each note or debt class separately, we determined that the conversion of each of the notes or other debt instruments into Series B Preferred should be accounted for as an extinguishment of debt. Because, in each instance, the fair value of the consideration given exceeded the carrying value of the debt, we incurred a loss on extinguishment in the settlement of each debt instrument or agreement. Nearly all of the 2014 Unit Notes 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 of the extinguishment and conversion of the 2014 Unit Notes, an aggregate of \$2,237,200, as a reduction to the loss on extinguishment of debt, with a corresponding reduction to additional paid-in capital.

The following table summarizes the carrying value of the debt instruments at the date they were converted into Series B Preferred, the components of the consideration given and the resulting loss on debt extinguishment attributable to each settlement and the number of shares and warrants, if any, issued in the settlement for each debt instrument or class. We recorded the aggregate loss on debt extinguishment, \$26,700,200, in the first and second quarters of our fiscal year ended March 31, 2016, as reflected in the accompanying Consolidated Statement of Operations and Comprehensive Loss for the fiscal year ended March 31, 2016.

	Carrying Amount (Principal plus Accrued Interest less Discount)	Consideration Given			Repurchase of Beneficial Conversion Feature	Loss on Extinguishment of Debt	Series B Preferred Shares Issued	New Warrants Issued
		Fair Value of Series B Preferred at Issuance	Fair Value of Warrants at Issuance	Incremental Fair Value of Warrant Modifications				
Senior Secured Convertible Notes (1)	\$ 4,489,300	\$ 10,413,400	\$ 8,270,800	\$ -	\$ -	\$(14,194,900)	1,041,335	1,200,000
PLTG Unit Notes	1,345,700	2,403,100	1,656,300	-	-	(2,713,700)	240,305	240,305
Acquired Unit Notes	1,487,900	2,657,000	1,827,200	-	(514,900)	(2,481,400)	265,699	265,699
Investor Unit Notes	1,831,200	2,616,100	1,684,900	-	(1,722,300)	(747,500)	327,016	327,016
University Health Network note	628,900	937,800	-	-	-	(308,900)	93,775	-
Cato Holding Company and Cato Research Ltd. notes and accounts payable	1,708,300	3,285,700	-	222,700	-	(1,800,100)	328,571	-
Morrison & Foerster Note A	1,191,700	2,359,700	-	-	-	(1,168,000)	192,628	-
Morrison & Foerster Note B and accounts payable	1,510,000	2,571,400	-	244,200	-	(1,305,600)	257,143	-
McCarthy Tetrault note and accounts payable	381,700	829,200	-	-	-	(447,500)	59,230	-
Burr Pilger & Mayer note and accounts payable	123,100	353,600	-	-	-	(230,500)	21,429	-
Icahn School of Medicine at Mount Sinai note and accounts payable	289,500	676,000	-	16,600	-	(403,100)	43,000	-
National Jewish Health note	115,000	267,900	-	-	-	(152,900)	17,857	-
Desjardins Securities note	187,400	450,000	-	-	-	(262,600)	32,143	-
MicroConstants note and accounts payable	92,400	250,000	-	-	-	(157,600)	17,857	-
Other service provider accounts payable	497,900	823,800	-	-	-	(325,900)	80,929	-
	<u>\$ 15,880,000</u>	<u>\$ 30,894,700</u>	<u>\$ 13,439,200</u>	<u>\$ 483,500</u>	<u>\$ (2,237,200)</u>	<u>\$26,700,200</u>	<u>3,018,917</u>	<u>2,033,020</u>

(1) Includes 400,000 Series B Preferred shares with fair value of \$4,000,000 issued as Additional Consideration Shares and warrants to purchase 1,200,000 shares of common stock with fair value of \$8,270,800 issued as Additional Consideration Warrants for the various agreements of PLTG pursuant to the PLTG Agreement in May 2015

Series B Preferred Unit Offering

Between May 2015 and May 2016, in self-placed private placement transactions, we sold to accredited investors an aggregate of \$5,303,800 of units in our Series B Preferred Unit offering, which units consisted of Series B Preferred and Series B Warrants (together *Series B Preferred Units*), including \$2,650,000 to PLTG. We issued 757,692 shares of Series B Preferred and Series B Warrants to purchase 757,692 shares of our common stock. During our fiscal year ended March 31, 2017, we received an aggregate of \$278,000 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 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 \$4.14 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 and \$2,058,000 in arriving at net loss attributable to common stockholders in the accompanying Consolidated Statement of Operations and Comprehensive Loss for the fiscal years ended March 31, 2017 and 2016, respectively.

Unit Warrants											Aggregate Allocation of Proceeds Based on Relative Fair Value of:	
Warrant Shares Issued	Market Price	Weighted Average Issuance Date Valuation Assumptions					Per Share Fair Value of Warrant	Aggregate Fair Value of Unit Warrants	Aggregate Proceeds of Unit Sales	Unit Stock		
		Exercise Price	Term (Years)	Risk free Interest Rate	Volatility	Dividend Rate						
757,692	\$ 10.34	\$ 7.00	5.00	1.60%	77.36%	0.0%	\$ 7.27	\$ 5,512,100	\$ 5,303,800	\$ 3,134,800	\$ 2,169,000	

Registration Statement for Common Stock underlying Series B Preferred and Series B Warrants

The securities purchase agreements for the Series B Preferred and Series B Preferred Units executed with PLTG, the holders of the Investor Unit Notes, the holders of our promissory notes and other indebtedness converted into shares of Series B Preferred, initial investors in Series B Preferred Units, and certain others to whom we issued Series B Preferred, contained registration rights requiring that a Registration Statement on Form S-1 (*Secondary Registration Statement*) registering, under the Securities Act of 1933, as amended, (the *Securities Act*), certain shares of common stock underlying the Series B Preferred and the Series B Warrants be declared effective on or before August 30, 2015. We filed the initial Secondary Registration Statement with the SEC on July 21, 2015, which we later amended on August 25, 2015, and which was declared effective by the SEC on August 28, 2015. The Secondary Registration Statement registered an aggregate of 3,992,479 shares of our common stock underlying outstanding Series B Preferred and Series B Warrants. Accordingly, we incurred no cash or in kind penalties under the securities purchase agreements.

Conversion of Series B Preferred into Common Stock

Between September 2015 and March 2016, holders of an aggregate of 228,818 shares of Series B Preferred voluntarily converted such shares into an equivalent number of registered shares of our common stock. In connection with these conversions, we issued an aggregate of 6,837 shares of our restricted common stock in payment of \$50,900 in accrued dividends on the Series B Preferred that was converted.

During April 2016, 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 these 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, following 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 Series B Preferred accrued 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.

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 were offered, issued and sold under a prospectus filed with the Commission pursuant to an effective registration statement (*Primary Registration Statement*) filed with the Commission on Form S-1 (File No. 333-210152) pursuant to the Securities Act. The Primary 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.

Common Stock and Warrants Issued in Private Placement

In December 2016, in self-placed private transactions, we sold to two individual accredited 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, the entire amount of which was credited to stockholders' equity.

In March 2017, in a self-placed private transaction, we sold to an accredited investor units, at a purchase price of \$2.00 per unit, consisting of an aggregate of 57,250 unregistered shares of our common stock and warrants, exercisable through April 2021, to purchase an aggregate of 28,625 unregistered shares of our common stock at an exercise price of \$4.00 per share. The purchaser of the units has 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 \$114,500 in connection with this private placement, the entire amount of which was credited to stockholders' equity. See Note 16, *Subsequent Events*, for disclosure of additional sales of our securities in private placement offerings.

Issuance of Common Stock, Series B Preferred Stock and Warrants to Professional Services Providers

During our fiscal years ended March 31, 2017 and 2016, we issued the following securities in private placement transactions as compensation for various professional services. Unless otherwise noted, we recorded the related non-cash expense as a component of general and administrative expense in the Consolidated Statement of Operations and Comprehensive Loss for the fiscal years ended March 31, 2017 and 2016, as appropriate.

- During the quarter ended June 30, 2015, we issued an aggregate of 25,000 unregistered shares of our Series B Preferred having a fair value of \$250,000 on the date of issuance as compensation for legal services related to our debt restructuring and other corporate finance matters.
- During the quarter ended June 30, 2015, we issued an aggregate of 90,000 unregistered shares of our Series B Preferred having an aggregate value on the date of issuance of \$1,350,000 as compensation for financial advisory and corporate development service contracts with two independent contractors for services to be performed through June 2016. The value of the Series B Preferred grants was recorded as a prepaid expense at the date of the grant and was expensed ratably over the twelve months ending June 2016, with \$337,500 and \$1,012,500 expensed during the fiscal years ended March 31, 2017 and 2016, respectively.
- During the quarter ended June 30, 2015, we also issued an aggregate of 50,000 shares of our unregistered common stock having an aggregate fair value on the date of issuance of \$500,000, as compensation under two corporate development service contracts.
- During the quarter ended September 30, 2015 we issued to two providers of intellectual property-related legal services an aggregate of 10,000 unregistered shares of our Series B Preferred having an aggregate fair value on the date of issuance of \$120,000.
- During the quarter ended December 31, 2015 we issued 15,750 unregistered shares of our common stock having a fair value on the date of issuance of \$106,300 as partial compensation for investment banking services.
- During the quarter ended March 31, 2016, we issued an aggregate of 26,625 shares of our unregistered common stock having an aggregate fair value on the dates of issuance of \$223,000 in connection with legal (\$140,000) and investor relations (\$83,000) services.
- During the quarter ended September 30, 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 various 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.
- During the quarter ended December 31, 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 various professional services providers.
- During the quarter ended March 31, 2017, we issued an aggregate of 200,000 unregistered shares of our common stock, of which 150,000 unregistered shares were issued from our 2016 Stock Plan (defined below), having an aggregate fair value of \$422,500 on the dates of issuance to various professional services providers.

During the quarter ended December 31, 2015, we issued warrants to purchase an aggregate of 45,000 shares of our unregistered common stock to four parties as compensation under certain investment banking agreements. In connection with one of the warrant grants, we also issued 15,750 shares of unregistered common stock valued at \$106,300 and, in connection with another warrant grant, we made a cash payment of \$20,000. In March 2016, we issued warrants to purchase an aggregate of 230,000 shares of our common stock to eleven professional service providers in connection with investment banking, strategic planning and financing, tax, legal and research and development consulting services. We recognized \$1,042,400 of general and administrative expense and \$127,100 of research and development expense attributable to the March 2016 grants. We valued the warrants granted on the dates indicated using the Black Scholes Option Pricing Model and the following assumptions:

Assumption:	November 2015	December 2015	March 2016
Market price per share	\$ 6.75	\$ 5.00	8.00
Exercise price per share	\$ 7.00	\$ 7.00	8.00
Risk-free interest rate	1.70%	1.16%	1.39%
Contractual term in years	5.0	3.0	5.0
Volatility	77.95%	77.88%	78.96%
Dividend rate	0.0%	0.0%	0.0%
Fair Value per share	\$ 4.22	\$ 2.12	\$ 5.08
Warrant shares granted	7,500	37,500	230,000
Expense recognized	\$ 31,700	\$ 79,600	\$ 1,169,500

Warrant Exchanges into Series C Preferred and Common Stock

In January 2016, we entered into an Exchange Agreement (the *Exchange Agreement*) with PLTG and Montsant Partners, LLC, an organization affiliated with PLTG (*Montsant* and, together with PLTG, the *Holder*s), pursuant to which (i) 200,000 shares of our common stock held by the Holders were exchanged for 200,000 shares of Series C Preferred; and (ii) the Holders canceled outstanding warrants to purchase an aggregate of 2,368,658 shares of our unregistered common stock (the *Outstanding PLTG Warrants*) in exchange for a total of 1,776,494 shares of Series C Preferred. In addition, PLTG terminated its right under the October 2012 Note Exchange and Purchase Agreement, as amended (the *NEPA*), to receive the Series A Exchange Warrant to purchase a total of 455,358 shares of our common stock upon conversion of all of its shares of our Series A Preferred, and, as consideration, we issued to PLTG 341,518 shares of Series C Preferred. Upon execution of the Exchange Agreement and the termination of PLTG's right to receive Series A Exchange Warrants under the NEPA, we issued a Series A Exchange Warrant to purchase a total of 80,357 shares of our common stock to the current holder of shares of Series A Preferred previously held, but subsequently assigned, by PLTG.

During the quarter ended March 31, 2016, we entered into Warrant Exchange Agreements with certain holders of other outstanding warrants (*Other Warrants*) to purchase an aggregate of 1,086,610 shares of our common stock pursuant to which the holders agreed to the cancellation of such warrants in exchange for our issuance to them of an aggregate of 814,989 shares of our unregistered common stock. In connection with these exchanges, we extended the expiration date of certain warrants by three months.

We accounted for the exchange of the Outstanding PLTG Warrants, the Series A Preferred Exchange Warrant, and the Other Warrants as warrant modifications, determining the fair value of the Outstanding PLTG Warrants and the Other Warrants, and the Series A Preferred Exchange Warrant as if issued on the Exchange Agreement date, as of the respective exchange agreement dates, and comparing that to the fair value of the Series C Preferred or common stock issued. Considering the direct exchangeability of the Series C Preferred shares into shares of our common stock, we determined that the fair value of a share of Series C Preferred issued pursuant to the Exchange Agreement with PLTG was equal to the market value of a share of our common stock on the date of the Exchange Agreement. 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 each exchange, as also indicated in the table below. We recognized the amount of the incremental fair value of the unregistered Series C Preferred or common stock issued in excess of the fair value of the warrants cancelled, \$5,608,300, as a component of warrant modification expense, which is included in general and administrative expenses in our accompanying Consolidated Statement of Operations and Comprehensive Loss for the fiscal year ended March 31, 2016.

Warrant Exchanges - FY 2016

	January 2016				January - March 2016	
	PLTG Outstanding Warrants		PLTG Series A Exchange Warrant		Other outstanding warrants	
	Pre-modification	Post-modification	Pre-modification	Post-modification	Pre-modification	Post-modification
Market Price per share	\$ 8.25	\$ 8.25	\$ 8.25	\$ 8.25	\$ 8.00	\$ 7.97
Exercise price per share	\$ 7.13		\$ 7.00		\$ 8.47	
Risk-free interest rate	1.27%		1.47%		0.88%	
Contractual term (years)	3.99		5.00		3.04	
Volatility	79.5%		77.9%		81.0%	
Dividend Rate	0%		0%		0%	
Weighted average fair value per share	\$ 4.98		\$ 5.45		\$ 3.76	
Warrant shares cancelled and exchanged	2,368,658		455,358		1,986,610	
Common (Series C Preferred for PLTG Warrants) shares issued in exchange		1,776,494		341,518		814,989
Fair Value	\$ 11,797,400	\$ 14,656,100	\$ 2,481,300	\$ 2,817,500	\$ 4,081,600	\$ 6,495,000
Incremental fair value recognized as warrant modification expense		\$ 2,858,700		\$ 336,200		\$ 2,413,400

During our fiscal year ended March 31, 2017, we entered into additional Warrant Exchange Agreements with certain other 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 also 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, using the same procedures as described previously. 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 incremental fair value of the unregistered common stock issued in excess of the fair value of the warrants cancelled, \$350,700, as a component of warrant modification expense which is included in general and administrative expenses in our accompanying Consolidated Statement of Operations and Comprehensive Loss for the fiscal year ended March 31, 2017.

Warrant Exchanges - FY 2017

	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		2.40		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 as warrant modification expense		\$ 40,300		\$ 17,100		\$ 201,700		\$ 91,600

Additional Warrant Modifications

In addition to warrants modified in connection with conversions of certain of our outstanding promissory notes into Series B Preferred during the first and second quarters of our fiscal year ended March 31, 2016, as described earlier in this note, the incremental fair value of which modifications was included in the determination of loss on extinguishment of debt, and the warrants modified in connection with the various warrant exchange transactions described immediately above, we modified other outstanding warrants during our fiscal years ended March 31, 2017 and 2016.

In June 2015, we modified certain outstanding warrants to purchase an aggregate of 54,576 shares of our common stock to reduce their exercise price. We calculated the fair value of the modified warrants immediately before and after the modifications and determined that the fair value of the warrants increased by an aggregate of \$122,300, which we recognized as a component of warrant modification expense which is included in general and administrative expense in the accompanying Consolidated Statement of Operations and Comprehensive Loss for the fiscal year ended March 31, 2016. The warrants subject to the exercise price modifications were valued using the Black-Scholes Option Pricing Model and the following assumptions:

Assumption:	Pre- modification	Post- modification
Market price per share	\$ 10.00	\$ 10.00
Exercise price per share (weighted average)	\$ 30.23	\$ 11.92
Risk-free interest rate (weighted average)	0.83%	0.83%
Remaining contractual term in years (weighted average)	2.26	2.26
Volatility (weighted average)	73.7%	73.7%
Dividend rate	0.0%	0.0%
Fair Value per share (weighted average)	\$ 1.55	\$ 3.79

In November 2015, our Board of Directors (the *Board*) authorized the modification of outstanding warrants to purchase an aggregate of 1,123,533 shares of our common stock, including warrants to purchase an aggregate of 600,000 shares granted in September 2015 to company officers, independent members of the Board and a key scientific advisor to reduce the exercise prices thereof to \$7.00 per share and to extend through March 19, 2019 the expiration date of such warrants to purchase an aggregate of 10,803 shares of our unregistered common stock otherwise scheduled to expire during calendar 2016. We calculated the fair value of the modified warrants immediately before and after the modifications and determined that the fair value of the warrants increased by an aggregate of \$492,600. We recognized \$357,500 of such increase as a component of general and administrative expense in the accompanying Consolidated Statement of Operations and Comprehensive Loss for the fiscal year ended March 31, 2016, and the remaining \$135,100 as a component of research and development expense in the same period. The warrants subject to the exercise price modifications were valued using the Black-Scholes Option Pricing Model and the following assumptions:

Assumption:	Pre- modification	Post- modification
Market price per share	\$ 6.50	\$ 6.50
Exercise price per share (weighted average)	\$ 9.97	\$ 7.00
Risk-free interest rate (weighted average)	1.74%	1.75%
Remaining contractual term in years (weighted average)	5.13	5.16
Volatility (weighted average)	78.8%	78.7%
Dividend rate	0.0%	0.0%
Fair Value per share (weighted average)	\$ 3.65	\$ 4.08

As noted with respect to the exchange of the Other Warrants into shares of our common stock, in January 2016, we extended the term of certain warrants to purchase an aggregate of 91,230 unregistered shares of our common stock otherwise due to expire between January 31, 2016 and June 11, 2016 by three months. We calculated the fair value of the extended warrants immediately before and after the extension and determined that the fair value of the warrants increased by an aggregate of \$45,700, which we treated as an additional component of warrant modification expense for the fiscal year ended March 31, 2016 in the accompanying Consolidated Statement of Operations and Comprehensive Loss. The warrants subject to the term extension were valued using the Black-Scholes Option Pricing Model and the following weighted average assumptions:

Assumption:	Pre- modification	Post- modification
Market price per share	\$ 8.25	\$ 8.25
Exercise price per share	\$ 12.99	\$ 12.99
Risk-free interest rate	0.28%	0.36%
Remaining contractual term in years	0.15	0.40
Volatility	91.2%	91.2%
Dividend rate	0.0%	0.0%
Fair Value per share	\$ 0.30	\$ 0.80

For warrants which were extended and subsequently exchanged, the pre-modification fair value used in the warrant exchange calculation was the post-modification term extension fair value, since those warrants were treated as having been modified twice in a twelve-month period.

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. We recognized the additional fair value, \$76,900, as warrant modification expense, included as a component of general and administrative expenses, in our Consolidated Statement of Operations and Comprehensive Loss for the fiscal year ended March 31, 2017.

Assumption:	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%
Remaining contractual term in years	4.26	5.03
Volatility	87.1%	85.8%
Dividend rate	0.0%	0.0%
Number of warrant shares	25,000	50,000
Weighted average fair value per share	\$ 1.71	\$ 2.39

Warrants Outstanding

The following table summarizes outstanding warrants to purchase shares of our common stock as of March 31, 2017. The weighted average exercise price of outstanding warrants at March 31, 2017 was \$6.29 per share.

Exercise Price per Share	Expiration Date	Weighted Average Remaining Term (Years)	Shares Subject to Purchase at March 31, 2017
\$ 3.51	12/31/2021	4.75	50,000
\$ 4.00	4/30/2021	4.08	28,625
\$ 4.50	9/26/2019	2.49	25,000
\$ 5.30	5/16/2021	4.13	2,705,883
\$ 6.00	9/26/2019 to 11/30/2019	2.52	97,750
\$ 7.00	12/11/2018 to 3/3/2023	3.41	1,346,931
\$ 8.00	3/25/2021	3.98	185,000
\$ 10.00	11/15/2017 to 1/11/2020	2.39	24,394
\$ 20.00	9/15/2019	2.46	110,448
\$ 30.00	11/20/2017	0.64	3,600
		3.82	<u>4,577,631</u>

Reserved Shares

At March 31, 2017, we have reserved shares of our common stock for future issuance as follows:

Upon exchange of all shares of Series A Preferred Stock currently issued and outstanding ⁽¹⁾	750,000
Upon exchange of all shares of Series B Preferred Stock currently issued and outstanding ⁽²⁾	1,823,700
Upon exchange of all shares of Series C Preferred Stock currently issued and outstanding	2,318,012
Pursuant to warrants to purchase common stock:	
Subject to outstanding warrants	4,577,631
Pursuant to stock incentive plans:	
Subject to outstanding options under the Amended and Restated 2016 and 1999 Stock Incentive Plans	1,659,324
Available for future grants under the Amended and Restated 2016 Stock Incentive Plan	<u>1,134,911</u>
	<u>2,794,235</u>
Total	<u><u>12,263,578</u></u>

⁽¹⁾ assumes exchange under the terms of the October 11, 2012 Note Exchange and Purchase Agreement with PLTG

⁽²⁾ includes 663,460 common shares issuable in payment of an estimated \$1,658,600 in accrued dividends through April 30, 2017 at \$2.50 per share

10. Research and Development Expenses

We recorded research and development expenses of approximately \$5.2 million and \$3.9 million in the fiscal years ended March 31, 2017 and 2016, respectively. Research and development expense is composed primarily of employee compensation expenses, including stock-based compensation, direct project expenses, particularly in Fiscal 2017 related to our preparations for our AV-101 MDD Phase 2 Adjunctive Treatment Study, and costs to maintain and prosecute our intellectual property suite, including new patent applications for AV-101 for various indications.

11. Income Taxes

The provision for income taxes for the periods presented in the Consolidated Statements of Operations and Comprehensive Loss represents minimum California franchise taxes. Income tax expense differed from the amounts computed by applying the U.S. federal income tax rate of 34% to pretax losses as a result of the following:

	Fiscal Years Ended March 31,	
	2017	2016
Computed expected tax benefit	(34.00)%	(34.00)%
Tax effect of loss on debt extinguishment	-%	19.22%
Tax effect of warrant modifications	1.42%	4.38%
Tax effect of Warrant Liability mark to market	-%	1.36%
Other losses not benefitted	32.58%	9.04%
Other	0.02%	0.01%
	<u>0.02%</u>	<u>0.01%</u>
Income tax expense	<u>0.02%</u>	<u>0.01%</u>

Deferred income taxes reflect the net tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of our deferred tax assets are as follows (in thousands):

	March 31,	
	2017	2016
Deferred tax assets:		
Net operating loss carryovers	\$ 30,184	\$ 26,606
Basis differences in fixed assets	(4)	-
Stock based compensation	3,674	3,681
Accruals and reserves	928	928
	<u>34,782</u>	<u>31,215</u>
Total deferred tax assets	34,782	31,215
Valuation allowance	<u>(34,782)</u>	<u>(31,215)</u>
Net deferred tax assets	<u>\$ -</u>	<u>\$ -</u>

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by \$3,567,000 and \$5,443,000 during the fiscal years ended March 31, 2017 and 2016, respectively. When realized, deferred tax assets related to employee stock options will be credited to additional paid-in capital.

As of March 31, 2017, we had U.S. federal net operating loss carryforwards of approximately \$77.1 million, which will expire in fiscal years 2020 through 2037. As of March 31, 2017, we had state net operating loss carryforwards of approximately \$67.6 million, which will expire in fiscal years 2018 through 2037.

U.S. federal and state tax laws include substantial restrictions on the utilization of net operating loss carryforwards in the event of an ownership change of a corporation. We have not performed a change in ownership analysis since our inception in 1998 and accordingly some or all of our net operating loss carryforwards may not be available to offset future taxable income, if any.

We file income tax returns in the U.S. federal and Canadian jurisdictions and California and Maryland state jurisdictions. We are subject to U.S. federal and state income tax examinations by tax authorities for tax years 2000 through 2017 due to net operating losses that are being carried forward for tax purposes, but we are not currently under examination by tax authorities in any jurisdiction.

Uncertain Tax Positions

Our unrecognized tax benefits at March 31, 2017 and 2016 relate entirely to research and development tax credits. The total amount of unrecognized tax benefits at March 31, 2017 and 2016 is \$290,500 and \$142,400, respectively. If recognized, none of the unrecognized tax benefits would impact our effective tax rate. The following table summarizes the activity related to our unrecognized tax benefits.

	Fiscal Years Ended March 31,	
	2017	2016
Unrecognized benefit - beginning of period	\$ 142,400	\$ 48,200
Current period tax position increases	77,700	35,300
Prior period tax position increases	70,400	58,900
	<u>290,500</u>	<u>142,400</u>
Unrecognized benefit - end of period	<u>\$ 290,500</u>	<u>\$ 142,400</u>

Our policy is to recognize interest and penalties related to income taxes as components of interest expense and other expense, respectively. We incurred no interest or penalties related to unrecognized tax benefits in the years ended March 31, 2017 or 2016. We do not anticipate any significant changes of our uncertain tax positions within twelve months of this reporting date.

12. Licensing, Sublicensing and Collaborative Agreements

BlueRock Therapeutics Sublicense Agreement

In December 2016, we entered into an Exclusive License and Sublicense Agreement (*BlueRock Therapeutics 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 received 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 in January 2017 and have recognized \$1.25 million in sublicense revenue in the accompanying Consolidated Statement of Operations and Comprehensive Loss for the fiscal year ended March 31, 2017.

U.S. National Institutes of Health

During fiscal years 2006 through 2008, the NIH awarded a \$4.2 million grant to the Company to support preclinical development of AV-101 for pain. In June 2009, the NIH further awarded the Company a \$4.2 million grant to support the Phase I clinical development of AV-101, which amount was subsequently increased to a total of \$4.6 million in July 2010. The grant expired in the ordinary course on June 30, 2012 and all funds had been expended. AV-101, our orally available prodrug candidate is currently in Phase 2 development, initially for the adjunctive treatment of MDD in patients with an inadequate response to standard antidepressants. In February 2015, we entered into the CRADA with the NIMH to collaborate on an NIH-sponsored Phase 2 clinical study of the efficacy and safety of AV-101 in subjects with MDD. The first patient in the NIMH AV-101 MDD Phase 2 Monotherapy Study was dosed in November 2015 and we currently anticipate that the NIMH will complete the study in 2017, with top line results in the first half of 2018. We believe AV-101 may also have broad therapeutic utility with multiple near term central nervous system pipeline expansion opportunities, including chronic neuropathic pain, epilepsy, Huntington's disease and Parkinson's disease.

Cato Research Ltd.

We have built a strategic development relationship with Cato Research Ltd. (*CRL*), a global contract research and development organization, or CRO, and an affiliate of one of our largest institutional stockholders. CRL has provided us with access to essential CRO services and regulatory expertise supporting our AV-101 preclinical and clinical development programs and other projects. We recorded research and development expenses for CRO services provided by CRL in the amounts of \$254,600 and \$52,600 for the fiscal years ended March 31, 2017 and 2016, respectively.

University Health Network

In September 2007, we entered into a Sponsored Research Collaboration Agreement (*SRCA*) with University Health Network to develop certain stem cell technologies for drug discovery, development and rescue technologies. Under the terms of the SRCA, we have acquired exclusive worldwide rights to patent applications in the U.S. and foreign countries on multiple inventions arising from studies we have sponsored, under pre-negotiated license terms. Those license terms provide for royalty payments based on product sales that incorporate the licensed technology and milestone payments based on the achievement of certain events. Any drug rescue new chemical entity that we develop will not incorporate the licensed technology and, therefore, will not require any royalty payments. To the extent we incur royalty payment obligations from other business activities, the royalty payments will be subject to anti-stacking provisions, which reduce our payments by a percentage of any royalty payments paid to third parties who have licensed necessary intellectual property to us. These licenses will remain in force for so long as we have an obligation to make royalty or milestone payments to UHN, but may be terminated earlier upon mutual consent, by us at any time, or by UHN for our breach of any material provision of the license agreement that is not cured within 90 days. The SRCA with UHN, as amended, had a term of ten years, ending in September 2017, but was terminated in December 2016, as described below.

In December 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 the SRCA; (ii) amended two exclusive cardiac stem cell technology patent license agreements previously entered into between us and UHN under the SRCA; (iii) terminated the SRCA to facilitate the BlueRock Therapeutics Agreement, described above; 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 these agreements with UHN, aggregating \$233,400, are reflected in research and development expense in the accompanying Consolidated Statement of Operations and Comprehensive Loss for the fiscal year ended March 31, 2017.

13. Stock Option Plans and 401(k) Plan

We have the following share-based compensation plans.

Amended and Restated 2016 Stock Incentive Plan

Our Board unanimously approved the Company's Amended and Restated 2016 Equity Incentive Plan ("2016 Plan"), formerly titled the 2008 Equity Incentive Plan, on July 26, 2016. Our stockholders approved the 2016 Plan on September 26, 2016. The 2008 Stock Incentive Plan (the 2008 Plan) was adopted by the shareholders of VistaGen California in December 2018 and we assumed it in connection with our going-public transaction. The maximum number of shares of common stock issuable under the 2016 Plan is 3.0 million shares, subject to adjustments for stock splits, stock dividends or other similar changes in our common stock or our capital structure.

Board-approved amendments to the 2016 Plan included increasing the number of shares of our common stock authorized for issuance from 1.0 million to 3.0 million, increasing the maximum number of shares of common stock that may be granted to a Grantee (as such term is defined in the 2016 Plan) in any calendar year from 125,000 to 300,000 shares (350,000 shares if the grant is issued in connection with the commencement of service to the Company), extending the expiration date of the 2016 Plan to July 26, 2026, and removing certain provisions that only pertained to the Company or the plan before the Company became a publicly traded entity. The 2016 Plan delegates the authority to administer the plan to the Board's Compensation Committee (the *Committee*).

1999 Stock Incentive Plan

Our 1999 Stock Incentive Plan (the 1999 Plan) was adopted by the shareholders of VistaStem on December 6, 1999 and we assumed it in connection with our going-public transaction. We initially reserved 45,000 shares for the issuance of awards under the 1999 Plan. The 1999 Plan has terminated under its own terms and, as a result, no awards may currently be granted under the 1999 Plan. The unexpired options and awards that have already been granted pursuant to the 1999 Plan remain operative.

Description of the 2016 Plan

The 2016 Plan provides for the grant of stock options, restricted shares of common stock, stock appreciation rights and dividend equivalent rights, collectively referred to as "Awards". Stock options granted under the 2016 Plan may be either incentive stock options or non-qualified stock options. We may grant incentive stock options only to employees of the Company or any parent or subsidiary of the Company. Awards other than incentive stock options may be granted to employees, directors and consultants.

The Committee administers the 2016 Plan, including selecting the Award recipients, determining the number of shares to be subject to each Award, the exercise or purchase price of each Award and the vesting and exercise periods of each Award.

The exercise price of all incentive stock options granted under the 2016 Plan must be at least equal to 100% of the fair market value of the shares on the date of grant. If, however, incentive stock options are granted to an employee who owns stock possessing more than 10% of the voting power of all classes of our stock or the stock of any of our subsidiaries, the exercise price of any incentive stock option granted may not be less than 110% of the fair market value on the grant date. The maximum term of incentive stock options granted to employees who own stock possessing more than 10% of the voting power of all classes of our stock or the stock of any of our subsidiaries may not exceed five years. The maximum term of an incentive stock option granted to any other participant may not exceed 10 years. The Committee determines the term and exercise or purchase price of all other Awards granted under the 2016 Plan.

Under the 2016 Plan, incentive stock options may not be sold, pledged, assigned, hypothecated, transferred or disposed of in any manner other than by will or by the laws of descent or distribution and may be exercised, during the lifetime of the participant, only by the participant. Other Awards shall be transferable:

- by will and by the laws of descent and distribution; and
- during the lifetime of the participant, to the extent and in the manner authorized by the Committee by gift or pursuant to a domestic relations order to members of the participant's Immediate Family (as defined in the 2016 Plan).

The maximum number of shares with respect to which options, restricted stock, restricted shares of common stock or stock appreciation rights may be granted to any participant in any calendar year will be 300,000 shares of common stock. In connection with a participant's commencement of service with the Company, a participant may be granted options, restricted stock or stock appreciation rights for up to an additional 50,000 shares that will not count against the foregoing limitation. In addition, for Awards of restricted stock and restricted shares of common stock that are intended to be "performance-based compensation" (within the meaning of Section 162(m) of the Code), the maximum number of shares with respect to which such Awards may be granted to any participant in any calendar year will be 300,000 shares of common stock. The limits described in this paragraph are subject to adjustment in the event of any change in our capital structure as described below.

The terms and conditions of Awards are determined by the Committee, including the vesting schedule and any forfeiture provisions. Awards under the 2016 Plan may vest upon the passage of time or upon the attainment of certain performance criteria. Although we do not currently have any Awards outstanding that vest upon the attainment of performance criteria, the Committee may establish criteria based on any one of, or combination of, a number of financial measurements.

Effective upon the consummation of a Corporate Transaction (as defined below), all outstanding Awards under the 2016 Plan will terminate unless the acquirer assumes or replaces such Awards. The Committee has the authority, exercisable either in advance of any actual or anticipated Corporate Transaction or Change in Control (as defined below) or at the time of an actual Corporate Transaction or Change in Control and exercisable at the time of the grant of an Award under the 2016 Plan or any time while an Award remains outstanding, to provide for the full or partial automatic vesting and exercisability of one or more outstanding unvested Awards under the 2016 Plan and the release from restrictions on transfer and repurchase or forfeiture rights of such Awards in connection with a Corporate Transaction or Change in Control, on such terms and conditions as the Committee may specify. The Committee also has the authority to condition any such Award's vesting and exercisability or release from such limitations upon the subsequent termination of the service of the grantee within a specified period following the effective date of the Corporate Transaction or Change in Control. The Committee may provide that any Awards so vested or released from such limitations in connection with a Change in Control, shall remain fully exercisable until the expiration or sooner termination of the Award.

Under the 2016 Plan, a Corporate Transaction is generally defined as:

- an acquisition of securities possessing more than fifty percent (50%) of the total combined voting power of our outstanding securities but excluding any such transaction or series of related transactions that the Committee determines shall not be a Corporate Transaction;
- a reverse merger in which we remain the surviving entity but: (i) the shares of common stock outstanding immediately prior to such merger are converted or exchanged by virtue of the merger into other property, whether in the form of securities, cash or otherwise; or (ii) in which securities possessing more than fifty percent (50%) of the total combined voting power of our outstanding securities are transferred to a person or persons different from those who held such securities immediately prior to such merger;
- a sale, transfer or other disposition of all or substantially all of the assets of the Company;
- a merger or consolidation in which the Company is not the surviving entity; or
- a complete liquidation or dissolution.

Under the 2016 Plan, a Change in Control is generally defined as: (i) the acquisition of more than 50% of the total combined voting power of our stock by any individual or entity which a majority of our Board of Directors (who have served on our board for at least 12 months) do not recommend our stockholders accept; (ii) or a change in the composition of our Board of Directors over a period of 12 months or less.

Unless terminated sooner, the 2016 Plan will automatically terminate in 2026. Our Board of Directors may at any time amend, suspend or terminate the 2016 Plan. To the extent necessary to comply with applicable provisions of U.S. federal securities laws, state corporate and securities laws, the Code, the rules of any applicable stock exchange or national market system, and the rules of any non-U.S. jurisdiction applicable to Awards granted to residents therein, we will obtain stockholder approval of any such amendment to the 2016 Plan in such a manner and to such a degree as required.

During our fiscal year ended March 31, 2017, we granted from the 2016 Plan:

- 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 one newly-employed officer, in June 2016;
- options to purchase 125,000 shares of our common stock at an exercise price of \$4.27 per share to a newly-employed officer in September 2016
- options to purchase an aggregate of 560,000 shares of our common stock at an exercise price of \$3.80 per share to the independent members of our Board, officers, non-officer employees and a consultant in November 2016; and
- an aggregate of 150,000 unregistered shares of our common stock pursuant to four consulting agreements in March 2017.

During our fiscal year ended March 31, 2016, we granted from the 2008 Plan:

- 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 strategic consultants in September 2015;
- options to purchase an aggregate of 30,000 shares of our common stock at an exercise price of \$8.00 per share to two parties in connection with an investor relations agreement in February 2016; and
- options to purchase 25,000 shares of our common stock at an exercise price of \$8.00 per share to a new independent member of our Board of Directors in March 2016.

The following table summarizes share-based compensation expense, including share-based expense related to grants of warrants in prior years to certain of our officers, independent directors, consultants and service providers, included in the accompanying Consolidated Statement of Operations and Comprehensive Loss for the years ended March 31, 2017 and 2016.

	Fiscal Years Ended March 31,	
	2017	2016
Research and development expense:		
Stock option grants	\$ 375,100	\$ 227,700
Warrants granted to officer in March 2014	-	11,400
Fully-vested warrants granted to officer in September 2015	-	852,200
	<u>375,100</u>	<u>1,091,300</u>
General and administrative expense:		
Stock option grants	476,200	93,800
Warrants granted to officers and directors in March 2014	-	15,600
Fully-vested warrants granted to officers, directors and consultants in September 2015	-	2,840,700
	<u>476,200</u>	<u>2,950,100</u>
Total stock-based compensation expense	<u>\$ 851,300</u>	<u>\$ 4,041,400</u>

In September 2015, when the market price of our common stock was \$9.11 per share, our Board of Directors (*Board*) authorized the grant of fully-vested five-year warrants to purchase an aggregate of 650,000 restricted shares of our common stock at an exercise price of \$9.25 per share, including an aggregate of 600,000 of such shares to company officers and independent members of the Board. We valued the new warrant grants at \$5.68 per share, or an aggregate of \$3,692,900, using the Black Scholes Option Pricing Model and the following assumptions: market price per share: \$9.11; exercise price per share: \$9.25; risk-free interest rate: 1.52%; contractual term: 5.0 years; volatility: 77.2%; expected dividend rate: 0%. As indicated in the table above, we recognized non-cash research and development and general and administrative stock compensation expense in the amounts of \$852,200 and \$2,840,700, respectively, in the accompanying Consolidated Statement of Operations and Comprehensive Loss for the fiscal year ended March 31, 2016.

The fair value of the 150,000 unregistered shares of common stock granted from the 2016 Plan in March 2017, an aggregate of \$442,500, is reflected as an additional component of general and administrative expense in the accompanying Consolidated Statement of Operations and Comprehensive Loss for the year ended March 31, 2017.

We used the Black-Scholes Option Pricing model with the following weighted average assumptions to determine share-based compensation expense related to option grants during the fiscal years ended March 31, 2017 and 2016:

	Fiscal Years Ended March 31,	
	2017	2016
	(weighted average)	(weighted average)
Exercise price	\$ 3.69	\$ 8.78
Market price on date of grant	\$ 3.69	\$ 8.69
Risk-free interest rate	1.51%	1.99%
Expected term (years)	6.68	8.45
Volatility	82.96%	93.27%
Expected dividend yield	0.00%	0.00%
Fair value per share at grant date	\$ 2.68	\$ 7.09

The expected term of options represents the period that our share-based compensation awards are expected to be outstanding. We have calculated the weighted-average expected term of the options using the simplified method as prescribed by Securities and Exchange Commission Staff Accounting Bulletins No. 107 and No. 110 (*SAB No. 107 and 110*). The utilization of SAB No. 107 and 110 is based on the lack of relevant historical data due to both our limited historical experience as a publicly traded company as well as the historical lack of liquidity resulting from the limited number of freely-tradable shares of our common stock. Those factors also resulted in our decision to utilize the historical volatilities of a peer group of public companies' stock over the expected term of the option in determining our expected volatility assumptions. The risk-free interest rate for periods related to the expected life of the options is based on the U.S. Treasury yield curve in effect at the time of grant. The expected dividend yield is zero, as we have not paid any dividends and do not anticipate paying dividends in the near future. We calculated the forfeiture rate based on an analysis of historical data, as it reasonably approximates the currently anticipated rate of forfeitures for granted and outstanding options that have not vested.

The following table summarizes activity for the fiscal years ended March 31, 2017 and 2016 under our stock option plans:

	Fiscal Years Ended March 31,			
	2017		2016	
	Number of Shares	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
Options outstanding at beginning of period	336,987	\$ 9.56	207,638	\$ 10.09
Options granted	1,340,000	\$ 3.69	145,000	\$ 8.78
Options exercised	-	\$ -	-	\$ -
Options forfeited	-	\$ -	(10,359)	\$ 9.26
Options expired	(17,663)	\$ 15.52	(5,292)	\$ 9.42
Options outstanding at end of period	<u>1,659,324</u>	<u>\$ 4.76</u>	<u>336,987</u>	<u>\$ 9.56</u>
Options exercisable at end of period	<u>351,532</u>	<u>\$ 8.27</u>	<u>201,779</u>	<u>\$ 10.11</u>
Weighted average grant-date fair value of options granted during the period		<u>\$ 2.69</u>		<u>\$ 7.09</u>

The following table summarizes information on stock options outstanding and exercisable under our stock option plans as of March 31, 2017:

Exercise Price	Options Outstanding			Options Exercisable		
	Number Outstanding	Weighted Average Remaining Years until Expiration	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price	
\$ 3.49	655,000	9.22	\$ 3.49	-	\$ 3.49	
\$ 3.80	560,000	9.61	\$ 3.80	62,215	\$ 3.80	
\$ 4.27	125,000	9.50	\$ 4.27	-	\$ 4.27	
\$ 8.00	98,335	7.47	\$ 8.00	98,335	\$ 8.00	
\$ 9.25	80,000	8.42	\$ 9.25	49,993	\$ 9.25	
\$ 10.00	138,488	3.00	\$ 10.00	138,488	\$ 10.00	
\$14.40 to \$15.00	<u>2,501</u>	1.22	\$ 14.52	<u>2,501</u>	\$ 14.52	
	<u>1,659,324</u>	8.70	\$ 4.76	<u>351,532</u>	\$ 8.27	

At March 31, 2017, there were 1,184,911 shares of our common stock remaining available for grant under the 2016 Plan. There were no option exercises during the years ended March 31, 2017 or 2016.

Aggregate intrinsic value is the sum of the amount by which the fair value of the underlying common stock exceeds the aggregate exercise price of the outstanding options (*in-the-money-options*). Based on the \$1.96 per share quoted market price of our common stock on March 31, 2017, there was no intrinsic value in any of our outstanding options at that date.

As of March 31, 2017, there was approximately \$3,004,900 of unrecognized compensation cost related to non-vested share-based compensation awards from the 2016 Plan, which is expected to be recognized through September 2020.

401(k) Plan

Through a third-party agent, we maintain a retirement and deferred savings plan for our employees. This plan is intended to qualify as a tax-qualified plan under Section 401(k) of the Internal Revenue Code. The retirement and deferred savings plan provides that each participant may contribute a portion of his or her pre-tax compensation, subject to statutory limits. Under the plan, each employee is fully vested in his or her deferred salary contributions. Employee contributions are held and invested by the plan's trustee. The retirement and deferred savings plan also permits us to make discretionary contributions, subject to established limits and a vesting schedule. To date, we have not made any discretionary contributions to the retirement and deferred savings plan on behalf of participating employees.

14. Related Party Transactions

Cato Holding Company (CHC), doing business as Cato BioVentures (CBV), is the parent of CRL. CRL is a contract research, development and regulatory services organization (CRO) engaged by us for certain aspects of the development and regulatory affairs associated with AV-101. CBV is among our largest institutional stockholders at March 31, 2017, holding approximately 6.9% 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. As described in Note 9, *Capital Stock*, 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 contract research arrangement with CRL related to the development of AV-101, we incurred expenses of \$254,600 and \$52,600 for the fiscal years ended March 31, 2017 and 2016, respectively. Total interest expense on the Cato Notes was \$28,200 for the fiscal year ended March 31, 2016.

15. Commitments, Contingencies, Guarantees and Indemnifications

From time to time, we may become involved in claims and other legal matters arising in the ordinary course of business. Management is not currently aware of any claims made or other legal matters that will have a material adverse effect on our consolidated financial position, results of operations or its cash flows.

We indemnify our officers and directors for certain events or occurrences while the officer or director is or was serving at our request in such capacity. The term of the indemnification period is for the officer's or director's lifetime. We will indemnify the officers or directors against any and all expenses incurred by the officers or directors because of their status as one of our directors or executive officers to the fullest extent permitted by Nevada law. We have never incurred costs to defend lawsuits or settle claims related to these indemnification agreements. We have a director and officer insurance policy which limits our exposure and may enable us to recover a portion of any future amounts paid. We believe the fair value of these indemnification agreements is minimal. Accordingly, there are no liabilities recorded for these agreements at March 31, 2017 or 2016.

In the normal course of business, we provide indemnifications of varying scopes under agreements with other companies, typically clinical research organizations, investigators, clinical sites, suppliers and others. Pursuant to these agreements, we generally indemnify, hold harmless, and agree to reimburse the indemnified parties for losses suffered or incurred by the indemnified parties in connection with the use or testing of our product candidates or with any U.S. patents or any copyright or other intellectual property infringement claims by any third party with respect to our product candidates. The terms of these indemnification agreements are generally perpetual. The potential future payments we could be required to make under these indemnification agreements is unlimited. We maintain liability insurance coverage that limits our exposure. We believe the fair value of these indemnification agreements is minimal. Accordingly, we have not recorded any liabilities for these agreements as of March 31, 2017 or 2016.

Leases

As of March 31, 2017 and 2016, the following assets are subject to capital lease obligations and included in property and equipment:

	March 31,	
	2017	2016
Office equipment	14,600	4,500
Accumulated depreciation	(600)	(3,400)
Net book value	<u>\$ 14,000</u>	<u>\$ 1,100</u>

Amortization expense for assets recorded under capital leases is included in depreciation expense. Future minimum payments, by year and in the aggregate, required under capital leases are as follows:

Fiscal Years Ending March 31,	Capital Leases
2018	\$ 3,800
2019	3,800
2020	3,800
2021	3,800
2022	3,300
Future minimum lease payments	18,500
Less imputed interest included in minimum lease payments	(4,200)
Present value of minimum lease payments	14,300
Less current portion	(2,400)
Non-current capital lease obligation	<u>\$ 11,900</u>

At March 31, 2017, future minimum payments under operating leases relate to our facility lease in South San Francisco, California through July 31, 2022 and are as follows:

Fiscal Years Ending March 31,	Amount
2018	\$ 388,400
2019	602,800
2020	623,900
2021	645,800
2022	668,400
2023	225,300
	<u>\$ 3,154,600</u>

We incurred total facility rent expense for the fiscal years ended March 31, 2017 and 2016 of \$482,100 and \$337,200, respectively.

Debt Repayment

At March 31, 2017, future minimum principal payments on outstanding notes related only to our insurance premium financing arrangement in the principal amount of \$54,800, which will be repaid in monthly principal and interest installments of \$6,300 through December 2017.

16. Subsequent Events

We have evaluated subsequent events through the date of this report and have identified the following material events and transactions that occurred after March 31, 2017:

Private Placement Common Stock and Warrants

Between April 1 and June 27, 2017, in self-placed private placement transactions, we sold to accredited investors units consisting of (i) an aggregate of 437,751 shares of our unregistered common stock and (ii) warrants to purchase an aggregate of 218,875 shares of our common stock at an exercise price of \$4.00 per share. We received cash proceeds of \$873,300 from these sales of our securities, bringing total proceeds from the Spring 2017 Private Placement to approximately \$1.0 million.

Option Grants

On April 27, 2017, when the quoted market price of our common stock was \$1.96 per share, the Board granted options to purchase an aggregate of 880,000 shares of our common stock at an exercise price of \$1.96 per share to all officers, employees and independent members of the Board pursuant to the 2016 Plan.

17. Supplemental Financial Information (Unaudited)

The following table presents the unaudited statements of operations data for each of the eight quarters in the period ended March 31, 2017. The information has been presented on the same basis as the audited financial statements and all necessary adjustments, consisting only of normal recurring adjustments, have been included in the amounts below to present fairly the unaudited quarterly results when read in conjunction with the audited financial statements and related notes. The operating results for any quarter should not be relied upon as necessarily indicative of results for any future period.

Quarterly Results of Operations (Unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended				Total
	June 30,	September	December	March 31,	Fiscal Year
	2016	30, 2016	31, 2016	2017	2017
Sublicense revenue	\$ -	\$ -	\$ 1,250	\$ -	\$ 1,250
Total revenue	-	-	1,250	-	1,250
Operating expenses:					
Research and development	826	1,606	1,611	1,161	5,204
General and administrative	1,138	1,494	2,276	1,387	6,295
Total operating expenses	1,964	3,100	3,887	2,548	11,499
Loss from operations	(1,964)	(3,100)	(2,637)	(2,548)	(10,249)
Other expenses, net:					
Interest expense, net	(2)	(1)	(1)	(1)	(5)
Loss before income taxes	(1,966)	(3,101)	(2,638)	(2,549)	(10,254)
Income taxes	(2)	-	-	-	(2)
Net loss	(1,968)	(3,101)	(2,638)	(2,549)	(10,256)
Accrued dividend on Series B Preferred stock	(540)	(241)	(238)	(238)	(1,257)
Deemed dividend on Series B Preferred stock	(111)	-	-	-	(111)
Net loss attributable to common stockholders	\$ (2,619)	\$ (3,342)	\$ (2,876)	\$ (2,787)	\$ (11,624)
Basic and diluted net loss per common share attributable to common stockholders	\$ (0.51)	\$ (0.42)	\$ (0.34)	\$ (0.32)	\$ (1.54)
Weighted average shares used in computing:					
Basic and diluted net loss per common share attributable to common stockholders	5,097,832	8,047,619	8,381,824	8,602,107	7,531,642
	Three Months Ended				Total
	June 30,	September	December	March 31,	Fiscal Year
	2015	30, 2015	31, 2015	2016	2016
Operating expenses:					
Research and development	\$ 373	\$ 1,656	\$ 806	\$ 1,097	\$ 3,932
General and administrative	1,448	3,731	1,336	7,404	13,919
Total operating expenses	1,821	5,387	2,142	8,501	17,851
Loss from operations	(1,821)	(5,387)	(2,142)	(8,501)	(17,851)
Other expenses, net:					
Interest expense, net	(755)	(12)	(3)	(1)	(771)
Change in warrant liabilities	(1,895)	-	-	-	(1,895)
Loss on extinguishment of debt	(25,051)	(1,649)	-	-	(26,700)
Other expense, net	-	-	(2)	-	(2)
Loss before income taxes	(29,522)	(7,048)	(2,147)	(8,502)	(47,219)
Income taxes	(2)	-	-	-	(2)
Net loss	(29,524)	(7,048)	(2,147)	(8,502)	(47,221)
Accrued dividend on Series B Preferred stock	(213)	(615)	(631)	(681)	(2,140)
Deemed dividend on Series B Preferred stock	(256)	(887)	(669)	(246)	(2,058)
Net loss attributable to common stockholders	\$ (29,993)	\$ (8,550)	\$ (3,447)	\$ (9,429)	\$ (51,419)
Basic and diluted net loss per common share	\$ (19.23)	\$ (5.26)	\$ (1.95)	\$ (4.44)	\$ (29.08)
Weighted average shares used in computing:					
Basic and diluted net loss per common share	1,559,483	1,624,371	1,765,641	2,123,936	1,767,957

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures.

As required by Rule 13a-15(b) under the Securities Exchange Act of 1934, as amended, (the *Exchange Act*) our Chief Executive Officer (*CEO*) and our Chief Financial Officer (*CFO*) conducted an evaluation as of the end of the period covered by this Annual Report on Form 10-K, of the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on that evaluation, our CEO and our CFO each concluded that our disclosure controls and procedures are effective to provide reasonable assurance that information required to be disclosed in the reports that we file or submit under the Exchange Act, (i) is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and (ii) is accumulated and communicated to our management, including our CEO and our CFO, as appropriate to allow timely decisions regarding required disclosure.

Management's Report on Internal Control Over Financial Reporting.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Our internal control system is designed to provide reasonable assurance to our management and Board of Directors regarding the reliability of financial reporting and the preparation and fair presentation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance of achieving their control objectives. Smaller reporting companies may face additional limitations in achieving control objectives. Smaller reporting companies typically employ fewer individuals who are often tasked with a wide range of responsibilities, making it difficult to segregate duties. Often, one or two individuals control many, or all, aspects of the smaller reporting company's general and financial operations, placing such individual(s) in a position to override any system of internal control. Additionally, projections of an evaluation of current effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the controls may deteriorate.

Management has assessed the effectiveness of our internal control over financial reporting for our fiscal year ended March 31, 2017. Management's assessment was based on criteria set forth in *Internal Control - Integrated Framework (2013)*, issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based upon this assessment, management concluded that, as of March 31, 2017, our internal control over financial reporting was not effective, based upon those criteria, as a result of the material weaknesses identified below.

A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

Specifically, management identified the following control weaknesses: (i) the size and capabilities of the Company's staff does not permit appropriate segregation of duties to prevent one individual from overriding the internal control system by initiating, authorizing and completing all transactions; and (ii) the Company utilizes accounting software that does not prevent erroneous or unauthorized changes to previous reporting periods and/or can be adjusted so as to not provide an adequate audit trail of entries made in the accounting software. The Company does not believe that these control weaknesses have resulted in deficient financial reporting because each of our CEO and CFO is aware of his responsibilities under the SEC's reporting requirements and personally certifies our financial reports. Further, the Company has implemented a series of manual checks and balances to verify that no previous reporting period has been improperly modified and that no unauthorized entries have been made in the current reporting period.

Accordingly, while the Company has identified certain material weaknesses in its system of internal control over financial reporting, it believes that it has taken reasonable and sufficient steps to ascertain that the financial information contained in this Annual Report is in accordance with U.S. generally accepted accounting principles. Management has determined that current resources would be more appropriately applied elsewhere and when resources permit, they will alleviate the material weaknesses through various steps, which may include the addition of qualified financial personnel and/or the acquisition and implementation of alternative accounting software.

As a result of the enactment of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, and the resulting amendment of Section 404 of the Sarbanes-Oxley Act of 2002, as a smaller reporting company, we are not required to provide an attestation report by our independent registered public accounting firm regarding internal control over financial reporting for the fiscal year ended March 31, 2017 or thereafter, until such time as we are no longer eligible for the exemption for smaller issuers set forth within the Sarbanes-Oxley Act.

Item 9B. Other Information

None.

PART III**Item 10. Directors Officers and Corporate Governance.**

Our senior management is composed of individuals with significant management experience. Our directors and executive officers as of June 27, 2017 are as follows:

Name	Age	Position
Shawn K. Singh	54	Chief Executive Officer and Director
H. Ralph Snodgrass, Ph.D.	67	Founder, President, Chief Scientific Officer and Director
Mark A. Smith, M.D., Ph.D.	61	Chief Medical Officer
Jerrold D. Dotson	63	Vice President, Chief Financial Officer and Secretary
Jon S. Saxe (1)	80	Director
Brian J. Underdown, Ph.D. (2)	76	Director
Jerry B. Gin, Ph.D., MBA (3)	73	Director

(1) Chairman of the audit committee and member of the compensation committee and corporate governance and nominating committee.

(2) Chairman of the compensation committee and member of the audit committee and corporate governance and nominating committee.

(3) Chairman of the corporate governance and nominating committee and member of the audit committee and compensation committee.

Executive Officers

Shawn K. Singh has served as our Chief Executive Officer since August 2009, first as the Chief Executive Officer of VistaGen Therapeutics, Inc., a California corporation (*VistaGen California*), then as Chief Executive Officer of the Company after the merger by and between VistaGen California and the Company on May 11, 2011 (the *Merger*), at which time VistaGen California became a wholly-owned subsidiary of the Company. Mr. Singh first joined the Board of Directors of VistaGen California in 2000 and served on the VistaGen California management team (part-time) from late-2003, following VistaGen California's acquisition of Artemis Neuroscience, of which he was President, to August 2009. In connection with the Merger, Mr. Singh was appointed as a member of our Board in 2011. Mr. Singh has over 25 years of experience working with biotechnology, medical device and pharmaceutical companies, both private and public. From February 2001 to August 2009, Mr. Singh served as Managing Principal of Cato BioVentures, a life science venture capital firm, and as Chief Business Officer and General Counsel of Cato Research Ltd, a profitable global contract research organization (*CRO*) affiliated with Cato BioVentures. Mr. Singh served as President (part-time) of Echo Therapeutics (NASDAQ: ECTE), a medical device company developing a non-invasive, wireless continuous glucose monitoring (*CGM*) system, from September 2007 to June 2009, and as a member of its Board of Directors from September 2007 through December 2011. He also served as Chief Executive Officer (part-time) of Hemodynamic Therapeutics, a private biopharmaceutical company affiliated with Cato BioVentures, from November 2004 to August 2009. From late-2000 to February 2001, Mr. Singh served as Managing Director of Start-Up Law, a management consulting firm serving biotechnology companies. Mr. Singh also served as Chief Business Officer of SciClone Pharmaceuticals (NASDAQ: SCLN), a revenue-generating, specialty pharmaceutical company with a substantial commercial business in China and a product portfolio spanning major therapeutics markets, including oncology, infectious diseases and cardiovascular disorders, from late-1993 to late-2000, and as a corporate finance associate of Morrison & Foerster LLP, an international law firm, from 1991 to late-1993. Mr. Singh currently serves as a member of the Board of Directors of Armour Therapeutics, a private biotechnology company focused on prostate cancer. Mr. Singh earned a B.A. degree, with honors, from the University of California, Berkeley, and a Juris Doctor degree from the University of Maryland School of Law. Mr. Singh is a member of the State Bar of California.

We selected Mr. Singh to serve on our Board of Directors due to his substantial practical experience and expertise in senior leadership roles with multiple private and public biotechnology, pharmaceutical and medical device companies, and his extensive experience in corporate finance, venture capital, corporate governance and strategic partnering.

H. Ralph Snodgrass, Ph.D. co-founded VistaGen California with Dr. Gordon Keller in 1998 and served as the Chief Executive Officer of VistaGen California until August 2009. Dr. Snodgrass has served as the President and Chief Scientific Officer of VistaGen California from inception to the present, and in the same positions with the Company following the completion of the Merger. He served as a member of the Board of Directors of VistaGen California from 1998 to 2011, and was appointed to serve on our Board after the completion of the Merger. Prior to founding VistaGen California, Dr. Snodgrass served as a key member of the executive management team that led Progenitor, Inc., a biotechnology company focused on developmental biology, through its initial public offering, and was its Chief Scientific Officer from June 1994 to May 1998, and its Executive Director from July 1993 to May 1994. He received his Ph.D. in immunology from the University of Pennsylvania, and has 24 years of experience in senior biotechnology management and over 10 year's research experience as an assistant professor at the Lineberger Comprehensive Cancer Center, University of North Carolina Chapel Hill School of Medicine, and as a member of the Institute for Immunology, Basel, Switzerland. Dr. Snodgrass is a past Board Member of the Emerging Company Section of the Biotechnology Industry Organization (*BIO*), and past member of the International Society Stem Cell Research Industry Committee. Dr. Snodgrass has published more than 50 scientific papers, is the inventor on more than 17 patents and a number of patent applications, is, or has been, the Principal Investigator on U.S. federal and private foundation sponsored research grants with budgets totaling more than \$14.5 million and is recognized as an expert in stem cell biology with more than 31 years' experience in the uses of stem cells as biological tools for research, drug discovery and development.

We selected Dr. Snodgrass to serve on our Board of Directors due to his expertise in biotechnology focused on developmental biology, including stem cell biology, his extensive senior management experience leading biotechnology companies at all stages of development, as well as his reputation and standing in the fields of biotechnology and stem cell research, allow him to bring to us and the Board of Directors a unique understanding of the challenges and opportunities associated with pluripotent stem cell biology, as well as credibility in the markets in which we operate.

Mark A. Smith, M.D., Ph.D. joined VistaGen as our Chief Medical Officer effective June 18, 2016. Dr. Smith served as the Clinical Lead for Neuropsychiatry at Teva Pharmaceuticals from November 2013 through June 2016. He served as Senior Director of Experimental Medicine, Global Clinical Development and Innovation at Shire Pharmaceuticals from September 2012 to October 2013 and at AstraZeneca Pharmaceutical Company as Executive Director of Clinical Development and in other senior positions from June 2000 through September 2012. He served as a Senior Investigator and Principal Research Scientist in CNS Diseases Research at DuPont Pharmaceutical Company from 1996 to 2000 and in the Biological Psychiatry and Clinical Neuroendocrinology Branches of the National Institute of Mental Health from 1987 through 1996. Dr. Smith has significant expertise in drug discovery and development and clinical trial design and execution, having directed approximately fifty clinical trials from Phase 0 through Phase II B and served as project leader in both the discovery and development of approximately twenty investigational new drugs aimed at depression, anxiety, schizophrenia and other disorders. Dr. Smith received his Bachelor of Science and Master of Science degrees in Molecular Biophysics and Biochemistry from Yale University; his M.D and Ph.D. in Physiology and Pharmacology from the University of California, San Diego and completed his residency at Duke University Medical Center.

Jerrold D. Dotson, CPA has served as our Chief Financial Officer since September 2011, as our Corporate Secretary since October 2013 and as a Vice President since February 2014. Mr. Dotson served as Corporate Controller for Discovery Foods Company, a privately held Asian frozen foods company from January 2009 to September 2011. From February 2007 through September 2008, Mr. Dotson served as Vice President, Finance and Administration (principal financial and accounting officer) for Calypte Biomedical Corporation (OTCBB: CBMC), a publicly held biotechnology company. Mr. Dotson served as Calypte's Corporate Secretary from 2001 through September 2008. He also served as Calypte's Director of Finance from January 2000 through July 2005 and was a financial consultant to Calypte from August 2005 through January 2007. Prior to joining Calypte, from 1988 through 1999, Mr. Dotson worked in various financial management positions, including Chief Financial Officer, for California & Hawaiian Sugar Company, a privately held company. Mr. Dotson is licensed as a CPA in California and received his B.S. degree in Business Administration with a concentration in accounting from Abilene Christian College.

Directors

Jon S. Saxe, J.D., LL.M. has served as Chairman of our Board since 2000, first as Chairman of the Board of Directors of VistaGen California, then as Chairman of our Board after completion of the Merger. He also serves as the Chairman of our Audit Committee. Mr. Saxe is the retired President and was a director of PDL BioPharma from 1989 to 2008. From 1989 to 1993, he was President, Chief Executive Officer and a director of Synergen, Inc. (acquired by Amgen). Mr. Saxe served as Vice President, Licensing & Corporate Development for Hoffmann-Roche from 1984 through 1989, and Head of Patent Law for Hoffmann-Roche from 1978 through 1989. Mr. Saxe currently is a director of SciClone Pharmaceuticals, Inc. (NASDAQ: SCLN) and Durect Corporation (NASDAQ: DRRX), and six private life science companies, Arbor Vita Corporation, Arcuo Medical, LLC, Armetheon, Inc., Cancer Prevention Pharmaceuticals, Inc., Lumos Pharma, Inc. and Trellis Bioscience, Inc. Mr. Saxe also has served as a director of other biotechnology and pharmaceutical companies, including ID Biomedical (acquired by GlaxoSmithKline), Sciele Pharmaceuticals, Inc. (acquired by Shionogi), Amalyte (acquired by Kemin Industries), Cell Pathways (acquired by OSI Pharmaceuticals), and other companies, both public and private. Mr. Saxe has a B.S.Ch.E. from Carnegie-Mellon University, a J.D. degree from George Washington University and an LL.M. degree from New York University.

We selected Mr. Saxe to serve as Chairman of our Board of Directors due to his numerous years of experience as a senior executive with major biopharmaceutical and biotechnology companies, including Protein Design Labs, Inc., Synergen, Inc. and Hoffmann-Roche, Inc., as well as his extensive experience serving as a director of numerous private and public biotechnology and pharmaceutical companies, serving as Chairman, and Chair and member of audit, compensation and governance committees of both private and public companies. Mr. Saxe provides us and our Board of Directors with highly valuable insight and perspective into the biotechnology and pharmaceutical industries, as well as the strategic opportunities and challenges that we face.

Brian J. Underdown, Ph.D. has served as a member of our Board of Directors since November 2009, first as a director of VistaGen California, then as a member of our Board after the completion of the Merger. Dr. Underdown is currently a Venture Partner with Lumira Capital Corp. having served as a Managing Director with Lumira from September 1997 through December 2015. His investment focus has been on therapeutics in both new and established companies in both Canada and the United States. Prior to joining Lumira and its antecedent company MDS Capital Corp., Dr. Underdown held a number of senior management positions in the biopharmaceutical industry and at universities. Dr. Underdown's current board positions include the following private companies: enGene Inc. Kisoji Biotechnology Inc., Naegis Pharmaceuticals, Inc. and Osteo QC. Some of Dr. Underdown's previous board roles include: Argos Therapeutics (ARGS-Q), ID Biomedical (acquired by GlaxoSmithKline), Ception Therapeutics (acquired by Cephalon). He has served on a number of Boards and advisory bodies of government-sponsored research organizations including CANVAC, the Canadian National Centre of Excellence in Vaccines, Ontario Genomics Institute (Chair), Allergen Plc., the Canadian National Centre of Excellence in Allergy and Asthma. Dr. Underdown obtained his Ph.D. in immunology from McGill University and undertook post-doctoral studies at Washington University School of Medicine.

We selected Dr. Underdown to serve on our Board of Directors due to his extensive background working in the biotechnology and pharmaceutical industries, as a director of numerous private and public companies, as well as his venture capital experience funding and advising start-up and established companies focused on therapeutics.

Jerry B. Gin, Ph.D., M.B.A was appointed to serve on our Board of Directors on March 29, 2016. Dr. Gin is currently the co-founder and CEO of Nuvora, Inc., a private company founded in 2006 with a drug delivery platform for the sustained release of ingredients through the mouth for such indications as dry mouth, biofilm reduction and sore throat/cough relief. Dr. Gin is also co-founder and Chairman of Livionex, a private platform technology company founded in 2009 and focused on oral care, ophthalmology and wound care. Previously, Dr. Gin co-founded Oculex Pharmaceuticals in 1993, which developed technology for controlled release delivery of drugs to the interior of the eye, specifically to treat macular edema, and served as President and CEO until it was acquired by Allergan in 2003. Prior to forming Oculex, Dr. Gin co-founded and took public ChemTrak, which developed a home cholesterol test commonly available in drug stores today. Prior to ChemTrak, Dr. Gin was Director of New Business Development and Strategic Planning for Syva, the diagnostic arm of Syntex Pharmaceuticals, Director for Pharmaceutical and Diagnostic businesses for Dow Chemical, and Director of BioScience Labs (now Quest Laboratories), the clinical laboratories of Dow Chemical. Dr. Gin received his Bachelor's degree in Chemistry from the University of Arizona, his Ph.D. in Biochemistry from the University of California, Berkeley, his M.B.A. from Loyola College, and conducted his post-doctoral research at the National Institutes of Health.

We selected Dr. Gin to serve on our Board of Directors due to his extensive experience in the healthcare industry, focusing on founding and developing pharmaceutical, diagnostic and biotechnology companies and his expertise in propelling healthcare companies to their next platforms of growth.

Election of Executive Officers

Our executive officers are elected by, and serve at the discretion of, our Board of Directors. Each of our executive officers devotes his full time to our affairs. There are no family relationships among any of our directors or executive officers.

Board Composition

Our amended and restated bylaws provide that the authorized number of directors of the Company shall be not less than one nor more than seven, with the exact number of directors currently fixed at seven. The exact number may be amended only by the vote or written consent of a majority of the outstanding shares of our voting stock. Our Board of Directors currently consists of five members. Accordingly, there are currently two vacancies on our Board of Directors. Our Board of Directors anticipates filling each of such vacancies as soon as practicable. All actions of the Board of Directors require the approval of a majority of the directors in attendance at a meeting at which a quorum is present.

Board Committees

Our Board of Directors has established an Audit Committee, a Compensation Committee and a Corporate Governance and Nominating Committee. The composition and responsibilities of each committee are described below. Members serve on these committees until their resignation or until otherwise determined by our Board of Directors. Effective on April 1, 2017, our independent directors, Mr. Saxe, Dr. Underdown and Dr. Gin, serve as members of each of these committees.

Audit Committee

Our Audit Committee is comprised of Mr. Saxe, who serves as the committee chairman, Dr. Underdown and Dr. Gin. Mr. Saxe is also our Audit Committee financial expert, as that term is defined under SEC rules implementing Section 407 of the Sarbanes Oxley Act of 2002, and possesses the requisite financial sophistication, as defined under applicable rules. The Audit Committee operates under a written charter. Our Audit Committee charter is available on our website. Under its charter, our Audit Committee is primarily responsible for, among other things:

- overseeing our accounting and financial reporting process;
- selecting, retaining and replacing our independent auditors and evaluating their qualifications, independence and performance;
- reviewing and approving scope of the annual audit and audit fees;
- monitoring rotation of partners of independent auditors on engagement team as required by law;
- discussing with management and independent auditors the results of annual audit and review of quarterly financial statements;
- reviewing adequacy and effectiveness of internal control policies and procedures;
- approving retention of independent auditors to perform any proposed permissible non-audit services;
- overseeing internal audit functions and annually reviewing audit committee charter and committee performance; and
- preparing the audit committee report that the SEC requires in our annual proxy statement.

Compensation Committee

Our Compensation Committee is comprised of Dr. Underdown, who serves as the committee chairman, Mr. Saxe, and Dr. Gin. Our Compensation Committee charter is available on our website. Under its charter, the Compensation Committee is primarily responsible for, among other things:

- reviewing and approving our compensation programs and arrangements applicable to our executive officers (as defined in Rule I 6a-I (f) of the Exchange Act), including all employment-related agreements or arrangements under which compensatory benefits are awarded or paid to, or earned or received by, our executive officers, including, without limitation, employment, severance, change of control and similar agreements or arrangements;
- determining the objectives of our executive officer compensation programs;
- ensuring corporate performance measures and goals regarding executive officer compensation are set and determining the extent to which they are achieved and any related compensation earned;
- establishing goals and objectives relevant to CEO compensation, evaluating CEO performance in light of such goals and objectives, and determining CEO compensation based on the evaluation;
- endeavoring to ensure that our executive compensation programs are effective in attracting and retaining key employees and reinforcing business strategies and objectives for enhancing stockholder value, monitoring the administration of incentive-compensation plans and equity-based incentive plans as in effect and as adopted from time to time by the board;
- reviewing and approving any new equity compensation plan or any material change to an existing plan; and
- reviewing and approving any stock option award or any other type of award as may be required for complying with any tax, securities, or other regulatory requirement, or otherwise determined to be appropriate or desirable by the committee or board.

Corporate Governance and Nominating Committee

Our Corporate Governance and Nominating Committee is comprised of Dr. Gin, who serves as the committee chairman, Mr. Saxe and Dr. Underdown. Our Corporate Governance and Nominating Committee charter is available on our website. Under its charter, the Corporate Governance and Nominating Committee is primarily responsible for, among other things:

- monitoring the size and composition of the board;
- making recommendations to the board with respect to the nominations or elections of our directors;
- reviewing the adequacy of our corporate governance policies and procedures and our Code of Business Conduct and Ethics, and recommending any proposed changes to the board for approval; and
- considering any requests for waivers from our Code of Business Conduct and Ethics and ensure that we disclose such waivers as may be required by the exchange on which we are listed, if any, and rules and regulations of the SEC.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics applicable to our employees, officers and directors. Our Code of Business Conduct and Ethics is available on our website at www.vistagen.com. We intend to disclose any future amendments to certain provisions of our Code of Business Conduct and Ethics, or waivers of these provisions, on our website or in filings with the SEC under the Exchange Act.

Board Attendance at Board of Directors, Committee and Stockholder Meetings

Our Board of Directors met four times and acted by unanimous written consent six times during our fiscal year ended March 31, 2017. Our Audit Committee met four times. Our Compensation Committee requested action by the entire Board of Directors for grants of various equity securities and for amendments of employment agreements. Our Nominating and Corporate Governance Committee requested action by the entire Board of Directors with respect to resolutions to be presented to our stockholders at the annual meeting of stockholders and Board committee assignments. With the exception of Dr. Underdown, who was unable to attend one Board meeting due to international travel, each director serving during Fiscal 2017 attended all of the meetings of the Board and the committees of the Board upon which such director served that were held during the term of his service.

We do not have a formal policy regarding attendance by members of the Board at our annual meeting of stockholders, but directors are encouraged to attend. Mr. Saxe and Dr. Gin attended our annual meeting of stockholders held on September 26, 2016. Dr. Underdown was unavailable to participate due to international travel.

Compensation Committee Interlocks and Insider Participation

Our Compensation Committee consists of Dr. Underdown, Mr. Saxe and Dr. Gin, each of whom is a non-employee director. None of the members of the Compensation Committee has a relationship that would constitute an interlocking relationship with executive officers or directors of another entity.

Section 16 Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our officers, directors and persons who beneficially own more than ten percent of our common stock (collectively, *Reporting Persons*) to file reports of ownership on Form 3 and changes in ownership on Form 4 or Form 5 with the SEC. The Reporting Persons are also required by SEC rules to furnish us with copies of all reports that they file pursuant to Section 16(a). We believe that during our fiscal year ended March 31, 2017, all Reporting Persons, other than PLTG and/or its affiliate, Montsant Partners LLC, and Cato Holding Company complied with all applicable reporting requirements.

Item 11. Executive Compensation

Our Compensation Objectives

Our compensation practices are designed to attract key employees and to retain, motivate and reward our executive officers for their performance and contribution to our long-term success. Our Board of Directors, through the compensation committee, seeks to compensate our executive officers by combining short and long-term cash and equity incentives. It also seeks to reward the achievement of corporate and individual performance objectives, and to align executive officers' incentives with stockholder value creation. When possible, the compensation committee seeks to tie individual goals to the area of the executive officer's primary responsibility. These goals may include the achievement of specific financial or business development goals. Also, when possible and appropriate taking into account the Company's financial condition and other related facts and circumstances, the compensation committee seeks to set performance goals that reach across all business areas and include achievements in finance/business development and corporate development.

The Compensation Committee makes decisions regarding salaries, annual bonuses, if any, and equity incentive compensation for our executive officers, approves corporate goals and objectives relevant to the compensation of the Chief Executive Officer and our other executive officers. The Compensation Committee solicits input from our Chief Executive Officer regarding the performance of our other executive officers. Finally, the Compensation Committee also administers our incentive compensation and benefit plans.

Although we have no formal policy for a specific allocation between current and long-term compensation, or cash and non-cash compensation, when possible and appropriate taking into account the Company's financial condition and other related facts and circumstances, we seek to implement a pay mix for our officers with a relatively equal balance of both, providing a competitive salary with a significant portion of compensation awarded on both corporate and personal performance.

Compensation Components

As a general rule, and when possible and appropriate taking into account the Company's financial condition and other related facts and circumstances, our compensation consists primarily of three elements: base salary, annual bonus and long-term equity incentives. We describe each element of compensation in more detail below.

Base Salary

Base salaries for our executive officers are established based on the scope of their responsibilities and their prior relevant experience, taking into account competitive market compensation paid by other companies in our industry for similar positions and the overall market demand for such executives, both initially at the time of hire and thereafter, to ensure that we retain our executive management team.. An executive officer's base salary is also determined by reviewing the executive officer's other compensation to ensure that the executive officer's total compensation is in line with our overall compensation philosophy.

Base salaries are reviewed periodically as deemed necessary by the Compensation Committee and increased for merit reasons, based on the executive officers' success in meeting or exceeding individual objectives. Additionally, we may adjust base salaries as warranted throughout the year for promotions or other changes in the scope or breadth of an executive officer's role or responsibilities.

Annual Bonus

The Compensation Committee assesses the level of the executive officer's achievement of meeting individual goals, as well as that executive officer's contribution towards our corporate-wide goals. The amount of the cash bonus depends on the level of achievement of the individual performance goals, with a target bonus generally set as a percentage of base salary and based on the achievement of pre-determined milestones. To conserve our cash resources, our management team voluntarily decided to not seek and, in accordance with our management team's election, our Compensation Committee did not award cash bonuses in any fiscal year from Fiscal 2012 through Fiscal 2015. The Compensation Committee authorized cash bonuses to officers who served during Fiscal 2016, which bonuses were paid in July 2016.

Long-Term Equity Incentives

The Compensation Committee believes that to attract and retain management, key employees and non-management directors the compensation paid to these persons should include, in addition to base salary and potential annual cash incentives, equity based compensation that is competitive with peer companies. The Compensation Committee determines the amount and terms of equity-based compensation granted under our stock option plans or pursuant to other awards made to our executives and key employees.

Summary Compensation Table

The following table shows information regarding the compensation of our Named Executive Officers (NEO's) for services performed in the fiscal years ended March 31, 2017 and 2016:

Name and Principal Position	Fiscal Year	Salary (\$)	Bonus (\$)	Option and Warrant Awards (5) (\$)	All Other Compensation (\$)	Total (\$)
Shawn K. Singh (1) <i>Chief Executive Officer</i>	2017	385,107	173,750	752,210 (6)	-	1,316,067
	2016	347,500	-	1,629,574 (7)	-	1,977,074
H. Ralph Snodgrass, Ph.D. (2) <i>President, Chief Scientific Officer</i>	2017	340,625	152,500	520,946 (6)	-	1,014,071
	2016	305,000	-	985,025 (7)	-	1,290,025
Mark A. Smith, M.D., Ph.D. (3) <i>Chief Medical Officer</i>	2017	275,737	-	654,238 (6)	-	929,975
	2016	-	-	-	-	-
Jerrold D. Dotson (4) <i>Vice President, Chief Financial Officer, Secretary</i>	2017	289,583	100,000	318,018 (6)	-	707,601
	2016	250,000	-	635,297 (7)	-	885,297

- (1) Mr. Singh became Chief Executive Officer of VistaGen Therapeutics, Inc. (a California corporation) (*VistaGen California*) on August 20, 2009 and our Chief Executive Officer in May 2011, in connection with the Merger. In our fiscal years ended March 31, 2017 and 2016, Mr. Singh's annual base cash salary, pursuant to his January 2010 employment agreement, as amended in June 2016, was contractually set at \$395,000 and \$347,500, respectively. Pursuant to his employment agreement, Mr. Singh is eligible to receive an annual cash incentive bonus of up to fifty percent (50%) of his base cash salary. To conserve cash for our operations during our fiscal year ended March 31, 2016, Mr. Singh voluntarily refrained from receiving any cash bonus.
- (2) Through August 20, 2009, Dr. Snodgrass served as VistaGen California's President and Chief Executive Officer, at which time he became its President and Chief Scientific Officer. He became our President and Chief Scientific Officer in May 2011, in connection with the Merger. In our fiscal years ended March 31, 2017 and 2016, Dr. Snodgrass' annual base cash salary, pursuant to his January 2010 employment agreement, as amended in June 2016, was contractually set at \$350,000 and \$305,000, respectively. Pursuant to his employment agreement, Dr. Snodgrass is eligible to receive an annual cash incentive bonus of up to fifty percent (50%) of his base cash salary. To conserve cash for our operations during our fiscal years ended March 31, 2016 and 2015, Dr. Snodgrass voluntarily refrained from receiving any cash bonus.
- (3) Dr. Smith became our Chief Medical Officer upon his employment effective June 18, 2016. During our fiscal year ended March 31, 2017, Dr. Smith's annual base cash salary was \$350,000.
- (4) Mr. Dotson served as Chief Financial Officer on a part-time contract basis from September 19, 2011 through August 2012, at which time he became our full-time employee. In our fiscal years ended March 31, 2017 and 2016, Mr. Dotson's annual base cash salary was \$300,000 and \$250,000, respectively. To conserve cash for our operations, Mr. Dotson did not receive a cash bonus in our fiscal year ended March 31, 2016.
- (5) The amounts in the Option and Warrant Awards column represent the aggregate grant date fair value of options and/or warrants to purchase restricted shares of our common stock awarded to Mr. Singh, Dr. Snodgrass, Dr. Smith and Mr. Dotson, and, in Fiscal 2016, the effect of modifications to prior grants of warrants, occurring during the fiscal year presented, computed in accordance with the Financial Accounting Standards Board's Accounting Standards Codification Topic 718, Compensation – Stock Compensation (*ASC 718*). The amounts in this column do not represent any cash payments actually received by Mr. Singh, Dr. Snodgrass, Dr. Smith or Mr. Dotson with respect to any of such options or warrants to purchase restricted shares of our common stock awarded to them or modified during the periods presented. To date, Mr. Singh, Dr. Snodgrass, Dr. Smith and Mr. Dotson have not exercised any of such options or warrants to purchase common stock, and there can be no assurance that any of them will ever realize any of the ASC 718 grant date fair value amounts presented in the Option and Warrant Awards column.

- (6) The table below provides information regarding the option awards we granted to Mr. Singh, Dr. Snodgrass, Dr. Smith and Mr. Dotson during Fiscal 2017 and the assumptions used in the Black Scholes Option Pricing Model to determine the grant date fair values of the respective awards and modifications

	Option Grant 6/19/2016	Option Grant 11/9/2016	Total
Singh	\$ 484,700	\$ 272,510	\$ 757,210
Snodgrass	302,938	218,008	520,946
Smith	436,230	218,008	654,238
Dotson	181,763	136,255	318,018
	<u>\$ 1,405,631</u>	<u>\$ 844,781</u>	<u>\$ 2,250,412</u>
Market price per share	\$ 3.49	\$ 3.80	
Exercise price per share	\$ 3.49	\$ 3.80	
Risk-free interest rate	1.31%	1.71%	
Volatility	79.82%	83.17%	
Expected term (years)	6.25	6.25	
Dividend rate	0%	0%	
Fair value per share	\$ 2.42	\$ 2.73	
Aggregate shares	580,000	310,000	

- (7) The table below provides information regarding the warrant awards and modifications we granted to Mr. Singh, Dr. Snodgrass and Mr. Dotson during fiscal 2016 and the assumptions used in the Black Scholes Option Pricing Model to determine the grant date fair values of the respective awards and modifications

	Warrant Grant 9/2/2015	Warrant Modification 11/11/2015	Total
Singh	\$ 1,420,332	\$ 209,242	\$ 1,629,574
Snodgrass	852,199	132,826	985,025
Dotson	568,133	67,164	635,297
	<u>\$ 2,840,664</u>	<u>\$ 409,232</u>	<u>\$ 3,249,896</u>
		Weighted Average (except shares)	
		Before	After
Market price per share	\$ 9.11	\$ 6.50	\$ 6.50
Exercise price per share	\$ 9.25	\$ 9.99	\$ 7.00
Risk-free interest rate	1.15%	1.75%	1.76
Volatility	77.19%	78.8%	78.75%
Expected term (years)	5	5.17	5.19
Dividend rate	0%	0%	0%
Fair value per share	\$ 5.68	\$ 3.67	\$ 4.09
Aggregate shares	500,000	952,803	952,803

Mr. Singh, Dr. Snodgrass and Mr. Dotson were granted warrants to purchase 250,000, 150,000 and 100,000 restricted shares of our common stock, respectively. We modified warrants to purchase an aggregate of 477,803 shares, 310,000 shares and 165,000 shares held by Mr. Singh, Dr. Snodgrass and Mr. Dotson, respectively.

None of the NEOs is entitled to perquisites or other personal benefits that, in the aggregate, are worth over \$50,000 or over 10% of their base salary.

Benefit Plans

401(k) Plan

We maintain, through a registered agent, a retirement and deferred savings plan for our officers and employees. This plan is intended to qualify as a tax-qualified plan under Section 401(k) of the Internal Revenue Code of 1986, as amended. The retirement and deferred savings plan provides that each participant may contribute a portion of his or her pre-tax compensation, subject to statutory limits. Under the plan, each employee is fully vested in his or her deferred salary contributions. Employee contributions are held and invested by the plan's trustee. The retirement and deferred savings plan also permits us to make discretionary contributions subject to established limits and a vesting schedule. To date, we have not made any discretionary contributions to the retirement and deferred savings plan on behalf of participating employees.

Options and Warrants Granted to NEOs

The following table provides information regarding each unexercised stock option and warrant to purchase restricted shares of our common stock held by each of the named executive officers as of March 31, 2017:

Name	Stock Options and Warrants			
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date
Shawn K. Singh	2,000	-	14.40	5/17/2017
	1,000	-	10.00	1/17/2018
	1,000	-	10.00	1/17/2018
	3,000	-	10.00	3/24/2019
	1,125	-	10.00	6/17/2019
	50,000	-	10.00	11/4/2019
	21,250	-	10.00	12/30/2019
	5,000	-	10.00	4/26/2021
	4,017	-	7.00	3/19/2019
	1,786	-	7.00	3/19/2019
	72,000	-	7.00	3/3/2023
	150,000	-	7.00	1/11/2020
	250,000	-	7.00	9/2/2020
	-	200,000 (1)	3.49	6/19/2026
	11,111 (2)	88,889 (2)	3.80	11/9/2026
Total:	673,289	288,889		
H. Ralph Snodgrass, Ph.D.	2,500	-	10.00	3/24/2019
	1,250	-	10.00	6/17/2019
	12,500	-	10.00	12/30/2019
	50,000	-	7.00	3/3/2023
	2,500	-	7.00	3/19/2024
	7,500	-	7.00	3/19/2024
	100,000	-	7.00	1/11/2020
	150,000	-	7.00	9/20/2020
	-	125,000 (1)	3.49	6/19/2026
	8,888 (2)	71,112 (2)	3.80	11/9/2026
Total:	335,138	196,112		
Mark A. Smith, M.D. Ph.D.	-	180,000 (1)	3.49	6/19/2026
	8,888 (2)	71,112 (2)	3.80	11/9/2026
Total:	8,888	251,112		
Jerrold D. Dotson	5,001	-	10.00	10/30/2022
	1,000	-	8.00	10/27/2023
	10,000	-	7.00	3/3/2023
	5,000	-	7.00	3/19/2024
	50,000	-	7.00	1/11/2020
	-	75,000 (1)	3.49	6/19/2026
	5,555 (2)	44,445 (2)	3.80	11/9/2026
Total:	76,556	119,445		

(1) Represents an option to purchase shares of our common stock granted on June 19, 2016 when the market price of our common stock was \$3.49 per share. The option will become exercisable for 25% of the shares granted on June 19, 2017 with the remaining shares becoming exercisable ratably monthly through June 19, 2020, when all shares granted will be fully exercisable.

(2) Represents an option to purchase shares of our common stock granted on November 9, 2016 when the market price of our common stock was \$3.80 per share. The option becomes exercisable for 1/36th of the shares granted each month beginning December 9, 2016 through November 9, 2019, when all shares granted will be fully exercisable.

Employment or Severance Agreements

We currently have employment agreements with Mr. Singh and Dr. Snodgrass.

Singh Agreement

We entered into an employment agreement with Mr. Singh on April 28, 2010. Under the agreement, as amended on June 22, 2016, Mr. Singh's base salary was increased from \$347,500 per year to \$395,000 per year, effective June 16, 2016. Although under his agreement, Mr. Singh is eligible to receive an annual incentive cash bonus of up to 50% of his base salary, he has foregone any such cash bonus payment to conserve cash for our operations during our fiscal years 2012 through 2015. Mr. Singh received a cash bonus in the amount of \$173,750 in July 2016, for his service during fiscal 2016. Payment of his annual incentive bonus is at the discretion of our Board of Directors. In the event we terminate Mr. Singh's employment without cause, he is entitled to receive severance in an amount equal to:

- twelve months of his then-current base salary payable in the form of salary continuation;
- a pro-rated portion of the incentive cash bonus that the Board of Directors determines in good faith that Mr. Singh earned prior to his termination; and
- such amounts required to reimburse him for Consolidated Omnibus Budget Reconciliation Act (*COBRA*) payments for continuation of his medical health benefits for such twelve-month period.

In addition, in the event Mr. Singh terminates his employment with good reason following a change of control, he is entitled to twelve months of his then-current base salary payable in the form of salary continuation.

Snodgrass Agreement

We entered into an employment agreement with Dr. Snodgrass on April 28, 2010. Under the agreement, as amended on June 22, 2016, Dr. Snodgrass's base salary was increased from \$305,000 per year to \$350,000 per year, effective June 16, 2016. Although under his agreement, Dr. Snodgrass is eligible to receive an annual incentive cash bonus of up to 50% of his base salary, he has foregone any such cash bonus payment to conserve cash for our operations during our fiscal years 2012 through 2015. Dr. Snodgrass received a cash bonus in the amount of \$152,500 in July 2016, for his service during fiscal 2016. Payment of his annual incentive bonus is at the discretion of the Board of Directors. In the event we terminate Dr. Snodgrass's employment without cause, he is entitled to receive severance in an amount equal to:

- twelve months of his then-current base salary payable in the form of salary continuation;
- a pro-rated portion of the incentive bonus that the Board of Directors determines in good faith that Dr. Snodgrass earned prior to his termination; and
- such amounts required to reimburse him for *COBRA* payments for continuation of his medical health benefits for such twelve-month period.

In addition, in the event Dr. Snodgrass terminates his employment with good reason, he is entitled to twelve months of his then-current base salary payable in the form of salary continuation.

Change of Control Provisions

Pursuant to each of their respective employment agreements, Dr. Snodgrass is entitled to severance if he terminates his employment at any time for "good reason" (as defined below), while Mr. Singh is entitled to severance if he terminates his employment for good reason after a change of control. Under their respective agreements, "good reason" means any of the following events, if the event is affected by us without the executive's consent (subject to our right to cure):

- a material reduction in the executive's responsibility; or
- a material reduction in the executive's base salary except for reductions that are comparable to reductions generally applicable to similarly situated executives of VistaGen.

Furthermore, pursuant to their respective employment agreements and their stock option award agreements, as amended, in the event we terminate the executive without cause within twelve months of a change of control, the executive's remaining unvested option shares become fully vested and exercisable. Upon a change of control in which the successor corporation does not assume the executive's stock options, the stock options granted to the executive become fully vested and exercisable.

Pursuant to their respective employment agreements, a change of control occurs when: (i) any "person" as such term is used in Sections 13(d) and 14(d) of the Exchange Act (other than VistaGen, a subsidiary, an affiliate, or a VistaGen employee benefit plan, including any trustee of such plan acting as trustee) becoming the "beneficial owner" (as defined in Rule 13d-3 under the Exchange), directly or indirectly, of securities of VistaGen representing 50% or more of the combined voting power of VistaGen's then outstanding securities; (ii) a sale of substantially all of VistaGen's assets; or (iii) any merger or reorganization of VistaGen whether or not another entity is the survivor, pursuant to which the holders of all the shares of capital stock of VistaGen outstanding prior to the transaction hold, as a group, fewer than 50% of the shares of capital stock of VistaGen outstanding after the transaction.

In the event that, following termination of employment, amounts are payable to an executive pursuant to his employment agreement, the executive's eligibility for severance is conditioned on executive having first signed a release agreement.

Pursuant to their respective employment agreements, the estimated amount that could be paid by us assuming that a change of control occurred on the last business day of our current fiscal year, is \$395,000 for Mr. Singh and \$350,000 for Dr. Snodgrass, excluding the imputed value of accelerated vesting of incentive stock options, if any.

DIRECTOR COMPENSATION

We do not have a formal compensation plan for our non-employee directors. We adopted a director compensation policy for our independent directors, as independence is defined by the NASDAQ Stock Market, which became effective for our fiscal year beginning April 1, 2014. Under the independent director compensation policy, our independent directors are entitled to receive a \$25,000 annual retainer, payable in cash or shares of common stock. For service on a committee of the board, an independent director is entitled to receive an additional annual cash retainer as follows: \$7,500 for audit and compensation committee members and \$5,000 for nominating and governance committee members. In lieu of the annual cash retainer for committee participation, each independent director serving as a chair of a board committee shall receive the following annual cash retainer: \$15,000 for audit and compensation committee chairs and \$10,000 for the nominating and governance committee chairs. We paid our independent directors cash compensation consistent with the policy noted above during our fiscal year ended March 31, 2017. To conserve cash for our operations, we had accrued, but had not paid, our independent directors any cash compensation during the period January 1, 2012 through March 31, 2016. We paid all such unpaid amounts, aggregating \$278,500, during Fiscal 2017.

Under our director compensation policy, as updated in March 2016, each independent director will also receive an annual grant of an option or warrant to purchase a minimum of 12,000 shares of our common stock, which will vest monthly over a one-year period from the date of grant. In June 2016, we granted options to purchase 25,000 shares of our common stock at \$3.49 per share to each of our three independent directors. In November 2016, we granted options to purchase an additional 25,000 shares of our common stock at \$3.80 to each of the three independent directors. We expect to make future grants on the same date as our annual meeting, or as soon thereafter as reasonably practicable. Prorated grants will be made for partial years of service.

The following table sets forth a summary of the compensation earned by our non-employee directors in our fiscal year ended March 31, 2017.

Name	Fees Earned or Paid in Cash			Option Awards (2)	Other Compensation	Total
	(1)		(3)			
	(\$)	(\$)	(\$)	(\$)	(\$)	(\$)
Jon S. Saxe (3)	\$ 52,500	\$ 159,196	(6)	\$ -	\$ 211,696	
Brian J. Underdown, Ph.D. (4)	\$ 57,500	\$ 159,196	(6)	\$ -	\$ 216,696	
Jerry B. Gin, Ph.D., M.B.A (5)	\$ 32,500	\$ 159,196	(6)	\$ -	\$ 191,696	

- (1) The amounts shown represent fees earned for service on our Board of Directors, and Audit Committee, Compensation Committee and Corporate Governance and Nominating Committee during the fiscal year ended March 31, 2017, which amounts were paid in full during the fiscal year then ended. Fees paid during Fiscal 2017 for prior years' Board and committee service, \$136,500 to Mr. Saxe, and \$142,000 to Dr. Underdown, are excluded from the amounts shown as they had been reported, as appropriate, in the year in which they were accrued.
- (2) The amounts in the Option Awards column represent the aggregate grant date fair value of options to purchase shares of our common stock awarded to Mr. Saxe, Dr. Underdown and Dr. Gin during our fiscal year ended March 31, 2017, computed in accordance with the Financial Accounting Standards Board's Accounting Standards Codification Topic 718, Compensation – Stock Compensation (ASC 718). The amounts in this column do not represent any cash payments actually received by Mr. Saxe, Dr. Underdown or Dr. Gin with respect to any of such warrants or options to purchase shares of our common stock awarded to them during the fiscal year ended March 31, 2017. To date, Mr. Saxe, Dr. Underdown and Dr. Gin have not exercised such warrants or options to purchase common stock, and there can be no assurance that any of them will ever realize any of the ASC 718 grant date fair value amounts presented in the Option and Warrant Awards column.
- (3) Mr. Saxe has served as the Chairman of our Board of Directors, the Chairman of our Audit Committee and a member of our Compensation Committee and Corporate Governance and Nominating Committee throughout our fiscal year ended March 31, 2017. At March 31, 2017, Mr. Saxe holds: (i) 1,875 restricted shares of our common stock; (ii) options to purchase 61,875 registered shares of our common stock, of which options to purchase 14,652 shares are exercisable; and (iii) warrants to purchase 83,250 restricted shares of our common stock, all of which are exercisable.
- (4) Dr. Underdown has served as a member of our Board of Directors, as the Chairman of our Compensation Committee and Corporate Governance and Nominating Committee and as a member of our Audit Committee throughout our fiscal year ended March 31, 2017. At March 31, 2017, Dr. Underdown holds: (i) options to purchase 59,250 registered shares of our common stock, of which options to purchase 12,027 shares are exercisable; and (ii) warrants to purchase 82,500 restricted shares of our common stock, all of which are exercisable.
- (5) Dr. Gin was appointed to our Board of Directors and as a member of our Audit Committee on March 29, 2016 and served in those capacities throughout our fiscal year ended March 31, 2017. Effective on April 1, 2017, Dr. Gin was also appointed as a member of the Compensation Committee and assumed chairmanship of the Corporate Governance and Nominating Committee. At March 31, 2017, Dr. Gin holds options to purchase 75,000 registered shares of our common stock of which 27,777 are exercisable.

- (6) The table below provides information regarding the option awards we granted to Mr. Saxe, Dr. Underdown and Dr. Gin during Fiscal 2017 and the assumptions used in the Black Scholes Option Pricing Model to determine the grant date fair values of the respective awards and modifications.

	Option Grant 6/19/2016	Option Grant 11/9/2016	Total
Saxe	\$ 76,803	\$ 82,393	\$ 159,196
Underdown	76,803	82,393	159,196
Gin	76,803	82,393	159,196
	<u>\$ 230,409</u>	<u>\$ 247,179</u>	<u>\$ 477,588</u>
Market price per share	\$ 3.49	\$ 3.80	
Exercise price per share	\$ 3.49	\$ 3.80	
Risk-free interest rate	1.62%	2.07%	
Volatility	96.16%	91.65%	
Expected term (years)	10.00	10.00	
Dividend rate	0%	0%	
Fair value per share	\$ 3.07	\$ 3.30	
Aggregate shares	75,000	75,000	

Mr. Saxe, Dr. Underdown and Dr. Gin were each granted options to purchase 25,000 shares of our common stock on both of the dates indicated.

Director Independence

Our securities are currently listed on The NASDAQ Capital Market, which has a requirement that a majority of our directors be independent. Accordingly, we evaluate independence by the standards for director independence established by applicable laws, rules, and listing standards, including, without limitation, the standards for independent directors established by the SEC and the NASDAQ Stock Market.

Subject to some exceptions, these standards generally provide that a director will not be independent if (a) the director is, or in the past three years has been, an employee of ours; (b) a member of the director's immediate family is, or in the past three years has been, an executive officer of ours; (c) the director or a member of the director's immediate family has received more than \$120,000 per year in direct compensation from us other than for service as a director (or for a family member, as a non-executive employee); (d) the director or a member of the director's immediate family is, or in the past three years has been, employed in a professional capacity by our independent public accountants, or has worked for such firm in any capacity on our audit; (e) the director or a member of the director's immediate family is, or in the past three years has been, employed as an executive officer of a company where one of our executive officers serves on the compensation committee; or (f) the director or a member of the director's immediate family is an executive officer of a company that makes payments to, or receives payments from, us in an amount which, in any twelve-month period during the past three years, exceeds the greater of \$1,000,000 or two percent of that other company's consolidated gross revenues.

Our Board of Directors has undertaken a review of its composition, the composition of its committees and the independence of each director. Based upon information requested from and provided by each director concerning his background, employment and affiliations, including family relationships, our Board of Directors has determined that Mr. Saxe, Dr. Underdown and Dr. Gin are "independent" as that term is defined under the applicable rules and regulations of the SEC. Our Board of Directors has also determined that Mr. Saxe, Dr. Underdown and Dr. Gin, who together comprise our audit committee, compensation committee, and corporate governance and nominating committee, satisfy the independence standards for those committees established by applicable SEC rules. In making these determinations, our Board of Directors considered the current and prior relationships that each non-employee director has with the Company and all other facts and circumstances that our Board of Directors deemed relevant.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of June 27, 2017 for:

- each stockholder known by us to be the beneficial owner of more than 5% of our common stock;
- each of our directors;
- each of our named executive officers; and
- all of our directors and executive officers as a group.

Applicable percentage ownership is based on 9,301,472 shares of common stock outstanding at June 27, 2017. In computing the number of shares of common stock beneficially owned by a person, we deemed to be outstanding all shares of common stock subject to options or warrants and all shares of preferred stock held by that person or entity that are currently exercisable or exchangeable or that will become exercisable or exchangeable within 60 days of June 27, 2017. In computing the percentage of shares beneficially owned, we deemed to be outstanding all shares of common stock subject to options or warrants and all shares of preferred stock held by that person or entity that are currently exercisable or exchangeable or that will become exercisable or exchangeable within 60 days of June 27, 2017. Unless otherwise noted below, the address of each beneficial owner listed in the table is c/o VistaGen Therapeutics, Inc., 343 Allerton Avenue, South San Francisco, California 94080.

Name and address of beneficial owner	Number of shares beneficially owned	Percent of shares beneficially owned (1)
<i>Executive officers and directors:</i>		
Shawn K. Singh (2)	669,745	6.73%
H. Ralph Snodgrass, Ph.D (3)	442,932	4.57%
Mark A. Smith, M.D., Ph.D. (4)	72,499	*
Jerrold D. Dotson (5)	206,151	2.17%
Jon S. Saxe (6)	110,542	1.17%
Brian J. Underdown, Ph.D (7)	105,291	1.12%
Jerry B. Gin, Ph.D, MBA (8)	138,541	1.48%
<i>5% Stockholders:</i>		
Platinum Long Term Growth Fund VII/Montsant Partners, LLC (9)	4,819,101	35.99%
Empery Asset Management, LP (10)	717,667	7.72%
Cato BioVentures (11)	607,294	6.53%
Sphera Global Healthcare Master Fund (12)	544,100	5.85%
All executive officers and directors as a group (7 persons) (13)	1,745,601	16.08%

* less than 1%

- (1) Based on 9,301,472 shares of common stock issued and outstanding as of June 27, 2017.
- (2) Includes options to purchase 165,708 registered shares of common stock exercisable within 60 days of June 27, 2017 and warrants to purchase 477,803 restricted shares of common stock exercisable within 60 days of June 27, 2017.
- (3) Includes options to purchase 72,708 registered shares of common stock exercisable within 60 days of June 27, 2017 and warrants to purchase 310,000 restricted shares of common stock exercisable within 60 days of June 27, 2017.
- (4) Includes options to purchase 72,499 registered shares of common stock exercisable within 60 days of June 27, 2017.
- (5) Includes options to purchase 41,051 registered shares of common stock exercisable within 60 days of June 27, 2017, including options to purchase 676 shares of common stock held by Mr. Dotson's wife, and warrants to purchase 15,000 restricted shares of common stock exercisable within 60 days of June 27, 2017.
- (6) Includes options to purchase 25,416 registered shares of common stock exercisable within 60 days of June 27, 2017 and warrants to purchase 83,250 restricted shares of common stock exercisable within 60 days of June 27, 2017.
- (7) Includes options to purchase 22,791 registered shares of common stock exercisable within 60 days of June 27, 2017 and warrants to purchase 82,500 restricted shares of common stock exercisable within 60 days of June 27, 2017.
- (8) Includes 50,000 restricted shares of common stock held by Dr. Gin's wife and options to purchase 38,541 registered shares of common stock exercisable within 60 days of June 27, 2017.
- (9) Based upon information contained in Schedule 13G/A filed on February 18, 2015 by Platinum Long Term Growth Fund VII (PLTG) and adjusted to give effect to the transactions consummated between PLTG, Montsant Partners, LLC (Montsant), a PLTG affiliate, and Platinum Partners Value Arbitrage Fund, L.P. (In Official Liquidation) (PPVA), and us through June 27, 2017.

The number of beneficially owned shares reported includes 637,500 restricted shares of common stock that may currently be acquired by Montsant upon fixed exchange of 425,000 restricted shares of our Series A Preferred Stock ("Series A Preferred"). Pursuant to the October 11, 2012 Note Exchange and Purchase Agreement by and between us and PLTG. There is, however, a limitation on exchange such that the number of shares of our common stock that may be acquired by PLTG or its affiliates upon exchange of the Series A Preferred is limited to the extent necessary to ensure that, following such exchange, the total number of shares of our common stock then beneficially owned by PLTG or its affiliates does not exceed 9.99% of the total number of our then issued and outstanding shares of common stock without providing us with 61 days' prior notice thereof.

Further, the reported number of shares beneficially owned by Montsant also includes 1,131,669 shares of common stock pursuant to its ownership of 1,131,669 shares of our Series B 10% Convertible Preferred Stock ("*Series B Preferred*"), immediately convertible into a like number of shares of our common stock. Pursuant to the terms of the Certificate of Designation of the Relative Rights and Preferences of the Series B 10% Convertible Preferred Stock, there is, however, a limitation on conversion of the Series B Preferred such that the number of shares of common stock that Montsant may beneficially acquire upon such conversion is limited to the extent necessary to ensure that, following such conversion, the total number of shares of common stock then beneficially owned by PLTG or Montsant does not exceed 9.99% of the total number of then issued and outstanding shares of our common stock without providing us with 61 days' prior notice thereof.

Further, the reported number of shares beneficially owned by Montsant also includes 2,318,012 shares of common stock pursuant to its ownership of 2,318,012 shares of our Series C Convertible Preferred Stock (“*Series C Preferred*”), immediately convertible on a fixed 1:1 conversion basis into a like number of shares of our restricted common stock. Pursuant to the terms of the Certificate of Designation of the Relative Rights and Preferences of the Series C Convertible Preferred Stock, there is, however, a limitation on conversion of the Series C Preferred such that the number of shares of common stock that Montsant may beneficially acquire upon such conversion is limited to the extent necessary to ensure that, following such conversion, the total number of shares of common stock then beneficially owned by PLTG or Montsant does not exceed 9.99% of the total number of then issued and outstanding shares of our common stock without providing us with 61 days’ prior notice thereof. Excluding the shares otherwise subject to the beneficial ownership restrictions noted above, PLTG, Montsant and PPVA may be deemed to be the beneficial owner of 731,920 shares or 7.87% of our common stock.

In addition to the beneficial ownership blockers described above, on April 24, 2017, PPVA, Montsant and BAM Administrative Services LLC, as administrative and collateral agent for certain lenders to PPVA and Montsant (*BAM*), executed a Lock-Up Agreement, pursuant to which PPVA, Montsant and BAM agreed to not enter into any transaction involving the Company’s securities during the term of the agreement, which ends on October 24, 2017.

Matthew Wright, Operating Manager of RHSV (Cayman) Ltd., and/or Moshe Feuer, Chief Executive Officer and authorized signatory of BAM may, subject to certain restrictions, be deemed to have voting and investment control over the shares held by PPVA, PLTG and/or Montsant. The address for PLTG, PPVA and Montsant is c/o BAM Administrative Services LLC, 105 Madison Avenue, 19th Floor, New York, NY 10016.

- (10) Based upon information contained in Form 13G/A filed on January 27, 2017. The number of shares reported excludes immediately exercisable warrants to purchase 761,267 registered shares of our common stock, which warrants are subject to a limitation on exercise such that the number of shares of common stock that Empery Asset Management, LP and its affiliates, Empery Asset Master, Ltd.; Empery Tax Efficient, LP; and Empery Tax Efficient II, LP (together, *Empery*) may beneficially acquire upon such exercise is limited to the extent necessary to ensure that, following such exercise, the total number of shares of common stock then beneficially owned by Empery does not exceed 4.99% of the total number of issued and outstanding shares of our common stock without providing us with 61 days’ prior notice thereof. The primary business address of Empery Asset Management, LP and its affiliates is 1 Rockefeller Plaza, Suite 1205, New York, New York 10020. Messrs. Ryan M. Lane and Martin D. Hoe have voting and investment control over the shares held by Empery.
- (11) Based upon information contained in Form 4 filed on January 9, 2012, as updated to give effect to transactions through June 27, 2017 as recorded on our books. Lynda Sutton has voting and investment authority over the shares held by Cato Holding Company, dba Cato BioVentures. The primary business address of Cato BioVentures is 4364 South Alston Avenue, Durham, North Carolina 27713.
- (12) Based upon information contained in Form 13F filed on May 11, 2017. The number of shares reported excludes immediately exercisable warrants to purchase 294,100 registered shares of our common stock, which warrants are subject to a limitation on exercise such that the number of shares of common stock that Sphera Global Healthcare Master Fund and HFR HE Sphera Global Healthcare Mater Trust (together, *Sphera*) may beneficially acquire upon such exercise is limited to the extent necessary to ensure that, following such exercise, the total number of shares of common stock then beneficially owned by Sphera does not exceed 4.99% of the total number of issued and outstanding shares of our common stock without providing us with 61 days’ prior notice thereof. The primary business address of Sphera Global Healthcare Master Fund and its affiliates is c/o Sphera Funds Management Ltd., 21 Ha’arba’ah Street, Tel Aviv 64739, Israel. Moshe Arkin and Sphera Funds Management Ltd. have joint voting and investment control over the shares held by Sphera.
- (13) Includes options to purchase an aggregate of 438,714 shares of common stock exercisable within 60 days of June 27, 2017 and warrants to purchase an aggregate of 1,118,553 restricted shares of common stock exercisable within 60 days of June 27, 2017.

Securities Authorized for Issuance Under Equity Compensation Plans

Equity Grants

As of March 31, 2017, options to purchase a total of 1,659,324 registered shares of our common stock were outstanding at a weighted average exercise price of \$4.76 per share, of which 351,532 options were vested and exercisable at a weighted average exercise price of \$8.27 per share and 1,307,792 were unvested and not exercisable at a weighted average exercise price of \$3.81 per share. These options were issued under our 2016 Plan and our 1999 Plan, each as described below. At March 31, 2017, an additional 1,184,911 shares remained available for future equity grants under our 2016 Plan.

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	1,650,089	\$ 4.72	1,184,911
Equity compensation plans not approved by security holders	9,235	\$ 10.95	--
Total	1,659,324	\$ 4.76	1,184,911

Amended and Restated 2016 Stock Incentive Plan

Our Board unanimously approved the Company's Amended and Restated 2016 Equity Incentive Plan (*2016 Plan*), formerly titled the 2008 Equity Incentive Plan, on July 26, 2016. Our stockholders approved the 2016 Plan on September 26, 2016. Stockholders of VistaGen California adopted the 2008 Plan on December 19, 2008 and we assumed the plan in connection with the Merger.

In August 2015, our stockholders approved an amendment to the 2008 Plan to increase the number of shares of our common stock authorized for issuance to thereunder from 250,000 to 1.0 million shares. Board- and stockholder-approved amendments to the 2016 Plan included increasing the number of shares of our common stock authorized for issuance from 1.0 million to 3.0 million, increasing the maximum number of shares of common stock that may be granted to a Grantee (as such term is defined in the 2016 Plan) in any calendar year from 125,000 to 300,000 shares (350,000 shares if the grant is issued in connection with the commencement of service to the Company), and extending the expiration date of the 2016 Plan to July 26, 2026. The 2016 amendments also removed certain provisions that only pertained to the plan before the Company became a publicly traded entity. In all cases, the maximum number of shares of common stock issuable under the 2016 Plan will be subject to adjustments for stock splits, stock dividends or other similar changes in our common stock or our capital structure. Notwithstanding the foregoing, the maximum number of shares of common stock available for grant of options intended to qualify as "incentive stock options" under the provisions of Section 422 of the Internal Revenue Code of 1986, as amended, (the *Code*), is 3.0 million.

Below is a summary of the terms and conditions of the 2016 Plan. Unless otherwise indicated, all capitalized terms have the same meaning as defined in the 2016 Plan. This summary does not purport to be complete, and is qualified, in its entirety, by the specific language of the Amended and Restated 2016 Equity Incentive Plan.

Description of the 2016 Plan

The 2016 Plan provides for the grant of stock options, restricted shares of common stock, stock appreciation rights and dividend equivalent rights, collectively referred to as "Awards". Stock options granted under the 2016 Plan may be either incentive stock options under the provisions of Section 422 of the Code, or non-qualified stock options. We may grant incentive stock options only to employees of the Company or any parent or subsidiary of the Company. Awards other than incentive stock options may be granted to employees, directors and consultants.

The Compensation Committee of the Board of Directors, referred to as the "Committee", administers the 2016 Plan, including selecting the Award recipients, determining the number of shares to be subject to each Award, the exercise or purchase price of each Award and the vesting and exercise periods of each Award.

The exercise price of all incentive stock options granted under the 2016 Plan must be at least equal to 100% of the fair market value of the shares on the date of grant. If, however, incentive stock options are granted to an employee who owns stock possessing more than 10% of the voting power of all classes of our stock or the stock of any of our subsidiaries, the exercise price of any incentive stock option granted may not be less than 110% of the fair market value on the grant date. The maximum term of incentive stock options granted to employees who own stock possessing more than 10% of the voting power of all classes of our stock or the stock of any of our subsidiaries may not exceed five years. The maximum term of an incentive stock option granted to any other participant may not exceed 10 years. The Committee determines the term and exercise or purchase price of all other Awards granted under the 2016 Plan.

Under the 2016 Plan, incentive stock options may not be sold, pledged, assigned, hypothecated, transferred or disposed of in any manner other than by will or by the laws of descent or distribution and may be exercised, during the lifetime of the participant, only by the participant. Other Awards shall be transferable:

- by will and by the laws of descent and distribution; and
- during the lifetime of the participant, to the extent and in the manner authorized by the Committee by gift or pursuant to a domestic relations order to members of the participant's Immediate Family (as defined in the 2016 Plan).

The 2016 Plan permits the designation of beneficiaries by holders of Awards, including incentive stock options. In the event of termination of a participant's service for any reason other than disability or death, such participant may, but only during the period specified in the Award agreement of not less than 30 days (generally 90 days) commencing on the date of termination (but in no event later than the expiration date of the term of such Award as set forth in the Award Agreement), exercise the portion of the Grantee's Award that was vested at the date of such termination or such other portion of the Grantee's Award as may be determined by the Committee. The Grantee's Award Agreement may provide that upon the termination of the participant's service for cause, the participant's right to exercise the Award shall terminate concurrently with the termination of the participant's service. In the event of a participant's change of status from employee to consultant, an employee's incentive stock option shall convert automatically into a non-qualified stock option on the day three months and one day following such change in status. To the extent that the Grantee's Award was unvested at the date of termination, or if the participant does not exercise the vested portion of the Grantee's Award within the period specified in the Award Agreement of not less than 30 days commencing on the date of termination, the Award shall terminate. If termination was caused by death or disability, any options that have become exercisable prior to the time of termination, will remain exercisable for twelve months from the date of termination (unless a shorter or longer period of time is determined by the Committee).

The maximum number of shares with respect to which options and stock appreciation rights may be granted to any participant in any calendar year will be 300,000 shares of common stock. In connection with a participant's commencement of service with the Company, a participant may be granted options and stock appreciation rights for up to an additional 50,000 shares that will not count against the foregoing limitation. In addition, for Awards of restricted stock and restricted shares of common stock that are intended to be "performance-based compensation" (within the meaning of Section 162(m) of the Code), the maximum number of shares with respect to which such Awards may be granted to any participant in any calendar year will be 300,000 shares of common stock. The limits described in this paragraph are subject to adjustment in the event of any change in our capital structure as described below.

The terms and conditions of Awards are determined by the Committee, including the vesting schedule and any forfeiture provisions. Awards under the 2016 Plan may vest upon the passage of time or upon the attainment of certain performance criteria. Although we do not currently have any Awards outstanding that vest upon the attainment of performance criteria, the Committee may establish criteria based on any one of, or combination of, the following:

- increase in share price;
- earnings per share;
- total stockholder return;
- operating margin;
- gross margin;
- return on equity;
- return on assets;
- return on investment;
- operating income;
- net operating income;
- pre-tax profit;
- cash flow;
- revenue;
- expenses;
- earnings before interest, taxes and depreciation;
- economic value added; and
- market share.

Subject to any required action by our stockholders, the number of shares of common stock covered by outstanding Awards, the number of shares of common stock that have been authorized for issuance under the 2016 Plan, the exercise or purchase price of each outstanding Award, the maximum number of shares of common stock that may be granted subject to Awards to any participant in a calendar year, and the like, shall be proportionally adjusted by the Committee in the event of any increase or decrease in the number of issued shares of common stock resulting from certain changes in our capital structure as described in the 2016 Plan.

Effective upon the consummation of a Corporate Transaction (as defined below), all outstanding Awards under the 2016 Plan will terminate unless the acquirer assumes or replaces such Awards. The Committee has the authority, exercisable either in advance of any actual or anticipated Corporate Transaction or Change in Control (as defined below) or at the time of an actual Corporate Transaction or Change in Control and exercisable at the time of the grant of an Award under the 2016 Plan or any time while an Award remains outstanding, to provide for the full or partial automatic vesting and exercisability of one or more outstanding unvested Awards under the 2016 Plan and the release from restrictions on transfer and repurchase or forfeiture rights of such Awards in connection with a Corporate Transaction or Change in Control, on such terms and conditions as the Committee may specify. The Committee also has the authority to condition any such Award vesting and exercisability or release from such limitations upon the subsequent termination of the service of the grantee within a specified period following the effective date of the Corporate Transaction or Change in Control. The Committee may provide that any Awards so vested or released from such limitations in connection with a Change in Control, shall remain fully exercisable until the expiration or sooner termination of the Award.

Under the 2016 Plan, a Corporate Transaction is generally defined as:

- an acquisition of securities possessing more than fifty percent (50%) of the total combined voting power of our outstanding securities but excluding any such transaction or series of related transactions that the Committee determines shall not be a Corporate Transaction;
- a reverse merger in which we remain the surviving entity but: (i) the shares of common stock outstanding immediately prior to such merger are converted or exchanged by virtue of the merger into other property, whether in the form of securities, cash or otherwise; or (ii) in which securities possessing more than fifty percent (50%) of the total combined voting power of our outstanding securities are transferred to a person or persons different from those who held such securities immediately prior to such merger;
- a sale, transfer or other disposition of all or substantially all of the assets of the Company;
- a merger or consolidation in which the Company is not the surviving entity; or
- a complete liquidation or dissolution.

Under the 2016 Plan, a Change in Control is generally defined as: (i) the acquisition of more than 50% of the total combined voting power of our stock by any individual or entity which a majority of our Board of Directors (who have served on our board for at least 12 months) do not recommend our stockholders accept; (ii) or a change in the composition of our Board of Directors over a period of 12 months or less.

Unless terminated sooner, the 2016 Plan will automatically terminate in 2026. Our Board of Directors may at any time amend, suspend or terminate the 2016 Plan. To the extent necessary to comply with applicable provisions of U.S. federal securities laws, state corporate and securities laws, the Code, the rules of any applicable stock exchange or national market system, and the rules of any non-U.S. jurisdiction applicable to Awards granted to residents therein, we will obtain stockholder approval of any such amendment to the 2016 Plan in such a manner and to such a degree as required.

In April 2017, the Committee approved the grant of stock options from the 2016 Plan to all officers, employees and independent members of the Board of Directors to purchase an aggregate of 880,000 shares of our common stock. As of June 27, 2017, we have options to purchase an aggregate of 2,517,935 shares of our common stock outstanding under the 2016 Plan and 317,065 shares available for future grants under the 2016 Plan.

1999 Stock Incentive Plan

VistaGen California's Board of Directors adopted the 1999 Plan on December 6, 1999. The 1999 Plan terminated under its own terms in December 2009, and as a result, no awards may currently be granted under the 1999 Plan. However, the options and awards that have been granted pursuant to the 1999 Plan prior to its expiration remain operative.

The 1999 Plan permitted VistaGen California to make grants of incentive stock options, non-qualified stock options and restricted stock awards. VistaGen California initially reserved 22,500 restricted shares of its common stock for the issuance of awards under the 1999 Plan, which number was subject to adjustment in the event of a stock split, stock dividend or other change in capitalization. Prior to the 1999 Plan's expiration, shares that were forfeited or cancelled from awards under the 1999 Plan were generally available for future awards.

The 1999 Plan could be administered by either VistaGen California's Board of Directors or a committee designated by its Board of Directors. VistaGen California's Board of Directors designated its Compensation Committee as the committee with full power and authority to select the participants to whom awards were granted, to make any combination of awards to participants, to accelerate the exercisability or vesting of any award and to determine the specific terms and conditions of each award, subject to the provisions of the 1999 Plan. All directors, executive officers, and certain other key persons (including employees, consultants and advisors) of VistaGen California were eligible to participate in the 1999 Plan.

The exercise price of incentive stock options awarded under the 1999 Plan could not be less than the fair market value of the common stock on the date of the option grant and could not be less than 110% of the fair market value of the common stock to persons owning stock representing more than 10% of the voting power of all classes of our stock. The exercise price of non-qualified stock options could not be less than 85% of the fair market value of the common stock. The term of each option granted under the 1999 Plan could not exceed ten years (or five years, in the case of an incentive stock option granted to a 10% stockholder) from the date of grant. VistaGen California's Compensation Committee determined at what time or times each option might be exercised (provided that in no event could it exceed ten years from the date of grant) and, subject to the provisions of the 1999 Plan, the period of time, if any, after retirement, death, disability or other termination of employment during which options could be exercised.

The 1999 Plan also permitted the issuance of restricted stock awards. Restricted stock awards issued by VistaGen California were shares of common stock that vest in accordance with terms and conditions established by VistaGen California's Compensation Committee. The Compensation Committee could impose conditions to vesting that it determined to be appropriate. Shares of restricted stock that did not vest were subject to our right of repurchase or forfeiture. VistaGen California's Compensation Committee determined the number of shares of restricted stock granted to any employee. Our 1999 Plan also gave VistaGen California's Compensation Committee discretion to grant stock awards free of any restrictions.

Unless the Compensation Committee provided otherwise, the 1999 Plan did not generally allow for the transfer of incentive stock options and other awards and only the recipient of an award could exercise an award during his or her lifetime. Non-qualified stock options were transferable only to the extent provided in the award agreement, in a manner consistent with the applicable law, and by will and by the laws of descent and distribution. In the event of a change in control of the Company, as defined in the 1999 Plan, the outstanding options will automatically vest unless our Board of Directors and the Board of Directors of the surviving or acquiring entity make appropriate provisions for the continuation or assumption of any outstanding awards under the 1999 Plan.

As of June 27, 2017, we have options outstanding under the 1999 Plan to purchase an aggregate of 4,658 shares of our common stock, the last of which, if not exercised before, expire in March 2018.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Sales of Securities to Cato Holding Company

Cato Holding Company (*CHC*), doing business as Cato BioVentures (*CBV*), the parent of Cato Research Ltd. (*CRL*), was one of our largest institutional common stockholders at March 31, 2017, holding approximately 7% of our outstanding common stock. Shawn Singh, our Chief Executive Officer and member of our Board of Directors, served as Managing Principal of CBV and as an officer of CRL from February 2001 until August 2009. In October 2012, we issued to CHC an unsecured promissory note in the principal amount of \$310,443 (the *2012 CHC Note*) and a five-year warrant to purchase 12,500 restricted shares of the Company's common stock at a price of \$30.00 per share (the *CHC Warrant*).

Also in October 2012, we issued to CRL: (i) an unsecured promissory note in the initial principal amount of \$1,009,000, which was payable solely in restricted shares of our common stock and which accrued interest at the rate of 7.5% per annum, compounded monthly (the *CRL Note*), as payment in full for all contract research and development services and regulatory advice rendered to us by CRL through December 31, 2012 with respect to the preclinical and clinical development of AV-101, and (ii) a five-year warrant to purchase, at a price of \$20.00 per share, 50,450 restricted shares of our common stock (*CRL Warrant*). Each of the CRL Note and 2012 CHC Note were scheduled to mature on March 31, 2016. In June 2015, the outstanding balance of the 2012 CHC Note, the CRL Note and all other outstanding amounts owed to CRL for CRO services were converted into 328,571 shares of our Series B Preferred, and the exercise prices of the CHC Warrant and the CRL Warrant were each reduced to \$7.00 per share. CHC participated in the February 2016 warrant exchange for common stock, exchanging the CHC Warrant and the CRL Warrant, as adjusted to reflect accrued interest, for an aggregate of 54,894 shares of our unregistered common stock. In May 2016, subsequent to our consummation of the May 2016 Public Offering, all of the shares of Series B Preferred held by CHC were automatically converted into shares of our registered common stock.

Contract Research and Development Agreement with Cato Research Ltd.

During 2007, we entered into a contract research organization arrangement with CRL related to the development of AV-101, under which we incurred expenses of \$254,600 and \$52,600 for the fiscal years ended March 31, 2017 and 2016, respectively.

Item 14. Principal Accounting Fees and Services.

Fees and Services

OUM & Co. LLP (*OUM*) served as our independent registered public accounting firm for the fiscal years ended March 31, 2017 and March 31, 2016. Information provided below includes fees for professional services provided to us by OUM for the fiscal years ended March 31, 2017 and 2016.

	Fiscal Years Ended	
	March 31,	
	2017	2016
Audit fees	\$ 204,250	\$ 197,180
Audit-related fees	69,250	23,016
Tax fees	16,000	15,925
All other fees	-	-
Total fees	<u>\$ 289,500</u>	<u>\$ 236,121</u>

Audit Fees:

Audit fees include fees billed for the annual audit of the Company's financial statements and quarterly reviews for the fiscal years ended March 31, 2017 and 2016, and for services normally provided by OUM in connection with routine statutory and regulatory filings or engagements.

Audit-Related Fees:

Audit-related fees includes fees billed for assurance and related services that are reasonably related to the performance of the annual audit or reviews of the Company's financial statements and are not reported under "Audit Fees." During the fiscal year ended March 31, 2017 and 2016, OUM billed the Company for services related to consents for the use of its audit opinion in the Company's filings of Registration Statements on Form S-3 and Form S-1 that included the Company's audited financial statements for the fiscal year ended March 31, 2016 and 2015.

Tax Fees:

Tax fees include fees for professional services for tax compliance, tax advice and tax planning for the tax years ended March 31, 2017 and 2016.

All Other Fees:

All other fees include fees for products and services other than those described above. During the fiscal years ended March 31, 2017 and 2016, no such fees were billed by OUM.

Pre-Approval of Audit and Non-Audit Services

All auditing services and non-audit services provided to us by our independent registered public accounting firm are required to be pre-approved by the Audit Committee. OUM did not provide any non-audit-related or other services in Fiscal 2017 and 2016. The pre-approval of non-audit services to be provided by OUM includes making a determination that the provision of the services is compatible with maintaining OUM's independence as an independent registered public accounting firm and would be approved in accordance with SEC rules for maintaining auditor independence. None of the fees outlined above were approved using the "de minimis exception" under SEC rules.

Report of the Audit Committee of the Board of Directors

The Audit Committee has reviewed and discussed with management and OUM & Co. LLP (*OUM*), our independent registered public accounting firm, the audited consolidated financial statements in the VistaGen Therapeutics, Inc. Annual Report on Form 10-K for the year ended March 31, 2017. The Audit Committee has also discussed with OUM those matters required to be discussed by Public Company Accounting Oversight Board Auditing Standard No. 16.

OUM also provided the Audit Committee with the written disclosures and the letter required by the applicable requirements of the PCAOB regarding the independent auditor's communication with the Audit Committee concerning independence. The Audit Committee has discussed with the registered public accounting firm their independence from our company.

Based on its discussions with management and the registered public accounting firm, and its review of the representations and information provided by management and the registered public accounting firm, including as set forth above, the Audit Committee recommended to our Board of Directors that the audited financial statements be included in our Annual Report on Form 10-K for the year ended March 31, 2017.

Respectfully Submitted by:

MEMBERS OF THE AUDIT COMMITTEE

Jon S. Saxe, Audit Committee Chairman

Brian J. Underdown

Jerry B. Gin

Dated: June 22, 2017

The information contained above under the caption "Report of the Audit Committee of the Board of Directors" shall not be deemed to be soliciting material or to be filed with the SEC, nor shall such information be incorporated by reference into any future filing under the Securities Act or the Exchange Act, except to the extent that we specifically incorporate it by reference into such filing.

PART IV**Item 15. Exhibits, Financial Statement Schedules****(a)(1) Financial Statements**

See Index to Financial Statements under Item 8 on page 66.

(a)(2) Consolidated Financial Statement Schedules

Consolidated financial statement schedules are omitted because they are not applicable or are not required or the information required to be set forth therein is included in the Consolidated Financial Statements or notes thereto.

(a)(3) Exhibits

The exhibits listed in the Exhibit Index below are filed or incorporated by reference as part of this report.

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
2.1 *	Agreement and Plan of Merger by and among Excaliber Enterprises, Ltd., VistaGen Therapeutics, Inc. and Excaliber Merger Subsidiary, Inc.
3.1 *	Articles of Incorporation, dated October 6, 2005.
3.2	Certificate of Amendment filed with the Nevada Secretary of State on December 6, 2011, incorporated by reference from Exhibit 3.3 to the Company's Annual Report on Form 10-K, filed July 2, 2012.
3.3	Amended and Restated Bylaws as of February 5, 2014, incorporated by reference from the Company's Report on Form 8-K filed on February 7, 2014.
3.4	Articles of Merger filed with the Nevada Secretary of State on May 24, 2011, incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K filed on May 31, 2011.
3.5	Certificate of Designations Series A Preferred, incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K filed on December 23, 2011.
3.6	Certificate of Change filed with the Nevada Secretary of State on August 11, 2014 incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K filed on August 14, 2014.
3.7	Certificate of Designation of the Relative Rights and Preferences of the Series B 10% Convertible Preferred Stock of VistaGen Therapeutics, Inc., filed with the Nevada Secretary of State on May 7, 2015, incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K filed on May 13, 2015.
3.8	Certificate of Amendment to the Articles of Incorporation of VistaGen Therapeutics, Inc., dated August 24, 2015, incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K filed on August 25, 2015.
3.9	Certificate of Designation of the Relative Rights and Preferences of the Series C Convertible Preferred Stock of VistaGen Therapeutics, Inc., dated January 25, 2016, incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K filed on January 29, 2016.
3.10	Restated Articles of Incorporation of VistaGen Therapeutics, Inc., dated August 16, 2016, incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K, filed on August 16, 2016.
3.11	Second Amended and Restated Bylaws of VistaGen Therapeutics, Inc., dated August 16, 2016, incorporated by reference from Exhibit 3.2 to the Company's Current Report on Form 8-K, filed on August 16, 2016.
10.1 *	VistaGen's 1999 Stock Incentive Plan.
10.5 *	VistaGen's 2008 Stock Incentive Plan.
10.20 *	Strategic Development Services Agreement, dated February 26, 2007, by and between VistaGen and Cato Research Ltd.
10.22 *	License Agreement by and between Mount Sinai School of Medicine of New York University and the Company, dated October 1, 2004.
10.23 *	Non-Exclusive License Agreement, dated December 5, 2008, by and between VistaGen and Wisconsin Alumni Research Foundation, as amended by that certain Wisconsin Materials Addendum, dated February 2, 2009.
10.24 *	Sponsored Research Collaboration Agreement, dated September 18, 2007, between VistaGen and University Health Network, as amended by that certain Amendment No. 1 and Amendment No. 2, dated April 19, 2010 and December 15, 2010, respectively.
10.26 *	License Agreement, dated October 24, 2001, by and between the University of Maryland, Baltimore, Cornell Research Foundation and Artemis Neuroscience, Inc.
10.31 *	Unsecured Promissory Note dated April 28, 2011 issued by VistaGen to Desjardins Securities.
10.32 *	Unsecured Promissory Note dated April 28, 2011 issued by VistaGen to McCarthy Tetrault LLP.
10.34 *	Promissory Note dated February 25, 2010 issued by VistaGen to The Regents of the University of California.

10.40 *	Employment Agreement, by and between, VistaGen and Shawn K. Singh, dated April 28, 2010, as amended May 9, 2011.
10.41 *	Employment Agreement, by and between, VistaGen and H. Ralph Snodgrass, PhD, dated April 28, 2010, as amended May 9, 2011.
10.46	Notice of Award by National Institutes of Health, Small Business Innovation Research Program, to VistaGen Therapeutics, Inc. for project, Clinical Development of 4-CI-KYN to Treat Pain dated June 22, 2009, with revisions dated July 19, 2010 and August 9, 2011, incorporated by reference from Exhibit 10.46 to the Company's Current Report on Form 8-K/A filed on December 20, 2011.
10.47	Notice of Grant Award by California Institute of Regenerative Medicine and VistaGen Therapeutics, Inc. for Project: Development of an hES Cell-Based Assay System for Hepatocyte Differentiation Studies and Predictive Toxicology Drug Screening, dated April 1, 2009, incorporated by reference from Exhibit 10.47 to the Company's Current Report on Form 8-K/A filed on December 20, 2011.
10.48	Amendment No. 4, dated October 24, 2011, to Sponsored Research Collaboration Agreement between VistaGen and University Health Network, incorporated by reference from Exhibit 10.2 to the Company's Current Report on Form 8-K filed on November 30, 2011.
10.49	License Agreement No. 1, dated as of October 24, 2011 between University Health Network and VistaGen Therapeutics, Inc., incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 30, 2011.
10.50	Strategic Medicinal Chemistry Services Agreement, dated as of December 6, 2011, between Synterics, Inc. and VistaGen Therapeutics, Inc., incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 7, 2011.
10.51	Common Stock Exchange Agreement, dated as of December 22, 2011 between Platinum Long Term Growth VII, LLC and VistaGen Therapeutics, Inc., incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 23, 2011.
10.52	Note and Warrant Exchange Agreement, dated as of December 28, 2011 between Platinum Long Term Growth VII, LLC and VistaGen Therapeutics, Inc., incorporated by reference from Exhibit 10.1 to the Current Report on Form 8-K filed on January 4, 2012.
10.55	Form of Warrant to Purchase Common Stock, dated as of February 28, 2012, incorporated by reference from Exhibit 10.3 to the Company's Current Report on Form 8-K filed on March 2, 2012.
10.57	License Agreement No. 2, dated as of March 19, 2012 between University Health Network and VistaGen Therapeutics, Inc., incorporated by reference from Exhibit 10.57 to the Company's Annual Report on Form 10-K filed on July 2, 2012.
10.58	Exchange Agreement dated as of June 29, 2012 between Platinum Long Term Growth VII, LLC and VistaGen Therapeutics, Inc., incorporated by reference from Exhibit 10.58 to the Company's Annual Report on Form 10-K filed on July 2, 2012.
10.63	Unsecured Promissory Note in the face amount of \$1,000,000 issued to Morrison & Foerster LLP on August 31, 2012 (Replacement Note A), incorporated by reference from Exhibit 10.3 to the Company's Current Report on Form 8-K filed on September 6, 2012.
10.64	Unsecured Promissory Note in the face amount of \$1,379,376 issued to Morrison & Foerster LLP on August 31, 2012 (Replacement Note B), incorporated by reference from Exhibit 10.4 to the Company's Current Report on Form 8-K filed on September 6, 2012.
10.65	Stock Purchase Warrant issued to Morrison & Foerster LLP on August 31, 2012 to purchase 1,379,376 shares of the Company's common stock (New Morrison & Foerster Warrant), incorporated by reference from Exhibit 10.5 to the Company's Current Report on Form 8-K filed on September 6, 2012.
10.66	Warrant to Purchase Common Stock issued to Morrison & Foerster LLP on August 31, 2012 to purchase 425,000 shares of the Company's common stock (Amended Morrison & Foerster Warrant), incorporated by reference from Exhibit 10.6 to the Company's Current Report on Form 8-K filed on September 6, 2012.
10.67	Note Exchange and Purchase Agreement dated as of October 11, 2012 by and between VistaGen Therapeutics, Inc. and Platinum Long Term Growth VII, LLP, incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 16, 2012.
10.68	Form of Senior Secured Convertible Promissory Note issued to Platinum Long Term Growth VII, LLP under the Note Exchange and Purchase Agreement, incorporated by reference from Exhibit 10.2 to the Company's Current Report on Form 8-K filed on October 16, 2012.
10.69	Form of Warrant to Purchase Shares of Common Stock issued to Platinum Long Term Growth VII, LLP under the Note Exchange and Purchase Agreement, incorporated by reference from Exhibit 10.3 to the Company's Current Report on Form 8-K filed on October 16, 2012.
10.70	Amended and Restated Security Agreement as of October 11, 2012 between VistaGen Therapeutics, Inc. and Platinum Long Term Growth VII, LLP, incorporated by reference from Exhibit 10.4 to the Company's Current Report on Form 8-K filed on October 16, 2012.
10.71	Intellectual Property Security and Stock Pledge Agreement as of October 11, 2012 between VistaGen California and Platinum Long Term Growth VII, LLP, incorporated by reference from Exhibit 10.5 to the Company's Current Report on Form 8-K filed on October 16, 2012.

10.72	Negative Covenant Agreement dated October 11, 2012 between VistaGen California, Artemis Neuroscience, Inc. and Platinum Long Term Growth VII, LLP, incorporated by reference from Exhibit 10.6 to the Company's Current Report on Form 8-K filed on October 16, 2012.
10.73	Amendment to Note Exchange and Purchase Agreement as of November 14, 2012 between VistaGen Therapeutics Inc. and Platinum Long Term Growth VII, LLP, incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 20, 2012.
10.75	Amendment No. 2 to Note Exchange and Purchase Agreement as of January 31, 2013 between VistaGen Therapeutics Inc. and Platinum Long Term Growth VII, LLP, incorporated by reference from Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on February 14, 2013.
10.76	Amendment No. 3 to Note Exchange and Purchase Agreement as of February 22, 2013 between VistaGen Therapeutics Inc. and Platinum Long Term Growth VII, LLP, incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K filed on February 28, 2013.
10.77	Form of Warrant to Purchase Common Stock issued to independent members of the Company's Board of Directors and its executive officers on March 3, 2013, incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K filed on March 6, 2013.
10.80	Note Conversion Agreement as of April 4, 2013 between VistaGen Therapeutics Inc. and Platinum Long Term Growth VII, LLP, incorporated by reference from Exhibit 10.3 to the Company's Current Report on Form 8-K filed on April 10, 2013.
10.83	Lease between Bayside Area Development, LLC and VistaGen Therapeutics, Inc. (California) dated April 24, 2013, incorporated by reference from Exhibit 10.83 to the Company's Annual Report on Form 10-K filed July 18, 2013.
10.84	Indemnification Agreement effective May 20, 2013 between the Company and Jon S. Saxe, incorporated by reference from Exhibit 10.84 to the Company's Annual Report on Form 10-K filed on July 18, 2013.
10.85	Indemnification Agreement effective May 20, 2013 between the Company and Shawn K. Singh, incorporated by reference from Exhibit 10.85 to the Company's Annual Report on Form 10-K filed on July 18, 2013.
10.86	Indemnification Agreement effective May 20, 2013 between the Company and H. Ralph Snodgrass, incorporated by reference from Exhibit 10.86 to the Company's Annual Report on Form 10-K filed on July 18, 2013.
10.87	Indemnification Agreement effective May 20, 2013 between the Company and Brian J. Underdown, incorporated by reference from Exhibit 10.87 to the Company's Annual Report on Form 10-K filed on July 18, 2013.
10.88	Indemnification Agreement effective May 20, 2013 between the Company and Jerrold D. Dotson, incorporated by reference from Exhibit 10.88 to the Company's Annual Report on Form 10-K filed on July 18, 2013.
10.89	Amendment and Waiver effective May 24, 2013 between the Company and Platinum Long Term Growth VII, LLC, incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 3, 2013.
10.90	Amendment No 2 to Securities Purchase Agreement dated June 27, 2013 between the Company, Autilion AG and Bergamo Acquisition Corp. PTE LTD, incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 28, 2013.
10.91	Senior Secured Convertible Promissory Note, dated July 26, 2013 issued to Platinum Long Term Growth VII, LLP, incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K filed on August 2, 2013.
10.92	Common Stock Warrant, dated July 26, 2013 issued to Platinum Long Term Growth VII, LLP, incorporated by reference from Exhibit 10.2 to the Company's Current Report on Form 8-K filed on August 2, 2013.
10.93	Form of Subscription Agreement between the Company and investors in the Fall 2013 Unit Private Placement, incorporated by reference from Exhibit 10.93 to the Company's Annual Report on Form 10-K filed on June 24, 2014.
10.94	Form of Convertible Promissory Note between the Company and investors in the Fall 2013 Unit Private Placement, incorporated by reference from Exhibit 10.94 to the Company's Annual Report on Form 10-K filed on June 24, 2014.
10.95	Form of Common Stock Purchase Warrant between the Company and investors in the Fall 2013 Unit Private Placement, incorporated by reference from Exhibit 10.95 to the Company's Annual Report on Form 10-K filed on June 24, 2014.
10.96	Form of Amendment to Convertible Promissory Note and Warrant between the Company and investors in the Fall 2013 Unit Private Placement, effective May 31, 2014, incorporated by reference from Exhibit 10.96 to the Company's Annual Report on Form 10-K filed on June 24, 2014.
10.97	Form of Unit Subscription Agreement between the Company and investors in the Spring 2014 Unit Private Placement dated April 1, 2014, incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 8, 2014.
10.98	Form of Subordinate Convertible Promissory Note between the Company and investors in the Spring 2014 Unit Private Placement dated April 1, 2014, incorporated by reference from Exhibit 10.2 to the Company's Current Report on Form 8-K filed on April 8, 2014.
10.99	Form of Common Stock Purchase Warrant between the Company and investors in the Spring 2014 Unit Private Placement dated April 1, 2014, incorporated by reference from Exhibit 10.3 to the Company's Current Report on Form 8-K filed on April 8, 2014.

10.100	Common Stock Purchase Warrant between the Company and Platinum Long Term Growth Fund VII dated May 14, 2014, incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K filed on May 19, 2014.
10.101	Subordinate Convertible Promissory Note between the Company and Platinum Long Term Growth Fund VII dated May 14, 2014, incorporated by reference from Exhibit 10.2 to the Company's Current Report on Form 8-K filed on May 19, 2014.
10.102	Form of Promissory Note and Form of Warrant issued by the Company to Icahn School of Business at Mount Sinai effective April 10, 2014 in satisfaction of technology license maintenance fees and reimbursable patent costs, incorporated by reference from Exhibit 10.102 to the Company's Annual Report on Form 10-K filed on June 24, 2014.
10.103	Amendment No. 3 to Sponsored Research Collaboration Agreement, dated April 25, 2011, by and between VistaGen and University Health Network, incorporated by reference from Exhibit 10.103 to the Company's Annual Report on Form 10-K filed on June 24, 2014.
10.104	Amendment No. 5 to Sponsored Research Collaboration Agreement, dated October 10, 2012, by and between VistaGen and University Health Network, incorporated by reference from Exhibit 10.104 to the Company's Annual Report on Form 10-K filed on June 24, 2014.
10.105	Amended and Restated Note Conversion Agreement and Warrant Amendment, by and between VistaGen Therapeutics, Inc. and Platinum Long Term Growth VII, LLC, dated July 18, 2014, incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 22, 2014.
10.106	Amendment No. 1 to Amended and Restated Note Conversion Agreement and Warrant Amendment, by and between VistaGen Therapeutics, Inc. and Platinum Long Term Growth VII, LLC, dated September 2, 2014, incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K filed on September 4, 2014.
10.107	Amendment No. 2 to Amended and Restated Note Conversion Agreement and Warrant Amendment, by and between VistaGen Therapeutics, Inc. and Platinum Long Term Growth VII, LLC, dated September 30, 2014, incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 3, 2014.
10.108	Agreement, by and between VistaGen Therapeutics, Inc. and Platinum Long Term Growth VII, LLC, dated May 5, 2015, incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K filed on May 13, 2015.
10.109	Acknowledgement and Agreement, by and between VistaGen Therapeutics, Inc. and Platinum Long Term Growth VII, LLC, dated May 12, 2015, incorporated by reference from Exhibit 10.2 to the Company's Current Report on Form 8-K filed on May 13, 2015.
10.110	Form of Securities Purchase Agreement by and between VistaGen Therapeutics, Inc. and Platinum Long Term Growth VII, LLC, dated May 12, 2015, incorporated by reference from Exhibit 10.3 to the Company's Current Report on Form 8-K filed on May 13, 2015.
10.111	Exchange Agreement, by and between VistaGen Therapeutics, Inc., and Platinum Long Term Growth VII, LLC and Montsant Partners, LLC, dated January 25, 2016, incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 29, 2016.
10.112	Indemnification Agreement effective April 8, 2016 between the Company and Jerry B. Gin, incorporated by reference from Exhibit 10.112 to the Company's Annual Report on Form 10-K filed on June 24, 2016.
10.113	Underwriting Agreement, by and between Chardan Capital Markets, LLC and WallachBeth Capital, LLC, as representatives of the several underwriters, and VistaGen Therapeutics, Inc., dated May 10, 2016, incorporated by reference from Exhibit 1.1 to the Company's Current Report on Form 8-K filed on May 16, 2016.
10.114	Warrant Agency Agreement, by and between Computershare, Inc. and VistaGen Therapeutics, Inc., dated May 16, 2016, incorporated by reference from Exhibit 4.1 to the Company's Current Report on Form 8-K filed on May 16, 2016.
10.115	Form of Warrant; incorporated by reference from Exhibit 4.2 to the Company's Current Report on Form 8-K filed on May 16, 2016.
10.116	Second Amendment to Employment Agreement by and between VistaGen Therapeutics, Inc. and Shawn K. Singh, dated June 22, 2016, incorporated by reference from Exhibit 10.116 to the Company's Annual Report on Form 10-K filed on June 24, 2016.
10.117	Second Amendment to Employment Agreement by and between VistaGen Therapeutics, Inc. and H. Ralph Snodgrass, Ph.D., dated June 22, 2016, incorporated by reference from Exhibit 10.117 to the Company's Annual Report on Form 10-K filed on June 24, 2016.
10.118	Second Amendment to Lease between Bayside Area Development and the Company, effective November 10, 2016, incorporated by reference from Exhibit 10.1 to the Company's Quarterly report on Form 10-Q filed on November 15, 2016.
10.119	Indemnification Agreement effective November 10, 2016 between the Company and Mark A. Smith, incorporated by reference from Exhibit 10.2 to the Company's Quarterly report on Form 10-Q filed on November 15, 2016.

10.120 +	Exclusive License and Sublicense Agreement by and between VistaGen Therapeutics, Inc. and Apollo Biologics LP, effective December 9, 2016, incorporated by reference from Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on May 11, 2017.
10.121 +	Patent License Amendment Agreement between VistaGen Therapeutics Inc. and University Health Network effective December 9, 2016, incorporated by reference from Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q/A filed on May 1, 2017.
10.122	Amended and Restated 2016 Stock Incentive Plan, filed herewith.
21.1*	List of Subsidiaries.
23.1	Consent of Independent Registered Public Accounting Firm, filed herewith.
31.1	Certification of the Company's Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of the Company's Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Company's Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase

* Incorporated by reference from the like-numbered exhibit filed with our Current Report on Form 8-K on May 16, 2011.

+ Confidential treatment has been granted for certain confidential portions of this agreement.

SIG NATURES

Pursuant to the requirements of Section 13 or 15(d) 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, in the City of South San Francisco, State of California, on the 28th day of June, 2017

VistaGen Therapeutics, Inc.

Date: June 28, 2017

By: /s/ Shawn K. Singh
Shawn K. Singh, J.D.
Chief Executive Officer

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
<u>/s/ Shawn K. Singh</u> Shawn K. Singh, JD	Chief Executive Officer, and Director <i>(Principal Executive Officer)</i>	June 28, 2017
<u>/s/ Jerrold D. Dotson</u> Jerrold D. Dotson	Vice President and Chief Financial Officer <i>(Principal Financial and Accounting Officer)</i>	June 28, 2017
<u>/s/ H. Ralph Snodgrass</u> H. Ralph Snodgrass, Ph.D	President, Chief Scientific Officer and Director	June 28, 2017
<u>/s/ Jon S. Saxe</u> Jon S. Saxe	Chairman of the Board of Directors	June 28, 2017
<u>/s/ Brian J. Underdown</u> Brian J. Underdown, Ph. D	Director	June 28, 2017
<u>/s/ Jerry B. Gin, Ph.D</u> Jerry B. Gin, Ph.D.	Director	June 28, 2017

VISTAGEN THERAPEUTICS, INC.
AMENDED AND RESTATED
2016 STOCK INCENTIVE PLAN
(formerly, the 2008 Stock Incentive Plan)

1. Purposes of the Plan. The purposes of this Plan are to attract and retain the best available personnel, to provide additional incentives to Employees, Directors and Consultants and to promote the success of the Company's business.

2. Definitions. The following definitions shall apply as used herein and in the individual Award Agreements, except as defined otherwise in an individual Award Agreement. In the event a term is separately defined in an individual Award Agreement, such definition shall supersede the definition contained in this Section 2.

(b) "Affiliate" and "Associate" shall have the respective meanings ascribed to such terms in Rule 12b-2 promulgated under the Exchange Act.

(c) "Applicable Laws" means the legal requirements relating to the Plan and the Awards under applicable provisions of federal and state securities laws, the corporate laws of California and, to the extent other than California, the corporate law of the state of the Company's incorporation, the Code, the NASDAQ Stock Market Rules or the rules of any applicable stock exchange or national market system, and the rules of any non-U.S. jurisdiction applicable to Awards granted to residents therein.

(d) "Assumed" means that pursuant to a Corporate Transaction either (i) the Award is expressly affirmed by the Company or (ii) the contractual obligations represented by the Award are expressly assumed (and not simply by operation of law) by the successor entity or its Parent in connection with the Corporate Transaction with appropriate adjustments to the number and type of securities of the successor entity or its Parent subject to the Award and the exercise or purchase price thereof which at least preserves the compensation element of the Award existing at the time of the Corporate Transaction as determined in accordance with the instruments evidencing the agreement to assume the Award.

(e) "Award" means the grant of an Option, SAR, Dividend Equivalent Right, Restricted Stock, Restricted Stock Unit or other right or benefit under the Plan.

(f) "Award Agreement" means the written agreement evidencing the grant of an Award executed by the Company and the Grantee, including any amendments thereto.

(g) "Board" means the Board of Directors of the Company.

(h) "Cause" means, with respect to the termination by the Company or a Related Entity of the Grantee's Continuous Service, that such termination is for "Cause" as such term (or word of like import) is expressly defined in a then-effective written agreement between the Grantee and the Company or such Related Entity, or in the absence of such then-effective written agreement and definition, is based on, in the determination of the Committee, the Grantee's: (i) performance of any act or failure to perform any act in bad faith and to the detriment of the Company or a Related Entity; (ii) dishonesty, intentional misconduct or material breach of any agreement with the Company or a Related Entity; or (iii) commission of a crime involving dishonesty, breach of trust, or physical or emotional harm to any person; provided, however, that with regard to any agreement that defines "Cause" on the occurrence of or in connection with a Corporate Transaction or a Change in Control, such definition of "Cause" shall not apply until a Corporate Transaction or a Change in Control actually occurs.

(i) "Change in Control" means a change in ownership or control of the Company effected through either of the following transactions:

(i) the direct or indirect acquisition by any person or related group of persons (other than an acquisition from or by the Company or by a Company-sponsored employee benefit plan or by a person that directly or indirectly controls, is controlled by, or is under common control with, the Company) of beneficial ownership (within the meaning of Rule 13d-3 of the Exchange Act) of securities possessing more than fifty percent (50%) of the total combined voting power of the Company's outstanding securities pursuant to a tender or exchange offer made directly to the Company's shareholders which a majority of the Continuing Directors who are not Affiliates or Associates of the offeror do not recommend such shareholders accept, or

(ii) a change in the composition of the Board over a period of twelve (12) months or less such that a majority of the Board members (rounded up to the next whole number) ceases, by reason of one or more contested elections for Board membership, to be comprised of individuals who are Continuing Directors.

(j) "Code" means the Internal Revenue Code of 1986, as amended.

(k) "Committee" means the Compensation Committee of the Board of Directors, appointed by the Board to administer the Plan.

(l) "Common Stock" means the common stock, par value \$0.001 per share, of the Company.

(m) "Company" means VistaGen Therapeutics, Inc., a Nevada corporation, or any successor entity that adopts the Plan in connection with a Corporate Transaction.

(n) "Consultant" means any person (other than an Employee or a Director, solely with respect to rendering services in such person's capacity as a Director) who is engaged by the Company or any Related Entity to render consulting or advisory services to the Company or such Related Entity.

(o) "Continuing Directors" means members of the Board who either (i) have been Board members continuously for a period of at least twelve (12) months or (ii) have been Board members for less than twelve (12) months and were elected or nominated for election as Board members by at least a majority of the Board members described in clause (i) who were still in office at the time such election or nomination was approved by the Board.

(p) "Continuous Service" means that the provision of services to the Company or a Related Entity in any capacity of Employee, Director or Consultant is not interrupted or terminated. In jurisdictions requiring notice in advance of an effective termination as an Employee, Director or Consultant, Continuous Service shall be deemed terminated upon the actual cessation of providing services to the Company or a Related Entity notwithstanding any required notice period that must be fulfilled before a termination as an Employee, Director or Consultant can be effective under Applicable Laws. A Grantee's Continuous Service shall be deemed to have terminated either upon an actual termination of Continuous Service or upon the entity for which the Grantee provides services ceasing to be a Related Entity. Continuous Service shall not be considered interrupted in the case of (i) any approved leave of absence, (ii) transfers among the Company, any Related Entity, or any successor, in any capacity of Employee, Director or Consultant, or (iii) any change in status as long as the individual remains in the service of the Company or a Related Entity in any capacity of Employee, Director or Consultant (except as otherwise provided in the Award Agreement). An approved leave of absence shall include sick leave, military leave, or any other authorized personal leave. For purposes of each Incentive Stock Option granted under the Plan, if such leave exceeds three (3) months, and reemployment upon expiration of such leave is not guaranteed by statute or contract, then the Incentive Stock Option shall be treated as a Non-Qualified Stock Option on the day three (3) months and one (1) day following the expiration of such three (3) month period.

(q) "Corporate Transaction" means any of the following transactions, provided, however, that the Committee shall determine under parts (iv) and (v) whether multiple transactions are related, and its determination shall be final, binding and conclusive:

(i) a merger or consolidation in which the Company is not the surviving entity, except for a transaction the principal purpose of which is to change the state in which the Company is incorporated;

(ii) the sale, transfer or other disposition of all or substantially all of the assets of the Company;

(iii) the complete liquidation or dissolution of the Company;

(iv) any reverse merger or series of related transactions culminating in a reverse merger (including, but not limited to, a tender offer followed by a reverse merger) in which the Company is the surviving entity but (A) the shares of Common Stock outstanding immediately prior to such merger are converted or exchanged by virtue of the merger into other property, whether in the form of securities, cash or otherwise, or (B) in which securities possessing more than forty percent (50%) of the total combined voting power of the Company's outstanding securities are transferred to a person or persons different from those who held such securities immediately prior to such merger or the initial transaction culminating in such merger; or

(v) acquisition in a single or series of related transactions by any person or related group of persons (other than the Company or by a Company-sponsored employee benefit plan) of beneficial ownership (within the meaning of Rule 13d-3 of the Exchange Act) of securities possessing more than fifty percent (50%) of the total combined voting power of the Company's outstanding securities but excluding any such transaction or series of related transactions that the Committee determines shall not be a Corporate Transaction.

(r) "Covered Employee" means an Employee who is a "covered employee" under Section 162(m)(3) of the Code.

(s) "Director" means a member of the Board or the board of directors of any Related Entity.

(t) "Disability," means as defined under the long-term disability policy of the Company or the Related Entity to which the Grantee provides services regardless of whether the Grantee is covered by such policy. If the Company or the Related Entity to which the Grantee provides service does not have a long-term disability plan in place, "Disability" means that a Grantee is unable to carry out the responsibilities and functions of the position held by the Grantee by reason of any medically determinable physical or mental impairment for a period of not less than ninety (90) consecutive days. A Grantee will not be considered to have incurred a Disability unless he or she furnishes proof of such impairment sufficient to satisfy the Committee in its discretion.

(u) "Dividend Equivalent Right" means a right entitling the Grantee to compensation measured by dividends paid with respect to Common Stock.

(v) "Employee" means any person, including an Officer or Director, who is in the employ of the Company or any Related Entity, subject to the control and direction of the Company or any Related Entity as to both the work to be performed and the manner and method of performance. The payment of a director's fee by the Company or a Related Entity shall not be sufficient to constitute "employment" by the Company.

(w) "Exchange Act" means the Securities Exchange Act of 1934, as amended.

(x) "Fair Market Value" means, as of any date, the value of Common Stock determined as follows:

(i) If the Common Stock is listed on one or more established stock exchanges or national market systems, including without limitation The NASDAQ Global Select Market, The NASDAQ Global Market or The NASDAQ Capital Market of The NASDAQ Stock Market LLC, its Fair Market Value shall be the closing sales price for such stock (or the closing bid, if no sales were reported) as quoted on the principal exchange or system on which the Common Stock is listed (as determined by the Committee) on the date of determination (or, if no closing sales price or closing bid was reported on that date, as applicable, on the last trading date such closing sales price or closing bid was reported), as reported in The Wall Street Journal or such other source as the Committee deems reliable;

(ii) If the Common Stock is regularly quoted on an automated quotation system (including the OTC Bulletin Board) or by a recognized securities dealer, its Fair Market Value shall be the closing sales price for such stock as quoted on such system or by such securities dealer on the date of determination, but if selling prices are not reported, the Fair Market Value of a share of Common Stock shall be the mean between the high bid and low asked prices for the Common Stock on the date of determination (or, if no such prices were reported on that date, on the last date such prices were reported), as reported in The Wall Street Journal or such other source as the Committee deems reliable; or

(iii) In the absence of an established market for the Common Stock of the type described in (i) and (ii), above, the Fair Market Value thereof shall be determined by the Committee in good faith and in a manner consistent with Applicable Laws.

(y) “Grantee” means an Employee, Director or Consultant who receives an Award under the Plan.

(z) “Immediate Family” means any child, stepchild, grandchild, parent, stepparent, grandparent, spouse, former spouse, sibling, niece, nephew, mother-in-law, father-in-law, son-in law, daughter-in-law, brother-in-law, or sister-in-law, including adoptive relationships, any person sharing the Grantee’s household (other than a tenant or employee), a trust in which these persons (or the Grantee) have more than fifty percent (50%) of the beneficial interest, a foundation in which these persons (or the Grantee) control the management of assets, and any other entity in which these persons (or the Grantee) own more than fifty percent (50%) of the voting interests.

(aa) “Incentive Stock Option” means an Option intended to qualify as an incentive stock option within the meaning of Section 422 of the Code.

(bb) “Independent Director” means a member of the Board that satisfies the requirements to be considered an Independent Director in accordance with NASDAQ Stock Market Rule 5605(a)(2).

(cc) “Non-Qualified Stock Option” means an Option not intended to qualify as an Incentive Stock Option.

(dd) “Officer” means a person who is an officer of the Company or a Related Entity within the meaning of Section 16 of the Exchange Act and the rules and regulations promulgated thereunder.

(ee) “Option” means an option to purchase Shares pursuant to an Award Agreement granted under the Plan.

(ff) “Parent” means a “parent corporation”, whether now or hereafter existing, as defined in Section 424(e) of the Code.

(gg) “Performance-Based Compensation” means compensation qualifying as “performance-based compensation” under Section 162(m) of the Code.

(hh) “Plan” means this Amended and Restated 2016 Stock Incentive Plan.

(ii) “Post-Termination Exercise Period” means the period specified in the Award Agreement of not less than thirty (30) days commencing on the date of termination (other than termination by the Company or any Related Entity for Cause) of the Grantee’s Continuous Service, or such longer period as may be applicable upon death or Disability.

(jj) “Related Entity” means any Parent or Subsidiary of the Company.

(kk) “Replaced” means that pursuant to a Corporate Transaction the Award is replaced with a comparable stock award or a cash incentive program of the Company, the successor entity (if applicable) or Parent of either of them which preserves the compensation element of such Award existing at the time of the Corporate Transaction and provides for subsequent payout in accordance with the same (or a more favorable) vesting schedule applicable to such Award. The determination of Award comparability shall be made by the Committee and its determination shall be final, binding and conclusive.

(ll) “Restricted Stock” means Shares issued under the Plan to the Grantee for such consideration, if any, and subject to such restrictions on transfer, rights of first refusal, repurchase provisions, forfeiture provisions, and other terms and conditions as established by the Committee.

(mm) “Restricted Stock Units” means an Award which may be earned in whole or in part upon the passage of time or the attainment of performance criteria established by the Committee and which may be settled for cash, Shares or other securities or a combination of cash, Shares or other securities as established by the Committee.

(nn) “Rule 16b-3” means Rule 16b-3 promulgated under the Exchange Act or any successor thereto.

(oo) “SAR” means a stock appreciation right entitling the Grantee to Shares or cash compensation, as established by the Committee, measured by appreciation in the value of Common Stock.

(pp) “Share” means a share of the Common Stock.

(qq) “Subsidiary” means a “subsidiary corporation”, whether now or hereafter existing, as defined in Section 424(f) of the Code.

3. Stock Subject to the Plan.

(a) Subject to the provisions of Section 10 below, the maximum aggregate number of Shares which may be issued pursuant to all Awards (including Incentive Stock Options) is three million (3,000,000) Shares. Notwithstanding the foregoing, subject to the provisions of Section 10, below, the maximum aggregate number of Shares available for grant of Incentive Stock Options shall be three million (3,000,000) Shares. The Shares to be issued pursuant to Awards may be authorized, but unissued, or reacquired Common Stock.

(b) Any Shares covered by an Award (or portion of an Award) which is forfeited, canceled or expires (whether voluntarily or involuntarily) shall be deemed not to have been issued for purposes of determining the maximum aggregate number of Shares which may be issued under the Plan. Shares that actually have been issued under the Plan pursuant to an Award shall not be returned to the Plan and shall not become available for future issuance under the Plan, except that if unvested Shares are forfeited or repurchased by the Company, such Shares shall become available for future grant under the Plan. To the extent not prohibited by the listing requirements of The NASDAQ Stock Market LLC (or other established stock exchange or national market system on which the Common Stock is traded) and Applicable Law, any Shares covered by an Award which are surrendered (i) in payment of the Award exercise or purchase price or (ii) in satisfaction of tax withholding obligations incident to the exercise of an Award shall be deemed not to have been issued for purposes of determining the maximum number of Shares which may be issued pursuant to all Awards under the Plan, unless otherwise determined by the Committee.

4. Administration of the Plan.

(a) Plan Administration.

(i) Administration by the Committee. The Plan shall be administered by the Committee. The Committee shall consist of two or more Independent Directors of the Company, who shall be appointed by the Board. In addition, the composition of the Committee shall satisfy (i) such requirements as the Securities and Exchange Commission may establish for administrators acting under plans intended to qualify for exemption under Rule 16b-3 (or its successor) under the Exchange Act; and (ii) such requirements as the Internal Revenue Service may establish for outside directors acting under plans intended to qualify for exemption under Section 162(m)(4)(C) of the Code.

(ii) Officer Authorization to Grant Awards. The Committee may authorize one or more Officers to grant Awards subject to such limitations as the Committee determines from time to time.

(b) Powers of the Committee. Subject to Applicable Laws and the provisions of the Plan (including any other powers given to the Committee hereunder), and except as otherwise provided by the Board, the Committee shall have the authority, in its discretion:

(i) to select the Employees, Directors and Consultants to whom Awards may be granted from time to time hereunder;

(ii) to determine whether and to what extent Awards are granted hereunder;

(iii) to determine the number of Shares or the amount of other consideration to be covered by each Award granted hereunder;

(iv) to approve forms of Award Agreements for use under the Plan;

(v) to determine the terms and conditions of any Award granted hereunder;

(vi) to establish additional terms, conditions, rules or procedures to accommodate the rules or laws of applicable non-U.S. jurisdictions and to afford Grantees favorable treatment under such rules or laws; provided, however, that no Award shall be granted under any such additional terms, conditions, rules or procedures with terms or conditions which are inconsistent with the provisions of the Plan;

(vii) to amend the terms of any outstanding Award granted under the Plan, provided that any amendment that would adversely affect the Grantee's rights under an outstanding Award shall not be made without the Grantee's written consent, provided, however, that an amendment or modification that may cause an Incentive Stock Option to become a Non-Qualified Stock Option shall not be treated as adversely affecting the rights of the Grantee. Notwithstanding the foregoing, (A) the reduction or increase of the exercise price of any Option awarded under the Plan and the base appreciation amount of any SAR awarded under the Plan and (B) canceling an Option or SAR at a time when its exercise price or base appreciation amount (as applicable) exceeds the Fair Market Value of the underlying Shares, in exchange for another Option, SAR, Restricted Stock, or other Award, in each case, shall not be subject to shareholder approval;

(viii) to construe and interpret the terms of the Plan and Awards, including without limitation, any notice of award or Award Agreement, granted pursuant to the Plan; and

(ix) to take such other action, not inconsistent with the terms of the Plan, as the Committee deems appropriate.

The express grant in the Plan of any specific power to the Committee shall not be construed as limiting any power or authority of the Committee; provided that the Committee may not exercise any right or power reserved to the Board. Any decision made, or action taken, by the Committee or in connection with the administration of this Plan shall be final, conclusive and binding on all persons having an interest in the Plan.

(d) Indemnification. In addition to such other rights of indemnification as they may have as members of the Board or as Officers or Employees of the Company or a Related Entity, members of the Board and any Officers or Employees of the Company or a Related Entity to whom authority to act for the Board, the Committee or the Company is delegated shall be defended and indemnified by the Company to the extent permitted by law on an after-tax basis against all reasonable expenses, including attorneys' fees, actually and necessarily incurred in connection with the defense of any claim, investigation, action, suit or proceeding, or in connection with any appeal therein, to which they or any of them may be a party by reason of any action taken or failure to act under or in connection with the Plan, or any Award granted hereunder, and against all amounts paid by them in settlement thereof (provided such settlement is approved by the Company) or paid by them in satisfaction of a judgment in any such claim, investigation, action, suit or proceeding, except in relation to matters as to which it shall be adjudged in such claim, investigation, action, suit or proceeding that such person is liable for gross negligence, bad faith or intentional misconduct; provided, however, that within thirty (30) days after the institution of such claim, investigation, action, suit or proceeding, such person shall offer to the Company, in writing, the opportunity at the Company's expense to defend the same.

5. Eligibility. Awards other than Incentive Stock Options may be granted to Employees, Directors and Consultants. Incentive Stock Options may be granted only to Employees of the Company or a Parent or a Subsidiary of the Company. An Employee, Director or Consultant who has been granted an Award may, if otherwise eligible, be granted additional Awards. Awards may be granted to such Employees, Directors or Consultants who are residing in non-U.S. jurisdictions as the Committee may determine from time to time.

6. Terms and Conditions of Awards.

(a) Types of Awards. The Committee is authorized under the Plan to award any type of arrangement to an Employee, Director or Consultant that is not inconsistent with the provisions of the Plan and that by its terms involves or might involve the issuance of (i) Shares, (ii) cash or (iii) an Option, a SAR, or similar right with a fixed or variable price related to the Fair Market Value of the Shares and with an exercise or conversion privilege related to the passage of time, the occurrence of one or more events, or the satisfaction of performance criteria or other conditions. Such awards include, without limitation, Options, SARs, sales or bonuses of Restricted Stock, Restricted Stock Units or Dividend Equivalent Rights, and an Award may consist of one such security or benefit, or two (2) or more of them in any combination or alternative.

(b) Designation of Award. Each Award shall be designated in the Award Agreement. In the case of an Option, the Option shall be designated as either an Incentive Stock Option or a Non-Qualified Stock Option. However, notwithstanding such designation, an Option will qualify as an Incentive Stock Option under the Code only to the extent the \$100,000 dollar limitation of Section 422(d) of the Code is not exceeded. The \$100,000 limitation of Section 422(d) of the Code is calculated based on the aggregate Fair Market Value of the Shares subject to Options designated as Incentive Stock Options which become exercisable for the first time by a Grantee during any calendar year (under all plans of the Company or any Parent or Subsidiary of the Company). For purposes of this calculation, Incentive Stock Options shall be taken into account in the order in which they were granted, and the Fair Market Value of the Shares shall be determined as of the grant date of the relevant Option. In the event that the Code or the regulations promulgated thereunder are amended after the date the Plan becomes effective to provide for a different limit on the Fair Market Value of Shares permitted to be subject to Incentive Stock Options, then such different limit will be automatically incorporated herein and will apply to any Options granted after the effective date of such amendment.

(c) Conditions of Award. Subject to the terms of the Plan, the Committee shall determine the provisions, terms, and conditions of each Award including, but not limited to, the Award vesting schedule, repurchase provisions, rights of first refusal, forfeiture provisions, form of payment (cash, Shares, or other consideration) upon settlement of the Award, payment contingencies, and satisfaction of any performance criteria. The performance criteria established by the Committee may be based on any one of, or combination of, the following: (i) increase in share price, (ii) earnings per share, (iii) total shareholder return, (iv) operating margin, (v) gross margin, (vi) return on equity, (vii) return on assets, (viii) return on investment, (ix) operating income, (x) net operating income, (xi) pre-tax profit, (xii) cash flow, (xiii) revenue, (xiv) expenses, (xv) earnings before interest, taxes and depreciation, (xvi) economic value added and (xvii) market share. The performance criteria may be applicable to the Company, Related Entities and/or any individual business units of the Company or any Related Entity. Partial achievement of the specified criteria may result in a payment or vesting corresponding to the degree of achievement as specified in the Award Agreement. In addition, the performance criteria shall be calculated in accordance with generally accepted accounting principles, but excluding the effect (whether positive or negative) of any change in accounting standards and any extraordinary, unusual or nonrecurring item, as determined by the Committee, occurring after the establishment of the performance criteria applicable to the Award intended to be performance-based compensation. Each such adjustment, if any, shall be made solely for the purpose of providing a consistent basis from period to period for the calculation of performance criteria in order to prevent the dilution or enlargement of the Grantee's rights with respect to an Award intended to be performance-based compensation.

(d) Acquisitions and Other Transactions. The Committee may issue Awards under the Plan in settlement, assumption or substitution for, outstanding awards or obligations to grant future awards in connection with the Company or a Related Entity acquiring another entity, an interest in another entity or an additional interest in a Related Entity whether by merger, stock purchase, asset purchase or other form of transaction.

(e) Deferral of Award Payment. The Committee may establish one or more programs under the Plan to permit selected Grantees the opportunity to elect to defer receipt of consideration upon exercise of an Award, satisfaction of performance criteria, or other event that absent the election would entitle the Grantee to payment or receipt of Shares or other consideration under an Award. The Committee may establish the election procedures, the timing of such elections, the mechanisms for payments of, and accrual of interest or other earnings, if any, on amounts, Shares or other consideration so deferred, and such other terms, conditions, rules and procedures that the Committee deems advisable for the administration of any such deferral program.

(f) Separate Programs. The Committee may establish one or more separate programs under the Plan for the purpose of issuing particular forms of Awards to one or more classes of Grantees on such terms and conditions as determined by the Committee from time to time.

(g) Individual Limitations on Awards.

(i) Individual Limit for Options and SARs. Following the date that the exemption from application of Section 162(m) of the Code described in Section 18 (or any exemption having similar effect) ceases to apply to Awards, the maximum number of Shares with respect to which Options and SARs may be granted to any Grantee in any calendar year shall be three hundred thousand (300,000) Shares. In connection with a Grantee's commencement of Continuous Service, a Grantee may be granted Options and SARs for up to an additional fifty thousand (50,000) Shares which shall not count against the limit set forth in the previous sentence. The foregoing limitation[s] shall be adjusted proportionately in connection with any change in the Company's capitalization pursuant to Section 10, below. To the extent required by Section 162(m) of the Code or the regulations thereunder, in applying the foregoing limitation[s] with respect to a Grantee, if any Option or SAR is canceled, the canceled Option or SAR shall continue to count against the maximum number of Shares with respect to which Options and SARs may be granted to the Grantee. For this purpose, the repricing of an Option (or in the case of a SAR, the base amount on which the stock appreciation is calculated is reduced to reflect a reduction in the Fair Market Value of the Common Stock) shall be treated as the cancellation of the existing Option or SAR and the grant of a new Option or SAR.

(ii) Individual Limit for Restricted Stock and Restricted Stock Units. For awards of Restricted Stock and Restricted Stock Units that are intended to be Performance-Based Compensation, the maximum number of Shares with respect to which such Awards may be granted to any Grantee in any calendar year shall be three hundred thousand (300,000) Shares. The foregoing limitation shall be adjusted proportionately in connection with any change in the Company's capitalization pursuant to Section 10, below.

(h) Early Exercise. The Award Agreement may, but need not, include a provision whereby the Grantee may elect at any time while an Employee, Director or Consultant to exercise any part or all of the Award prior to full vesting of the Award. Any unvested Shares received pursuant to such exercise may be subject to a repurchase right in favor of the Company or a Related Entity or to any other restriction the Committee determines to be appropriate.

(i) Term of Award. The term of each Award shall be the term stated in the Award Agreement, provided, however, that the term shall be no more than ten (10) years from the date of grant thereof. However, in the case of an Incentive Stock Option granted to a Grantee who, at the time the Option is granted, owns stock representing more than ten percent (10%) of the voting power of all classes of stock of the Company or any Parent or Subsidiary of the Company, the term of the Incentive Stock Option shall be five (5) years from the date of grant thereof or such shorter term as may be provided in the Award Agreement. Notwithstanding the foregoing, the specified term of any Award shall not include any period for which the Grantee has elected to defer the receipt of the Shares or cash issuable pursuant to the Award.

(j) Transferability of Awards. Incentive Stock Options may not be sold, pledged, assigned, hypothecated, transferred, or disposed of in any manner other than by will or by the laws of descent or distribution and may be exercised, during the lifetime of the Grantee, only by the Grantee. Other Awards shall be transferable (i) by will and by the laws of descent and distribution and (ii) during the lifetime of the Grantee, to the extent and in the manner authorized by the Committee by gift or pursuant to a domestic relations order to members of the Grantee's Immediate Family. Notwithstanding the foregoing, the Grantee may designate one or more beneficiaries of the Grantee's Award in the event of the Grantee's death on a beneficiary designation form provided by the Committee.

(k) Time of Granting Awards. The date of grant of an Award shall for all purposes be the date on which the Committee makes the determination to grant such Award, or such other later date as is determined by the Committee.

7. Award Exercise or Purchase Price, Consideration and Taxes.

(a) Exercise or Purchase Price. The exercise or purchase price, if any, for an Award shall be as follows:

(i) In the case of an Incentive Stock Option:

(A) granted to an Employee who, at the time of the grant of such Incentive Stock Option owns stock representing more than ten percent (10%) of the voting power of all classes of stock of the Company or any Parent or Subsidiary of the Company, the per Share exercise price shall be not less than one hundred ten percent (110%) of the Fair Market Value per Share on the date of grant; or

(B) granted to any Employee other than an Employee described in the preceding paragraph, the per Share exercise price shall be not less than one hundred percent (100%) of the Fair Market Value per Share on the date of grant.

(ii) In the case of a Non-Qualified Stock Option, the per Share exercise price shall be not less than one hundred percent (100%) of the Fair Market Value per Share on the date of grant.

(iii) In the case of SARs, the base appreciation amount shall not be less than one hundred percent (100%) of the Fair Market Value per Share on the date of grant.

(iv) In the case of Awards intended to qualify as Performance-Based Compensation, the exercise or purchase price, if any, shall be not less than one hundred percent (100%) of the Fair Market Value per Share on the date of grant.

(v) In the case of the sale of Shares, the per Share purchase price, if any, shall be such price as is determined by the Committee.

(vi) In the case of other Awards, such price as is determined by the Committee.

(vii) Notwithstanding the foregoing provisions of this Section 7(a), in the case of an Award issued pursuant to Section 6(d) above, the exercise or purchase price for the Award shall be determined in accordance with the provisions of the relevant instrument evidencing the agreement to issue such Award.

(b) Consideration. Subject to Applicable Laws, the consideration to be paid for the Shares to be issued upon exercise or purchase of an Award including the method of payment, shall be determined by the Committee. In addition to any other types of consideration the Committee may determine, the Committee is authorized to accept as consideration for Shares issued under the Plan the following:

(i) cash;

(ii) check;

(iii) surrender of Shares held for the requisite period, if any, necessary to avoid a charge to the Company's earnings for financial reporting purposes, or delivery of a properly executed form of attestation of ownership of Shares as the Committee may require which have a Fair Market Value on the date of surrender or attestation equal to the aggregate exercise price of the Shares as to which said Award shall be exercised;

(iv) with respect to Options, payment through a broker-dealer sale and remittance procedure pursuant to which the Grantee (A) shall provide written instructions to a Company designated brokerage firm to effect the immediate sale of some or all of the purchased Shares and remit to the Company sufficient funds to cover the aggregate exercise price payable for the purchased Shares and (B) shall provide written directives to the Company to deliver the certificates for the purchased Shares directly to such brokerage firm in order to complete the sale transaction;

(v) with respect to Options, payment through a "net exercise" such that, without the payment of any funds, the Grantee may exercise the Option and receive the net number of Shares equal to (i) the number of Shares as to which the Option is being exercised, multiplied by (ii) a fraction, the numerator of which is the Fair Market Value per Share (on such date as is determined by the Committee) less the Exercise Price per Share, and the denominator of which is such Fair Market Value per Share (the number of net Shares to be received shall be rounded down to the nearest whole number of Shares); or

(vi) any combination of the foregoing methods of payment.

The Committee may at any time or from time to time, by adoption of or by amendment to the standard forms of Award Agreement described in Section 4(b)(iv), or by other means, grant Awards which do not permit all of the foregoing forms of consideration to be used in payment for the Shares or which otherwise restrict one or more forms of consideration.

(c) Taxes. No Shares shall be delivered under the Plan to any Grantee or other person until such Grantee or other person has made arrangements acceptable to the Committee for the satisfaction of any non-U.S., federal, state, or local income and employment tax withholding obligations, including, without limitation, obligations incident to the receipt of Shares. Upon exercise or vesting of an Award the Company shall withhold or collect from the Grantee an amount sufficient to satisfy such tax obligations, including, but not limited to, by surrender of the whole number of Shares covered by the Award sufficient to satisfy the minimum applicable tax withholding obligations incident to the exercise or vesting of an Award (reduced to the lowest whole number of Shares if such number of Shares withheld would result in withholding a fractional Share with any remaining tax withholding settled in cash).

8. Exercise of Award.

(a) Procedure for Exercise; Rights as a Shareholder.

(i) Any Award granted hereunder shall be exercisable at such times and under such conditions as determined by the Committee under the terms of the Plan and specified in the Award Agreement.

(ii) An Award shall be deemed to be exercised when written notice of such exercise has been given to the Company in accordance with the terms of the Award by the person entitled to exercise the Award and full payment for the Shares with respect to which the Award is exercised has been made, including, to the extent selected, use of the broker-dealer sale and remittance procedure to pay the purchase price as provided in Section 7(b)(iv).

(b) Exercise of Award Following Termination of Continuous Service. In the event of termination of a Grantee's Continuous Service for any reason other than Disability or death (but not in the event of a Grantee's change of status from Employee to Consultant or from Consultant to Employee), such Grantee may, but only during the Post-Termination Exercise Period (but in no event later than the expiration date of the term of such Award as set forth in the Award Agreement), exercise the portion of the Grantee's Award that was vested at the date of such termination or such other portion of the Grantee's Award as may be determined by the Committee. The Grantee's Award Agreement may provide that upon the termination of the Grantee's Continuous Service for Cause, the Grantee's right to exercise the Award shall terminate concurrently with the termination of Grantee's Continuous Service. In the event of a Grantee's change of status from Employee to Consultant, an Employee's Incentive Stock Option shall convert automatically to a Non-Qualified Stock Option on the day three (3) months and one day following such change of status. To the extent that the Grantee's Award was unvested at the date of termination, or if the Grantee does not exercise the vested portion of the Grantee's Award within the Post-Termination Exercise Period, the Award shall terminate.

(c) Disability of Grantee. In the event of termination of a Grantee's Continuous Service as a result of his or her Disability, such Grantee may, but only within twelve (12) months from the date of such termination (or such longer period as specified in the Award Agreement but in no event later than the expiration date of the term of such Award as set forth in the Award Agreement), exercise the portion of the Grantee's Award that was vested at the date of such termination; provided, however, that if such Disability is not a "disability" as such term is defined in Section 22(e)(3) of the Code, in the case of an Incentive Stock Option such Incentive Stock Option shall automatically convert to a Non-Qualified Stock Option on the day three (3) months and one day following such termination. To the extent that the Grantee's Award was unvested at the date of termination, or if Grantee does not exercise the vested portion of the Grantee's Award within the time specified herein, the Award shall terminate.

(d) Death of Grantee. In the event of a termination of the Grantee's Continuous Service as a result of his or her death, or in the event of the death of the Grantee during the Post-Termination Exercise Period or during the twelve (12) month period following the Grantee's termination of Continuous Service as a result of his or her Disability, the Grantee's estate or a person who acquired the right to exercise the Award by bequest or inheritance may exercise the portion of the Grantee's Award that was vested as of the date of termination, within twelve (12) months from the date of death (or such longer period as specified in the Award Agreement but in no event later than the expiration of the term of such Award as set forth in the Award Agreement). To the extent that, at the time of death, the Grantee's Award was unvested, or if the Grantee's estate or a person who acquired the right to exercise the Award by bequest or inheritance does not exercise the vested portion of the Grantee's Award within the time specified herein, the Award shall terminate.

(e) Extension if Exercise Prevented by Law. Notwithstanding the foregoing, if the exercise of an Award within the applicable time periods set forth in this Section 8 is prevented by the provisions of Section 9 below, the Award shall remain exercisable until one (1) month after the date the Grantee is notified by the Company that the Award is exercisable, but in any event no later than the expiration of the term of such Award as set forth in the Award Agreement.

9. Conditions Upon Issuance of Shares.

(a) If at any time the Committee determines that the delivery of Shares pursuant to the exercise, vesting or any other provision of an Award is or may be unlawful under Applicable Laws, the vesting or right to exercise an Award or to otherwise receive Shares pursuant to the terms of an Award shall be suspended until the Committee determines that such delivery is lawful and shall be further subject to the approval of counsel for the Company with respect to such compliance. The Company shall have no obligation to effect any registration or qualification of the Shares under federal or state laws.

(b) As a condition to the exercise of an Award, the Company may require the person exercising such Award to represent and warrant at the time of any such exercise that the Shares are being purchased only for investment and without any present intention to sell or distribute such Shares if, in the opinion of counsel for the Company, such a representation is required by any Applicable Laws.

10. Adjustments Upon Changes in Capitalization. Subject to any required action by the shareholders of the Company and Section 11 hereof, the number of Shares covered by each outstanding Award, and the number of Shares which have been authorized for issuance under the Plan but as to which no Awards have yet been granted or which have been returned to the Plan, the exercise or purchase price of each such outstanding Award, the maximum number of Shares with respect to which Awards may be granted to any Grantee in any calendar year, as well as any other terms that the Committee determines require adjustment shall be proportionately adjusted for (i) any increase or decrease in the number of issued Shares resulting from a stock split, reverse stock split, stock dividend, combination or reclassification of the Shares, or similar transaction affecting the Shares, (ii) any other increase or decrease in the number of issued Shares effected without receipt of consideration by the Company, or (iii) any other transaction with respect to Common Stock including a corporate merger, consolidation, acquisition of property or stock, separation (including a spin-off or other distribution of stock or property), reorganization, liquidation (whether partial or complete) or any similar transaction; provided, however that conversion of any convertible securities of the Company shall not be deemed to have been "effected without receipt of consideration." In the event of any distribution of cash or other assets to shareholders other than a normal cash dividend, the Committee shall also make such adjustments as provided in this Section 10 or substitute, exchange or grant Awards to effect such adjustments (collectively "adjustments"). Any such adjustments to outstanding Awards will be effected in a manner that precludes the enlargement of rights and benefits under such Awards. In connection with the foregoing adjustments, the Committee may, in its discretion, prohibit the exercise of Awards or other issuance of Shares, cash or other consideration pursuant to Awards during certain periods of time. Except as the Committee determines, no issuance by the Company of shares of any class, or securities convertible into shares of any class, shall affect, and no adjustment by reason hereof shall be made with respect to, the number or price of Shares subject to an Award.

11. Corporate Transactions and Changes in Control.

(a) Termination of Award to Extent Not Assumed in Corporate Transaction. Effective upon the consummation of a Corporate Transaction, all outstanding Awards under the Plan shall terminate. However, all such Awards shall not terminate to the extent they are Assumed in connection with the Corporate Transaction.

(b) Acceleration of Award Upon Corporate Transaction or Change in Control. The Committee shall have the authority, exercisable either in advance of any actual or anticipated Corporate Transaction or Change in Control or at the time of an actual Corporate Transaction or Change in Control and exercisable at the time of the grant of an Award under the Plan or any time while an Award remains outstanding, to provide for the full or partial automatic vesting and exercisability of one or more outstanding vested Awards under the Plan and the release from restrictions on transfer and repurchase or forfeiture rights of such Awards in connection with a Corporate Transaction or Change in Control, on such terms and conditions as the Committee may specify. The Committee also shall have the authority to condition any such Award vesting and exercisability or release from such limitations upon the subsequent termination of the Continuous Service of the Grantee within a specified period following the effective date of the Corporate Transaction or Change in Control. The Committee may provide that any Awards so vested or released from such limitations in connection with a Change in Control, shall remain fully exercisable until the expiration or sooner termination of the Award.

(c) Effect of Acceleration on Incentive Stock Options. Any Incentive Stock Option accelerated under this Section 11 in connection with a Corporate Transaction or Change in Control shall remain exercisable as an Incentive Stock Option under the Code only to the extent the \$100,000 dollar limitation of Section 422(d) of the Code is not exceeded.

12. Effective Date and Term of Plan. The Plan shall become effective upon the earlier to occur of its adoption by the Board or its approval by the shareholders of the Company. It shall continue in effect for a term of ten (10) years unless sooner terminated. Subject to Section 17 below, and Applicable Laws, Awards may be granted under the Plan upon its becoming effective.

13. Amendment, Suspension or Termination of the Plan.

(a) The Board may at any time amend, suspend or terminate the Plan. To the extent necessary to comply with Applicable Laws, the Company shall obtain shareholder approval of any Plan amendment in such a manner and to such a degree as required.

(b) No Award may be granted during any suspension of the Plan or after termination of the Plan.

(c) No suspension or termination of the Plan (including termination of the Plan under Section 12, above) shall adversely affect any rights under Awards already granted to a Grantee.

14. Reservation of Shares.

(a) The Company, during the term of the Plan, will at all times reserve and keep available such number of Shares as shall be sufficient to satisfy the requirements of the Plan.

(b) The inability of the Company to obtain authority from any regulatory body having jurisdiction, which authority is deemed by the Company's counsel to be necessary to the lawful issuance and sale of any Shares hereunder, shall relieve the Company of any liability in respect of the failure to issue or sell such Shares as to which such requisite authority shall not have been obtained.

15. No Effect on Terms of Employment/Consulting Relationship. The Plan shall not confer upon any Grantee any right with respect to the Grantee's Continuous Service, nor shall it interfere in any way with his or her right or the right of the Company or any Related Entity to terminate the Grantee's Continuous Service at any time, with or without cause, including but not limited to, Cause, and with or without notice. The ability of the Company or any Related Entity to terminate the employment of a Grantee who is employed at will is in no way affected by its determination that the Grantee's Continuous Service has been terminated for Cause for the purposes of this Plan.

16. No Effect on Retirement and Other Benefit Plans. Except as specifically provided in a retirement or other benefit plan of the Company or a Related Entity, Awards shall not be deemed compensation for purposes of computing benefits or contributions under any retirement plan of the Company or a Related Entity, and shall not affect any benefits under any other benefit plan of any kind or any benefit plan subsequently instituted under which the availability or amount of benefits is related to level of compensation. The Plan is not a "Pension Plan" or "Welfare Plan" under the Employee Retirement Income Security Act of 1974, as amended.

17. Shareholder Approval. Continuance of the Plan shall be subject to approval by the shareholders of the Company within twelve (12) months before or after the date the Plan is adopted. Such shareholder approval shall be obtained in the degree and manner required under Applicable Laws. Any Award exercised before shareholder approval is obtained shall be rescinded if shareholder approval is not obtained within the time prescribed, and Shares issued on the exercise of any such Award shall not be counted in determining whether shareholder approval is obtained.

18. Information to Grantees. To the extent required by Applicable Law, the Company shall provide to each grantee, during the period for which such Grantee has one or more Awards outstanding, copies of financial statements at least annually. The Company shall not be required to provide such information to persons whose duties in connection with the Company assure them access to equivalent information.

19. Effect of Section 162(m) of the Code. The Plan, and all Awards (except Awards of Restricted Stock that vest over time) issued thereunder, are intended to be exempt from the application of Section 162(m) of the Code, which restricts under certain circumstances the Federal income tax deduction for compensation paid by a public company to named executives in excess of \$1 million per year. The exemption is based on Treasury Regulation Section 1.162-27(f), in the form existing on the effective date of the Plan, with the understanding that such regulation generally exempts from the application of Section 162(m) of the Code compensation paid pursuant to a plan that existed before a company becomes publicly held. Under such Treasury Regulation, this exemption is available to the Plan for the duration of the period that lasts until the earliest of (i) the expiration of the Plan, (ii) the material modification of the Plan, (iii) the exhaustion of the maximum number of shares of Common Stock available for Awards under the Plan, as set forth in Section 3(a), (iv) the first meeting of shareholders at which directors are to be elected that occurs after the close of the third calendar year following the calendar year in which the Company first becomes subject to the reporting obligations of Section 12 of the Exchange Act, or (v) such other date required by Section 162(m) of the Code and the rules and regulations promulgated thereunder. To the extent that the Committee determines as of the date of grant of an Award that (i) the Award is intended to qualify as Performance-Based Compensation and (ii) the exemption described above is no longer available with respect to such Award, such Award shall not be effective until any shareholder approval required under Section 162(m) of the Code has been obtained.

20. Unfunded Obligation. Grantees shall have the status of general unsecured creditors of the Company. Any amounts payable to Grantees pursuant to the Plan shall be unfunded and unsecured obligations for all purposes, including, without limitation, Title I of the Employee Retirement Income Security Act of 1974, as amended. Neither the Company nor any Related Entity shall be required to segregate any monies from its general funds, or to create any trusts, or establish any special accounts with respect to such obligations. The Company shall retain at all times beneficial ownership of any investments, including trust investments, which the Company may make to fulfill its payment obligations hereunder. Any investments or the creation or maintenance of any trust or any Grantee account shall not create or constitute a trust or fiduciary relationship between the Committee, the Company or any Related Entity and a Grantee, or otherwise create any vested or beneficial interest in any Grantee or the Grantee's creditors in any assets of the Company or a Related Entity. The Grantees shall have no claim against the Company or any Related Entity for any changes in the value of any assets that may be invested or reinvested by the Company with respect to the Plan.

21. Construction. Captions and titles contained herein are for convenience only and shall not affect the meaning or interpretation of any provision of the Plan. Except when otherwise indicated by the context, the singular shall include the plural and the plural shall include the singular. Use of the term "or" is not intended to be exclusive, unless the context clearly requires otherwise.

22. Nonexclusivity of the Plan. Neither the adoption of the Plan by the Board, the submission of the Plan to the shareholders of the Company for approval, nor any provision of the Plan will be construed as creating any limitations on the power of the Board to adopt such additional compensation arrangements as it may deem desirable, including, without limitation, the granting of Awards otherwise than under the Plan, and such arrangements may be either generally applicable or applicable only in specific cases.

Adopted by the Board of Directors of VistaGen Therapeutics, Inc. on July 26, 2016

Approved by the stockholders of VistaGen Therapeutic, Inc. effective September 26, 2016

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (File No. 333-208354) and Form S-3 (333-215671) of VistaGen Therapeutics, Inc. of our report dated June 28, 2017 (which report expresses an unqualified opinion and includes an explanatory paragraph expressing substantial doubt about the Company's ability to continue as a going concern), relating to the consolidated financial statements of VistaGen Therapeutics, Inc., which appears in this Annual Report on Form 10-K.

/s/ OUM & CO. LLP

San Francisco, California
June 28, 2017

CERTIFICATION

I, Shawn K. Singh, certify that;

1. I have reviewed this Annual Report on Form 10-K of VistaGen Therapeutics, Inc., a Nevada corporation;
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.

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

June 28, 2017

CERTIFICATION

I, Jerrold D. Dotson, certify that:

1. I have reviewed this Annual Report on Form 10-K of VistaGen Therapeutics, Inc., a Nevada corporation;
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.

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

June 28, 2017

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

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of VistaGen Therapeutics, Inc. (the “*Company*”) hereby certifies, to such officer’s knowledge, that:

(i) the accompanying Annual Report on Form 10-K of the Company for the annual period ended March 31, 2017 (the “*Report*”) fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

June 28, 2017

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

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