VistaGen Therapeutics, Inc.
Form 10-K
June 24, 2016

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

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

For the fiscal year ended: March 31, 2016

or

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

Commission file number: 000-54014

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

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

343 Allerton Avenue
South San Francisco, 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	Name of each exchange on which registered
Common Stock, par value $0.001 per share	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 o No x

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

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 x No o

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 x No o

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. o

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

Large accelerated filer o	Accelerated filer o	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company x

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

The aggregate market value of the common stock of the registrant held by non-affiliates of the registrant on September 30, 2015, the last business day of the registrant's second fiscal quarter, was: $13,691,410.

As of June 22, 2016, there were 7,970,705 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,” “w
“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;

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;

our ability to initiate and complete our clinical trials and to advance our 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 development collaborators and regulatory service providers;

our ability to obtain and maintain intellectual property protection for our core assets;

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 and nonclinical development, 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. 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.

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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 VistaG Therapeutics, Inc., a Nevada corporation.

Item 1. Business

Company Overview

We are a clinical-stage biopharmaceutical company dedicated to developing and commercializing innovative product candidates for patients with diseases and disorders involving the central nervous system (CNS). Our lead product candidate, AV-101, is a next generation, orally available prodrug candidate in Phase 2 development, initially for the adjunctive treatment of Major Depressive Disorder (MDD) in patients with an inadequate response to standard antidepressants approved by the U.S. Food and Drug Administration (FDA). We believe AV-101 may also have potential therapeutic utility in CNS indications beyond MDD, including chronic neuropathic pain, epilepsy, Huntington's disease and Parkinson's disease.

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

Our ongoing Phase 2a clinical study of AV-101 in subjects with treatment-resistant MDD is being conducted and funded by the U.S. National Institute of Mental Health (NIMH) under our February 2015 Cooperative Research and Development Agreement (CRADA) with the NIMH. The first patient in this NIMH-sponsored Phase 2a study was dosed in November 2015. The Principal Investigator of the study is Dr. Carlos Zarate, Jr., Chief of the NIMH's Experimental Therapeutics & Pathophysiology Branch and its Section on Neurobiology and Treatment of Mood and Anxiety Disorders. Previous NIMH studies, including studies conducted by Dr. Zarate, have focused on the effects of low dose intravenous (I.V.) ketamine on treatment-resistant depression. These NIMH studies, as well as clinical research by others, have demonstrated robust antidepressant effects in patients with treatment-resistant MDD within hours of a single low dose of I.V. ketamine and stimulated research and development around a new generation of antidepressants with potential to deliver ketamine-like fast-acting antidepressant benefits without ketamine's serious side effects.

We are preparing to launch our Phase 2b clinical study of AV-101 for the adjunctive treatment of MDD in patients with an inadequate response to standard, FDA-approved antidepressants. We anticipate commencement of this multi-center, multi-dose, double blind, placebo-controlled Phase 2b efficacy and safety study at the end of the fourth quarter of 2016. Dr. Maurizio Fava, Professor of Psychiatry at Harvard Medical School and Director, Division of Clinical Research, Massachusetts General Hospital (MGH) Research Institute and Executive Director, MGH Clinical Trials Network and Institute, will be the Principal Investigator of our Phase 2b study of AV-101 in MDD. Dr. Fava was the co-Principal Investigator with Dr. A. John Rush of the largest clinical trial ever conducted in depression, the STAR*D study, whose findings were published in journals such the New England Journal of Medicine (NEJM) and the Journal of the American Medical Association (JAMA). We anticipate top line results in this Phase 2b study in the second quarter of 2018.

In addition to clinical development of AV-101, we are focused on advancing potential commercial applications of our human pluripotent stem cell (hPSC) technology platform with respect to drug rescue programs aimed at developing proprietary small molecule new chemical entities (NCEs) for our drug candidate pipeline. We are also focused on potential regenerative medicine (RM) applications using blood, cartilage, heart and/or liver cells derived from hPSCs,

and may pursue these applications in collaboration with third-parties.

AV-101 and Major Depressive Disorder

Background

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

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

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All standard antidepressants have risks of significant side effects, including, among others, potentially anxiety, metabolic syndrome, sleep disturbance and sexual dysfunction. They also have a "Black Box" warning due to risks of worsening depression and suicide in certain groups. Use of atypical antipsychotics to augment inadequately performing standard antidepressants increases the risk of serious side effects, including, potentially, tardive dyskinesia, significant weight gain, diabetes and heart disease, while offering only a modest potential increase in therapeutic benefit. Use of ECT increases the risk of serious side effects, including, headaches, tiredness, disorientation, intense sleepiness, hallucinations and long-term memory loss.

AV-101

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

Following the completion of our NIH-funded, randomized, double blind, placebo-controlled Phase 1a and Phase 1b safety studies, we are now collaborating with the NIMH in Phase 2a. Under our February 2015 CRADA, the NIMH is sponsoring, and Dr. Carlos Zarate Jr. of the NIMH as Principal Investigator is conducting, our ongoing Phase 2a efficacy and safety study of AV-101 in subjects with treatment-resistant MDD. The trial is expected to enroll 20 to 28 patients. The first patient was dosed in November 2015, and we currently anticipate receiving topline results in the second quarter of 2017.

We are preparing to launch our Phase 2b clinical study of AV-101 for the adjunctive treatment of MDD in patients with an inadequate response to standard, FDA-approved antidepressants. We anticipate the launch of this Phase 2b study, with Dr. Maurizio Fava of Harvard Medical School serving as Principal Investigator, at the end of the fourth quarter of 2016. We anticipate top line results from this Phase 2b study in the second quarter of 2018. Although no assurances can be given, we currently estimate that AV-101 may be ready for commercialization in 2021.

Several preclinical studies support the hypothesis that AV-101 also has the potential to treat multiple additional CNS disorders and neurodegenerative diseases beyond MDD, including chronic neuropathic pain, epilepsy, Parkinson's disease and Huntington's disease, where modulation of the NMDAR, AMPA pathway and/or active metabolites of AV-101 may achieve therapeutic benefit.

CardioSafe 3D™; NCE Drug Rescue and Regenerative Medicine

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. Our current strategic interests involving our stem cell technology platform include (i) advancing current internal efforts focused on CardioSafe 3D drug rescue to expand our drug candidate pipeline with selected proprietary small molecule NCEs, leveraging substantial prior research and development investments by pharmaceutical companies and others related to public domain NCEs terminated before FDA approval due to heart toxicity risks and (ii) establishing collaborative

arrangements with qualified third-parties focused on regenerative medicine (RM) applications, including (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), involving hPSC-derived blood, bone, cartilage, heart and/or liver cells.

Our Strategy

Our core strategy is to develop, and commercialize innovative small molecule CNS drugs that address significant unmet medical needs. We have assembled a management team and a team of scientific, clinical, and regulatory advisors, including recognized experts in the fields of depression, multiple other CNS diseases and disorders, and stem cell biology, with significant industry and regulatory experience to lead and execute the development and commercialization of AV-101 and any additional CNS or other product candidates we may develop internally or acquire from third-parties.

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Key elements of our strategy are to:

Develop and commercialize AV-101 for depression, including, initially, as an adjunctive treatment for MDD patients with an inadequate response to standard, FDA-approved antidepressants. Under our 2015 CRADA with the NIMH, in collaboration with Dr. Carlos Zarate of the NIMH, we launched our ongoing NIMH-sponsored AV-101 MDD Phase 2a clinical study in patients with treatment resistant MDD. The first patient in this study was dosed in November 2015. We are currently preparing to launch our multi-center Phase 2b clinical study of AV-101 for the adjunctive treatment of MDD in patients with an inadequate response to standard, FDA-approved, antidepressants. We are developing AV-101 internally, and may either continue to do so through our submission of a New Drug Application (NDA) to the FDA or, prior to submitting an AV-101 NDA, collaborate with a pharmaceutical company with a strong commercial presence in depression and other CNS markets. If AV-101 is approved by the FDA and other regulatory agencies, we may collaborate with one or more pharmaceutical companies with extensive commercial capabilities in multiple depression and other CNS markets and/or contract with a specialty sales force focused primarily on psychiatrists and long-term care physicians who are high prescribers of standard antidepressants and atypical antipsychotics.

Leverage the commercial potential of AV-101 by expanding our development and commercialization programs to additional CNS-related diseases and disorders. We believe AV-101 has broad therapeutic potential. Accordingly, we may pursue clinical development and commercialization opportunities for AV-101 across a range of CNS-related indications that are underserved by currently available CNS medicines and represent significant unmet medical needs. Based on AV-101 preclinical studies, and by leveraging our successful NIH-funded AV-101 Phase 1a and 1b clinical safety studies, we may now have opportunities to expand Phase 2 development of AV-101 beyond MDD to include, among other CNS-related indications, chronic neuropathic pain, epilepsy, Huntington's disease and Parkinson's disease.

Capitalize on our drug rescue and RM opportunities using our stem cell technology. CardioSafe 3D enables us to screen NCEs in drug rescue programs intended to produce proprietary NCEs for our internal drug candidate pipeline, without incurring many of the substantial costs and risks typically inherent in new drug discovery and nonclinical drug development. We are also focused on establishing new strategic collaborations, including potential license and/or spin-off opportunities, involving potential RM applications of our stem cell platform. As most of our resources are currently focused on the clinical development of AV-101, we believe one or more strategic licensing or development collaborations and/or spin-off transactions involving RM applications of our stem cell technology platform could allow us to realize potential value from our stem cell technology platform while focusing primarily on clinical development of AV-101, other CNS drug candidates we may acquire and/or drug candidates we may develop through internal drug rescue.

Pursue in-licensing and acquisition of other product candidates for treatment of CNS-related disorders. While our resources are currently focused primarily on clinical development of AV-101 for MDD, we anticipate pursuing license or acquisition of additional CNS-related product candidates. These may be developed independently or in partnerships. We believe 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 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 nonclinical drug development.

Our Product Opportunities

AV-101 (L-4-chlorokynurenine 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 the brain into its active metabolite, 7-chlorokynurenic acid (7-Cl-KYNA), a well-characterized, potent and highly selective antagonist of the NMDAR at the GlyB co-agonist site.

Current evidence suggests that AV-101's modulation of NMDAR signaling may provide fast-acting antidepressant effects in the treatment of MDD. In addition, as confirmed in our AV-101 Phase 1 clinical studies, targeting the GlyB site of the NMDAR does not have the adverse effects typically associated with classic NMDAR antagonists, such as ketamine, and other NMDA channel blockers.

Major Depressive Disorder

Depression is a serious medical illness that can occur at any time over a person's life. If not effectively treated, depression is likely to become a chronic disease. Just experiencing one episode of depression places an individual at a 50% risk for experiencing another episode, and further increases the chances of having more depression episodes in the future. The WHO estimates that depression is the leading cause of disability worldwide, and is a major contributor to the global burden of disease, affecting 350 million people globally. According to the CDC, approximately one in every 10 Americans aged 12 and over takes antidepressant medication.

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While most people will experience depressed mood at some point during their lifetime, MDD is different. MDD is the chronic, pervasive feeling of apathy, 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. Depression is also associated with an increased risk of suicide.

Standard Antidepressants

For many people, depression cannot be controlled for any length of time without treatment. Standard medications available in the multi-billion dollar global antidepressant 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 certain patients experience any significant therapeutic benefit. In addition, most standard antidepressants have an FDA-required "Black Box" safety warning due to a risk, in certain groups, of worsening depression and an increased risk of suicidal thoughts and behaviors during treatment, a property not expected to occur with AV-101. About two out of every three depression sufferers, including an estimated 6.9 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 effective standard antidepressant. In addition, this trial and error process and the systemic effects of the various antidepressants involved, increases the risks of patient tolerability issues and serious side effects, including suicidal thoughts and behaviors in certain groups.

Augmentation Strategies for Major Depressive Disorder

For many MDD sufferers, FDA-approved antidepressants provide less than adequate therapeutic benefit. If an MDD patient fails to respond adequately to a standard antidepressant, typically (A) the dose of their current antidepressant can be adjusted, (B) a change can be made to a different antidepressant medication, or (C) the current antidepressant regimen can be augmented with another drug. Atypical antipsychotics have recently become a common focus for augmentation of inadequate standard antidepressant therapy. Although augmenting treatment-refractory or treatment-resistant depression with atypical antipsychotics may be effective as adjunctive therapy for some MDD patients, their use as augmentation therapy increases the risk of adverse effects, such as akathisia (restlessness, a feeling of inner distress or an inability to sit still), fatigue, and weight gain.

Ketamine and NIH Clinical Studies in Major Depressive Disorder

Intravenous (I.V.) ketamine hydrochloride (ketamine) is a rapid-acting general anesthetic approved by the FDA in the 1970s. The use of ketamine (an NMDA receptor antagonist which acts as an NMDA channel blocker) to treat MDD has been studied in multiple clinical trials conducted by depression experts at several clinical research centers, including the NIMH, including Dr. Carlos Zarate, Jr. is the NIMH's Chief of Experimental Therapeutics & Pathophysiology Branch and of the Section on Neurobiology and Treatment of Mood and Anxiety Disorders and Clinical Professor of Psychiatry and Behavioral Sciences at The George Washington University. In randomized, placebo-controlled, double blind clinical trials reported by Dr. Zarate and others at the NIMH, a single low dose of I.V. ketamine (0.5 mg/kg over 40 minutes) produced robust and rapid antidepressant effects in MDD patients who had not responded to standard FDA-approved antidepressants. These results were in contrast to the very slow onset of traditional antidepressant therapies, notably SSRIs and SNRIs, that usually require many weeks or months of chronic usage to achieve similar antidepressant effects in certain patients. The potential for widespread therapeutic use of current FDA-approved I.V. 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, when administered in a low dose by I.V., revolutionized thinking about the current MDD treatment paradigm involving FDA-approved SSRIs and/or SNRIs, and increased interest in the development of a new generation of antidepressants with a fast-acting mechanism of action similar to ketamine's. Our orally available AV-101 is among the next generation of antidepressants with potential to deliver fast-acting ketamine-like antidepressant effects, without ketamine's side effects nor requiring I.V. administration.

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 NMDAR, resulting in the down-regulation of NMDAR signaling. Growing evidence suggests that the glutamatergic system 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 antidepressants and all atypical antipsychotics used to augment inadequate response with standard antidepressants, placing it among a new generation of glutamatergic 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, but not structurally, similar to an active metabolite of ketamine in that both induce antidepressant activity via glutamatergic activation involving AMPA receptor pathways. However, because AV-101 down-regulates the NMDAR channel activity, whereas ketamine blocks it, AV-101 does not cause ketamine-like side effects, such as hallucinations. AV-101, as a prodrug, produces in the brain an antagonist that down-regulates the NMDAR by selectively binding to the functionally required GlyB site of the NMDAR. Strong experimental evidence confirms that down-regulating the NMDAR by targeting the GlyB site can produce potent antidepressive effects and bypass adverse effects that result when ketamine blocks the NMDAR ion channel. Experimental evidence supports the conclusion that this NMDAR modulation by AV-101 may then result in a glutamatergic activation that depends on the AMPA receptor pathway, resulting in an increase in neuronal connections, synaptogenesis, that has been associated with the fast-acting antidepressant effects similar to those seen with an active metabolite of ketamine.

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In recently published preclinical studies, AV-101 has demonstrated the antidepressant-like activity of ketamine, including rapid onset and extended duration of effect, without causing ketamine's serious 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, even at the highest dose. There were no signs of sedation, hallucinations or schizophrenia-like side effects often associated with ketamine and traditional NMDAR channel blockers.

Building on over $8.8 million of prior grant award funding to VistaGen from the NIH for preclinical, and Phase 1a and Phase 1b clinical development of AV-101, in February 2015, we entered into a CRADA with the NIMH. Under the CRADA, we are collaborating with Dr. Carlos Zarate and the NIMH on a Phase 2a clinical study of AV-101 as a chronic monotherapy in subjects with treatment-resistant MDD. Pursuant to the CRADA, this study is being conducted at the NIMH by Dr. Zarate and being fully-funded by the NIMH. The primary objective of the NIH-funded Phase 2a study will be to evaluate the ability of AV-101 to improve overall depressive symptoms in subjects with treatment-resistant MDD, specifically whether subjects with MDD have a greater decrease in depressive symptoms when treated with AV-101 than with placebo. The first patient in this Phase 2a study was dosed in November 2015. We anticipate top line results in this study in the second quarter of 2017.

We are currently preparing to launch our Phase 2b clinical study of AV-101 for the adjunctive treatment of MDD in patients with an inadequate response to standard antidepressants. This study will be an acute adjunctive study with clinical objectives intended to further inform the ultimate clinical usage of AV-101. We anticipate the launch of this multi-center, multi-dose, double blind, placebo-controlled Phase 2b efficacy and safety study, which is expected to enroll approximately 325 patients, in the fourth quarter of 2016. The Principal Investigator of the 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, the STAR*D study, whose findings were published in journals such the New England Journal of Medicine (NEJM) and the Journal of the American Medical Association (JAMA). We anticipate top line results in this study in the second quarter of 2018.

AV-101 Preclinical Studies in Chronic Neuropathic Pain, Epilepsy, Parkinson's disease and Huntington's disease

In addition to well-established nonclinical models of depression, AV-101 preclinical data in several other CNS-related disorders support our hypothesis that AV-101 has therapeutic and commercial potential beyond treatment of depression.

Chronic Neuropathic Pain and Acute Tissue Injury Hyperalgesia

The effect of AV-101 on chronic neuropathic pain due to inflammation and nerve damage was assessed in rats by using multiple models of neuropathic pain, including the Chung nerve ligation model. AV-101 effects were compared to either saline, MK-801 or gabapentin controls. AV-101 had a positive effect on chronic neuropathic pain in the Chung model, with no observed adverse behavioral effects. The efficacy observed for AV-101 in both the acute and chronic neuropathic pain model systems was dose dependent, and the drug response was not associated with any side effects within the range of doses administered.

The positive antihyperalgesic effect of in the Chung ligation model, AV-101 has been evaluated in two standard tissue injury model systems: inflammatory thermal hyperalgesia and the formalin paw test. AV-101 was compared to two positive controls, the classic NMDAR antagonist MK-801 (a channel blocker discontinued in preclinical development by Merck due to neurotoxicity) and the anticonvulsant gabapentin. A significant drug response was defined as a response that was greater than or equal to 2 standard deviations (SD) from the response produced by the vehicle only, the solution used to deliver the drugs. Animal behavior and motor function were observed and evaluated throughout the study.

In the formalin hyperalgesia model, as has been reported by others, MK-801 caused significant spontaneous locomotor activity that prevented assessment of its analgesic activity. However, AV-101 displayed dose-dependent antihyperpathic effects in the absence of behavioral deficits for both Phase 1 (acute nociceptive pain) and Phase 2 (chronic and neuropathic pain) of hyperalgesia. In contrast, gabapentin did not have a significant anti-hyperalgesia response at any dose during Phase 1, but showed a significant positive response during Phase 2.

For the carrageenan inflammatory thermal hyperalgesia model, neither MK-801, gabapentin, nor AV-101 had an effect on acute thermal nociception, but produced a dose dependent block of the carrageenan-induced hyperalgesia that were greater than 2 SD of the vehicle: There were no behavioral changes observed at any AV-101 dose, but signs of behavioral and motor dysfunction were observed for gabapentin and MK-801 treated animals. The profile of analgesic activity observed for AV-101 in the formalin and inflammatory thermal hyperalgesia model systems supports the conclusion that AV-101 demonstrates anti-hyperalgesia activity in validated models of facilitated pain processing produced by peripheral tissue inflammation.

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Epilepsy

AV-101 has been shown to protect against seizures in animal models of epilepsy, providing preclinical support for its potential as a novel treatment of epilepsy. Epilepsy is one of the most prevalent neurological disorders, affecting almost 1% of the worldwide population. Approximately 2.5 million Americans have epilepsy. Nearly half of the people suffering from epilepsy are not effectively treated with currently available medications. In addition, the anticonvulsants used today 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 NMDAR subtype, glutamate has been implicated in the neuropathology and clinical symptoms of the disease. In support of this, NMDAR antagonists are potent anticonvulsants. However, classic NMDAR 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 NMDAR function and are therefore anticonvulsant and neuroprotective. Importantly, GlyB site antagonists have fewer and less severe side effects than classic NMDAR 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.

The ability of astrocytes to respond to pathology and/or injury becoming activated resulting in an enhanced focal delivery of an anti-epileptic active metabolite of AV-101, and the dual action resulting from AV-101 as a NMDAR GlyB antagonist and quinolinic acid synthesis inhibitor, make AV-101 a potential Phase 2a development candidate for treatment of epilepsy.

Parkinson's Disease

AV-101 has been shown to activate ventral tegmental area (VTA) dopaminergic (DA) neurons. Kynurenic acid (KYNA) is an endogenous NMDAR antagonist, as well as a blocker of the alpha-7-nicotinic acid receptor. Mounting evidence suggests that this compound participates in the pathophysiology of schizophrenia. Preclinical studies have shown that elevated levels of endogenous KYNA are associated with increased firing of midbrain DA neurons. AV-101 is converted to the selective NMDAR GlyB antagonist 7-Cl-KYNA, which is 20 times more potent and selective than KYNA in binding the GlyB site. Utilizing extra cellular single unit cell recording techniques, we have shown that AV-101, which is converted to the selective NMDAR GlyB antagonist 7-Cl-KYNA, significantly increases the firing rate and percent burst firing activity of VTA DA neurons. These results have potential therapeutic implications for Parkinson's disease.

Huntington's Disease

Working together with metabotropic glutamate receptors, the NMDAR 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 NMDAR-associated channel, which in turn influences a wide variety of cellular components, like cytoskeletal proteins or second- messenger synthases. However, over activation at the NMDAR triggers an excessive entry of calcium ions, initiating a series of cytoplasmic and nuclear processes that promote excitotoxicity, neuronal cell death through necrosis as well as apoptosis. These mechanisms have been implicated in several neurodegenerative diseases, and typically involve dysregulation of the endogenous levels of KYNA and quinolinic acid, with a reduction of KYNA and an increase of quinolinic acid.

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 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).

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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 OUIN and to potentially increase local concentrations of 7-Cl-KYNA, presents an exciting opportunity for Phase 2a clinical investigation of AV-101 as a potential chronic treatment of the symptoms of HD.

Summary of AV-101 Nonclinical Pharmacology, Pharmacokinetic (PK)/toxicokinetic (TK), and Toxicology Programs

A comprehensive nonclinical pharmacology, pharmacokinetic (PK)/toxicokinetic (TK), and toxicology program has been conducted to support the clinical use of AV-101 in multiple CNS-related indications. The primary pharmacological activity of AV-101 has been investigated in a series of in vitro and in vivo studies. Pharmacology (absorption, distribution, metabolism, and excretion), PK/TK, and toxicology studies have been conducted with AV-101 in rats, dogs, and monkeys. The excellent safety profile of AV-101 was confirmed by pilot tolerability, single-dose range finding, and repeated-dose toxicology studies in rats, dogs and monkeys. In multiple in vitro genotoxicity studies (bacterial mutation, chromosomal aberration, mouse lymphoma TK+/-, and micronucleus tests), AV-101 and its active metabolite, 7-Cl-KYNA, demonstrated no genotoxic potential.

The behavioral effects of AV-101 assessed in a Good Laboratory Practice (GLP) Irwin test in rats show it to have no adverse effect on the CNS following single oral administration at doses up to 2,000 mg/kg. Although AV-101 inhibited the human ether à-go-go–related gene (hERG) current in a dose-dependent manner (median concentration that causes 50% inhibition for the inhibitory effect [IC50] of 70.5 μM), its active metabolite, 7-Cl-KYNA, showed no inhibitory effect on the hERG channel current. Electrocardiograms (ECGs) recorded during in vivo dog toxicology studies showed no AV-101–related adverse cardiovascular effects. Furthermore, in a pivotal GLP dog 14-day toxicology study, no treatment-related effects on ECGs, including QT interval and QTc, at dose levels up to 120 mg/kg/d. No evidence of any treatment-related adverse effects on the respiratory system has been noted with AV-101.

Oral administration of AV-101 to Sprague-Dawley rats and mice was shown to result in rapid absorption of AV-101 (rats: time to maximum plasma concentration [Tmax], approximately 0.25 to 0.5 hours), adequate bioavailability (rats: approximately 39% to 94%), and plasma elimination half-life (rats: t1/2 approximately 1 to 3 hours). Furthermore, in rats 7-Cl-KYNA was detected in the plasma and reached the maximum plasma concentration (Cmax) approximately 0.25 to 0.5 hours after oral administration, suggesting a rapid conversion of AV-101 to 7-Cl-KYNA. Pharmacokinetic analyses were conducted in many of the toxicology studies in rats, dogs, and monkeys. These analyses showed that the AV-101-related clinical signs observed in dogs (versus monkeys) were associated with a similar, and at some does a significantly higher, exposure. Furthermore, although AUC and Cmax values increased non-proportionately with dose level in dogs, AUC values only marginally increased with dose in monkeys, with little change in Cmax values.

Low levels of potential metabolites of AV-101 were detected following in vitro incubations with hepatocytes from the mouse, rat, dog, monkey, and humans, indicating little concern with liver metabolism issues. No appreciable conversion of AV-101 to D-4-Cl-KYN during these hepatocyte incubations was noted. Results from cytochrome P-450 (CYP) inhibition and induction studies showed that AV-101 was not a potent inhibitor or inducer of the human CYP isoforms evaluated.

Single-dose studies in rats and monkeys did not show evidence of toxicity at maximal doses of 2,000 mg/kg. In dogs, consistent with the expected drug mechanism of action, oral administration of AV-101 resulted in CNS-related clinical signs, including decreased activity, abnormal gait/stance, ataxia, and prostration at the maximum tolerated dose.

A repeated-dose (14-day) ocular toxicity study in Sprague-Dawley rats (unpigmented) and brown Norway rats (pigmented) at dose levels up to 2,000 mg/kg/d did not reveal any signs of retinal degeneration at any dose level or rat

strain. A subsequent pivotal GLP 14-day repeated-dose toxicity study in Sprague-Dawley rats showed no treatment-related ocular findings after daily dosing of AV-101 for 14 consecutive days at dose levels up to 2,000 mg/kg/d.

A GLP 14-day repeated-dose CNS toxicity study conducted in dogs, at dose levels up to 100 mg/kg/d showed no treatment-related lesions in the brain of any animal. The pivotal GLP 14-day repeated-dose toxicity study in Beagle dogs, also showed no treatment-related CNS findings after daily dosing of AV-101 for 14 consecutive days at dose levels up to 120 mg/kg/d.

The genotoxic potential of AV-101 and 7-Cl-KYNA was assessed in multiple in vitro genotoxicity studies (bacterial reverse mutation, chromosomal aberration, mouse lymphoma TK+/-, and micronucleus tests), and the overall results confirmed that both AV-101 and 7-Cl-KYNA are not mutagenic.

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A rat Olney lesion study was conducted to assess the potential CNS toxicity. No lesions were observed in the brain after a single oral dose of AV-101 at doses up to 2,000 mg/kg.

Nonclinical Pharmacology Studies

Primary Pharmacodynamics

Much of the nonclinical pharmacology information of AV-101 is derived from many published research results on 4-Cl-KYN or 7-Cl-KYNA. Primary pharmacodynamic studies conducted in rodent models for neuropathic pain demonstrated AV-101's antihyperalgesic activity in models of facilitated pain processing, its analgesic properties, its ability to provide neuroprotection from excitotoxic death, its ability to reduce seizures, and its activity in multiple preclinical models of depression.

Nonclinical Absorption, Distribution, Metabolism and Excretion Studies

In rats, area under the concentration-time curve from time of dosing extrapolated to infinity (AUC0-) values were proportional to dose for AV-101, but Cmax was less than proportional to dose, suggesting a saturation of absorption rate. 7-Cl-KYNA Cmax was less than proportional to dose, and generally females tended to have a higher exposure to AV-101 than males, but no sex difference was noted for 7-Cl-KYNA exposure. In the repeated-dose studies, D-4-Cl-KYN, 4-Cl-KYN, and 7-Cl-KYNA mean area under the concentration-time curves from time of dosing to the last sampling time (AUC0-t) and AUC0- values were higher on Day 14 than on Day 1 in both sexes of most treatment groups, indicating that exposure increased following daily repeated dosing of AV-101. Sex differences were noted for D-4-Cl-KYN and 4-Cl-KYN, with mean AUC0-t and AUC0- estimates higher in females relative to males for most treatment groups. Conversely, mean AUC0-t and AUC0- values of 7-Cl-KYNA were generally higher in males relative to females.

In dogs, AUC0- values were slightly less than proportional to dose up to 100 mg/kg AV-101 and Cmax values were less than proportional to dose, suggesting a saturation of absorption. No consistent sex differences were noted for Cmax or AUC values. AUC0- and Cmax values for 7-Cl-KYNA were less than proportional to dose. In the repeated-dose study, D-4-Cl-KYN, 4-Cl-KYN, and 7-Cl-KYNA showed a proportional increase in Cmax with the administered dose level of AV-101 in both sexes. There was no evidence of plasma accumulation for any of the analytes. Sex differences were noted for D-4-Cl-KYN, with slightly higher mean AUC0-t and AUC0- estimates in females relative to males on Day 1 and Day 14, in all treatment groups. For 7-Cl-KYNA, mean Cmax was elevated in females relative to males at all dose levels on Days 1 and Day 14, and mean AUC0-t and AUC0- estimates were also generally higher in females relative to males at all dose levels. No clear sex differences were noted for 4-Cl-KYN.

In monkeys, AUC0- values were relatively proportional to dose, but Cmax values were not proportional to dose (comparable or lower Cmax with increasing doses). The AUC0- and Cmax values for 7-Cl-KYNA were less than proportional to dose, and no major sex differences were noted.

Nonclinical Toxicology Studies

The safety profile of AV-101 was determined in single-dose, range-finding, and repeated-dose toxicology studies in rats and dogs, and in a single-dose study in monkeys. A GLP CNS safety pharmacology study in rats that included a microscopic evaluation for Olney lesions was also conducted. Additionally, pivotal GLP 14-day repeated-dose toxicology studies in rats and dogs have been conducted. The genotoxic potentials of AV-101 and 7-Cl-KYNA were assessed in multiple in vitro and in vivo genotoxicity studies, including bacterial reverse mutation, chromosomal aberration, mouse lymphoma TK+/-, and micronucleus tests. Neither was determined to be mutagenic.

Local tolerance studies have not been conducted with AV-101. However, no lesions in the gastrointestinal tract were observed after oral administration of AV-101 in the repeated-dose toxicity studies in the rat and dog.

The results of the pivotal 14-day studies show the dog to be the most sensitive species. The dog NOAEL was determined to be the highest dose level (120 mg/kg/d), and therefore the maximum recommended starting dose (MRSD) would be 6.5 mg/kg (12 mg/kg/d x 0.54 [conversion factor]) or 390 mg per subject for a 60-kg person. As a further added margin of safety for the clinical use of AV-101, the Company applied an additional safety factor to the calculated MRSD, and set the starting dose in the proposed Phase 1a clinical trial at 0.5 mg/kg (i.e., 30 mg for 60 kg subjects).

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AV-101 Phase 1 Clinical Safety Studies

Summary

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 the healthy subjects in these studies were considered to be typical for studies in healthy volunteers. All AEs were completely resolved, and no Serious Adverse Events (SAEs) were reported.

Although the Phase 1 safety and pharmacokinetic 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% (0/30) of the 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 Clinical Safety 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 (VSG-CL-001). 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. For the first five cohorts (30, 120, 360, 710 and 1,080 mg) only two subjects were dosed at a time as a pair (1:1, AV-101: placebo) on Day 1. The safety and tolerability of AV-101 in each pair of subjects was assessed by the investigator before proceeding to the next pair within the dose cohort of the study. If no safety concerns were found after analysis of the laboratory samples, physical assessments, and results of the neurological and ophthalmological examinations, the next two subjects in the cohort were dosed, but no sooner than 48 hours after the previous pair of subjects. The next cohort was dosed when the investigator and medical monitor agreed that it was safe to proceed based on review of the previous dose group’s preliminary safety information. In addition, PK assessments were to be reviewed for each cohort starting with the 720 mg through the 1,800 mg dose cohort. A minimum of four evaluable subjects (two AV-101 and two placebo) were required for determination of tolerability and safety of a dose level. The PK stopping criteria would be reached when the 4-C1-KYN mean AUC0-t reaches 900,486 ng·h/mL, or a mean Cmax of 81,633 ng/mL, or a PK extrapolation predicts exceeding one of these values in the next cohort.

All the subjects from the 1,440 mg cohort were dosed during a single day (3 subjects receiving active drug and 3 subjects receiving placebo). The safety and tolerability of AV-101 in the 1,440 mg dose cohort was to be assessed by the investigator and medical monitor before proceeding to the 1,800 mg dose cohort. If no safety concerns were found after analysis of the laboratory samples including the PK results, physical assessments, and results of the neurological and ophthalmological examinations for the 1,440 mg cohort, the 1,800-mg cohort was to be dosed. However, the PK stopping criteria were reached by one subject in the 1,440-mg cohort, and the dosing was stopped and did not proceed to the planned 1,800 mg cohort.

Phase 1a Clinical Study Pharmacokinetics Summary

Validated bioanalytical methods were used to measure plasma analyte concentrations. These assays had lower limits of quantification of 2 ng/mL for 7-Cl-KYNA and 5 ng/mL for 4-Cl-KYN and D-4-Cl- KYN. Pharmacokinetic parameters were calculated by using WinNonlin Pro v. 5.2. Parameters calculated included observed maximal concentration (Cmax), observed time to Cmax (Tmax), area under the concentration-time curve to the last sample collected (AUC0-t) or extrapolated to infinity (AUC0-), and half-life (t1/2). Concentrations of all three analytes were measurable in both plasma and urine after administration of each of the six dose levels: 30, 120, 360, 720, 1,080 and 1,440 mg.

Concentration-time data were obtained after dosing of the six cohorts. Three subjects received AV-101 and three received placebo in each cohort. Plasma concentrations of 4-Cl-KYN and 7-Cl-KYNA were obtained in addition to urine concentrations of these two analytes. Plasma and urine concentrations of D-4-Cl-KYN also were determined, but will be reported only for the first two cohorts.

This study was conducted under dose escalation stopping criteria as determined by the FDA of 4-Cl-KYN mean Cmax and AUC limits of 81,633 ng/mL and 900,486 ng·h/mL, respectively. Although these criteria were not met for the mean data of the 1,440-mg dose, one subject had a Cmax that was slightly greater than the limit of 81,633 ng/mL. Therefore, dose escalation to the planned seventh cohort of 1,800 mg of AV-101 did not occur in this study. However, from a safety perspective, a maximum tolerable dose was not achieved. Also, maximum AUC values at the highest dose level remained substantially lower than the limit.

Concentrations of all three analytes were measurable in both plasma and urine after administration of all dose levels, although many of the samples from the 30-mg dose group had concentrations below the limit of quantification for 7-Cl-KYNA. Plasma concentration-time profiles were consistent with rapid absorption of the oral dose and first-order elimination. The plasma concentration-time profiles were well defined for 4-Cl-KYN at all dose levels. Maximum concentrations occurred fairly rapidly, with individual values of Tmax ranging from 0.5 to 2 hours, with greater values tending to be in the higher dose groups. Individual t1/2 values were fairly consistent within cohorts, and mean values ranged from 1.80 to 3.33 hours. Mean t1/2 values also tended to increase with increasing dose. Mean Cmax and AUC0- values appeared to be approximately dose proportional except for those of the highest dose group.

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The 7-Cl-KYNA plasma concentration-time profiles were not well defined for the 30-mg dose. Most samples for the 30-mg dose cohort had concentrations below the lower limits of quantification, and t1/2 values could not be calculated; however, profiles were sufficient after the 120-mg and greater doses to calculate all parameters.

In general, 7-Cl-KYNA maximum concentrations occurred at the same time or later than those for 4-Cl-KYN, as may be expected since 7-Cl-KYNA is a metabolite of 4-Cl-KYN. Individual values of Tmax ranged from 0.5 to 2 hours for both analytes. Individual 7-Cl-KYNA t1/2 values were fairly consistent within cohorts, and mean values ranged from 2.17 to 3.19 hours. Mean t1/2 values did not appear to be dose-related. Mean 7-Cl-KYNA Cmax values were somewhat dose proportional for the two initial dose groups, but tended to increase in a more than dose-proportional manner. Similarly, mean 7-Cl-KYNA AUC0-t values for all dose groups and AUC0- values for dose groups of 120 mg or greater tended to increase in a more than dose-proportional manner. Mean plasma concentrations of 4-Cl-KYN (Figure 1) and 7-Cl-KYNA (Figure 2) are depicted for all six cohorts.

As with the 120-mg dose cohort, the plasma concentration-time profiles were well defined for both 4-Cl-KYN and 7-Cl-KYNA at the four higher dose levels. Interestingly, the mean concentration-time profiles suggest that maximum concentrations were lower than expected, particularly for 7-Cl-KYNA.

Assessment of Dose Proportionality

For 4-Cl-KYN, mean Cmax and AUC0- values appeared to be approximately dose proportional except for those of the highest dose group. These values are presented by dose in Figure 3 (Cmax) and in Figure 4 (AUC0-) below. Figure 3 indicates that for 4-Cl-KYN the mean Cmax values are approximately dose linear and proportional up to a dose of 1,080 mg of AV-101. After a dose of 1,440 mg, the mean Cmax values increased only 8.8% while the dose increased by 33.3%. This is evident in the deviation of the graph from linearity at the highest dose.

Although the 4-Cl-KYN mean Cmax values were not linear after the 1,080-mg dose, AUC0- values are approximately linear and dose proportional throughout the dose range. The nonlinearity of Cmax values at the highest dose could be a result of an outlier or simply variability in a small number of subjects (Cmax values of 44,600, 54,900, and 89,500 ng/mL were observed after the dose of 1,040-mg AV-101), it suggests that the rate or extent of absorption could be limited. The fact that AUC0- values were linear throughout the dose range suggests that the extent of absorption was not a limitation, but the rate of absorption may be limited at doses above 1,080 mg.

The lack of linearity of the 4-Cl-KYN mean Cmax values would be expected to have a similar effect on the 7-Cl-KYNA mean Cmax values. Similarly, because the extent of absorption of 4-Cl-KYN was linear throughout the dose range, exposure to 7-Cl-KYNA would be expected to also be linear. Mean values of 7-Cl-KYNA are presented by dose in Figure 5 (Cmax) and in Figure 6 (AUC0-).

Phase 1a Clinical Study Safety Summary

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 (2 AEs) when compared with that at the 120-mg dose (1 AE), 360-mg dose (1 AE), 720-mg dose (0 AEs), 1,080-mg dose (0 AEs), or 1,440-mg dose (2 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 2 days of onset. This AE was also considered not serious.

Even though these safety studies were not designed to quantitatively assess effects on mood, during the interviews 2 out of 3 subjects who received the highest dose (1440 mg) of AV-101, voluntarily acknowledged positive effects on mood. Similar comments were not made by any of the 18 placebo group subjects. One incident lasted approximately 15 minutes after study drug dosing, and the other event of euphoria lasted approximately 3 hours after study drug dosing. There were no other reported AEs for this cohort. The events resolved and were considered not serious.

Phase 1b Clinical Safety 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 to have been 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.

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The safety and tolerability of AV-101 were assessed by evaluating AEs and by physical examinations, vital signs, and clinical laboratory tests (chemistry and hematology assessments) that were performed on Days 1, 7 (±1 day), and 14. Blood sampling for PK was performed on Days 1, 2, 14, and 15. Additionally, ophthalmological examinations were performed at screening and Day 15. Physical examinations, including vital signs, 12-lead ECGs, neurocognitive tests, and ataxia tests were performed on Day 1 and Day 14. Before proceeding to the next higher dose, the following criteria were met:

Blinded safety and tolerability data were reviewed and assessed as being satisfactory by the investigator and medical monitor; and

PK assessments were reviewed by the blinded Cato Research PK specialist to determine if the PK stopping criteria were reached.

The doses evaluated in this Phase 1b multi-dose study of AV-101 were based on results obtained in a previously conducted Phase 1a single-dose study of AV-101 in healthy adults. The dose-escalation design was consistent with a standard scheme, and careful monitoring occurred to ensure the safety of all subjects.

The minimum toxic dose was defined as the dose at which the stopping criteria were reached. For this study, the minimum toxic dose was to be (1) the dose at which a drug-related SAE occurred in an AV-101–treated subject, or (2) 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 (Table 2). 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. No SAEs were reported.

The majority of the reported AEs were nervous system disorders (23 subjects, 46% of subjects) and gastrointestinal disorders (7 subjects, 14.0%). The remaining AEs were classified as eye disorders (3 subjects, 6.0%); psychiatric disorders (3 subjects, 6.0%); respiratory, thoracic, and mediastinal disorders (3, 6.0%); skin and subcutaneous tissue disorders (3 subjects, 6.0%); general disorders and administration site conditions (2 subjects, 4.0%); cardiac disorders (1 subject, 2.0%); infections and infestations (1 subject, 2.0%); musculoskeletal and connective tissue disorders (1 subject, 2.0%); and renal disorders (1 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, 3 (16.7%) were in the 1,440-mg group, and 1 (5.6%) was in the 360-mg group. Three (42.9%) of the 7 reported gastrointestinal disorders were in the 360-mg group, 2 (28.6%) were in the placebo group, 1 (14.3%) was in the 1,080-mg group, and 1 (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, 7 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 8 (14.0%) were of moderate intensity. There were 2 moderate intensity AEs in the 360-mg AV-101 group; 1 was unrelated pain in the right foot, and 1 was a possibly related headache. All other moderate AEs occurred

in the placebo group and included nausea or vomiting (2 AEs), headache (2 AEs), and rash around the neck (1 AE). No SAEs were reported.

Even though these safety studies were not designed to quantitatively assess effects on mood, during the interviews 3 (one each in the 360, 1080, and the 1440 mg cohort) out of 36 subjects who received AV-101, voluntarily acknowledged positive effects on mood, whereas none of 12 subjects on placebo expressed similar feelings.

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Phase 1b Clinical Study Pharmacokinetics Summary

Concentration-time data were obtained after dosing of the three cohorts. Plasma concentrations of 4-Cl-KYN (AV-101) and the metabolite, 7-Cl-KYNA, were obtained from subjects that received AV-101. PK parameters were calculated by using WinNonlin Pro Version 5.3. Parameters calculated included Cmax, Tmax, AUC0-t, AUC0- , and t1/2.

Plasma concentration-time profiles obtained for 4-Cl-KYN after administration of once-daily oral doses of 360, 1,080, or 1,440 mg AV-101 were consistent with rapid absorption of the oral dose and first-order elimination of both 4-Cl-KYN and 7-Cl-KYNA, with evidence of multicompartment kinetics, particularly for the metabolite 7-Cl-KYNA. Several subjects had plasma concentration-time profiles with a last measurable sample that appeared to be an outlier or suggested multicompartment kinetics, making it challenging to identify a terminal log-linear elimination phase. Particularly for 7-Cl-KYNA, using the last two measurable samples to calculate t1/2 resulted in unrealistic values for some subjects.

Plasma concentration-time profiles for 4-Cl-KYN were more consistently single compartment, but several had a subtle multicompartment appearance. To be consistent in the calculation of t1/2 and to report a meaningful value, the final three samples with measurable concentrations were used to calculate t1/2 for subjects for whom those samples appeared to be log-linear. Otherwise, the last sample was essentially treated as an outlier, and the prior samples in the log-linear phase were used to calculate t1/2 (these samples had a higher coefficient of determination value than the last three samples). In addition, the AUC0- values reported are calculated using the predicted last value rather than observed.

An absolute bioavailability evaluation is not possible from the data; however, an estimate of exposure can be done by comparing the AUC at the same doses. The mean AUC0- values in the Phase 1b study were higher at all three doses than seen in Phase 1a study, suggesting similar or even higher bioavailability than that in the Phase 1a study, i.e. ≥ 31%.

In summary, the PK of AV-101 was fully characterized across the range of doses in this study. Plasma concentration-time profiles obtained for 4-Cl-KYN (AV-101) and 7-Cl-KYNA after administration of a single and multiple, once daily oral doses 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.

Phase 1 Clinical Safety Program - Summary

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 AEs reported by subjects who 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 of the AEs were completely resolved. No SAEs were reported.

Although the Phase 1 safety and pharmacokinetic 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% (0/30) of the 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.

The five reports of feelings of well-being occurred in one subject each at 360 (7%, 1/15 subjects) and 1,080 mg (7%, 1/15 subjects), and three subjects at 1,440 mg (20%, 3/15 subjects) in the Phase 1a and Phase 1b clinical studies,

combined. Four of the five subjects reporting feelings of well-being did not have any other adverse experiences, and one subject (1,080 mg) also reported a mild headache. These results suggest a dose response and that AV-101 at the higher doses may lead to an increased positive mood.

Stem Cell Technology

Overview

Our stem cell technology platform is based on proprietary and licensed technologies for directing the differentiation of human pluripotent stem cells (hPSCs) and producing multiple types of mature, non-transformed, functional, adult human cells for potential drug rescue and regenerative medicine (RM) applications. .

We use our hPSC-derived heart cells (cardiomyocytes) in CardioSafe 3D™, our novel, customized in vitro bioassay system, to predict potential cardiotoxicity of drug rescue NCEs. As a result of their high purity and functionality, we believe our hPSC-derived heart cells provide potential therapeutic and commercial opportunities related to RM, including cardiac tissue engineering and cardiac cell therapy. Similarly, we believe blood, cartilage and liver cells derived from our stem cell technology provide an additional diverse range of RM opportunities.

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.

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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 in many ways relevant to drug development and RM.

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 for RM applications. 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 RM applications.

Our stem cell technology platform is based on proprietary and licensed technologies for controlling the differentiation of human pluripotent stem cells (hPSCs) and producing multiple types of mature, non-transformed, functional, adult human cells for potential drug rescue and regenerative medicine (RM) applications. .

We use our hPSC-derived heart cells (cardiomyocytes) in CardioSafe 3D™, our novel, customized in vitro bioassay system, to predict potential cardiotoxicity of drug rescue NCEs. As a result of their high purity and functionality, we believe our hPSC-derived heart cells provide potential therapeutic and commercial opportunities related to RM, including cardiac tissue engineering and cardiac cell therapy. Similarly, we believe blood, cartilage and liver cells derived from our stem cell technology provide an additional diverse range of RM opportunities.

Heart Cells (Cardiomyocytes) and CardioSafe 3D Drug Rescue

We produce fully functional, non-transformed hPSC-derived cardiomyocytes (hPSC-CMs) at a level of purity greater than 95% 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. We believe our hPSC-CMs are suitable for both drug development and RM applications.

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 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. 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

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.

Broad Clinical Predictivity of CardioSafe 3D

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 five 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.

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This suite of five CardioSafe 3D cytotoxicity assays provide measurement of cardiac drug effects with high sensitivity that are consistent with expected cardiac responses to drugs in numerous classes. We believe CardioSafe 3D provides valuable and comprehensive bioanalytical tools for assessing the effects of pharmaceutical compounds on cardiac cytotoxicity and can elucidate for us specific mechanisms of cardiac toxicity, thereby laying what we believe is a novel and advantageous foundation for our CardioSafe 3D drug rescue 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 twelve drugs, each with known toxic or non-toxic cardiac effects in humans.

CardioSafe 3D is capable of assessing important electrophysiological activity of drugs or new drug candidates, including spike amplitude, beat period and field potential duration. Our CardioSafe 3D MEA assay, which we refer to as ECG in a test tube™, was reproducible and consistent with the known human cardiac effects of numerous 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 (Seldane™), withdrawn by the FDA due to cardiotoxicity, and the cardiac effects of the closely structurally-related compound, fexofenadine (Allegra™), a safe variant of terfenadine, which remains on the market. We believe our correlation data demonstrate that CardioSafe 3D provides valuable and comprehensive bioanalytical tools for in vitro cardiac safety screening, well beyond the capabilities of the hERG assay. The table below reflects the broad cardiotoxicity screening capabilities CardioSafe 3D, which we believe go far beyond what is possible to assess in vitro using the FDA-required hERG assay:

Detects cardiac effects mediated by:	hERG assay	CardioSafe 3D™
hERG potassium ion channels	ü	ü
Other potassium ion channels		ü
Calcium ion channels		ü
Sodium ion channels		ü
Interactions between ion channels		ü
Channel regulatory proteins		ü
Cell viability		ü
Apoptosis		ü
Mitochondria		ü
Energy		ü
Oxidative Stress		ü

Using Stem Cell Technology to Produce and 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. 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.

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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.

Strategic Development and Commercialization of Drug Rescue NCEs

Once we optimize a patentable drug rescue NCE, we intend to develop it internally to establish preclinical POC in established in vitro and in vivo efficacy and safety models, as well as in CardioSafe 3D. After we establish preclinical POC of a patentable drug rescue NCE, we will decide between continuing to develop it internally and out-licensing it to a pharmaceutical company. If we license it to the pharmaceutical company, it will be responsible for all subsequent development, manufacturing, regulatory approval, marketing and sale of the drug rescue NCE and we will generate revenue through payments to us from the license upon signing the license agreement, achievement of development and regulatory milestones, and, if approved and marketed, upon commercial sales, although no assurances can be given that we will seek and complete a partnership, or that the terms of such a beneficial arrangement will be available or offered to us.

Regenerative Medicine

We believe stem cell technology-based RM has the potential to transform healthcare in the U.S. and other established pharmaceutical markets 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 and intellectual property. We believe 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 regenerative medicine purposes, including both novel human disease models for discovery of small molecule drugs with regenerative and therapeutic potential and cellular therapies. Among our key objectives will be to establish one or more RM-related collaborations designed to advance potential commercial opportunities related to RM, including (A) cell-based therapy (injection of progenitor or tissue-specific mature cells obtained through directed differentiation), (B) cell repair therapy (induction of regeneration by biologically active molecules administered alone or secreted by infused engineered cells), or (C) tissue engineering (transplantation of in vitro grown tissues), each involving hPSC-derived blood, bone, cartilage, heart and/or liver cells through nonclinical and early clinical POC studies.

Strategic Relationships

Strategic collaborations are an important cornerstone of our corporate development strategy. We believe that our strategic outsourcing model gives us flexible access to medicinal chemistry, research and development capabilities, and manufacturing, clinical development and regulatory expertise at a lower overall cost than developing and maintaining the full extent of such capabilities and expertise internally on a full-time basis. In particular, we collaborate with the types of third parties identified below for the following functions:

- academic and non-profit research institutions, such as the University Health Network, the McEwen Centre for Regenerative Medicine and the Centre for the Commercialization of Regenerative Medicine for stem cell technology research, development and cell production;

contract manufacturing and manufacturing service, medicinal chemistry and process development companies, such as Norac Pharma, Pharmatek and Synterys, Inc., to design, produce and analyze AV-101 clinical trial materials and potential drug rescue NCEs; and

contract clinical development and regulatory organizations (CROs), such as Pharmaceutical Product Development, LLC, Cato Research, Ltd. and Massachusetts General Hospital Clinical Trials Network and Institute for regulatory expertise and clinical development support.

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Cato Research

Cato Research 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 25 years of experience interacting with the FDA and international regulatory agencies and a successful track record of product approvals.

Cato BioVentures

Cato Holding Company, doing business as Cato BioVentures, is the venture capital affiliate of Cato Research. Through strategic CRO service agreements with Cato Research, Cato BioVentures invests in therapeutics and medical devices, as well as platform technologies such as our stem cell technology platform, which its principals believe, based on their experience as management of Cato Research, are capable of transforming the traditional drug development process and the research and development productivity of the biotechnology and pharmaceutical industries.

As a result of the access Cato Research has to potential drug rescue NCEs from its biotechnology and pharmaceutical industry network, as well as Cato BioVentures' strategic long term equity interest in the Company, we believe that our relationships with Cato BioVentures and Cato Research may provide us with unique opportunities relating to our drug rescue efforts that will permit us to leverage both their industry connections and the CRO resources of Cato Research, either on a contract research basis or in exchange for economic participation rights, should we develop drug rescue NCEs internally rather than out-license them to strategic partners.

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 (MGH) 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 Phase 2b clinical study of AV-101 for treatment of MDD. 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 our Phase 2b study of AV-101 in MDD. Dr. Laughren is the former FDA Division Director, Division of Psychiatry Products, Center for Drug Evaluation and Research (CDER).

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Pharmaceutical Product Development, LLC

Pharmaceutical Product Development, LLC (PPD) is a leading global CRO providing comprehensive, integrated drug development, laboratory and lifecycle management services. With offices in 46 countries and more than 15,000 professionals worldwide, PPD applies innovative technologies, therapeutic expertise and a firm commitment to quality to help its clients and partners bend the cost and time curve of drug development to deliver life-changing therapies that improve health. We are currently working with PPD as our full-service CRO in connection with the planning and execution of our Phase 2b clinical study of AV-101 for treatment of MDD.

Synterys, Inc.

We have entered into a strategic medicinal chemistry collaboration agreement with Synterys, Inc., a medicinal chemistry and collaborative drug discovery company. We believe this important collaboration will further our drug rescue initiatives with the support of Synterys' medicinal chemistry expertise. In addition to providing flexible, real-time contract medicinal chemistry services in support of our drug rescue programs, we anticipate potential collaborative opportunities with Synterys wherein we may jointly identify and develop drug rescue NCEs.

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 nonclinical and Phase 1 clinical development of AV-101.

United States National Institute of Mental Health

The U.S. National Institute of Mental Health, 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. In February 2015, we entered into CRADA with the NIH providing for our ongoing AV-101 Phase 2a efficacy and safety study in MDD. This Phase 2a study is 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.

University Health Network, McEwen Centre for Regenerative Medicine

University Health Network (UHN) in Ontario, Canada is a major landmark in Canada's healthcare system. UHN is one of the world's largest research hospitals, with major research in transplantation, cardiology, neurosciences, oncology, surgical innovation, infectious diseases and genomic medicine.

The McEwen Centre for Regenerative Medicine (McEwen Centre) is a world-renowned center for stem cell biology and regenerative medicine and a stem cell research facility affiliated with UHN. Dr. Gordon Keller, our co-founder and Chairman of our Scientific Advisory Board, is Director of the McEwen Centre. Dr. Keller's lab is considered one of the leaders in successfully applying principles from the study of developmental biology of many animal systems to the differentiation of pluripotent stem cell systems, resulting in reproducible, high-yield production of human heart, liver, blood and vascular cells. The results and procedures developed in Dr. Keller's lab are often quoted and used by academic scientists worldwide.

In September 2007, we entered into a long-term sponsored stem cell research and development collaboration with UHN. In December 2010, we extended the collaboration to September 2017. The primary goal of this ten-year collaboration is to leverage the stem cell research, technology and expertise of Dr. Gordon Keller to develop and commercialize industry-leading human pluripotent stem cell differentiation technology and bioassay systems for drug rescue and development and regenerative cell therapy applications. This sponsored research collaboration builds on our existing strategic licenses from National Jewish Health and the Icahn School of Medicine at Mount Sinai to certain pluripotent stem cell technologies developed by Dr. Keller, and is directed to diverse human pluripotent stem cell-based research projects, including, as expanded and amended, strategic projects related to drug rescue and regenerative medicine.

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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 a development-stage prodrug candidate presently being studied in an NIH-sponsored Phase 2a clinical trial for the treatment of MDD. We have developed a broad and diverse 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 not 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. Patent rights included in that license that were relevant to AV-101, however, 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 market exclusivity.

Presently, we are prosecuting a family of patent applications in the USPTO, European Patent Office 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. We have recently filed a continuation application in this family in the U.S., focused on the treatment of depression, that is undergoing accelerated examination. There is no guarantee, however, that the USPTO will allow any of the pending claims.

We are also prosecuting a second 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 separate 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 compounds related to 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 was filed in the U.S. as a provisional application in 2015. A PCT patent application corresponding to the provisional was filed in May 2016, and we plan to seek patent protection at the national phase in appropriate global markets.

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 R&D activity in the second half of 2016.

As noted, we are involved with an ongoing Phase 2a study of AV-101 in MDD 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.

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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. 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 in the U.S. or other countries related to AV-101, 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. And 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 IP portfolio relates to drug development, drug rescue/toxicity testing, drug discovery and cell therapy. 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, the IP 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.

Overall, our stem cell patent portfolio includes nine patent families, which collectively include 11 issued U.S. patents that remain in force and eight pending U.S. patent applications, as well as several foreign counterpart patents and patent applications in countries of commercial interest to VistaGen. The portfolio also includes several patent applications pending in the U.S. and in various foreign countries. For convenience of reference, our stem cell patent portfolio is based on published PCT patent applications WO 1997/021802, WO2000/034525, WO2004/098490, WO2001/096866, WO2012/024782, WO2013/075222, WO2014/124527, WO2014/161075 and WO2015035506, several of which are discussed below.

The patent properties in these families are based on discoveries from our internal research and development activities, research that we have sponsored at various academic institutions, as well as from patent license agreements signed with the National Jewish Medical and Research Center, University Health Network 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 fees for sublicensing. As noted above in the context of AV-101 intellectual property, there is no guarantee that we will successfully obtain or maintain patents in the countries in which we are pursuing patent rights or that we would be successful in enforcing granted patent rights against infringers.

Trademarks

We have a U.S. 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™, LiverSafe 3D™ and “Better Cells Lead to Better Medicine™.”

Sponsored Research Collaborations and Intellectual Property Rights

University Health Network (UHN), McEwen Centre for Regenerative Medicine, Toronto, Ontario

Our strategic relationship with our co-founder, Dr. Gordon Keller, Director of the UHN’s McEwen Centre, is focused on, among other things, developing improved methods for differentiation of cardiomyocytes (heart cells) from hPSCs, and their uses in bioassay systems for drug discovery and drug development, including drug rescue, cell therapy and regenerative medicine. Pursuant to our sponsored research collaboration agreement with UHN, 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. Such pre-negotiated 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 compounds 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.

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The sponsored research collaboration agreement (SRCA) with UHN, as amended, has a term of ten years, ending on September 18, 2017. We are currently in discussions with Dr. Keller and UHN regarding the scope of potential new sponsored research projects under the SRCA. The ten-year term of the agreement is subject to renewal upon mutual agreement of the parties. The agreement may be terminated earlier upon a material breach by either party that is not cured within 30 days. UHN may elect to terminate the agreement if we become insolvent or if any license granted pursuant to the agreement is prematurely terminated. We have the option to terminate the agreement if Dr. Keller stops conducting his research or ceases to work for UHN.

UHN Licenses for Stem Cell Culture Technology

In October 2011, we licensed stem cell culture technology from UHN's McEwen Centre pursuant to Sponsored Research Collaboration Agreement (SCRA). This exclusive license conveyed rights to a patent application published as a PCT application WO/2012/024782, entitled "Methods for Enriching Pluripotent Stem Cell Derived Cardiomyocyte Progenitor Cells and Cardiomyocyte Cells Based on SIRPA Expression,", and any related patent application or patent claiming priority from it. This technology involves a cell surface protein, SIRPA (signal-regulatory protein alpha), that heretofore was not known to be expressed by early immature precursors for cardiomyocytes. Antibodies and other binding moieties specific to SIRPA allow the identification and enrichment of these early cardiomyocyte precursors, which we believe will provide benefits in terms of purity, functionality and reproducibility for not only CardioSafe 3D™ in vitro safety assays for drug screening and development, but also potentially for production of cardiomyocytes for cell therapy and regenerative medicine applications.

In April 2012, we licensed additional stem cell culture technology from UHN's McEwen Centre pursuant to the SCRA. The licensed technology may be used to develop hematopoietic precursor stem cells from human pluripotent stem cells, with the goal of developing drug discovery screening and regenerative medicine applications for human blood system disorders. This exclusive license conveyed rights to a patent application published as PCT patent application WO/2013/075222, entitled "Populations of Hematopoietic Progenitiors and Methods of Enriching Stem Cells Therefor," and any related patent application or patent claiming priority from it. We believe this stem cell technology substantially advances our ability to produce and purify this important blood stem cell precursor for both in vitro drug discovery screening and potential regenerative medicine applications. In addition to defining new cell culture methods for our use, the technology describes the surface characteristics of stem cell-derived adult hematopoietic stem cells. Most groups study embryonic blood development from stem cells, but we are able to not only purify the stem cell-derived precursor of all adult hematopoietic cells, but also pinpoint the precise timing when adult blood cell differentiation takes place in these cultures. We believe these early cells, isolated through our licensed technology, have the potential to be the precursors of the ultimate adult, bone marrow-repopulating hematopoietic stem cells potentially useful to repopulate the blood and immune system when transplanted into bone marrow transplantation patients. These cells have important potential therapeutic applications for the restoration of healthy blood and immune systems in individuals undergoing transplantation therapies for cancer, organ grafts, HIV infections or for acquired or genetic blood and immune deficiencies.

In December 2014, we licensed additional stem cell culture technology from UHN's McEwen Centre pursuant to the SCRA. This exclusive license conveyed rights to a patent application published as PCT patent application WO/2014/124527, entitled "Methods for Generating Hepatocytes and Cholangiocytes from Pluripotent Stem Cells," and any related patent application or patent claiming priority from it. The licensed technology describes advanced methods for the production of mature hepatocytes and cholangiocytes, the primary cell types of the liver. The liver plays an important role in many bodily functions including protein production, blood clotting, as well as glucose, iron and lipid metabolism. Hepatocytes are the major cells responsible for metabolizing drugs, drug-drug interactions, and are the target for a variety of liver diseases and disorders, including drug-induced liver failure, Cirrhosis, and viral infections. Cholangiocytes are the precursors for the biliary system found in the liver, i.e. bile ducts and gallbladder. The biliary system is a significant target for many conditions, including drug toxicities, cholecystitis, and liver-related abnormal

function associated with the cystic fibrosis mutation. We believe the licensed technology will enable us to more efficiently produce, human hepatocytes and cholangiocytes with more adult-like functions for potential drug discovery, drug rescue and regenerative medicine applications.

In December 2014, we also licensed another stem cell culture technology from UHN's McEwen Centre pursuant to the SCRA. This exclusive license conveyed rights to a patent application entitled "Methods and Compositions for Generating Epicardium Cells," published as PCT patent application WO/2015/035506, and any patent application or patent claiming priority from it. The epicardium is the outer cell layer on top of the heart muscle (cardiomyocytes), and is essential for proper development of the heart and plays an important role in cardiac recovery during disease. The epicardium plays a critical role in the differentiation, expansion, and maturation of cardiomyocytes during development, or during cardiac repair responses. This patent application also relates to the differentiation of cardiomyocytes, fibroblast-like cells and smooth muscle-like cells. This technology will be important to developing the next generation of engineered cardiac tissue and their use in cell therapy approaches.

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Also in December 2014, we licensed an additional stem cell culture technology from UHN's McEwen Centre pursuant to the SCRA. This exclusive license conveyed rights to a patent application entitled "Methods and Compositions for Generating Chondrocyte Lineage Cells and/or Cartilage Like Tissue" published as PCT patent application WO/2014/161075, and any related patent application or patent claiming priority from it. There are two types of chondrocytes, "articular" and "growth plate." Articular chondrocytes are responsible for cartilage that lines our joints, whereas growth plate chondrocytes are involved with new bone formation. Osteoarthritis is debilitating joint diseases resulting from the degeneration of the first kind, articular cartilage, leading to inappropriate bone development (spurs) in the joint. This technology will allow us to develop in vitro assays to study the process of the degeneration of articular cartilage, and it provides novel tools for testing drugs that have the potential to reduce this degeneration. It also provides the necessary cells for developing cell therapy approaches for treating osteoarthritis.

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 certain of our patent applications relating to AV-101 and certain of our patent applications relating to 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 exercise certain rights reserved by statute with respect to inventions made in the course of programs funded by NIH, NIMH or other federal grants.

Competition

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

Currently, there are no FDA-approved therapies for MDD with the mechanism of action of AV-101. However, products approved for other indications, for example, low doses of the anesthetic ketamine, are being or may be increasingly used off-label for treatment-resistant MDD, as well as other CNS indications for which AV-101 may have therapeutic potential. Additionally, other treatment options, such psychotherapy and electroconvulsive therapy, are sometimes used instead of and before antidepressant medications to treat patients with MDD.

In the field of new generation antidepressants focused on modulation of the NMDAR at its GlyB site, our principal competitor is Allergan plc, which is developing rapastinel (formerly GLYX-13) and NRX-1074 for treatment-resistant MDD. On August 28, 2015, Allergan acquired rapastinel and NRX-1074 from Naurex, Inc. (Naurex) in an all-cash transaction of $571.7 million, plus future contingent payments up to $1.15 billion. Although each of these drug candidates is a peptide and may not be orally active (rapastinel is only administered intravenously and, we believe, NRX-1074 has not yet been administered orally to patients), both are new generation NMDAR modulators focused on the GlyB site of the NMDAR.

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 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, Ono, Otsuka, Pfizer, Roche, Sanofi, Shire, Sumitomo, Takeda and Teva. 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 our 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 , 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 hPSCl technology includes the following: Acea Biosciences, Astellas, Athersys, BioCardia, BioTime, Cellectis Bioresearch, Cellerant Therapeutics, Cytori Therapeutics, Fujifilm Holdings, HemoGenix, International Stem Cell, NeoStem, Neuralstem, Organovo Holdings, PluriStem Therapeutics, Stem Cells, and Stemina BioMarker Discovery. Pharmaceutical companies and other established corporations such as Bristol-Myers Squibb, GE Healthcare Life Sciences, GlaxoSmithKline, Novartis, Pfizer, Roche Holdings, Thermo Fischer 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.

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Government Regulation

Government authorities in the U.S. at the federal, state and local level and in other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug products. Generally, before a new drug can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific to each regulatory authority, submitted for review and approved by the regulatory authority.

U.S. Drug Development

In the U.S., the FDA regulates drugs under the FDCA and its implementing regulations. Drugs are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Our product candidates must be approved by the FDA through the NDA process before they may be legally marketed in the U.S.. The process required by the FDA before a drug may be marketed in the U.S. generally involves the following:

Completion of extensive non-clinical, sometimes referred to as non-clinical laboratory tests, non-clinical animal studies and formulation studies in accordance with applicable regulations, including the FDA's current Good Laboratory Practice (cGLP), regulations;

Submission to the FDA of an IND application, which must become effective before human clinical trials may begin;

Approval by an independent institutional review board (IRB) or ethics committee at each clinical trial site before each trial may be initiated;

Performance of adequate and well-controlled human clinical trials in accordance with applicable IND and other clinical trial-related regulations, sometimes referred to as good clinical practices (GCPs) to establish the safety and efficacy of the proposed drug for each proposed indication;

Submission to the FDA of an NDA, for a new drug;

A determination by the FDA within 60 days of its receipt of an NDA to file the NDA for review;

Satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the drug is produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;

Potential FDA audit of the non-clinical and/or clinical trial sites that generated the data in support of the NDA; and

FDA review and approval of the NDA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the drug in the United States.

The non-clinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all. Non-clinical tests include laboratory evaluation of product chemistry, formulation, stability and toxicity, as well as animal studies to assess the characteristics and potential safety and efficacy of the product.

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The data required to support an NDA is generated in two distinct development stages: non-clinical and clinical. For new chemical entities, the non-clinical development stage generally involves synthesizing the active component, developing the formulation and determining the manufacturing process, as well as carrying out non-human toxicology, pharmacology and drug metabolism studies in the laboratory, which support subsequent clinical testing. The conduct of the non-clinical tests must comply with federal regulations, including GLPs. The sponsor must submit the results of the non-clinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational drug product to humans. Some non-clinical testing may continue even after the IND is submitted, but an IND must become effective before human clinical trials may begin. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human trials. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials, including subjects will be exposed to unreasonable health risks, and places the IND on clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a drug candidate at any time before or during clinical trials due to safety concerns or non-compliance. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that could cause the trial to be suspended or terminated.

The clinical stage of development involves the administration of the drug candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Further, each clinical trial must be reviewed and approved by an independent IRB at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries.

A sponsor who wishes to conduct a clinical trial outside the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of an NDA so long as the clinical trial is conducted in compliance with an international guideline for the ethical conduct of clinical research known as the Declaration of Helsinki and/or the laws and regulations of the country or countries in which the clinical trial is performed, whichever provides the greater protection to the participants in the clinical trial.

Clinical Trials

Clinical trials are generally conducted in three sequential phases that may overlap, known as Phase 1, Phase 2 and Phase 3 clinical trials.

Phase 1 clinical trials generally involve a small number of healthy volunteers who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the drug.

Phase 2 clinical trials typically involve studies in disease-affected patients to determine the dose required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, as well as identification of possible adverse effects and safety risks and preliminary evaluation of efficacy.

Phase 3 clinical trials generally involve large numbers of patients at multiple sites (from several hundred to several thousand subjects) and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use, and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product approval. Phase 3 clinical trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing.

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Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse events, finding from other studies, or any finding from animal or in vitro testing that suggests a significant risk for human subjects. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA, the IRB, or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial. Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, we must develop methods for testing the identity, strength, quality and purity of the final drug product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

NDA and FDA Review Process

The results of non-clinical studies and of the clinical trials, together with other detailed information, including extensive manufacturing information and information on the composition of the drug and proposed labeling, are submitted to the FDA in the form of an NDA requesting approval to market the drug for one or more specified indications. The FDA reviews an NDA to determine, among other things, whether a drug is safe and effective for its intended use and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. FDA approval of an NDA must be obtained before a drug may be offered for sale in the United States.

In addition, under the Pediatric Research Equity Act (PREA) an NDA or supplement to an NDA must contain data to assess the safety and efficacy 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. The FDA may grant deferrals for submission of pediatric data or full or partial waivers.

Under the Prescription Drug User Fee Act (PDUFA) as amended, each NDA must be accompanied by a user fee. The FDA adjusts the PDUFA user fees on an annual basis. According to the FDA's fee schedule, effective through December 31, 2014, the user fee for an application requiring clinical data, such as an NDA, is $2.2 million. PDUFA also imposes an annual product fee for human drugs of $0.1 million and an annual establishment fee of $0.6 million on facilities used to manufacture prescription drugs. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. The FDA must make a decision on accepting an NDA for filing within 60 days of receipt. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has 10 months from the filing date in which to complete its initial review of a standard NDA and respond to the applicant, and six months from the filing date for a priority NDA. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs, and the review process is often significantly extended by FDA requests for additional information or clarification.

After the NDA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. Before approving an NDA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMPs. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. In addition, before approving an NDA, the FDA may also audit data from clinical trials to ensure compliance with GCP requirements. Additionally, the FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. The FDA will likely re-analyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. The review and evaluation of an NDA by the FDA is extensive and time consuming and may take longer than originally planned to complete, and we may not receive a timely approval, if at all.

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After the FDA evaluates an NDA, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant and time-consuming requirements related to clinical trials, non-clinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data.

There is no assurance that the FDA will ultimately approve a drug product for marketing in the United States and we may encounter significant difficulties or costs during the review process. If a product receives marketing approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling or may condition the approval of the NDA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-marketing testing or clinical trials and surveillance to monitor the effects of approved products. For example, the FDA may require Phase 4 testing which involves clinical trials designed to further assess a drug's safety and efficacy and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. The FDA may also place other conditions on approvals including the requirement for a risk evaluation and mitigation strategy (REMS) to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS. The FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory requirements or if problems occur following initial marketing.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S., or more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making a drug product available in the U.S. for this type of disease or condition will be recovered from sales of the product. Orphan product designation must be requested before submitting an NDA. After the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication than that for which the orphan product has exclusivity. Orphan product exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same product as defined by the FDA or if our product candidate is determined to be contained

within the competitor's product for the same indication or disease. If a drug designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity. Orphan drug status in the European Union has similar, but not identical, benefits.

Expedited Development and Review Programs

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new drugs that meet certain criteria. Specifically, new drugs are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug or biologic may request the FDA to designate the drug as a Fast Track product at any time during the clinical development of the product. Unique to a Fast Track product, the FDA may review sections of the marketing application on a rolling basis before the complete NDA is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

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Any product submitted to the FDA for marketing, including under a Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or offers a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug designated for priority review in an effort to facilitate the review. A product may also be eligible for accelerated approval. Drugs studied for their safety and efficacy in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. If the FDA concludes that a drug shown to be effective can be safely used only if distribution or use is restricted, it will require such post-marketing restrictions, as it deems necessary to assure safe use of the drug, such as:

distributionrestricted to certain facilities or physicians with special training or experience; or

distribution conditioned on the performance of specified medical procedures.

The limitations imposed would be commensurate with the specific safety concerns presented by the drug. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Additionally, a drug may be eligible for designation as a breakthrough therapy if the drug is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more indications. The benefits of breakthrough therapy designation include the same benefits as fast track designation, plus intensive guidance from FDA to ensure an efficient drug development program. Fast Track designation, priority review, accelerated approval and breakthrough designation do not change the standards for approval, but may expedite the development or approval process.

Pediatric Trials

The Food and Drug Administration Safety and Innovation Act (FDASIA) which was signed into law on July 9, 2012, amended the FDCA to require that a sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan (PSP) within sixty days of an end-of-Phase 2 meeting or as may be agreed between the sponsor and FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from non-clinical studies, early phase clinical trials, and/or other clinical development programs.

Post-Marketing Requirements

Following approval of a new product, a pharmaceutical company and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and recordkeeping activities, reporting to the

applicable regulatory authorities of adverse experiences with the product, providing the regulatory authorities with updated safety and efficacy information, product sampling and distribution requirements, and complying with promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting drugs for uses or in patient populations that are not described in the drug's approved labeling (known as "off-label use"), limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the Internet. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Further, if there are any modifications to the drug, including changes in indications, labeling, or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA or NDA supplement, which may require the applicant to develop additional data or conduct additional non-clinical studies and clinical trials. As with new NDAs, the review process is often significantly extended by FDA requests for additional information or clarification. Any distribution of prescription drug products and pharmaceutical samples must comply with the U.S. Prescription Drug Marketing Act (PDMA) a part of the FDCA.

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In the United States, once a product is approved, its manufacture is subject to comprehensive and continuing regulation by the FDA. The FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. NDA holders using contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. These manufacturers must comply with cGMP regulations that require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMP, could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute products manufactured, processed or tested by them. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved NDA, including, among other things, recall or withdrawal of the product from the market.

Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

Other Regulatory Matters

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including, in the U.S., the Centers for Medicare & Medicaid Services, other divisions of the Department of Health and Human Services, the U.S. Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments. In the U.S., sales, marketing and scientific/educational programs must also comply with state and federal fraud and abuse laws. These laws include the federal Anti-Kickback Statute, which makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase, order, or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by up to five years in prison, criminal fines, administrative civil money penalties, and exclusion from participation in federal healthcare programs. In addition, the Patient Protection and Affordable Health Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, among other things, amends the intent requirement of the federal Anti-Kickback Statute and criminal healthcare fraud statutes created by the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. Moreover, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

Although we would not submit claims directly to payors, drug manufacturers can be held liable under the federal False Claims Act, which prohibits anyone from knowingly presenting, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services, including drugs, that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. The government may deem manufacturers to have "caused" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. In addition, our future activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state, and third-party reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under this law. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties of between $5,500 and $11,000 for each separate false claim, the potential for exclusion from participation in federal healthcare programs, and, although the federal False Claims Act is a civil statute, conduct that results in a False Claims Act violation may also implicate various federal criminal statutes. If the government were to allege that we were, or convict us of, violating these false claims laws, we could be subject to a substantial fine and may suffer a decline in our stock price. In addition, private individuals have the ability to bring actions under the federal False Claims Act and certain states have enacted laws modeled after the federal False Claims Act.

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Pricing and rebate programs must comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in ACA. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. The handling of any controlled substances must comply with the U.S. Controlled Substances Act and Controlled Substances Import and Export Act. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities are also potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, or refusal to allow a firm to enter into supply contracts, including government contracts. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of the FDA approval of our drug candidates, some of our U.S. patents may be eligible for limited patent term extension under the U.S. Drug Price Competition and Patent Term Restoration Act of 1984, commonly 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, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we intend to apply for restoration of patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA.

Marketing exclusivity provisions under the FDCA can also delay the submission or the approval of certain marketing applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application (ANDA) or a 505(b)(2) NDA submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovator

drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder. The FDCA also provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the non-clinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and efficacy. Orphan drug exclusivity, as described above, may offer a seven-year period of marketing exclusivity, except in certain circumstances. Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued “Written Request” for such a trial.

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European Union Drug Development

In the European Union (EU), our future products may also be subject to extensive regulatory requirements. As in the United States, medicinal products can only be marketed if a marketing authorization from the competent regulatory agencies has been obtained.

Similar to the U.S., the various phases of non-clinical and clinical research in the European Union are subject to significant regulatory controls. Although the EU Clinical Trials Directive 2001/20/EC has sought to harmonize the EU clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the EU, the EU Member States have transposed and applied the provisions of the Directive differently. This has led to significant variations in the member state regimes. Under the current regime, before a clinical trial can be initiated it must be approved in each of the EU countries where the trial is to be conducted by two distinct bodies: the National Competent Authority (NCA) and one or more Ethics Committees (ECs). Under the current regime all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the Member State where they occurred.

The EU clinical trials legislation is currently undergoing a revision process mainly aimed at harmonizing and streamlining the clinical trials authorization process, simplifying adverse event reporting procedures, improving the supervision of clinical trials, and increasing their transparency.

European Union Drug Review and Approval

In the European Economic Area (EEA) (which is comprised of the 27 Member States of the European Union (excluding Croatia) plus Norway, Iceland and Liechtenstein), medicinal products can only be commercialized after obtaining a Marketing Authorization, (MA). There are two types of marketing authorizations:

The Community MA is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) and is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicinal products containing a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.

National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member States through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure. Under the Decentralized Procedure an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member State (RMS). The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics (SPC) and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Member States Concerned) for their approval. If the Member States Concerned raise no objections, based on a potential serious risk to public health, to the assessment, SPC, labeling, or packaging proposed by the RMS, the product is subsequently granted a national MA in all the Member States (i.e., in the RMS and the Member States Concerned).

Under the above-described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

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European Union New Chemical Entity Exclusivity

In the EU, new chemical entities, sometimes referred to as new active substances, qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. This data exclusivity, if granted, prevents regulatory authorities in the EU from referencing the innovator's data to assess a generic application for eight years, after which generic marketing authorization can be submitted, and the innovator's data may be referenced, but not approved for two years. The overall ten-year period will be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

European Union Orphan Designation and Exclusivity

In the EU, the EMA's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than 5 in 10,000 persons in the European Union Community and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or the product would be a significant benefit to those affected). Additionally, designation is granted for products intended for the diagnosis, prevention, or treatment of a life threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the medicinal product.

In the EU, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity is granted following medicinal product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. Orphan drug designation must be requested before submitting an application for marketing approval. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Rest of the World Regulation

For other countries outside of the EU and the U.S., such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials must be conducted in accordance with cGCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Reimbursement

Sales of our products will depend, in part, on the extent to which our products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. In the United States no uniform policy of coverage and reimbursement for drug products exists. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of our products will be made on a payor by payor basis. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

Third-party payors are increasingly reducing reimbursements for medical products and services. Additionally, the containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in 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 net revenue and results. Decreases in third-party reimbursement for our product candidate or a decision by a third-party payor to not cover our product candidate could reduce physician usage of the product candidate and have a material adverse effect on our sales, results of operations and financial condition.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the MMA) established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Unlike Medicare Part A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

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The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. The plan for the research was published in 2012 by the U.S. Department of Health and Human Services, the Agency for Healthcare Research and Quality and the NIH, and periodic reports on the status of the research and related expenditures will be made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of our product candidate, if any such product or the condition that it is intended to treat is the subject of a trial. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of our product candidate. If third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

The ACA is expected to have a significant impact on the health care industry. The ACA is expected to expand coverage for the uninsured while at the same time containing overall healthcare costs. With regard to pharmaceutical products, among other things, the ACA is expected to expand and increase industry rebates for drugs covered under Medicaid programs and make changes to the coverage requirements under the Medicare Part D program. We cannot predict the full impact of the ACA on our business as many of the ACA reforms require the promulgation of detailed regulations implementing the statutory provisions that has not yet occurred. For example, the ACA imposed new reporting requirements on drug manufacturers for payments made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year (or up to an aggregate of $1 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Drug manufacturers were required to begin collecting data on August 1, 2013 and were required to submit reports to CMS by March 31, 2014 (and by the 90th day of each subsequent calendar year). In addition, many states have adopted laws similar to the federal laws discussed above. Some of these state prohibitions apply to the referral of patients for healthcare services reimbursed by any insurer, not just federal healthcare programs such as Medicare and Medicaid. There has also been a recent trend of increased federal and state regulation of payments made to physicians. Certain states mandate implementation of compliance programs, impose restrictions on drug manufacturers' marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians. In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, started in April 2013. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012 (the ATRA), which delayed for another two months the budget cuts mandated by these sequestration provisions of the Budget Control Act of 2011. The ATRA, among other things, also reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. We expect that additional 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, and in turn could significantly reduce the projected value of certain development projects and reduce our profitability.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect

controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the EU do not follow price structures of the U.S. and generally prices tend to be significantly lower.

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.

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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. We anticipate conducting additional hPSC research (with both hESCs and hiPSCs), in collaboration with Dr. Keller and his research team, at UHN's McEwen Centre during 2015 and beyond. 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, is our wholly-owned subsidiary and has the following two wholly-owned subsidiaries: VistaStem Canada Inc., a corporation incorporated pursuant to the laws of the Province of Ontario, intended to facilitate our stem cell-based research and development and drug rescue activities in Canada should we elect to expand our U.S. operations into Canada; and Artemis Neuroscience, Inc., a corporation incorporated pursuant to the laws of the State of Maryland. The operations of VistaGen Therapeutics, Inc., a California corporation, and each of its two wholly owned subsidiaries are managed by our senior management team based in South San Francisco, California.

Employees

As of June 24, 2016, we employed nine full-time employees, four of whom have doctorate degrees. Six full-time employees work in research and development and laboratory support services and three 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, stock plan administration, 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 10,000 square feet located in South San Francisco, California. Our lease expires on July 31, 2017. We intend to renew the lease at our current location in the ordinary course of business, prior to the end of July 2017.

Legal Proceedings

None.

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Environmental Regulation

Our business does not require us to comply with any particular unique 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 of the 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 results of operations could be materially and adversely affected.

Risks Related to Product Development, Regulatory Approval and Commercialization

We depend heavily on the success of AV-101. We cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize AV-101, or any product candidate.

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

We are not permitted to market our product candidates in the United States until we receive approval of a New Drug Application (NDA) from the FDA, or in any foreign countries until we receive the requisite approval from such countries. In late 2015, in collaboration with the NIMH under our CRADA, we began a Phase 2a clinical trial involving AV-101, to study its safety, tolerability and efficacy in patients with MDD. If our Phase 2a clinical trial of AV-101 is successful, we expect the FDA to require us to complete at least one pivotal Phase 2B clinical trial and at least one pivotal Phase 3 clinical trial in order to submit an NDA for AV-101 as an adjunctive treatment for MDD. However, the FDA may require that we conduct more than one Phase 2B clinical study and more than one Phase 3 pivotal trial of AV-101 before we can submit an NDA. Also, we anticipate that the FDA will require that we conduct additional toxicity studies and additional non-clinical studies before submitting an NDA for AV-101.

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

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

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

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

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

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Any of these factors, many of which are beyond our control, could jeopardize our ability to obtain regulatory approval for and successfully commercialize AV-101 or any other product candidate we may develop, including drug rescue NCEs. Any such setback in our pursuit of regulatory approval would have a material adverse effect on our business and prospects.

We intend to seek a Fast Track designation from the FDA for AV-101 for treatment of MDD. Even if the FDA approves Fast Track designation for AV-101 for treatment of MDD, it may not actually lead to a faster development or regulatory review or approval process.

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

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

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

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

The results of preclinical studies and early clinical trials of AV-101 and other product candidates may not be predictive of the results of later-stage clinical trials. AV-101 or other product candidates in later stages of clinical trials may fail to show the desired safety and efficacy results despite having progressed through preclinical studies and initial clinical trials. Many companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to adverse safety profiles or lack of efficacy, notwithstanding promising results in earlier studies. Similarly, our future clinical trial results may not be successful for these or other reasons.

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

For example, the results of planned clinical trials may be adversely affected if we or our collaborator seek to optimize and scale-up production of a product candidate. In such case, we will need to demonstrate comparability between the newly manufactured drug substance and/or drug product relative to the previously manufactured drug substance

and/or drug product. Demonstrating comparability may cause us to incur additional costs or delay initiation or completion of our clinical trials, including the need to initiate a dose escalation study and, if unsuccessful, could require us to complete additional preclinical or clinical studies of our product candidates.

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

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

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

Positive results from preclinical studies of our product candidates, and any positive results we may obtain from early clinical trials of our product candidates, may not necessarily be predictive of the results from required later preclinical studies and clinical trials. Similarly, even if we are able to complete our planned preclinical studies or clinical trials of our product candidates according to our current development timeline, the positive results from our preclinical studies and clinical trials of our product candidates may not be replicated in subsequent preclinical studies or clinical trial results. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA approval. We have not yet completed a Phase 2a clinical trial for AV-101, and if we fail to produce positive results in our NIH-sponsored Phase 2a clinical trial of AV-101 in MDD, 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 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, we and the NIH have commenced an NIH-funded Phase 2a clinical trial of AV-101 as a treatment for MDD. We will need to complete at least two additional large clinical trials prior to the submission of an NDA for AV-101 as a 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 NIH-funded Phase 2a study of AV-101 or any of our future-planned clinical trials will be completed on schedule, if at all, as the commencement and completion of clinical trials can be delayed or prevented for a number of reasons, including, among others:

- the FDA may deny permission to proceed with our planned clinical trials or any other clinical trials we may initiate, or may place a clinical trial on hold;

- delays in filing or receiving approvals of additional INDs that may be required;

negative results from our ongoing pre-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 clinical trials, for example delays in the manufacturing of sufficient supply of finished drug product;

difficulties obtaining Institutional Review Board (IRB) approval to conduct a clinical trial at a prospective site or sites;

challenges in recruiting and enrolling patients to participate in clinical trials, including the proximity of patients to trial sites;

eligibility criteria for the clinical trial, the nature of the clinical trial protocol, the availability of approved effective treatments for the relevant disease and competition from other clinical trial programs for similar indications;

severe or unexpected drug-related side effects experienced by patients in a clinical trial;

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delays in validating any endpoints utilized in a clinical trial;

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

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

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

Clinical trials may also be delayed or terminated 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 preclinical studies and clinical trials of our product candidates may occur, which may result in changes to preclinical studies and clinical trial protocols or additional preclinical 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 preclinical studies and clinical trials may force us to amend preclinical studies and clinical trial protocols or the FDA may impose additional preclinical 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 pre-clinical studies may adversely impact the cost, timing, or successful completion of those pre-clinical studies. If we experience delays completing, or if we terminate, any of our pre-clinical studies or clinical trials, or if we are required to conduct additional pre-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 any clinical trials for our product candidates. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We do not have the ability to independently conduct clinical trials. We rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct clinical trials on our product candidates. We enter into agreements with third-party CROs to provide monitors for and to manage data for our clinical trials. We rely heavily on these parties for execution of clinical trials for our product candidates and control only certain aspects of their activities. As a result, we have less direct control over the conduct, timing and completion of these clinical trials and the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

have staffing difficulties;

fail to comply with contractual obligations;

experience regulatory compliance issues;

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undergo changes in priorities or become financially distressed; or

form relationships with other entities, some of which may be our competitors.

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

Although we design our clinical trials for our product candidates, we plan to have CROs, and in the case of our initial AV-101 Phase 2a study in MDD, the NIH, 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 NIH, 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 NIH 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 NIH devote to our program or our clinical products. If we are unable to rely on clinical data collected by our CROs or the NIH, 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 NIH terminate, we may not be able to enter into arrangements with alternative CROs or collaborators. If CROs or the NIH 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 NIH are associated with may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, we believe that our financial results and the commercial prospects for our product candidates in the subject indication would be harmed, our costs could increase and our ability to generate revenue could be delayed.

We rely completely on third-party suppliers to manufacture our clinical drug supplies for our product candidates, and we intend to rely on third parties to produce non-clinical, clinical and commercial supplies of any future product

candidate.

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

We do not control the manufacturing process of, and are completely dependent on, our contract manufacturers to comply with cGMPs for manufacture of both active drug substances and finished drug products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or applicable foreign regulatory agencies, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no direct control over our contract manufacturers' ability to maintain adequate quality control, quality assurance and qualified personnel. Furthermore, all of our contract manufacturers are engaged with other companies to supply and/or manufacture materials or products for such companies, which exposes our third-party contract manufacturers to regulatory risks for the production of such materials and products. As a result, failure to satisfy the regulatory requirements for the production of those materials and products may affect the regulatory clearance of our contract manufacturers' facilities generally. If the FDA or an applicable foreign regulatory agency determines now or in the future that these facilities for the manufacture of our product candidates are noncompliant, we may need to find alternative manufacturing facilities, which would adversely impact our ability to develop, obtain regulatory approval for or market our product candidates. Our reliance on contract manufacturers also exposes us to the possibility that they, or third parties with access to their facilities, will have access to and may appropriate our trade secrets or other proprietary information.

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

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

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

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

We do not currently have an infrastructure for the sales, marketing and distribution of pharmaceutical products, nor do we intend to create such capabilities. Therefore, in order to market our product candidates globally, if approved by the FDA or any other regulatory body, we must make contractual arrangements with third parties to perform services related to sales, marketing, managerial and other non-technical capabilities relating to the commercialization of our product candidates. If we are unable to establish adequate contractual arrangements for such sales, marketing and distribution capabilities, or if we are unable to do so on commercially reasonable terms, our business, results of operations, financial condition and prospects will be materially adversely affected.

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

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

- the efficacy 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;

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the potential and perceived advantages of our product candidates over current treatment options or alternative treatments, including future alternative treatments;

the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;

the strength of marketing and distribution support and timing of market introduction of competitive products;

publicity concerning our products or competing products and treatments;

pricing and cost effectiveness;

the effectiveness of our sales and marketing strategies;

our ability to increase awareness of our product candidates through marketing efforts;

our ability to obtain sufficient third-party coverage or reimbursement; or

the willingness of patients to pay out-of-pocket in the absence of third-party coverage.

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

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

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

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

regulatory authorities may withdraw or limit their approval of such product candidates;

regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;

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

we may be subject to regulatory investigations and government enforcement actions;

we may decide to remove such product candidates from the marketplace;

we could be sued and held liable for injury caused to individuals exposed to or taking our product candidates; and

our reputation may suffer.

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

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

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

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

issue warning letters or untitled letters;

seek an injunction or impose civil or criminal penalties or monetary fines;

suspend or withdraw marketing approval;

suspend any ongoing clinical trials;

refuse to approve pending applications or supplements to applications submitted by us;

suspend or impose restrictions on operations, including costly new manufacturing requirements; or

seize or detain products, refuse to permit the import or export of products, or require that we initiate a product recall.

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

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

Currently, management is unaware of any FDA-approved adjunctive therapy for treatment-resistant MDD with the same mechanism of action and safety profile as AV-101. However, new antidepressant products with other mechanisms of action or products approved for other indications, including the anesthetic ketamine, are being or may be used off-label for treatment of MDD, as well as other CNS indications for which AV-101 may have therapeutic

potential. Additionally, other non-pharmaceutical treatment options, such psychotherapy and electroconvulsive therapy (ECT) are sometimes used before or instead of standard antidepressants to treat patients with MDD.

In the field of new generation antidepressants focused on modulation of the NMDA receptor at the glycine binding co-agonist site, we believe our principal competitor is Allergan, which recently acquired from and is now developing both the intravenously-administered peptide, rapastinel (formerly GLYX-13), and NRX-1074, which may be or may become orally-available, for treatment-resistant MDD.

Many of our potential competitors, alone or with their strategic partners, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of treatments and the commercialization of those treatments. We believe that a range of pharmaceutical and biotechnology companies have programs to develop small molecule drug candidates for the treatment of depression, including MDD, epilepsy, neuropathic pain, Parkinson's disease and other neurological conditions and diseases, including, but not limited to, Abbott Laboratories, Acadia, Allergan, Alkermes, Astra Zeneca, Eli Lilly, GlaxoSmithKline, IntraCellular, Johnson & Johnson, Lundbeck, Merck, Novartis, Ono, Otsuka, Pfizer, Roche, Sumitomo Dainippon, Teva 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.

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

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

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

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

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

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

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

The success of our business depends primarily upon our ability to identify, develop and commercialize product candidates with commercial and therapeutic potential. Although AV-101 is in Phase 2 clinical development for treatment of depression, we may fail to pursue additional CNS-related Phase 2 development opportunities for AV-101, or identify additional product candidates for clinical development for a number of reasons. Our research methodology may be unsuccessful in identifying new product candidates or our product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval.

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

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

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

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

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

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

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

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

The federal transparency requirements, sometimes referred to as the “Sunshine Act,” under the Patient Protection and Affordable Care Act, require manufacturers of drugs, devices, biologics and medical supplies that are reimbursable

under Medicare, Medicaid, or the Children's Health Insurance Program to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests.

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

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

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

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

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

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

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

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

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

Even if we obtain Orphan Drug designation from the FDA for one or more of our product candidates, there are limitations to exclusivity afforded by such designation. In the United States, the company that first obtains FDA approval for a designated orphan drug for the specified rare disease or condition receives orphan drug marketing exclusivity for that drug for a period of seven years. This orphan drug exclusivity prevents the FDA from approving another application, including a full NDA to market the same drug for the same orphan indication, except in very limited circumstances, including when the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. For purposes of small molecule drugs, the FDA defines "same drug" as a drug that contains the same active moiety and is intended for the same use as the drug in question. To obtain orphan drug exclusivity for a drug that shares the same active moiety as an already approved drug, it must be demonstrated to the FDA that the

drug is safer or more effective than the approved orphan designated drug, or that it makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition or if another drug with the same active moiety is determined to be safer, more effective, or represents a major contribution to patient care.

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

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

our customers' ability to obtain reimbursement for our product candidates in foreign markets;

our inability to directly control commercial activities because we are relying on third parties;

the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;

different medical practices and customs in foreign countries affecting acceptance in the marketplace;

import or export licensing requirements;

longer accounts receivable collection times;

longer lead times for shipping;

language barriers for technical training;

reduced protection of intellectual property rights in some foreign countries;

the existence of additional potentially relevant third party intellectual property rights;

foreign currency exchange rate fluctuations; and

the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

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

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

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

produce product candidates;

develop and obtain required regulatory approvals for commercialization of products we produce;

maintain, leverage and expand our intellectual property portfolio;

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

gain market acceptance for our products; and

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

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Our future success is highly dependent upon our ability to successfully develop and commercialize AV-101 and discover, as well as produce, develop and commercialize proprietary drug rescue NCEs using our stem cell technology, and we cannot provide any assurance that we will successfully develop and commercialize AV-101 or drug rescue NCEs, or that, if produced, AV-101 or any drug rescue NCE will be successfully commercialized.

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

our drug rescue research methodology may not be successful in identifying potential drug rescue NCEs;

competitors may develop alternatives that render our drug rescue NCEs obsolete;

a drug rescue NCE may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;

a drug rescue NCE may not be capable of being produced in commercial quantities at an acceptable cost, or at all; or

a drug rescue NCE may not be accepted as safe and effective by regulatory authorities, patients, the medical community or third-party payors.

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

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

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

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

our ability to identify potential drug rescue candidates in the public domain, obtain sufficient quantities of them, and assess them using our bioassay systems;

if we seek to rescue drug rescue candidates that are not available to us in the public domain, the extent to which third parties may be willing to out-license or sell certain drug rescue candidates to us on commercially reasonable terms;

our medicinal chemistry collaborator's ability to design and produce proprietary drug rescue NCEs based on the novel biology and structure-function insight we provide using CardioSafe 3D; and

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

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

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

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

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

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

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

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

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

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

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

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

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The use of embryonic or fetal tissue in research (including the derivation of hESCs) in other countries is regulated by the government, and 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.

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

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

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

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

Risks Related to Our Financial Position

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

We have incurred significant net losses in each fiscal year since our inception in 1998, including net losses of $47.2 million and $13.9 million during the fiscal years ending March 31, 2016 and 2015, respectively. As of March 31, 2016, we had an accumulated deficit of approximately $131.7 million. We do not know whether or when we will become profitable. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to incur increasing levels of operating losses over the next several years and for the foreseeable future. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' deficit and working capital. We expect our research and development expenses to significantly increase in connection with non-clinical studies and clinical trials of our product candidates. In addition, if we obtain marketing approval for our product candidates, we may incur significant sales, marketing and outsourced-manufacturing expenses should we elect not to collaborate with one or more third parties for such services and capabilities. As a public company, we incur additional costs associated with operating as a public company. As a result, we expect to

continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

Our ability to become profitable depends upon our ability to generate revenues. To date, we have generated approximately $16.4 million in revenues, primarily from the receipt of research and development grants from the NIH. We have not yet commercialized any product or generated any revenues from product sales, and we do not know when, or if, we will generate any revenue from product sales. We do not expect to generate significant revenue unless and until we obtain marketing approval of, and begin to experience sales of, AV-101, or we enter into one or more development and commercialization agreements with respect to AV-101 or one or more other product candidates. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

initiate and successfully complete preclinical and clinical trials that meet their prescribed endpoints;

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initiate and successfully complete all safety studies required to obtain U.S. and foreign marketing approval for our product candidates;

commercialize our product candidates, if approved, by developing a sales force or entering into collaborations with third parties; and

achieve market acceptance of our product candidates in the medical community and with third-party payors.

Unless we enter into a development and commercialization collaboration or partnership agreement, we expect to incur significant sales and marketing costs as we prepare to commercialize AV-101 or other product candidates. Even if we initiate and successfully complete pivotal clinical trials of AV-101 or other product candidates, and AV-101 or other product candidates are approved for commercial sale, and despite expending these costs, AV-101 or other product candidates may not be commercially successful. We may not achieve profitability soon after generating product sales, if ever. If we are unable to generate product revenue, we will not become profitable and may be unable to continue operations without continued funding.

Despite consummation of the May 2016 Public Offering (defined below), we require additional financing to execute our business plan and continue to operate as a going concern.

Our consolidated financial statements for the year ended March 31, 2016 have been prepared assuming we will continue to operate as a going concern. Because we continue to experience net operating losses, our ability to continue as a going concern is subject to our ability to obtain necessary funding from outside sources, including obtaining additional funding from the sale of our securities or obtaining loans and grants from financial institutions and/or government agencies where possible. Our continued net operating losses increase the difficulty in completing such sales or securing alternative sources of funding, and there can be no assurances that we will be able to obtain such funding on favorable terms or at all. If we are unable to obtain sufficient financing from the sale of our securities or from alternative sources, we may be required to reduce, defer, or discontinue certain or all of our research and development activities or we may not be able to continue as a going concern.

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

At March 31, 2016, our existing cash and cash equivalents were not sufficient to fund our current operations for the next 12 months. As described in Note 16, Subsequent Events, to the accompanying Consolidated Financial Statements for the fiscal year ended March 31, 2016 included elsewhere in this Annual Report, on May 16, 2016, we consummated an underwritten public offering, pursuant to which we issued an aggregate of 2,570,040 registered shares of our common stock at a public sales price of $4.24 per share and five-year warrants, exercisable at $5.30 per share, to purchase an aggregate of 2,705,883 shares of our common stock at a public sales price of $0.01 per warrant share, including shares and warrants issued pursuant to the exercise of the underwriters' over-allotment option, resulting in gross proceeds of $10,924,000 (May 2016 Public Offering). Our net proceeds from the May 2016 Public Offering were approximately $9.5 million after deducting underwriters' commissions and other expenses of the offering. Additionally, in February 2015, we entered into the CRADA with the NIH, under which the NIH is fully funding and conducting the initial Phase 2a clinical efficacy and safety of AV-101 in MDD. However, we have no

current source of revenue to sustain our present activities, and we do not expect to generate revenue until, and unless, we (i) out-license or sell AV-101, a drug rescue NCE, and/or another drug candidate unrelated to AV-101 to third-parties, (ii) enter into license arrangements involving our stem cell technology, or (iii) obtain approval from the FDA or other regulatory authorities and successfully commercialize, on our own or through a future collaboration, one or more of our compounds.

As the outcome of our AV-101 and NCE drug rescue activities and future anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates, on our own or in collaboration with others. In addition, other unanticipated costs may arise. As a result of these and other factors, we will need to seek additional capital in the near term to meet our future operating requirements, including capital necessary to obtain regulatory approval for, and to commercialize, our product candidates, and may seek additional capital in the event there exists favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. We are considering a range of potential sources of funding, including public or private equity or debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or a combination of these approaches, and we may complete additional financing arrangements in 2016. Raising funds in the current economic environment may present additional challenges. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations.

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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 our management 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.

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

Although we anticipate that the net proceeds from the May 2016 Public Offering will provide sufficient funding for our operations through the release of topline results of our fully-funded, NIH-sponsored AV-101 Phase 2a clinical study in MDD (Phase 2a MDD Study), anticipated in the second quarter of 2017, as well as the launch and conduct of a substantial portion of our AV-101 Phase 2b clinical study in MDD (Phase 2b MDD Study), the proceeds received will not be sufficient to complete the Phase 2b MDD Study, unless we also receive, prior to the end of the second quarter of 2017, proceeds resulting from the exercise of a substantial portion of the warrants offered in the May 2016 Public Offering and the underwriters exercise their option to purchase additional shares of common stock. Assuming no exercise of the warrants issued in the May 2016 Public Offering and no exercise of the underwriters' option to purchase additional shares of common stock, we believe an additional $10.0 million to $12.0 million will be required prior to the end of the second quarter of 2017 in order to complete the Phase 2b MDD Study before the second half of 2018. No assurances can be provided that such additional capital will be available to us when necessary, on reasonable terms, or at all. In the event we are unable to raise such additional capital, our operations, including the conduct of the Phase 2b MDD Study, will be negatively and materially affected

Raising additional capital will cause dilution to our existing stockholders, and may restrict our operations or require us to relinquish rights.

We intend to pursue private and public equity offerings, debt financings, collaborations and licensing arrangements in 2016 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.

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

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

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

As of March 31, 2016, we had federal and state net operating loss carryforwards of $67.9 million and $60.1 million, respectively, which begin to expire in fiscal 2017. Under Section 382 of the Internal Revenue Code of 1986, as amended (the Code) changes in our ownership may limit the amount of our net operating loss carryforwards that could be utilized annually to offset our future taxable income, if any. This limitation would generally apply in the event of a cumulative change in ownership of our company of more than 50% within a three-year period. Any such limitation may significantly reduce our ability to utilize our net operating loss carryforwards and tax credit carryforwards before they expire. Any such limitation, whether as the result of future offerings, prior private placements, sales of our common stock by our existing stockholders or additional sales of our common stock by us in the future, could have a material adverse effect on our results of operations in future years. We have not completed a study to assess whether an ownership change for purposes of Section 382 has occurred, or whether there have been multiple ownership changes since our inception, due to the significant costs and complexities associated with such study.

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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 recuse NCEs or disrupt our administrative functions.

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

In addition, we rely on a diverse range of strategic consultants and advisors, including manufacturing, scientific and clinical development, and regulatory advisors, to assist us in designing and implementing our research and development and regulatory strategies and plans, including our AV-101 development and drug rescue strategies and plans. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

As we seek to advance development of AV-101 for MDD and other CNS-related conditions, as well as drug rescue and stem cell technology-related RM programs, we will need to expand our research and development capabilities and/or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners and other third parties. Future growth will impose significant added responsibilities on members of management. Our future financial performance and our ability to develop and commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our research and development efforts effectively and hire, train and integrate additional management, administrative and technical personnel. The hiring, training and integration of new employees may be more difficult, costly and/or time-consuming for us because we have fewer resources than a larger organization. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing the company.

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

If we develop AV-101, drug rescue NCEs, other product candidates, or regenerative medicine product candidates, either on our own or in collaboration with others, we will face inherent risks of product liability as a result of the required clinical testing of such product candidates, and will face an even greater risk if we or our collaborators commercialize any such product candidates. For example, we may be sued if AV-101, any drug rescue NCE, other product candidate, or regenerative medicine product candidate we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product,

negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

decreased demand for products that we may develop;

injury to our reputation;

withdrawal of clinical trial participants;

costs to defend the related litigation;

a diversion of management's time and our resources;

substantial monetary awards to trial participants or patients;

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

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loss of revenue;

the inability to commercialize our product candidates; and

a decline in our stock price.

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

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

As a public company with common stock listed on The NASDAQ Capital Market, we must comply with various laws, regulations and requirements, including certain provisions of the Sarbanes-Oxley Act of 2002, as well as rules implemented by the SEC and The NASDAQ Stock Market. Complying with these statutes, regulations and requirements, including our public company reporting requirements, continues to occupy a significant amount of the time of management and involves significant accounting, legal and other expenses. Furthermore, these laws, regulations and requirements require us to observe greater corporate governance practices than we have employed in the past, including, but not limited to maintaining a sufficient number of independent directors, increased frequency of board meetings, and holding annual stockholder meetings. Our efforts to comply with these regulations are likely to result in increased general and administrative expenses and management time and attention directed to compliance activities.

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

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

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

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

business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business.

Our internal computer systems, or those of our third-party CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product candidates' development programs.

Despite the implementation of security measures, our internal computer systems and those of our third-party CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs. For example, the loss of clinical trial data for AV-101 or other product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications or other data or applications relating to our technology or product candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of our product candidates could be delayed.

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

We may acquire additional businesses or products, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction.

Risks Related to Our Intellectual Property Rights

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

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

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

We currently have no issued patents covering AV-101. We cannot provide any assurances that any of our numerous pending U.S. and foreign patent applications relating to AV-101 will mature into issued patents and, if they do, that such patents will include claims with a scope sufficient to protect AV-101 or otherwise provide any competitive advantage. Moreover, other parties may have developed technologies that may be related or competitive to our approach, and may have filed or may file patent applications and may have received or may receive patents that may overlap or conflict with our patent applications, either by claiming the same methods or formulations or by claiming subject matter that could dominate our patent position. Such third-party patent positions may limit or even eliminate our ability to obtain patent protection.

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

proceeding can result in a third party receiving the patent right sought by us, which in turn could affect our ability to develop, market or otherwise commercialize our product candidates.

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

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

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

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

any of our AV-101 or other pending patent applications, if issued, will include claims having a scope sufficient to protect AV-101 or any other products or product candidates, particularly considering that the compound patent to AV-101 has expired;

any of our pending patent applications will issue as patents at all;

we will be able to successfully commercialize our product candidates, if approved, before our relevant patents expire;

we were the first to make the inventions covered by each of our patents and pending patent applications;

we were the first to file patent applications for these inventions;

others will not develop similar or alternative technologies that do not infringe our patents;

others will not use pre-existing technology to effectively compete against us;

any of our patents, if issued, will be found to ultimately be valid and enforceable;

any patents issued to us will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;

we will develop additional proprietary technologies or product candidates that are separately patentable; or

that our commercial activities or products will not infringe upon the patents or proprietary rights of others.

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

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

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

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

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

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

cease developing, selling or otherwise commercializing our product candidates;

pay substantial damages for past use of the asserted intellectual property;

obtain a license from the holder of the asserted intellectual property, which license may not be available on reasonable terms, if at all; and

in the case of trademark claims, redesign, or rename, some or all of our product candidates to avoid infringing the intellectual property rights of third parties, which may not be possible and, even if possible, could be costly and time-consuming.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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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.

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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.

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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.

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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 the Company’s securities may adversely affect an investor’s ability to liquidate an investment in the Company.

Although the Company's common stock is currently quoted on The NASDAQ Capital Market, there is limited trading activity. The Company can give no assurance that an active market will develop, or if developed, that it will be sustained. If an investor acquires shares of the Company's common stock, including shares sold in connection with the Offering, the investor may not be able to liquidate the Company's shares should there be a need or desire to do so.

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

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

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

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

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

The stock market in general, and biotechnology-based companies like ours in particular, has frequently experienced volatility in the market prices for securities that often has been unrelated to the operating performance of the underlying companies. These broad market and industry fluctuations may adversely affect the market price of our

common stock, regardless of our operating performance. In certain recent situations in which the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against such company that issued the stock. If any of our stockholders were to bring a lawsuit against us, the defense and disposition of the lawsuit could be costly and divert the time and attention of our management and harm our operating results. Additionally, if the trading volume of our common stock remains low and limited there will be an increased level of volatility and you may not be able to generate a return on your investment.

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

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

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

Certain of our current institutional stockholders own a substantial portion of our outstanding capital stock, including our common stock, all of our Series A Preferred, a substantial portion of our Series B Preferred, and all of our Series C Preferred, all of which preferred stock is convertible into a substantial number of shares of common stock. Accordingly, institutional stockholders may exert significant influence over us and over the outcome of any corporate actions requiring approval of holders of our common stock, including the election of directors and amendments to our organizational documents, such as increases in our authorized shares of common stock, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transactions. These stockholders may also delay or prevent a change of control of us, even if such a change of control would benefit our other stockholders. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise. Furthermore, the interests of our principal institutional stockholders may not always coincide with your interests or the interests of other stockholders may act in a manner that advances its best interests and not necessarily those of other stockholders, including seeking a premium value for its common stock, which might affect the prevailing market price for our common stock.

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

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

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

Our Articles of Incorporation (the Articles) permit us to issue up to 10.0 million shares of preferred stock. Our Board of Directors has authorized the issuance of (i) 500,000 shares of Series A Preferred, all of which shares are currently issued and outstanding; (ii) 4.0 million shares of Series B 10% Convertible Preferred stock, of which approximately 1.3 million shares are issued and outstanding as of the date of this Annual Report; and (iii) 3.0 million shares of Series C Convertible Preferred Stock, of which approximately 2.3 million shares are issued and outstanding as of the date of this Annual Report. Our Board of Directors could authorize the issuance of additional series of preferred stock in the future and such preferred stock could grant holders preferred rights to our assets upon liquidation, the right to receive dividends before dividends would be declared to holders of our common stock, and the right to the redemption of such

shares, possibly together with a premium, prior to the redemption of the common stock. In the event and to the extent that we do issue additional preferred stock in the future, the rights of holders of our common stock could be impaired thereby, including without limitation, with respect to liquidation.

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

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

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

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.

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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, 2017. We believe that our facilities are suitable and adequate for our current and foreseeable needs.

Item 3. Legal Proceedings

We are not a party to any legal proceedings and we are not aware of any claims or actions pending or threatened against us.

Item 4. Mine Safety Disclosures

Not applicable.

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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 began trading on The NASDAQ Capital Market under the symbol "VTGN" on May 11, 2016. 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 OTCQB. The market quotations reflect inter-dealer prices, without retail mark-up, mark-down or commissions and may not necessarily represent actual transactions. Effective August 14, 2014, we consummated a 1-for-20 reverse split of our authorized, and issued and outstanding shares of common stock (the Stock Consolidation). Each reference to the price per share of common stock in the table below is on a post-Stock Consolidation basis, and reflects the 1-for-20 adjustment as a result of the Stock Consolidation.

	High	Low
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
Year Ending March 31, 2015		
First quarter ending June 30, 2014	$ 14.80	$ 5.60
Second quarter ending September 30, 2014	$ 15.00	$ 7.99
Third quarter ending December 31, 2014	$ 10.50	$ 8.00
Fourth quarter ending March 31, 2015	$ 12.00	$ 3.16

On June 22, 2016 the closing price of our common stock on The NASDAQ Capital Market was $3.85 per share.

As of June 22, 2016, we had 7,970,705 shares of common stock outstanding and approximately 300 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 1,247,740 outstanding shares of our Series B 10% Convertible Preferred Stock, which shares are convertible into 1,247,740 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.

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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 in Series B Preferred Unit Private Placement

Between February 17, 2016 and May 4, 2016, we entered into self-placed private placement transactions involving securities purchase agreements with accredited investors, pursuant to which we sold Series B Preferred Units consisting of an aggregate of (i) 111,142 shares of our Series B Preferred Stock; and (ii) five-year warrants to purchase an aggregate of 111,142 shares of our common stock at a fixed exercise price of $7.00 per share, subject to adjustment only for customary stock dividends, reclassifications, splits and similar transactions (Series B Warrants). We received cash proceeds of $778,000, which we expect to use for general corporate purposes. The Series B Preferred 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.

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 (Fixed Conversion Price). All shares of Series B Preferred are also convertible automatically into 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 Common Stock with aggregate gross proceeds to us of at least $10.0 million (Registered Offering); 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 customary beneficial ownership blockers and certain other equity conditions. Prior to Conversion, shares of Series B Preferred will accrue dividends, payable only in unregistered shares of Common Stock, at a rate of 10% per annum (the Accrued Dividend). The Accrued Dividend is payable on the date of Conversion solely in that number of shares of Common Stock equal to the Accrued Dividend. Effective on May 19, 2016, 82,571 shares of the Series B Preferred reported herein automatically converted into an equivalent number of unregistered shares of our common stock upon the consummation of the May 2016 Public Offering, and, as further described below, all Accrued Dividends were paid in shares of unregistered common stock.

Warrants Exchanged for Common Stock

Between February 17, 2016 and May 4, 2016, we entered into Warrant Exchange Agreements with certain holders of outstanding warrants to purchase an aggregate of 303,373 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 227,542 shares of our unregistered common stock. The common stock was issued in private placement transactions exempt from registration under the Securities Act, in reliance on Section 3(a)(9) and/or 4(2) thereof.

Securities Issued for Professional Services

On March 25, 2016, we granted warrants to purchase an aggregate of 230,000 unregistered shares of our common stock to eleven accredited investors as compensation for various legal, business development, regulatory and other

professional services. We will receive all proceeds from the exercise of the warrants granted; however, there can be no assurance that we will receive any proceeds therefrom. The warrants 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.

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Common Stock issued for Dividends on Series B Preferred

Effective on May 19, 2016 and June 15, 2016, upon the automatic conversion of 2,403,051 shares and 44,500 shares, respectively, of our Series B Preferred into an equivalent number of shares of our common stock pursuant to the consummation of our May 2016 Public Offering and the exercise of the underwriters' over-allotment option, we issued an aggregate of 426,386 unregistered shares of our common stock in payment of accrued dividends to the accredited investor holders of our Series B Preferred. The common stock issued in payment of dividends was issued in a private placement transaction exempt from registration under the Securities Act, in reliance on Section 3(a)(9) and/or 4(2) thereof.

Item 6. Selected Financial Data

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

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 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.

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Business Overview

We are a clinical-stage biopharmaceutical company dedicated to developing and commercializing innovative product candidates for patients with diseases and disorders involving the central nervous system (CNS). Our lead product candidate, AV-101, is a next generation, orally available prodrug candidate in Phase 2 development, initially for the adjunctive treatment of Major Depressive Disorder (MDD) in patients with an inadequate response to standard antidepressants currently approved by the U.S. Food and Drug Administration (FDA).

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

Our ongoing Phase 2a clinical study of AV-101 in subjects with treatment-resistant MDD is being conducted and funded by the U.S. National Institute of Mental Health (NIMH) under our February 2015 Cooperative Research and Development Agreement (CRADA) with the NIMH. The first patient in this NIMH-sponsored Phase 2a study was dosed in November 2015. The Principal Investigator of the study is Dr. Carlos Zarate, Jr., Chief of the NIMH's Experimental Therapeutics & Pathophysiology Branch and its Section on Neurobiology and Treatment of Mood and Anxiety Disorders. Previous NIMH studies, including studies conducted by Dr. Zarate, have focused on the effects of low dose intravenous (I.V.) ketamine on treatment-resistant depression. These NIMH studies, as well as clinical research by others, have demonstrated robust antidepressant effects in patients with treatment-resistant MDD within hours of a single low dose of I.V. ketamine and stimulated research and development around a new generation of antidepressants with potential to deliver ketamine-like fast-acting antidepressant benefits without ketamine-like side effects.

We are preparing to launch our Phase 2b clinical study of AV-101 for the adjunctive treatment of MDD in patients with an inadequate response to standard, FDA-approved antidepressants. We anticipate commencement of this multi-center, multi-dose, double blind, placebo-controlled Phase 2b efficacy and safety study in the fourth quarter of 2016. Dr. Maurizio Fava, Professor of Psychiatry at Harvard Medical School and Director, Division of Clinical Research, Massachusetts General Hospital (MGH) Research Institute and Executive Director, MGH Clinical Trials Network and Institute, will be the Principal Investigator of our Phase 2b study of AV-101 in MDD.

We also believe AV-101 has broad therapeutic utility, with multiple CNS pipeline expansion opportunities, including chronic neuropathic pain, epilepsy, Huntington's disease and Parkinson's disease.

In addition to clinical development of AV-101, we are focused on collaborating with third-parties to advance potential commercial applications of our human pluripotent stem cell (hPSC) technology platform, including drug rescue to develop proprietary small molecule new chemical entities (NCEs) for our internal drug candidate pipeline, and regenerative medicine (RM) using blood, cartilage, heart and/or liver cells derived from hPSCs.

The Merger

VistaGen Therapeutics, Inc., a California corporation incorporated on May 26, 1998 (VistaGen California), 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 VistaGen California in exchange for 341,823 shares of our common stock and assumed all of VistaGen California's pre-Merger obligations (the Merger). Shortly after the Merger, Excaliber's name was changed to "VistaGen Therapeutics, Inc." (a Nevada corporation).

VistaGen California, 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 have been 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.

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The Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K represent the activity of VistaGen California from May 26, 1998, and the consolidated activity of VistaGen California 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 VistaGen California'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

Although we do not currently have any such arrangements, we have historically generated revenue principally from collaborative research and development arrangements, 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 milestone and future product 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.

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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.

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 prodrug candidate in 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 our stem cell technology platform and AV-101. 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 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.

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Warrant Liability

Between October 2013 and July 2014, we issued to Platinum Long Term Growth VII, LLC (PLTG) warrants to purchase a substantial number of unregistered shares of our common stock and, subject to PLTG's exercise of its rights to exchange shares of our Series A Preferred Stock that it holds, we were obligated to issue to PLTG an additional warrant to purchase unregistered shares of common stock (Series A Exchange Warrant) (collectively, the PLTG Warrants). The PLTG Warrants contained an exercise price adjustment feature that would reduce the exercise price of the warrants in the event we subsequently issued equity instruments at a price lower than the exercise price of the PLTG Warrants. We accounted for the PLTG Warrants as non-cash liabilities and estimated their fair value at the end of each financial reporting period and recorded 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 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 this Annual Report, on May 12, 2015, we entered into an agreement with PLTG pursuant to which PLTG agreed to amend the PLTG Warrants to (A) fix the exercise price thereof at $7.00 per share, (B) eliminate the exercise price reset features and (C) 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 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

Comparison of Years Ended March 31, 2016 and 2015

Although our financial resources have been limited, we have continued to advance development of AV-101 for MDD and other possible CNS indications, and explore NCE drug rescue and regenerative medicine opportunities related to

our stem cell technology platform. Pursuant to our February 2015 Cooperative Research and Development Agreement (CRADA) with the NIH, the NIH is funding and conducting our Phase 2 clinical study of AV-101 101 in subjects with treatment-resistant MDD.

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Throughout fiscal 2015 and 2016, through self-placed private placement transactions and other corporate finance initiatives, our executive management has been focused on raising sufficient operating capital to continue to advance development of AV-101, as well as other research and development objectives, while meeting our continuing operational needs. Our most significant accomplishments during fiscal 2015 and 2016 have included the following: (i) entering into CRADA with the NIMH; (ii) launching, under the CRADA, our NIH-funded Phase 2A clinical study of AV-101 in subjects with treatment-resistant MDD, with Dr. Carlos Zarate, Jr., Chief of the Section on the Neurobiology and Treatment of Mood Disorders and Chief of the Experimental Therapeutics and Pathophysiology Branch at the NIMH, as Principal Investigator; (iii) bolstering our Clinical and Scientific Advisory Board with the additions of Maurizio Fava, M.D., Professor of Psychiatry at Harvard Medical School and Director of the Division of Clinical Research of the Massachusetts General Hospital Research Institute; Gerard Sanacora, M.D., Ph.D., Associate Professor at Yale School of Medicine and Director of the Yale Depression Research Program; Thomas Laughren, M.D., former Division Director for the FDA's Division of Psychiatry Products, Center for Drug Evaluation and Research; and Sanjay Matthew, M.D., Associate Professor of Psychiatry and Behavioral Sciences at Baylor College of Medicine; (iv) publishing AV-101 preclinical data in the October 2015 issue of the peer-reviewed, Journal of Pharmacology and Experimental Therapeutics, in an article entitled "The prodrug 4-chlorokynurenine causes ketamine-like antidepressant effects, but not side effects, by NMDA/glycineB-site inhibition;" (v) successfully negotiating, extinguishing and converting (in self-placed private placement transactions) approximately $17.2 million (substantially all) of our outstanding indebtedness into our equity securities; and (vi) completing self-placed private placement financing transactions with accredited investors to provide additional operating capital through the sale of our equity securities.

To meet our working capital needs, in April and May 2015, we completed self-placed private placement transactions involving securities purchase agreements with accredited investors, pursuant to which we sold to such accredited investors 2014 Private Placement Units, for aggregate cash proceeds of $280,000, consisting of (i) 10% convertible notes in the aggregate face amount of $280,000 due between April 30, 2015 and May 15, 2015; (ii) an aggregate of 33,000 restricted shares of our common stock; and (iii) warrants exercisable through December 31, 2016 to purchase an aggregate of 24,250 restricted shares of our common stock at an exercise price of $10.00 per share. Between May 2015 and March 31, 2016, we entered into self-placed private placement transactions involving securities purchase agreements with accredited investors, pursuant to which we sold Series B Preferred Units, for aggregate cash proceeds of approximately $5.0 million, consisting of an aggregate of (i) 717,978 shares of our Series B 10% Convertible Preferred Stock (Series B Preferred); and (ii) five-year warrants to purchase an aggregate of 717,978 shares of our common stock. In May 2016, we completed an underwritten registered public offering of our common stock and warrants pursuant to which we received net proceeds after commissions and expenses of approximately $8.7 million.

As a matter of course, we seek to minimize cash commitments and expenditures for both internal and external research and development and general and administrative services to the greatest extent possible. The conversion of such a substantial portion of our outstanding indebtedness during fiscal 2016 materially reduced our cash requirements for debt service.

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The following table summarizes the results of our operations for the fiscal years ended March 31, 2016 and 2015 (amounts in thousands).

	Fiscal Years Ended March 31,	
	2016	2015
Operating expenses:		
Research and development	$3,932	$2,433
General and administrative	13,919	4,344
Total operating expenses	17,851	6,777
Loss from operations	(17,851)	(6,777)
Interest expense (net)	(771)	(4,549)
Change in warrant liabilities	(1,895)	(35)
Loss on extinguishment of debt	(26,700)	(2,388)
Other expense	(2)	(135)
Loss before income taxes	(47,219)	(13,884)
Income taxes	(2)	(2)
Net loss	$(47,221)	$(13,886)
Accrued dividend on Series B Preferred Stock	(2,140)	-
Deemed dividend on Series B Preferred Stock	(2,058)	-
Net loss attributable to common stockholders	$(51,419)	$(13,886)

Revenue

We reported no revenue for the years ended March 31, 2016 or 2015 and we presently have no revenue generating arrangements. However, as indicated previously, we entered into a CRADA with the NIH providing for a Phase 2a clinical study of AV-101 in treatment-resistant MDD. This Phase 2a study, which began in late-2015, is being funded by the NIH and being conducted at the NIMH.

Research and Development Expense

Research and development expense increased by 62% in fiscal 2016 compared to fiscal 2015. The following table compares the primary components of research and development expense between the periods (amounts in thousands):

	Fiscal Years Ended March 31,	
	2016	2015
Salaries and benefits	$818	$889
Stock-based compensation	1,093	849
Consulting and other professional services	112	109
Technology licenses and royalties	1,010	217
Project-related research and supplies:		
AV-101	406	51

Stem cell and all other	100	54
	506	105
Rent	219	220
Depreciation	37	44
Warrant modification expense	135	-
All other	2	-
Total Research and Development Expense	$3,932	$2,433

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The decrease in salaries and benefits is primarily the result of the departure of one member of our scientific staff at the end of September 2014 and another at the end of December 2015.

The increase in stock based compensation expense for 2016 primarily reflects the $852,200 fair value, determined using the Black-Scholes Option Pricing Model and the assumptions indicated in Note 9, Capital Stock, to the accompanying Consolidated Financial Statements for year ended March 31, 2016 of the September 2015 grant of immediately vested and expensed warrants to purchase 150,000 shares of our common stock granted to our CSO offset by reductions in expense related to the ratable amortization of option grants made to scientific staff and consultants, most recently in September 2015, March 2014 and October 2013, and the amortization of a warrant grant made to our CSO in March 2014. Our stock options are generally amortized over a two-year or four-year vesting period, and the warrant granted to the CSO in March 2014 has been amortized over a two-year vesting period. Essentially all of the option grants made prior to October 2013 and the warrant grants made to our CSO in March 2013 and March 2014 became fully-vested and fully-expensed during the fiscal year ended March 31, 2016 or earlier.

Consulting and other professional services reflects fees paid or accrued for scientific services rendered to us by third parties, primarily by members of our scientific and clinical advisory board.

Technology license and royalty expense reflects both recurring annual fees as well as costs for patent prosecution and protection that we are required to fund under the terms of certain of our stem cell technology license agreements, as well as those we elected to make for commercial purposes. We recognize these costs as they are invoiced to us by the licensors and they do not occur ratably throughout the year or between years. Additionally, in fiscal 2016, this expense includes significant costs we have incurred to advance, in the U.S. and numerous foreign counties, multiple pending patent applications with respect to AV-101 and our stem cell technology platform.

AV-101 expenses in both periods presented reflect the costs associated with monitoring for and responding to potential feedback related to the AV-101 Phase 1 clinical trial and preparing other reports required under the terms of our prior NIH grant, primarily through our contract research collaborator, Cato Research Ltd. We incurred additional expenses in fiscal 2016 to explore and develop more efficient and cost-effective production methods for AV-101 as well as for updating documentation to facilitate the Phase 2 clinical trial of AV-101 in treatment resistant MDD that is being funded and conducted by the NIH. Stem cell and other project related expenses in both periods were nominal.

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

General and Administrative Expense

General and administrative expense increased significantly in fiscal 2016 compared to fiscal 2015, primarily due to increased noncash stock compensation and warrant modification expenses. The following table compares the primary components of general and administrative expense between the periods (amounts in thousands):

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	Fiscal Years Ended March 31,	
	2016	2015
Salaries and benefits	$694	$714
Stock-based compensation	2,949	1,611
Consulting Services	98	112
Legal, accounting and other professional fees	3,405	1,197
Investor relations	172	132
Insurance	140	136
Travel expenses	96	71
Rent and utilities	157	155
Warrant modification expense	6,083	98
All other expenses	125	118
Total General and Administrative Expense	$13,919	$4,344

Administrative employee headcount and pay rates have remained essentially consistent between the periods reported.

The increase in stock based compensation expense for 2016 primarily reflects the $2,840,700 fair value, determined using the Black-Scholes Option Pricing Model and the assumptions indicated in Note 9, Capital Stock, to the accompanying Consolidated Financial Statements for the year ended March 31, 2016 of the September 2015 grant of immediately vested and expensed warrants to purchase an aggregate of 500,000 shares of our common stock granted to our officers, independent members of our Board of Directors and certain administrative consultants, offset by reductions in the ratable amortization of option grants made to administrative staff and consultants, most recently in September 2015, March 2014 and October 2013, and the amortization of warrant grants made to certain officers and independent members of our Board of Directors in March 2014. Our stock options are generally amortized over a two-year or four-year vesting period, and warrants granted to officers and directors in March 2014 were amortized over a two-year vesting period. Essentially all of the option grants made prior to October 2013 and the warrant grants made to our officers and independent members of our Board of Directors in March 2013 and March 2014 became fully-vested and fully-expensed during the fiscal year ended March 31, 2016 or earlier.

Consulting services primarily includes fees accrued for the services of independent members of our Board of Directors.

The increase in legal, accounting and other professional service fees results primarily from (i) the $1,012,500 noncash expense recognized pursuant to the June 30, 2015 grant of an aggregate of 90,000 shares of our Series B Preferred having an aggregate fair value 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 30, 2016; (ii) the grant of an aggregate of 50,000 shares of our common stock having an aggregate fair value of $500,000 pursuant to two corporate development contracts initiated during the quarter ended June 30, 2015; (iii) the grant of 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 (iv) $138,000 of noncash expense attributable to the fair value of 15,750 shares of our unregistered common stock and a five-year warrant to purchase 7,500 unregistered shares of our common stock granted in connection with investment banking services. As described in Note 9, Capital Stock, to the accompanying Consolidated Financial Statements for the year ended March 31, 2016, the $1,350,000 fair value of the 90,000 shares of Series B Preferred was recorded as a prepaid expense at the date of the grant and is being expensed ratably over the twelve months ending June 30, 2016. Legal expense for 2016 also includes one-time cash fees for services associated with the conversion of our promissory notes and other debt into

our Series B Preferred. Professional services expense in 2016 reflects a $100,000 reduction in expense related to a contract for strategic advisory and business development services compared to 2015. In both years, accounting service fees include the expense related to the annual audit of the prior year financial statements and current fiscal year quarterly financial statement review services.

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The increase in investor relations expense is primarily attributable to the March 2016 grant of 7,250 shares of our common stock having a fair value of $58,000 for website maintenance and other services and resulting in an equivalent amount of noncash expense.

In both fiscal 2016 and 2015, travel expense reflects costs associated with meetings with accredited investors in connection with the self-placed private placements of our securities, and in 2016, with various creditors in connection with extinguishment of a substantial portion of our indebtedness.

Noncash warrant modification expense in 2016 includes (i) $122,000 representing the increase in the fair value attributable to the June 2015 strategic modification of outstanding warrants to purchase an aggregate of 54,576 shares of our common stock to reduce the exercise prices thereof, generally from $30.00 per share to $10.00 per share; (ii) $358,000 representing 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 accounted for this transaction as a warrant modification and recognized related noncash 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 also accounted for this transaction as a warrant modification, resulting in our recognition of an additional $2,362,000 in noncash 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 noncash expense as a result of such modifications.

Interest and Other Expenses, Net

Interest expense, net totaled $770,800 for the year ended March 31, 2016 compared to $4,548,700 reported for the year ended March 31, 2015, reflecting the impact of the extinguishment of substantially all of our promissory notes and related discounts upon conversion into our Series B Preferred between May 2015 and August 2015. The following table summarizes the primary components of interest expense for each of the periods (amounts in thousands):

	Fiscal Years Ended March 31,	
	2016	2015
Interest expense on promissory notes	$209	$1,238
Amortization of discount on promissory notes	565	3,372
Other interest expense, including on capital leases and premium financing	3	7
	777	4,617
Effect of foreign currency fluctuations on notes payable	(6)	(63)
Interest income	-	(5)
Interest expense, net	$771	$4,549

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The substantial overall decrease in interest expense on promissory notes and the related amortization of discounts on such notes between the periods primarily reflects the cessation of interest accrual and discount amortization upon the conversion of all outstanding Senior Secured Convertible Promissory Notes, 10% convertible promissory notes (2014 Unit Notes) and other outstanding promissory notes aggregating approximately $13.3 million into shares of our Series B Preferred between May 2015 and August 2015, offset by accrued interest and discount amortization recorded for the issuances between July 2014 and May 2015 of an aggregate of approximately $1.8 million of 2014 Unit Notes.

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. Further, upon PLTG's exchange of the shares of our Series A Preferred Stock held by PLTG into shares of our common stock, we would also be required to issue a Series A Exchange Warrant to PLTG (all of the warrants, collectively, the PLTG Warrants). We determined that the PLTG Warrants included certain exercise price 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, and Note 4, Fair Value Measurements, to the Consolidated Financial Statements for the year ended March 31, 2016, on May 12, 2015, we entered into an agreement with PLTG pursuant to which we amended the various warrants to fix the exercise price thereof and eliminate the anti-dilution reset features that had previously required the warrants to be treated as liabilities and carried at fair value. Accordingly, during the quarter ended June 30, 2015, we adjusted these warrants to their fair value, estimated to be $4,903,200, reflecting an increase of $1,894,700 since March 31, 2015, resulting primarily from the increase in the market price of our common stock in relation to the exercise price of the warrants, and then subsequently eliminated the entire warrant liability with respect to these warrants. As indicated previously, during the fourth quarter of fiscal 2016, we entered into an agreement with PLTG whereby PLTG exchanged the PLTG Warrants 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. During the year ended March 31, 2015, we recognized noncash expense of $34,600 related to the net increase in the estimated fair value of the warrant liabilities since March 31, 2014.

As described more completely in Note 8, Convertible Promissory Notes and other Notes Payable, and Note 9, Capital Stock, to the accompanying Consolidated Financial Statements for the year ended March 31, 2016, between May 2015 and August 2015, we extinguished the outstanding balances of approximately $17.2 million of promissory notes, including our Senior Secured 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. 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 noncash losses on each of the extinguishments. Additionally, under the terms of the PLTG Agreement, we issued to PLTG 400,000 shares of Series B Preferred having an aggregate fair value of $4.0 million and Series B Warrants to purchase 1.2 million shares of our common stock having an aggregate of fair value of $8,270,900. We recognized this aggregate fair value as an additional 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 have accounted for the repurchase of the beneficial conversion feature at the time the 2014 Unit Notes were extinguished and converted, an aggregate of $2,237,100, as a reduction to the loss on extinguishment of debt. We recorded a nonrecurring aggregate net noncash loss of $26.7 million attributable to the extinguishment of the indebtedness converted into Series B Preferred.

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During the quarter ended June 30, 2014, we entered into agreements with substantially all holders of our 2013 Unit Notes and 2013 Unit Warrants to amend certain terms of the notes and the warrants to essentially conform them to the 2014 Unit Notes and 2014 Unit Warrants. We treated the amendments as an extinguishment of debt for accounting purposes and recognized noncash losses on the extinguishment of debt in the aggregate amount of $526,200 attributable to the amendments. We also recognized an additional $241,800 as a noncash loss on extinguishment of debt as a result of the promissory note, shares of our common stock and warrants issued to Icahn School of Medicine at Mount Sinai in settlement of stem cell technology license maintenance fees and reimbursable patent prosecution costs during the quarter ended June 30, 2014. In July 2014, we entered into an agreement with PLTG, as further amended in September 2014, pursuant to which PLTG agreed to convert into our unregistered equity securities all then outstanding Senior Secured Notes and related accrued interest held by PLTG upon our consummation prior to October 31, 2014 of either (i) a Private Financing or a Public Offering, each as defined in the agreement. Prior to the agreement, the Senior Secured Notes were convertible, at PLTG's option, at any time prior to maturity at a conversion price of $10.00 per share. The modification of the conversion feature in the Senior Secured Notes was treated as an extinguishment of the debt for accounting purposes and we recognized a non-cash loss on the extinguishment of debt in the aggregate amount of $1,603,400 attributable to the amendment in the quarter ended September 30, 2014. In March 2015, we issued 16,667 shares of our common stock valued at $166,700 in settlement of legal fees related to services provided with respect to certain financing initiatives. We recognized a loss on extinguishment of debt in the amount of $16,700 with respect to this settlement.

In October 2014, we accepted a cash payment of $60,000 as settlement in full for a promissory note issued to us in May 2011 for the purchase of shares of our common stock. At the time of the payment, the principal and accrued interest due to us on the note receivable was $195,000, resulting in a noncash loss of $135,000 related to the settlement, which was recognized in Other Expense in the year ended March 31, 2015. Other expense in the year ended March 31, 2016 reflects the noncash loss on the disposition of a piece of failed lab equipment.

We allocated the proceeds from the self-placed private placement sales of Series B Preferred Units between May 2015 and March 31, 2016 to the Series B Preferred and the Series B Warrants based on their relative fair values on the dates of the sales. The difference, for accounting purposes, between the relative fair value per share of the Series B Preferred, approximately $4.13 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 $2,058,000 in arriving at net loss attributable to common stockholders for the year ended March 31, 2016 in the accompanying Consolidated Statement of Operations and Comprehensive Loss for the year ended March 31, 2016. Further, we have recognized $2,140,500 representing the 10% cumulative dividend payable on our Series B Preferred as an additional deduction in arriving at net loss attributable to common stockholders for the year ended March 31, 2016 in the accompanying Consolidated Statement of Operations and Comprehensive Loss for the year ended March 31, 2016.

Liquidity and Capital Resources

Since our inception in May 1998 through March 31, 2016, we have financed our operations through (1) the issuance and sale of our common stock, preferred stock, warrants for common stock, and promissory notes for aggregate cash proceeds of approximately $34.5 million; (2) issuance of common stock and preferred stock with an approximate value at issuance of $29.1 million as consideration for, among other things, technology licenses and patent prosecution, sponsored research, contract research, drug development, drug manufacturing, regulatory services, and legal, investor relations, corporate development and financial advisory services; and (3) receipt of aggregate non-dilutive cash proceeds of approximately $16.4 million from government research and development grant awards and strategic collaboration transactions.

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As described more completely in Note 8, Convertible Promissory Notes and other Notes Payable, and Note 9, Capital Stock, to the accompanying Consolidated Financial Statements for the year ended March 31, 2016, between May 2015 and March 31, 2016, we created our Series B Preferred and eliminated the outstanding balances of approximately $17.2 million of promissory notes, other indebtedness and certain adjustments thereto that was either already due and payable or would have otherwise matured prior to March 31, 2016, through conversion into our Series B Preferred and, with respect to a portion of the indebtedness converted, warrants to purchase common stock. More specifically, through March 31, 2016, we have extinguished and converted (i) all of the Senior Secured Convertible Promissory Notes originally issued to PLTG, (ii) all of the 2014 Unit Notes outstanding at March 31, 2015 and those issued subsequently, and (iii) substantially all other outstanding promissory notes and accounts payable, including those issued to Cato Research Ltd., Cato Holding Company, Morrison & Foerster (Note A and Note B), University Health Network, McCarthy Tetrault, Desjardins Securities, Burr Pilger & Mayer, National Jewish Health, MicroConstants and several others, into an aggregate of 2,618,917 shares of our Series B Preferred. Additionally, through March 31, 2016, in our self-placed private placement of Series B Units, we have sold Series B Preferred Units consisting of an aggregate of 717,978 unregistered shares of Series B Preferred and five year warrants to purchase 717,978 shares of our common stock, and we have received cash proceeds of $5,025,800.

At March 31, 2016, we did not have sufficient cash and cash equivalents to enable us to fund our planned operations over the next twelve months, including expected cash expenditures of approximately $9.1 million. However, as disclosed in Note 16, Subsequent Events, to the accompanying Consolidated Financial Statements, between April 1, 2016 and May 4, 2016, we sold to accredited investors additional Series B Preferred Units consisting of 39,714 unregistered shares of Series B Preferred and five year warrants to purchase 39,714 shares of our common stock, and we received cash proceeds of $278,000. Further, on May 16, 2016 we consummated an underwritten public offering pursuant to which we issued an aggregate of 2,570,040 registered shares of our common stock at the public offering price of $4.24 per share and five-year warrants to purchase up to 2,705,883 registered shares of our 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 (May 2016 Public Offering). We received net cash proceeds of approximately $9.5 million from the May 2016 Public Offering after deducting fees and expenses. We expect the proceeds of these transactions to provide sufficient cash to sustain our operations through our fiscal year ending March 31, 2017, however they will not be adequate to enable the completion of our Phase 2b clinical trial of AV-101 in MDD. Accordingly, we intend to raise additional capital through sales of our securities, which may include both debt and equity securities. We may also seek research and development collaborations that could generate revenue, as well as government grant awards. Further, strategic collaborations, similar to our February 2015 CRADA with the NIMH providing NIMH funding of our Phase 2a study of AV-101 in MDD, may provide resources to support a portion of our future cash needs and working capital requirements. Although we may seek additional collaborations that could generate revenue, as well as new government grant awards, no assurance can be provided that any such collaborations or awards 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 of AV-101 as a treatment for MDD and other CNS conditions, and our stem cell technology platform, the availability of, and our ability to obtain, government grant awards 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 the size of our staff and staff salaries and benefits, as well as costs relating to regulatory consulting, contract research and development, investor relations and corporate development, legal, 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 in the near term, our business, financial condition, and results of operations may be harmed, the price of our stock may decline,

we may be required to reduce, defer, or discontinue certain of our research and development activities and we may not be able to continue as a going concern.

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

	Fiscal Years Ended March 31,	
	2016	2015
Net cash used in operating activities	$(4,809)	$(2,769)
Net cash used in investing activities	(26)	-
Net cash provided by financing activities	5,193	2,839
Net increase in cash and cash equivalents	358	70
Cash and cash equivalents at beginning of period	70	-
Cash and cash equivalents at end of period	$428	$70

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. VistaGen California 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 since we qualify as a smaller reporting company.

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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, 2016 and 2015 and the related consolidated statements of operations and comprehensive loss, cash flows, and stockholders' deficit for the fiscal years then ended. 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, 2016 and 2015, and the consolidated results of its operations and its cash flows for the fiscal years then ended, in conformity with U.S. generally accepted accounting principles.

/s/ OUM & Co. LLP

San Francisco, California
June 24, 2016

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VISTAGEN THERAPEUTICS, INC.

CONSOLIDATED BALANCE SHEETS
(Amounts in dollars, except share amounts)

	March 31, 2016	March 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$428,500	$70,000
Prepaid expenses and other current assets	426,800	35,700
Total current assets	855,300	105,700
Property and equipment, net	87,600	117,100
Security deposits and other assets	46,900	46,900
Total assets	$989,800	$269,700
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$936,000	$2,251,100
Accrued expenses	814,000	1,206,500
Current portion of senior secured convertible promissory notes and accrued interest	-	4,146,100
Current portion of notes payable, net of discount of $0 at March 31, 2016 and $474,500 at March 31, 2015, and accrued interest	43,600	4,117,000
Current portion of notes payable to related parties, net of discount of $0 at March 31, 2016 and $54,500 at March 31, 2015, and accrued interest	-	1,508,800
Convertible promissory notes and accrued interest, net of discount of $0 at March 31, 2016 and $180,000 at March 31, 2015, respectively	-	4,157,600
Capital lease obligations	1,100	1,000
Total current liabilities	1,794,700	17,388,100
Non-current liabilities:		
Senior secured convertible promissory notes and accrued interest	-	296,200
Notes payable	27,200	35,600
Warrant liability	-	3,008,500
Accrued dividends on Series B Preferred Stock	2,089,600	-
Deferred rent liability	55,500	83,000
Capital lease obligations	-	1,100
Total non-current liabilities	2,172,300	3,424,400
Total liabilities	3,967,000	20,812,500
Commitments and contingencies		
Stockholders' deficit:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at March 31, 2016 and 2105:		
Series A Preferred, 500,000 shares authorized and outstanding at March 31, 2016 and 2015	500	500
Series B Preferred; 4,000,000 shares and no shares authorized at March 31, 2016 and March 31, 2015, respectively; 3,663,077 shares and no shares issued and outstanding	3,700	-

at March 31, 2016 and 2015, respectively		
Series C Preferred; 3,000,000 shares and no shares authorized at March 31, 2016 and 2015, respectively; 2,318,012 shares and no shares issued and outstanding at March 31, 2016 and 2015, respectively	2,300	-
Common stock, $0.001 par value; 30,000,000 shares and 10,000,000 shares authorized at March 31, 2016 and 2015, respectively; 2,623,145 and 1,677,110 shares issued at March 31, 2016 and 2015, respectively	2,600	1,700
Additional paid-in capital	132,725,000	67,945,800
Treasury stock, at cost, 135,665 shares of common stock held at March 31, 2016 and 2015	(3,968,100)	(3,968,100)
Accumulated deficit	(131,743,200)	(84,522,700)
Total stockholders' deficit	(2,977,200)	(20,542,800)
Total liabilities and stockholders' deficit	$989,800	$269,700

See accompanying notes to consolidated financial statements.

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VISTAGEN THERAPEUTICS, INC.

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

	Fiscal Years Ended March 31,	
	2016	2015
Operating expenses:		
Research and development	$3,931,600	$2,432,700
General and administrative	13,918,600	4,344,400
Total operating expenses	17,850,200	6,777,100
Loss from operations	(17,850,200)	(6,777,100)
Other expenses, net:		
Interest expense, net	(770,800)	(4,548,700)
Change in warrant liability	(1,894,700)	(34,600)
Loss on extinguishment of debt	(26,700,200)	(2,388,000)
Other expense	(2,300)	(135,000)
Loss before income taxes	(47,218,200)	(13,883,400)
Income taxes	(2,300)	(2,400)
Net loss and comprehensive loss	$(47,220,500)	$(13,885,800)
Accrued dividends on Series B Preferred stock	(2,140,500)	-
Deemed dividend on Series B Preferred Units	(2,058,000)	-
Net loss attributable to common stockholders	$(51,419,000)	$(13,885,800)
Basic net loss attributable to common stockholders per common share	$(29.08)	$(10.53)
Diluted net loss attributable to common stockholders per common share	$(29.08)	$(10.61)
Weighted average shares used in computing:		
Basic net loss attributable to common stockholders per common share	1,767,957	1,318,813
Diluted net loss attributable to common stockholders per common share	1,767,957	1,318,813

See accompanying notes to consolidated financial statements.

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VISTAGEN THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(Amounts in dollars)

	Fiscal Years Ended March 31,	
	2016	2015
Cash flows from operating activities:		
Net loss	$(47,220,500)	$(13,885,800)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	53,500	59,100
Amortization of discounts on convertible and promissory notes	564,800	3,372,000
Change in warrant liability	1,894,700	34,600
Stock-based compensation	4,041,400	2,460,100
Expense related to modification of warrants, including exchange of warrants for Series C Preferred and common stock	6,218,000	98,400
Amortization of deferred rent	(27,500)	(14,400)
Fair value of common stock granted for services	829,200	469,000
Fair value of Series B Preferred stock granted for services	1,382,500	-
Fair value of warrants granted for services and interest	1,280,800	44,500
Gain on currency fluctuation	(6,400)	(63,600)
Loss on extinguishment of debt	26,700,200	2,388,000
Loss on disposition of equipment	2,300	-
Reversal of interest income on note receivable for stock purchase	-	2,800
Loss on settlement of note receivable for common stock purchase	-	134,900
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	25,700	107,400
Accounts payable and accrued expenses, including accrued interest	(547,200)	2,024,100
Net cash used in operating activities	(4,808,500)	(2,768,900)
Cash flows from investing activities:		
Purchases of equipment	(26,300)	-
Cash flows from financing activities:		
Net proceeds from issuance of common stock Units	280,000	3,146,600
Net proceeds from issuance of Series B Preferred Units	5,025,800	-
Repayment of capital lease obligations	(1,000)	(3,900)
Repayment of notes	(111,500)	(303,800)
Net cash provided by financing activities	5,193,300	2,838,900
Net increase in cash and cash equivalents	358,500	70,000
Cash and cash equivalents at beginning of period	70,000	-
Cash and cash equivalents at end of period	$428,500	$70,000
Supplemental disclosure of cash flow activities:		
Cash paid for interest	$12,700	$35,700
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	$79,400	$105,300
Accounts payable settled by issuance of common stock or notes payable and common stock	$-	$438,400

See accompanying notes to consolidated financial statements.

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VISTAGEN THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT
Fiscal Years Ended March 31, 2016 and 2015
(Amounts in dollars, except share amounts)

	Series A Preferred Stock		Series B Preferred Stock		Series C Preferred Stock		Common Stock		Additional Paid-in	Treasury	Note Receiva from Sa
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Stock	of Stock
Balances at March 31, 2014	500,000	$500	-	$-	-	$-	1,310,109	$1,300	$62,001,400	$(3,968,100)	$(198,1
Allocated proceeds from sale of Units for cash under 2014 Unit Private Placement, including beneficial conversion feature	-	-	-	-	-		280,350	300	2,746,800	-	-
Share-based compensation expense	-	-	-	-	-		-	-	2,460,100	-	-
Payment on and settlement of note receivable from sale of stock	-	-	-	-	-		-	-	-	-	198,10
Incremental fair value of modified warrants	-	-	-	-	-		-	-	98,400	-	-
Fair Value of common stock issued for services	-	-	-	-	-		71,667	100	635,600	-	-
Fair value of common stock and warrants issued in settlement	-	-	-	-	-		15,000	-	230,200	-	-

oftechnology license expenses											
Fair value of warrants issued to Morrison & Foerster, Cato Research Ltd. and University Health Network in connection with accruedinterest on underlying notes	-	-	-	-	-	-	-	44,400	-	-
Effect of amendments of 2013 Unit Notes and warrants, including repurchase of beneficial conversion feature	-	-	-	-	-	-	-	109,300	-	-
Effect of amendments of PLTG Senior Secured Promissory Notes, including repurchase of beneficial conversion feature	-	-	-	-	-	-	-	(380,400)	-	-
Net loss for fiscal year ended March 31, 2015	-	-	-	-	-	-	-	-	-	-
Balances at March 31, 2015	500,000	$500	-	$-	-	$-	1,677,126	$1,700	$67,945,800	$(3,968,100)	$-
Allocated proceeds from	-	-	-	-	-	-	33,000	-	277,200	-	-

sale of common stock Units for cash under 2014 Unit Private Placement, including beneficial conversion feature												
Proceeds from sale of Series B Preferred Units for cash under 2015 Series B Preferred Unit Private Placement	-	-	717,978	700	-	-	-	-	5,025,100	-	-	
Share-based compensation expense	-	-	-	-	-	-	-	-	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	-	-	
Elimination of warrant liability resulting from modification of PLTG Warrants	-	-	-	-	-	-	-	-	4,903,100	-	-	
Exchange of common stock for Series B Preferred stock	-	-	30,000	-	-	-	(30,000)	-	-	-	-	
Accrued dividends on	-	-	-	-	-	-	-	-	(2,140,500)	-	-	

Series B Preferred stock												
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	-	-
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	-	-
Exchange of outstanding warrants for common stock and other warrant modifications	-	-	-	-	-	-	814,989	800	3,022,300	-	-
Fair value of common stock, Series B Preferred stock and warrants granted for services	-	-	125,000	100	-	-	92,375	100	3,829,800	-	-
Net loss for fiscal year ended March 31, 2016	-	-	-	-	-	-	-	-	-	-	-
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)	$-

See accompanying notes to consolidated financial statements.

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VISTAGEN THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Description of Business

We are a clinical-stage biopharmaceutical company dedicated to developing and commercializing innovative product candidates for patients with diseases and disorders involving the central nervous system (CNS). Our lead product candidate, AV-101, is a next generation, orally available prodrug candidate in Phase 2 development, initially for the adjunctive treatment of Major Depressive Disorder (MDD) in patients with an inadequate response to standard antidepressants currently approved by the U.S. Food and Drug Administration (FDA).

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

Our ongoing Phase 2a clinical study of AV-101 in subjects with treatment-resistant MDD is being conducted and funded by the U.S. National Institute of Mental Health (NIMH) under our February 2015 Cooperative Research and Development Agreement (CRADA) with the NIMH. The first patient in this NIMH-sponsored Phase 2a study was dosed in November 2015. The Principal Investigator of the study is Dr. Carlos Zarate, Jr., Chief of the NIMH's Experimental Therapeutics & Pathophysiology Branch and its Section on Neurobiology and Treatment of Mood and Anxiety Disorders. Previous NIMH studies, including studies conducted by Dr. Zarate, have focused on the effects of low dose intravenous (I.V.) ketamine on treatment-resistant depression. These NIMH studies, as well as clinical research by others, have demonstrated robust antidepressant effects in patients with treatment-resistant MDD within hours of a single low dose of I.V. ketamine and stimulated research and development around a new generation of antidepressants with potential to deliver ketamine-like fast-acting antidepressant benefits without ketamine-like side effects.

We are preparing to launch our Phase 2b clinical study of AV-101 for the adjunctive treatment of MDD in patients with an inadequate response to standard, FDA-approved antidepressants. We anticipate commencement of this multi-center, multi-dose, double blind, placebo-controlled Phase 2b efficacy and safety study in the fourth quarter of 2016. Dr. Maurizio Fava, Professor of Psychiatry at Harvard Medical School and Director, Division of Clinical Research, Massachusetts General Hospital (MGH) Research Institute and Executive Director, MGH Clinical Trials Network and Institute, will be the Principal Investigator of our Phase 2b study of AV-101 in MDD.

We also believe AV-101 has broad therapeutic utility, with multiple CNS pipeline expansion opportunities, including chronic neuropathic pain, epilepsy, Huntington's disease and Parkinson's disease.

In addition to clinical development of AV-101, we are focused on collaborating with third-parties to advance potential commercial applications of our human pluripotent stem cell (hPSC) technology platform, including drug rescue to develop proprietary small molecule new chemical entities (NCEs) for our internal drug candidate pipeline, and regenerative medicine (RM) using blood, cartilage, heart and/or liver cells derived from hPSCs.

2. Basis of Presentation

Effective August 14, 2014, we consummated a 1-for-20 reverse split of our authorized, and issued and outstanding shares of common stock (the Stock Consolidation). Each reference to shares of common stock or the price per share of common stock in these financial statements is post-Stock Consolidation, and reflects the 1-for-20 adjustment as a result of the Stock Consolidation. See Note 9, Capital Stock, for more information regarding the Stock Consolidation.

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VISTAGEN THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The accompanying Consolidated Financial Statements have been prepared assuming that we will continue as a going concern. As a developing-technology company having not yet developed commercial products or achieved sustainable revenues, we have experienced recurring losses and negative cash flows from operations resulting in a deficit of $131.7 million accumulated from inception through March 31, 2016. We expect losses and negative cash flows from operations to continue for the foreseeable future as we engage in further potential development of AV-101 and launch and execute our drug rescue programs and pursue potential drug development and regenerative medicine opportunities.

Since our inception in May 1998 through March 31, 2016, 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 $34.5 million, as well as from an aggregate of approximately $16.4 million of government research grant awards, strategic collaboration payments and other revenues. Additionally, we have issued equity securities with an approximate value at issuance of $29.1 million in non-cash settlements of certain liabilities, including liabilities for professional services rendered to us or as compensation for such services.

Between late-March 2014 and March 31, 2015, we entered into securities purchase agreements with accredited investors and institutions, including Platinum Long Term Growth VII, LLC (PLTG), pursuant to which we sold units to such accredited investors, in private placement transactions (2014 Units or 2014 Unit Private Placement), for aggregate cash proceeds of approximately $3.1 million, consisting of (i) 2014 Unit Notes in the aggregate face amount of approximately $3.1 million which matured between March 31, 2015 and April 30, 2015, or were automatically convertible into securities we might issue upon the consummation of a Qualified Financing, as defined, (ii) an aggregate of 282,850 restricted shares of our common stock (2014 Unit Stock); and (iii) warrants exercisable through December 31, 2016 to purchase an aggregate of 282,850 restricted shares of our common stock at an exercise price of $10.00 per share (2014 Unit Warrants). Between April 1 and May 14, 2015, we continued the 2014 Unit Private Placement, pursuant to which we sold to accredited investors additional 2014 Units, for aggregate cash proceeds of $280,000, consisting of: (i) 10% convertible promissory notes maturing between April 30, 2015 and May 15, 2015, in the aggregate face amount of $280,000, (ii) an aggregate of 33,000 shares of our restricted common stock, and (iii) warrants exercisable through December 31, 2016 to purchase an aggregate of 24,250 restricted shares of our common stock at an exercise price of $10.00 per share.

As described more completely in Note 8, Convertible Promissory Notes and other Notes Payable, and Note 9, Capital Stock, in May 2015, we created our Series B 10% Convertible Preferred Stock (Series B Preferred). Between March 2015 and September 2015, we extinguished approximately $17.2 million of indebtedness through conversion of such indebtedness into our Series B Preferred and, with respect to a portion of the indebtedness converted, warrants to purchase our common stock. More specifically, we converted (i) all Senior Secured Convertible Promissory Notes originally issued to PLTG, (ii) all 2014 Unit Notes outstanding at March 31, 2015 and those issued subsequently, and (iii) certain other outstanding promissory notes and payables, including promissory notes issued to Cato Research Ltd., Cato Holding Company, Morrison & Foerster LLP (Note A and Note B), McCarthy Tetrault, Burr Pilger & Mayer, University Health Network (Toronto), the Icahn School of Medicine at Mount Sinai, National Jewish Health and others, into an aggregate of 2,618,917 shares of our Series B Preferred. Further, between May 2015 and March 31, 2016, we issued in self-placed private placement transactions with PLTG and other accredited investors, Series B Preferred Units consisting of an aggregate of 717,976 unregistered shares of Series B Preferred and five-year warrants to purchase 717,976 shares of our common stock, and we received cash proceeds of $5,025,800 therefrom. See Note 16, Subsequent Events, for disclosure of an additional $278,000 received from self-placed private placement sales of Series B Preferred Units after March 31, 2016.

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At March 31, 2016, we did not have sufficient cash and cash equivalents to enable us to fund our planned operations, including expected cash expenditures of approximately $9.1 million over the next twelve months, including expenditures required to prepare for and launch our Phase 2b clinical trial of AV-101. However, as disclosed in Note 16, Subsequent Events, between April 1, 2016 and May 4, 2016, we sold to accredited investors additional Series B Preferred Units consisting of 39,714 unregistered shares of Series B Preferred and five year warrants to purchase 39,714 shares of our common stock, and we received cash proceeds of $278,000. Further, on May 16, 2016 we consummated an underwritten public offering puruant to which we issued an aggregate of 2,570,040 registered shares of our common stock at the public offering price of $4.24 per share and five-year warrants to purchase up to 2,705,883 registered shares of common stock, with an exercise price of $5.30 per share, at the public offering price of $0.01 per warrant, including shares and warrants issued pursuant to to exercise of the underwriters' over-allotment option (the May 2016 Public Offering). We received net cash proceeds of approximately $9.5 million from the May 2016 Public offering after deducting fees and expenses. We expect the proceeds of these transactions to provide sufficient cash to sustain our operations through our fiscal year ending March 31, 2017, however they will not be adequate to enable the completion of our Phase 2b clinical trial of AV-101 in MDD. Accordingly, we intend to raise additional capital through sales of our securities, which may include both debt and equity securities. We may also seek research and development collaborations that could generate revenue, as well as government grant awards. Further, strategic collaborations, such as our February 2015 CRADA with the NIMH providing NIMH funding of our Phase 2a study of AV-101 in MDD, may provide resources to support a portion of our future cash needs and working capital requirements. Although we may seek additional collaborations that could generate revenue, as well as new government grant awards, no assurance can be provided that any such collaborations or awards 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 of AV-101 as a treatment for MDD and other CNS conditions, and our stem cell technology platform, the availability of, and our ability to obtain, government grant awards 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 the size of our staff and staff salaries and benefits, as well as costs relating to regulatory consulting, contract research and development, investor relations and corporate development, legal, 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 in the near term, our business, financial condition, and results of operations may be harmed, the price of our stock may decline, we may be required to reduce, defer, or discontinue certain of our research and development activities and we may not be able to continue as a going concern. These Consolidated Financial Statements do not include any adjustments that might result from the 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, and the accounts of VistaGen California's 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.

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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 or Disposal of Long-Lived Assets

We evaluate our long-lived assets, primarily property and equipment, for impairment whenever events or changes in circumstances indicate that their carrying value may not be recoverable from the estimated future cash flows expected to result from their use or eventual disposition. If the estimates of future undiscounted net cash flows are insufficient to recover the carrying value of the assets, we record an impairment loss in the amount by which the carrying value of the assets exceeds their fair value. If the assets are determined to be recoverable, but the useful lives are shorter than originally estimated, we depreciate or amortize the net book value of the assets over the newly determined remaining useful lives. We have not recorded any impairment charges to date.

Revenue Recognition

Although we do not currently have any such arrangements, we have historically generated revenue principally from collaborative research and development arrangements, technology transfer agreements, including strategic licenses, 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 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 up front technology access fees, cost reimbursements for specific research and development spending, and various milestone and future product 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.

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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 entering late-stage 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 our stem cell technology platform and AV-101. 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 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.

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 principally 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

Between October 2012 and July 2013, we issued to PLTG warrants to purchase a substantial number of unregistered shares of our common stock and, subject to PLTG's exercise of its rights to exchange shares of our Series A Preferred Stock that it holds, we were obligated to issue to PLTG an additional warrant (Series A Exchange Warrant) to purchase unregistered shares of common stock (collectively, the PLTG Warrants). The PLTG Warrants contained an

exercise price adjustment feature that would lower the exercise price of the warrants in the event we subsequently issued equity instruments at a price lower than the exercise price of the PLTG Warrants. We accounted for the PLTG Warrants as non-cash liabilities and estimated their fair value as described in Note 4, Fair Value Measurements, Note 8, Convertible Promissory Notes and Other Notes Payable, and Note 9, Capital Stock. We computed the fair value of the warrant liability at each reporting period and recorded 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.

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Notwithstanding the foregoing, and as described in Note 9, Capital Stock, on May 12, 2015, we entered into an agreement with PLTG pursuant to which PLTG agreed to amend the PLTG Warrants to (i) fix the exercise price thereof at $7.00 per share, (ii) eliminate the exercise price reset features and (iii) fix the number of shares of our common stock issuable thereunder. This agreement and the related 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.

Comprehensive Loss

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

Loss per Common Share

Basic net income (loss) per share of common stock excludes the effect of dilution and is computed by dividing net income (loss) by the weighted-average number of shares of common stock outstanding for the period. Diluted net income (loss) per share of common stock reflects the potential dilution that could occur if securities or other contracts to issue shares of common stock were exercised or converted into shares of common stock. In calculating diluted net income (loss) per share, we have adjusted the numerator for the change in the fair value of the warrant liability attributable to the 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. 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:

	Twelve Months Ended March 31,	
	2016	2015
Numerator:		
Net loss attributable to common stockholders for basic net loss per share	$(51,419,000)	$(13,885,800)
less: change in fair value of warrant liability attributable to outstanding warrants issued to PLTG	-	(105,200)
Net loss for diluted earnings per share attributable to common stockholders	$(51,419,000)	$(13,991,000)
Denominator:		
Weighted average basic common shares outstanding	1,767,957	1,318,813
Assumed conversion of dilutive securities:		
Warrants to purchase common stock	-	-
Potentially dilutive common shares assumed converted	-	-

Denominator for diluted earnings per share - adjusted weighted average shares	1,767,957	1,318,813
Basic net loss attributable to common stockholders per common share	$(29.08)	$(10.53)
Diluted net loss attributable to common stockholders per common share	$(29.08)	$(10.61)

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Potentially dilutive securities excluded in determining diluted net loss per common share for the fiscal years ended March 31, 2016 and 2015 are as follows:

	As of March 31, 2016	2015
Series A Preferred stock issued and outstanding (1)	750,000	750,000
Series B Preferred stock issued and outstanding (2)	3,663,077	-
Series C Preferred stock issued and outstanding (3)	2,318,012	-
Outstanding options under the 2008 and 1999 Stock Incentive Plans	336,987	207,638
Outstanding warrants to purchase common stock	1,907,221	1,544,474
Warrant shares issuable to PLTG upon exchange of Series A Preferred under the terms of the October 11, 2012 Note Exchange and Purchase Agreement, as subsequently amended	-	375,000
10% Senior Secured Convertible Notes issued to PLTG between October 2012 and July 2013, including accrued interest through March 31, 2015	-	444,235
10% convertible notes issued as a component of 2014 Unit Private Placement, including accrued interest through March 31, 2015	-	433,758
Total	8,975,297	3,755,105

(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

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers (Topic 606), which supersedes the revenue recognition requirements in ASC 605, Revenue Recognition. The amendment in this ASU provides guidance on revenue recognition to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The core principle of this update provides guidance to identify the performance obligations under the contract(s) with a customer and how to allocate the transaction price to the performance obligations in the contract. It further provides guidance to recognize revenue when (or as) the entity satisfies a performance obligation. In August 2015, the FASB issued an update to defer the effective date of this ASU by one year. The ASU is now effective for public entities for annual and interim periods beginning after December 15, 2017 (the first quarter of our fiscal year ending March 31, 2019). We do

not currently have, nor have we recently had, revenue generating activities. Accordingly, we have not determined the potential effects of adopting this ASU on our consolidated financial statements.

In March 2016, the FASB issued ASU 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net). The ASU does not change the core principle of the guidance in the aforementioned ASU 2014-09, instead, the amendments in this Update are intended to improve the operability and understandability of the implementation guidance on principal versus agent considerations and whether an entity reports revenue on a gross or net basis. ASU 2016-08 will have the same effective date and transition requirements as ASU 2014-09. We have not determined the potential effects of adopting this ASU on our consolidated financial statements.

In April 2016, the FASB issued ASU 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing. The amendments in this Update affect the guidance in the aforementioned ASU 2014-09 by clarifying two aspects: identifying performance obligations and the licensing implementation guidance. ASU 2016-10 will have the same effective date and transition requirements as the ASU 2014-09. We have not determined the potential effects of adopting this ASU on our consolidated financial statements.

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In May 2016, the FASB issued ASU 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow Scope Improvements and Practical Expedients. The amendments in this Update affect the guidance in the aforementioned ASU 2014-09 by clarifying certain specific aspects of the guidance, including assessment of collectability, treatment of sales taxes and contract modifications, and providing certain technical corrections. ASU 2016-12 will have the same effective date and transition requirements as the ASU 2014-09. We have not determined the potential effects of adopting this ASU on our consolidated financial statements.

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. 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. ASU 2014-15 is effective for annual periods ending after December 15, 2016, and interim and annual periods thereafter. Early application is permitted. In their opinion on our financial statements for our fiscal year ended March 31, 2015, our auditors indicated that there was substantial doubt about our ability to continue as a going concern. Based on our consummation of the May 2016 Registered Offering and other considerations, their opinion on our financial statements for our fiscal year ended March 31, 2016 did not indicate the presence of such doubt. Although we have not yet adopted ASU 2014-15, we have indicated in Note 2, Basis of Presentation, steps we have taken to provide sufficient additional financing that is expected to permit us to continue our operations for at least one year. Upon our adoption of ASU 2014-15, should conditions at such time indicate there is substantial doubt about our ability to continue as a going concern, or that such doubt has been alleviated, we will conform our disclosure to the guidance contained in ASU 2014-15.

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 as of the beginning of our fiscal year beginning April 1, 2016. Although adoption of this ASU has had no effect on the accompanying financial statements, should we incur debt issuance costs in the future, we will treat such costs as a deduction from the carrying amount of such liability.

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. The Company is required to adopt this ASU no later than April 1, 2017, with early adoption permitted, and the guidance may be applied either prospectively or retrospectively. 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 fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. We do not believe that this ASU will have a material effect on our consolidated financial statements.

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In February 2016, the FASB issued ASU 2016-02, Leases (ASC 842), 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. ASC 842 supersedes the previous leases standard, ASC 840, 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 do not expect that this ASU will have a material effect on our consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. The ASU includes multiple provisions intended to simplify various aspects of the accounting for share-based payments. While aimed at reducing the cost and complexity of the accounting for share-based payments, the amendments are expected to significantly impact net income, EPS, and the statement of cash flows. For public companies, the amendments in this ASU are effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Early adoption is permitted. We are evaluating the impact of this ASU on our consolidated financial statements.

4. Fair Value Measurements

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 the Company estimates 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.

We do not use derivative instruments for hedging of market risks or for trading or speculative purposes. In conjunction with the Senior Secured Convertible Promissory Notes issued to PLTG between October 2012 and July 2013 and the related PLTG Warrants (see Note 8, Convertible Promissory Notes and Other Notes Payable), and the contingently issuable Series A Exchange Warrant (see Note 9, Capital Stock), we determined that the warrants included certain exercise price adjustment features requiring the warrants to be treated as liabilities, which were recorded at their issuance-date estimated fair values. We determined the fair value of the warrant liabilities using a Monte Carlo simulation model with Level 3 inputs. Inputs used to determine fair value include the remaining contractual term of the notes, 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. Changes in the fair value of these warrant liabilities have been recognized as non-cash income or expense in the Consolidated Statements of Operations and Comprehensive Loss for the fiscal years ended March 31, 2016 and 2015.

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The fair value hierarchy for liabilities measured at fair value on a recurring basis is as follows:

	Total Carrying Value	Fair Value Measurements at Reporting Date Using: Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
March 31, 2016:				
Warrant liability	$-	$-	$-	$ -
March 31, 2015:				
Warrant liability	$3,008,500	$-	$-	$ 3,008,500

During the fiscal years ended March 31, 2016 and 2015, there were no significant changes to the valuation models used for purposes of determining the fair value of the Level 3 warrant liability.

The changes in Level 3 liabilities measured at fair value on a recurring basis are as follows:

	Fair Value Measurements Using Significant Unobservable Inputs (Level 3) Warrant Liability
Balance at March 31, 2015	$ 3,008,500
Mark to market loss included in net loss	1,894,700
Elimination of liability upon modification of warrants	(4,903,200)
Balance at March 31, 2016	$ -

As described in Note 9, Capital Stock, on May 12, 2015, we entered into an agreement with PLTG pursuant to which PLTG agreed to amend the PLTG Warrants to (i) fix the exercise price thereof at $7.00 per share, (ii) eliminate the exercise price reset features and (iii) fix the number of shares of our common stock issuable thereunder. This agreement and the related modification of the PLTG Warrants resulted in the elimination of the warrant liability with respect to the PLTG Warrants during the quarter ended June 30, 2015. 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.

No assets or other liabilities were measured on a recurring basis at fair value at March 31, 2016 or 2015.

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5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	March 31, 2016	March 31, 2015
Insurance	$27,000	$27,300
Prepaid compensation under financial advisory and other consulting agreements	337,500	-
Public offering expenses	57,400	-
Legal fees	-	3,400
Technology license fees and all other	4,900	5,000
	$426,800	$35,700

6. Property and Equipment

Property and equipment consists of the following:

	March 31, 2016	March 31, 2015
Laboratory equipment	$659,000	$653,600
Tenant improvements	26,900	26,900
Computers and network equipment	43,200	32,200
Office furniture and equipment	69,500	69,500
	798,600	782,200
Accumulated depreciation and amortization	(711,000)	(665,100)
Property and equipment, net	$87,600	$117,100

In connection with the issuance of Senior Secured Convertible Promissory Notes to PLTG beginning in October 2012, we entered into a Security Agreement with PLTG under which the repayment of all amounts due under the terms of the various Senior Secured Convertible Promissory Notes was secured by all of our assets, including our tangible and intangible personal property, licenses, patent licenses, trademarks and trademark licenses. As described more completely in Note 8, Convertible Promissory Notes and Other Notes Payable, and Note 9, Capital Stock, in May 2015, we entered into an agreement with PLTG pursuant to which PLTG converted all of the Senior Secured Convertible Promissory Notes it held into shares of our newly created Series B Preferred stock and terminated its security interests in our assets.

7. Accrued Expenses

Accrued expenses consist of:

	March 31, 2016	March 31, 2015
Accrued professional services	$318,000	$213,800
Accrued AV-101 development expenses	$186,000	$-
Accrued compensation	310,000	990,700
All other	-	2,000

	$814,000	$1,206,500

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8. Convertible Promissory Notes and Other Notes Payable

The following table summarizes the components of the Company's convertible promissory notes and other notes payable:

	March 31, 2016			March 31, 2015		
	Principal Balance	Accrued Interest	Total	Principal Balance	Accrued Interest	Total
Senior Secured 10% Convertible Promissory Notes issued to PLTG:						
Exchange Note issued on October 11, 2012	$ -	$ -	$ -	$ 1,272,600	$ 360,200	$ 1,632,800
Investment Note issued on October 11, 2012	-	-	-	500,000	141,500	641,500
Investment Note issued on October 19, 2012	-	-	-	500,000	140,100	640,100
Investment Note issued on February 22, 2013	-	-	-	250,000	59,100	309,100
Investment Note issued on March 12, 2013	-	-	-	750,000	172,600	922,600
	-	-	-	3,272,600	873,500	4,146,100
Convertible promissory note issued on July 26, 2013	-	-	-	250,000	46,200	296,200
Total Senior notes	-	-	-	3,522,600	919,700	4,442,300
Aggregate note discount	-	-	-	-	-	-
Net Senior notes	-	-	-	3,522,600	919,700	4,442,300
less: current portion	-	-	-	(3,272,600)	(873,500)	(4,146,100)
Senior notes - non-current portion and discount	$ -	$ -	$ -	$ 250,000	$ 46,200	$ 296,200
10% Convertible Promissory Notes (Unit Notes)						
2014 Unit Notes, including amended notes, due 3/31/15	$ -	$ -	$ -	$ 4,066,900	$ 270,700	$ 4,337,600
Note discounts	-	-	-	(180,000)	-	(180,000)
Net convertible notes (all current)	$ -	$ -	$ -	$ 3,886,900	$ 270,700	$ 4,157,600
Notes Payable to unrelated parties:						

7.5% Notes payable to service providers for accounts payable converted to notes payable:						
Burr, Pilger, Mayer	$ -	$ -	$ -	$ 90,400	$ 13,100	$ 103,500
Desjardins	-	-	-	156,300	24,100	180,400
McCarthy Tetrault	-	-	-	319,700	46,000	365,700
August 2012 Morrison & Foerster Note A	-	-	-	918,200	193,200	1,111,400
August 2012 Morrison & Foerster Note B	-	-	-	1,379,400	333,100	1,712,500
University Health Network	-	-	-	549,500	101,800	651,300
	-	-	-	3,413,500	711,300	4,124,800
Note discount	-	-	-	(474,500)	-	(474,500)
	-	-	-	2,939,000	711,300	3,650,300
less: current portion (and discount at March 31, 2015)	-	-	-	(2,939,000)	(711,300)	(3,650,300)
non-current portion and discount	$ -	$ -	$ -	$ -	$ -	$ -
5.75% and 10.25% Notes payable to insurance premium financing company (current)	$ -	$ -	$ -	$ 5,800	$ -	$ 5,800
10% Notes payable to vendors for accounts payable converted to notes payable	$ -	$ -	$ -	$ 378,300	$ 51,500	$ 429,800
less: current portion	-	-	-	(378,300)	(51,500)	(429,800)
non-current portion	$ -	$ -	$ -	$ -	$ -	$ -
7.0% Note payable (August 2012)	$ 58,800	$ 12,000	$ 70,800	$ 58,800	$ 7,900	$ 66,700
less: current portion	(31,600)	(12,000)	(43,600)	(23,200)	(7,900)	(31,100)
7.0% Notes payable - non-current portion	$ 27,200	$ -	$ 27,200	$ 35,600	$ -	$ 35,600
Total notes payable to unrelated parties	$ 58,800	$ 12,000	$ 70,800	$ 3,381,900	$ 770,700	$ 4,152,600
less: current portion (and discount at March 31, 2015)	(31,600)	(12,000)	(43,600)	(3,346,300)	(770,700)	(4,117,000)
Net non-current portion	$ 27,200	$ -	$ 27,200	$ 35,600	$ -	$ 35,600
Notes payable to related parties:						
October 2012 7.5% Note to Cato Holding Co.	$ -	$ -	$ -	$ 293,600	$ 55,900	$ 349,500
October 2012 7.5% Note to Cato Research Ltd.	-	-	-	1,009,000	204,800	1,213,800
	-	-	-	1,302,600	260,700	1,563,300

Note discount	-	-	-	(54,500)	-	(54,500)
Total notes payable to related parties	-	-	-	1,248,100	260,700	1,508,800
less: current portion	-	-	-	(1,248,100)	(260,700)	(1,508,800)
non-current portion and discount	$ -	$ -	$ -	$ -	$ -	$ -

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With the exception of the 10% convertible promissory notes issued in connection with our 2014 Unit Private Placement, described below, and a $300,000 promissory note issued in April 2014 to Icahn School of Medicine at Mount Sinai in satisfaction of certain stem cell technology license maintenance fees and reimbursable patent prosecution costs, all of our outstanding secured and unsecured promissory notes were issued prior to the beginning of our fiscal year ended March 31, 2015 and either no payments were required under the terms of such notes or, for strategic purposes, we did not make any principal or interest payments on them during our fiscal year ended March 31, 2015. As disclosed below, between May 2015 and September 2015, we reached agreements with the holders of essentially all of our outstanding notes to convert the outstanding balance of principal and interest into shares of our Series B Preferred. New promissory note issuances during fiscal years 2015 and 2016 and conversions of our secured and unsecured convertible promissory notes and other promissory notes into shares of our Series B Preferred during the fiscal year ended March 31, 2016 are described below.

10% Convertible Notes Issued in Connection with 2014 Unit Private Placement

As described more completely under the caption 2014 Unit Private Placement in Note 9, Capital Stock, between April 1, 2015 and May 14, 2015, we issued to accredited investors in self-placed private placement transactions 10% convertible notes (the 2014 Unit Notes) in the aggregate face amount of $280,000. The 2014 Unit Notes issued in April and May 2015 represented a continuation of the 2014 Unit Private Placement pursuant to which we had issued in self-placed private placement transactions to accredited investors an aggregate of $3,113,500 principal amount of substantially similar notes between late-March 2014 and March 31, 2015. The 2014 Unit Notes matured between April 30, 2015 and May 15, 2015 (Maturity) and the outstanding principal of the 2014 Unit Notes and their related accrued interest (the Outstanding Balance) was convertible into shares of our common stock at a conversion price of $10.00 per share at or prior to Maturity, at the option of the accredited investor. In addition, upon our consummation of either (i) an equity or equity-based public financing registered with the SEC, or (ii) an equity or equity-based private placement, or series of private placements, not registered with the SEC, in either case resulting in gross cash proceeds to us of at least $10.0 million prior to Maturity (a Qualified Financing), the Outstanding Balance of the 2014 Unit Notes would automatically convert into securities substantially similar to those sold in the Qualified Financing, based on the following formula: (the Outstanding Balance as of the closing of the Qualified Financing) x 1.25 / (the per security price of the securities sold in the Qualified Financing).

We allocated the proceeds from the self-placed private placement of the units to the 2014 Unit Notes, the common stock and the warrants comprising the units based on the relative fair value of the individual securities in the unit on the date of the unit sale. Based on the short-duration of the 2014 Unit Notes and their other terms, we determined that the fair value of the 2014 Unit Notes at the date of issuance was equal to their face value. Accordingly, we recorded an initial discount attributable to each 2014 Unit Note for an amount representing the difference between the face value of the 2014 Unit Note and its allocated relative value. Additionally, the 2014 Unit Notes contained an embedded conversion feature having intrinsic value at the issuance date, which value we treated as an additional discount attributable to those 2014 Unit Notes, subject to limitations on the absolute amount of discount attributable to each 2014 Unit Note. We recorded a corresponding credit to additional paid-in capital, an equity account, attributable to the beneficial conversion feature. We amortized the discounts attributable to the 2014 Unit Notes issued in April and May 2015, an aggregate of $277,200, using the effective interest method over the respective term of each 2014 Unit Note. Because the discount on each of these 2014 Unit Notes represented 99% of its initial face value, and because we were required to amortize such discount over the period from issuance to maturity, which was no more than two months for these notes, the calculated effective interest rate is extremely high. Based on the amounts of their respective discounts and the term between issuance and maturity, the effective interest rates attributable to the 2014 Unit Notes issued in April and May 2015 are in excess of 10,000%.

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Issuance of Securities in Satisfaction of Technology License and Maintenance Fees and Patent Expenses

As described more completely in Note 9, Capital Stock, in April 2014, we entered into an agreement with Icahn School of Medicine at Mount Sinai (ISMMS), one of our technology licensors, pursuant to which we issued to ISMMS (i) a 10% promissory note in the face amount of $300,000 due on the earlier of December 31, 2014, or the completion of a qualified financing, as defined, (ii) 15,000 restricted shares of our common stock and (iii) a warrant exercisable through March 31, 2019 to purchase 15,000 restricted shares of our common stock at an exercise price of $10.00 per share in satisfaction of $288,400 of stem cell technology license maintenance fees and reimbursable patent prosecution costs (the Agreement). Under the terms of the Agreement, an additional $35,800 of license maintenance fees and reimbursable patent prosecution costs was added to the principal amount of the promissory note through March 31, 2015. We made payments aggregating $100,000 on the note during the fiscal year ended March 31, 2015, prior to its conversion into shares of our Series B Preferred in June 2015.

Accounting for Notes and Other Indebtedness Converted into Series B Preferred

Between May 2015 and September 2015, we extinguished the outstanding balances of approximately $17.2 million of indebtedness, 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 (which is described more completely below under the caption Creation of Series B Preferred Stock in Note 9, Capital 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.

Conversion of Senior Secured 10% Convertible Promissory Notes issued to PLTG into Series B Preferred

As described more completely in Note 9, Capital Stock, effective on May 12, 2015, we entered in to a broad strategic agreement with PLTG (PLTG Agreement) pursuant to which PLTG, among other things, converted all of the $4,489,300 outstanding balance (principal and accrued interest) of the Senior Secured Notes having maturity dates between October 2015 and July 2016 into 641,335 shares of our Series B Preferred. Based on the $10.00 per share fair value of the Series B Preferred at the date the Senior Secured Notes were converted, we issued Series B Preferred having an aggregate fair value of $6,413,300 to PLTG. Accordingly, we recognized a non-cash loss on the extinguishment of the Senior Secured Notes in the amount of $1,924,000 in the quarter ended June 30, 2015.

Conversion of 2014 Unit Notes into Series B Preferred

Pursuant to the PLTG Agreement, PLTG also converted the $1,345,700 outstanding balance of the 2014 Unit Notes originally issued by us to PLTG that had matured on March 31, 2015 (PLTG Unit Notes) into shares of our Series B Preferred. PLTG additionally agreed to acquire and convert into our Series B Preferred other 2014 Unit Notes that had

matured on March 31, 2015 originally issued to other investors having an aggregate outstanding balance of $1,487,900 (Acquired Unit Notes). Further, effective May 20, 2015, the holders of other 2014 Unit Notes that had matured on March 31, 2015 or shortly thereafter, having an aggregate outstanding balance of $1,831,200 (Investor Unit Notes) individually converted such notes into our Series B Preferred. Consequently, the aggregate outstanding balance totaling $4,664,800 of all 2014 Unit Notes, including those issued in April and May 2015, was converted into shares of our Series B Preferred. We determined that the Series B Preferred Unit Offering, as described in Note 9, Capital Stock, would be treated as a Qualified Financing applicable to the 2014 Unit 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. Accordingly, we issued an aggregate of 833,020 shares of our Series B Preferred and warrants to purchase an aggregate of 833,020 shares of our common stock upon the conversion of the outstanding balance of all 2014 Unit Notes, including an aggregate conversion premium of $1,166,200.

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Based on the $10.00 per share fair value of the Series B Preferred at the date the PLTG Unit Notes and Acquired Unit Notes were converted and the $8.00 per share fair value of the Series B Preferred at the date the Investor Unit Notes were converted, we issued Series B Preferred having an aggregate fair value of $7,676,200 upon the conversions. We valued the warrants issued in connection with the 2014 Unit Note conversions at an aggregate of $5,168,400 using the Black Scholes option pricing model and the following assumptions:

Assumption:	PLTG Unit Notes and Acquired Unit Notes	Investor Unit Notes
Market price per share at conversion date	$ 10.00	$ 8.00
Exercise price per share	$ 7.00	$ 7.00
Risk-free interest rate	1.58	1.57
Contractual term in years	5.00	5.00
Volatility	76.5%	75.7%
Dividend rate	0.0%	0.0%
Warrant shares	506,004	327,016
Fair Value per share	$ 6.89	$ 5.15

Nearly all of the 2014 Unit Notes contained a beneficial conversion feature at the time they were originally issued. We have accounted for the repurchase of the beneficial conversion feature at the time of the extinguishment and conversion, an aggregate of $2,237,100, as a reduction to the loss on extinguishment of debt in the accompanying Consolidated Statements of Operations and Comprehensive Loss, with a corresponding reduction to additional paid-in capital. In aggregate, we recognized a non-cash loss on extinguishment of debt attributable to the conversion of the 2014 Unit Notes in the amount of $5,942,700 in the quarter ended June 30, 2015.

Conversion of Promissory Note issued to University Health Network into Series B Preferred

On May 29, 2015, University Health Network (UHN) converted the entire $656,400 outstanding balance (principal and accrued interest) of our promissory note maturing on March 31, 2016 into 93,775 shares of our Series B Preferred. Based on the $10.00 per share fair value of the Series B Preferred at the date the UHN note was converted, we issued Series B Preferred having an aggregate fair value of $937,800 to UHN. After eliminating the remaining $27,500 of unamortized discount on the UHN note, we recognized a non-cash loss on the extinguishment of debt attributable to the conversion of the UHN Note of $308,900 in the quarter ended June 30, 2015.

Conversion of Promissory Notes and Accounts Payable issued to Cato Holding Company (CHC) and Cato Research Ltd. (CRL) into Series B Preferred

On June 10, 2015, CHC, the parent company of CRL and a related party, converted the entire aggregate outstanding balance (principal and accrued interest) of $1,583,000 of our outstanding promissory notes issued to CHC and CRL and maturing on March 31, 2016 (together, the Cato Notes), plus an additional $171,300 of past due accounts payable to CRL and a strategic adjustment thereto (CRL Payables) into a total of 328,571 shares of our Series B Preferred. Based on the $10.00 per share fair value of the Series B Preferred at the date the Cato Notes and CRL Payables were converted, we issued Series B Preferred having an aggregate fair value of $3,285,700 to CHC.

As additional consideration for the conversion of the Cato Notes and the CRL Payables, we amended certain outstanding warrants held by CHC and CRL to purchase 12,500 and 60,691 restricted shares of our common stock, respectively, to reduce the exercise price thereof from $30.00 and $20.00 per share, respectively, to $7.00 per share. We calculated the fair value of the warrants immediately before and after the modifications and determined that the fair value of the warrants increased by $222,700. The warrants subject to the exercise price modifications were valued using the Black-Scholes Option Pricing Model and the following assumptions:

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Assumption:	Pre-modification	Post-modification
Market price per share at modification date	$ 10.00	$ 10.00
Exercise price per share	$20.00 and $30.00	$ 7.00
Risk-free interest rate	0.87%	0.87%
Contractual term in years	2.31	2.31
Volatility	73.9%	73.9%
Dividend rate	0.0%	0.0%
Weighted Average Fair Value per share	$ 2.44 and $1.57	$ 5.33

After eliminating the remaining unamortized discount of $46,000 attributable to the Cato Notes, we recognized a non-cash loss on the extinguishment of debt attributable to the conversion of the Cato Notes and CRL Payables of $1,800,100 in the quarter ended June 30, 2015.

Conversion of Promissory Note B issued to Morrison & Foerster into Series B Preferred

On June 12, 2015, Morrison & Foerster (M&F) converted the entire aggregate outstanding balance (principal and accrued interest) of $1,735,500 of our August 2012 promissory Note B maturing on March 31, 2016 (M&F Note B), plus an agreed strategic adjustment thereto into a total of 257,143 shares of our Series B Preferred. Based on the $10.00 per share fair value of the Series B Preferred at the date M&F Note B was converted, we issued Series B Preferred having an aggregate fair value of $2,571,400 to M&F.

As additional consideration for the conversion of M&F Note B, we amended two outstanding warrants held by M&F to purchase an aggregate of 110,448 restricted shares of our common stock to reduce the exercise price of one of the warrants from $40.00 per share to $20.00 per share and to extend the term of both warrants from September 15, 2017 to September 15, 2019. We calculated the fair value of the warrants immediately before and after the modifications and determined that the fair value of the warrants increased by $244,200. The warrants subject to the exercise price and term modifications were valued using the Black-Scholes Option Pricing Model and the following assumptions:

Assumption:	Pre-modification	Post-modification
Market price per share at modification date	$ 10.00	$ 10.00
Exercise price per share	$20.00 and $40.00	$ 20.00
Risk-free interest rate	0.86%	1.57%
Contractual term in years	2.27	4.27
Volatility	73.8%	76.7%
Dividend rate	0.0%	0.0%
Weighted Average Fair Value per share	$ 2.39 and $1.04	$ 4.35

After eliminating the remaining unamortized discount of $225,500 attributable to M&F Note B, we recognized a non-cash loss on the extinguishment of debt attributable to the conversion of M&F Note B of $1,305,600 in the quarter ended June 30, 2015.

In addition to its agreement to convert M&F Note B into Series B Preferred, M&F also agreed to withhold, through the later of (i) December 31, 2016 or (ii) our consummation of a registered public offering or a strategic transaction involving AV-101 in which, in either case, we received gross proceeds of at least $20.0 million, any and all action to collect amounts due under our August 2012 promissory Note A maturing on March 31, 2016 (M&F Note A) and all past due amounts owed by us to M&F in connection with professional services previously rendered by M&F (M&F Payables).

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Conversion of Morrison & Foerster Note A and Morrison & Foerster Payables into Series B Preferred

In a transaction to which we were not a party, M&F sold M&F Note A, which, at the time of the sale, had an outstanding balance (principal and accrued interest) of $1,149,000, as well as the M&F Payables in the amount of $165,100, to two third-party accredited investors (the M&F Note A Investors). On August 10, 2015, the M&F Note A Investors converted M&F Note A and the M&F Payables into 192,628 shares of our Series B Preferred. Based on the $12.25 per share fair value of the Series B Preferred at the date M&F Note A and the M&F Payables were converted, we issued Series B Preferred having an aggregate fair value of $2,359,700 to the M&F Note A Investors. After eliminating the remaining unamortized discount of $122,400 attributable to M&F Note A, we recognized a non-cash loss on extinguishment of debt attributable to the conversion of M&F Note A and the M&F Payables of $1,168,000 in the quarter ended September 30, 2015.

Conversion of Promissory Note issued to McCarthy Tetrault into Series B Preferred

On June 18, 2015, McCarthy Tetrault (McCarthy) converted the entire $379,600 outstanding balance (principal and accrued interest) of our past due promissory note issued in May 2011, plus an additional $2,100 of past due accounts payable (together, the McCarthy Note), into 59,230 shares of our Series B Preferred. Based on the $14.00 per share fair value of the Series B Preferred at the date the McCarthy Note was converted, we issued Series B Preferred having an aggregate fair value of $829,200 to McCarthy. Accordingly, we recognized a non-cash loss on extinguishment of debt attributable to the conversion of the McCarthy Note of $447,500 in the quarter ended June 30, 2015.

Conversion of Promissory Note issued to Burr Pilger & Mayer into Series B Preferred

On June 24, 2015, Burr Pilger & Mayer (Burr) converted the entire $105,200 outstanding balance (principal and accrued interest) of our past due promissory note issued in May 2011, plus an additional $17,900 of past due accounts payable (together, the Burr Note), into 21,429 shares of our Series B Preferred. Based on the $16.50 per share fair value of the Series B Preferred at the date the Burr Note was converted, we issued Series B Preferred having an aggregate fair value of $353,600 to Burr. Accordingly, we recognized a non-cash loss on the extinguishment of debt attributable to the conversion of the Burr Note of $230,500 in the quarter ended June 30, 2015.

Conversion of Promissory Note and Accounts Payable Issued to Icahn School of Medicine at Mount Sinai into Series B Preferred

On June 26, 2015, Icahn School of Medicine at Mount Sinai (ISMMS) converted the entire $270,400 outstanding balance (principal and accrued interest) of our past due April 2014 promissory note into a total of 40,000 shares of our Series B Preferred. Based on the $16.00 per share fair value of the Series B Preferred at the date the note was converted, we issued Series B Preferred having an aggregate fair value of $640,000 to ISMMS.

As additional consideration for the conversion of the ISMMS note, we amended an outstanding warrant held by ISMMS to purchase 15,000 restricted shares of our common stock to reduce the exercise price from $10.00 per share to $7.00 per share. We calculated the fair value of the warrant immediately before and after the modification and determined that the fair value of the warrant increased by $16,600. The warrant subject to the exercise price modification was valued using the Black-Scholes Option Pricing Model and the following assumptions:

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Assumption:	Pre-modification	Post-modification
Market price per share at modification date	$ 16.00	$ 16.00
Exercise price per share	$ 10.00	$ 7.00
Risk-free interest rate	1.34%	1.34%%
Contractual term in years	3.76	3.76
Volatility	76.3%	76.3%
Dividend rate	0.0%	0.0%
Weighted Average Fair Value per share	$ 10.48	$ 11.60

We recognized a non-cash loss on extinguishment of debt attributable to the conversion of ISMMS note of $386,200 in the quarter ended June 30, 2015.

On July 13, 2015, ISMMS also converted accounts payable in the amount of $19,100 (ISMMS Payables) into an additional 3,000 shares of our Series B Preferred. Based on the $12.00 per share fair value of the Series B Preferred at the date the ISMMS Payables were converted, we issued Series B Preferred having an aggregate fair value of $36,000 to ISMMS. Accordingly, we recognized a non-cash loss on the extinguishment of debt attributable to the conversion of the ISMMS Payables of $16,900 in the quarter ended September 30, 2015.

Conversion of Promissory Note issued to National Jewish Health into Series B Preferred

On June 29, 2015, National Jewish Health (NJH) converted the entire $115,000 outstanding balance (principal and accrued interest) of our past due promissory note into 17,857 shares of our Series B Preferred. Based on the $15.00 per share fair value of the Series B Preferred at the date the NJH note was converted, we issued Series B Preferred having an aggregate fair value of $267,900 to NJH. Accordingly, we recognized a non-cash loss on the extinguishment of debt attributable to the conversion of the NJH note of $152,900 in the quarter ended June 30, 2015.

Conversion of Promissory Note issued to Desjardins Securities into Series B Preferred

On July 2, 2015, Desjardins Securities (Desjardins) converted the entire $187,400 outstanding balance (principal and accrued interest) of our past due promissory note into 32,143 shares of our Series B Preferred. Based on the $14.00 per share fair value of the Series B Preferred at the date the Desjardins note was converted, we issued Series B Preferred having an aggregate fair value of $450,000 to Desjardins. Accordingly, we recognized a non-cash loss on extinguishment of the debt attributable to the conversion of the Desjardins note of $262,600 in the quarter ended September 30, 2015.

Conversion of Promissory Note and Accounts Payable issued to MicroConstants into Series B Preferred

On July 6, 2015, MicroConstants, Inc. (MicroConstants) converted the $22,000 outstanding balance (principal and accrued interest) of our past due promissory note and outstanding accounts payable in the amount of $70,400 into an aggregate of 17,857 shares of our Series B Preferred. Based on the $14.00 per share fair value of the Series B Preferred at the date the MicroConstants note and accounts payable were converted, we issued Series B Preferred having an aggregate fair value of $250,000. Accordingly, we recognized a non-cash loss on extinguishment of debt attributable to the conversion of the MicroConstants note and payables of $157,600 in the quarter ended September 30, 2015.

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Conversion of Accounts Payable to Professional Services Providers and Other Debt into Series B Preferred

During June and July 2015, two of our professional service providers and a former employee to whom we were contractually obligated for certain accrued compensation amounts converted an aggregate of $497,900 past due amounts for prior services (Service Provider Payables) into an aggregate of 80,929 shares of our Series B Preferred. Based on the per share fair value of the Series B Preferred on the respective dates that each Service Provider Payable was converted, which ranged from $10.00 per share to $12.00 per share, we issued Series B Preferred having an aggregate fair value of $823,800 to the Service Providers. Accordingly, we recognized an aggregate non-cash loss on the extinguishment of debt attributable to the conversion of the Service Provider Payables in the amounts of $281,800 and $44,100 in the quarters ended June 30, 2015 and September 30, 2015, respectively.

9. Capital Stock

Reverse Split (Stock Consolidation) of our Common Stock

As indicated in Note 2, Basis of Presentation, we consummated the Stock Consolidation, a 1-for-20 reverse split of our authorized, and issued and outstanding shares of common stock, effective on August 14, 2014. The par value of our common stock remained unchanged at $0.001 per share following the Stock Consolidation. The Stock Consolidation was approved by the Financial Industry Regulatory Authority (FINRA) on August 13, 2014, and became effective on the OTCQB at the opening of trading on August 14, 2014. Each reference to shares of common stock or the price per share of common stock in these financial statements is post-Stock Consolidation, and reflects the 1-for-20 adjustment as a result of the Stock Consolidation.

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, 2016 and 2015, 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, 2016 and 2015.

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Creation of Series B Preferred Stock

On July 17, 2014, our Board of Directors authorized the creation of a class of Series B Preferred Stock. On May 7, 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, 2016, we have recognized a liability in the amount of $2,089,600 for Accrued Dividends in the accompanying Consolidated Balance Sheet at March 31, 2016, 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 $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 year ended March 31, 2016. The liquidation value of the Series B Preferred at March 31, 2016 is approximately $27,731,200.

Refer to Note 16, Subsequent Events, for disclosure regarding the Automatic Conversion of certain shares of Series B Preferred upon our consummation of the May 2016 Public Offering and our related issuance of shares of unregistered common stock in payment of Accrued Dividends thereon.

Creation of Series C Preferred Stock

On January 13, 2016, our Board authorized the creation of, and effective January 25, 2016, 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 PreferredCertificate 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, 2016, PLTG or its affiliates held all outstanding shares of Series C Preferred.

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VISTAGEN THERAPEUTICS, INC.
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2014 Unit Private Placement

Between late-March 2014 and March 31, 2015, we entered into securities purchase agreements with accredited investors, including PLTG, pursuant to which we sold units to such accredited investors in private placement transactions (2014 Units), for aggregate cash proceeds of $3,113,500, consisting of (i) 2014 Unit Notes in the aggregate face amount of $3,113,500 which were due on March 31, 2015 or automatically convertible into securities we might have issued upon the consummation of a Qualified Financing, defined as (a) an equity-based public financing registered with the SEC, or (b) a private equity-based financing or series of private equity-based financings, in either case in which we receive at least $10 million in gross cash proceeds prior to March 31, 2015; (ii) an aggregate of 282,850 restricted shares of our common stock (2014 Unit Stock); and (iii) warrants exercisable through December 31, 2016 to purchase an aggregate of 282,850 restricted shares of our common stock at an exercise price of $10.00 per share (2014 Unit Warrants). We sold $1,250,000 of such Units to PLTG, issuing 2014 Unit Notes in the face amount of $1,250,000; 125,000 restricted shares of 2014 Unit Stock and 2014 Unit Warrants to purchase 125,000 shares of our common stock to PLTG. The Outstanding Balance of each 2014 Unit Notes was convertible into shares of our common stock at a conversion price of $10.00 per share at or prior to maturity, at the option of each investor. In addition, however, the Outstanding Balance was automatically convertible into securities substantially similar to those we issued in a Qualified Financing at an amount determined by multiplying the Outstanding Balance by 1.25, and dividing the resulting number by the price per share of securities offered in the Qualified Financing. Under certain circumstances, the holders of the 2014 Unit Notes could request payment in cash in lieu of automatic conversion into the securities of the Qualified Financing. We sold $50,000 of 2014 Units prior to March 31, 2014, which Units are reflected in the figures above.

We allocated the proceeds from the sale of the 2014 Units to the various securities based on their relative fair values on the dates of the sales. As described in Note 8, Convertible Promissory Notes and Other Notes Payable, based on the short-term nature of the Unit Notes, we determined that fair value of the 2014 Unit Notes was equal to their face value. We determined the fair value of the 2014 Unit Stock based on the quoted market price of our common stock on the date of the 2014 Unit sale. We calculated the fair value of the 2014 Unit 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 2014 Unit sales proceeds based on the relative fair values of the 2014 Unit Stock, 2014 Unit Warrants and 2014 Unit Notes as of their respective 2014 Unit sales dates.

	Unit Warrants Weighted Average Issuance Date Valuation Assumptions											
Warrant Shares Issued	Market Price	Exercise Price	Term (Years)	Risk free Interest Rate	Volatility	Dividend Rate	Per Share Fair Value of Warrant	Aggregate Fair Value of Unit Warrants	Aggregate Proceeds of Unit Sales	Aggregate Allocation of Proce Based on Relative Fair Value o Unit Stock	Unit Warrant	Unit Note
282,850	$9.28	$10.00	2.17	0.62%	72.36%	0.00%	$3.63	$1,027,000	$3,133,500	$1,122,400	$454,200	$1,55

Between April 1, 2015 and May 14, 2015, we entered into additional securities purchase agreements with accredited investors pursuant to which we sold 2014 Units to such accredited investors for aggregate cash proceeds of $280,000, such 2014 Units consisting of (i) 2014 Unit Notes in the aggregate face amount of $280,000 due between April 30, 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 33,000 restricted shares 2014 Unit Stock; and (iii) 2014 Unit Warrants exercisable through December 31, 2016 to purchase an aggregate of 24,250 restricted shares of our common stock at an exercise price of $10.00 per share.

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As described above, we allocated the proceeds from the private placement sales of the 2014 Units sold during the fiscal year ended March 31, 2016 to the various securities based on their relative fair values on the dates of the sales. We calculated the fair value of these 2014 Unit 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 2014 Unit sales proceeds based on the relative fair values of the 2014 Unit Stock, 2014 Unit Warrants and 2014 Unit Notes as of their respective 2014 Unit sales dates during the fiscal year ended March 31, 2016.

	Unit Warrants Weighted Average Issuance Date Valuation Assumptions									Aggregate Allocation of Proceeds Based on Relative Fair Value of:		
Warrant Shares Issued	Market Price	Exercise Price	Term (Years)	Risk free Interest Rate	Volatility	Dividend Rate	Per Share Fair Value of Warrant	Aggregate Fair Value of Unit Warrants	Aggregate Proceeds of Unit Sales	Unit Stock	Unit Warrant	Unit Note
24,250	$10.00	$10.00	1.70	0.45%	73.19%	0.00%	$3.69	$89,600	$280,000	$128,900	$2,057,900	$118,200

In aggregate, between late-March 2014 and May 14, 2015, we entered into securities purchase agreements with accredited investors for the 2014 Unit Private Placement pursuant to which we sold 2014 Units to such accredited investors for aggregate cash proceeds of $3,413,500, consisting of (i) 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 2014 Unit Stock; and (iii) 2014 Unit 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.

May 2015 Agreement with PLTG

On May 5, 2015, we entered into an Agreement with PLTG, which, as modified, became effective on May 12, 2015 (PLTG Agreement) and 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, as described previously in Note 8, Convertible Promissory Notes and Other Notes Payable;

Released all of 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 dated October 11, 2012 between us and PLTG;

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, as described previously in Note 8, Convertible Promissory Notes and Other Notes Payable;

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, as described previously in Note 8, Convertible Promissory Notes and Other Notes Payable;

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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 shares of Series B Preferred and Series B Warrants have been purchased and issued;

Amended the PLTG Warrants previously issued by us 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 relating to resale of certain specified shares of common stock under the Securities Act of 1933, as amended, or the closing price of our common stock is at least $15.00 per share.

As additional consideration for the several agreements of PLTG 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 May 12, 2015 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 same assumptions used in valuing the Series B Warrants issued to PLTG in connection with the conversion of the PLTG Unit Notes and the Acquired Unit Notes, as described previously in Note 8, Convertible Promissory Notes and Other Notes Payable. We recognized the aggregate fair value of the Additional Consideration Shares and Additional Consideration Warrants, $12,270,900, as an additional non-cash component of loss on debt extinguishment in the quarter ended June 30, 2015.

August 2015 Agreement with PLTG

On August 3, 2015, we entered into the August 2015 Agreement with PLTG pursuant to which we agreed to sell to PLTG an additional $3.0 million of our Series B Preferred and Series B Warrants (together Series B Preferred Units) between August 15, 2015 and October 15, 2015 and issue an aggregate of 458,571 shares of Series B Preferred and Series B Warrants to purchase 458,571 shares of our common stock. Through December 31, 2015, PLTG had purchased an aggregate of $1,650,000 of Series B Preferred Units contemplated under the August 2015 Agreement and we had issued 235,714 shares of Series B Preferred and Series B Warrants to purchase 235,714 shares of our common stock related to such purchases. As of December 31, 2015, we agreed with PLTG to terminate their right under the August 2015 Agreement to purchase any additional Series B Preferred Units.

2015 Series B Preferred Unit Offering

Between May 26, 2015 and March 31, 2016, in self-placed private placement transactions, we sold to accredited investors an aggregate of $5,025,800 of units in our Series B Preferred Unit offering, which units consist of Series B Preferred and Series B Warrants (together Series B Preferred Units), including $2,650,000 to PLTG, which amount includes $1,650,000 pursuant to the August 2015 Agreement with PLTG. We issued 717,978 shares of Series B

Preferred and Series B Warrants to purchase 717,978 shares of our common stock. Through March 31, 2016, we received an aggregate of $5,025,800 in cash proceeds from our self-placed private placement and sale of the Series B Preferred Units.

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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. As described in Note 8, Convertible Promissory Notes and Other Notes Payable, 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 $4.13 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 $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 year ended March 31, 2016.

	Unit Warrants Weighted Average Issuance Date Valuation Assumptions										
Warrant Shares Issued	Market Price	Exercise Price	Term (Years)	Risk free Interest Rate	Volatility	Dividend Rate	Per Share Fair Value of Warrant	Aggregate Fair Value of Unit Warrants	Aggregate Proceeds of Unit Sales	Aggregate Allocation of Proceeds Based on Relative Fair Value of: Unit Stock	Unit Warrant
717,978	$10.45	$7.00	5.00	1.61%	77.30%	0.0%	$7.37	$5,288,600	$5,025,800	$2,967,900	$2,057,900

See Note 16, Subsequent Events, for disclosure regarding additional sales of Series B Preferred Units after March 31, 2016.

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 (Registration Statement) registering, under 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 an initial Registration Statement with the SEC on July 21, 2015, which we amended on August 25, 2015, and which was declared effective by the SEC on August 28, 2015. The 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 31, 2016, holders of an aggregate of 228,818 shares of Series B Preferred converted such shares into an equivalent number of registered shares of our common stock. Additionally, 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 converted.

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VISTAGEN THERAPEUTICS, INC.
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Warrant Exchanges into Series C Preferred and Common Stock

On January 25, 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 Holders), 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 Note Exchange and Purchase Agreement, originally dated October 11, 2012 (the NEPA), as amended, 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.

We accounted for the exchange of the Outstanding PLTG Warrants and the Series A Preferred Exchange Warrant as a warrant modification, determining the fair value of the Outstanding PLTG Warrants, and the Series A Preferred Exchange Warrant as if issued on the Exchange Agreement date, as of the Exchange Agreement date, and comparing that to the fair value of the Series C Preferred stock issued. We calculated the weighted average fair value of the Outstanding PLTG Warrants to be $6.03 per share, or $11,797,400, using the Black Scholes Option Pricing Model and the following weighted average assumptions: market price per share: $8.25; exercise price per share: $7.13; risk-free interest rate: 1.27%; remaining contractual term: 3.99 years; volatility: 79.5%; expected dividend rate: 0%. We calculated the fair value of the Series A Exchange Warrants to be $5.45 per share, or an aggregate of $2,919,200, allocated as $2,481,300 to PLTG and $437,900 to the other Holder, using the Black Scholes Option Pricing Model and the following assumptions: market price per share: $8.25; exercise price per share: $7.00; risk-free interest rate: 1.47%; remaining contractual term: 5.00 years; volatility: 77.9%; expected dividend rate: 0%. 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 was equal to the market value of a share of our common stock on the date of the Exchange Agreement. Accordingly, the fair value of the aggregate of 2,118,012 Series C Preferred issued to PLTG pursuant to the Exchange Agreement was $17,473,600 and we recognized the additional fair value, $3,194,900, as warrant modification expense, included as a component of general and administrative expenses in the accompanying Consolidated Statement of Operations and Comprehensive Loss for the fiscal year ended March 31, 2016.

Between January 29, 2016 and March 31, 2016, we entered into Warrant Exchange Agreements with certain holders of outstanding 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 also accounted for the exchange of these warrants as warrant modifications, comparing their fair value prior to the exchange with the fair value of the common stock issued. We calculated the weighted average fair value of the warrants prior to the exchange to be $3.76 per share, or $4,081,600, using the Black Scholes Option Pricing Model and the following weighted average assumptions: market price per share: $8.00; exercise price per share: $8.47; risk-free interest rate: 0.88%; remaining contractual term: 3.04 years; volatility: 81.0%; expected dividend rate: 0%. The weighted average fair value of the aggregate of 814,989 shares of common stock issued in the exchange was

$7.97 per share or $6,495,000. Accordingly, we recognized the additional fair value, $2,143,400, as warrant modification expense, included as a component of general and administrative expenses in the accompanying Consolidated Statement of Operations and Comprehensive Loss for the fiscal year ended March 31, 2016. As noted, effective on January 25, 2016, we extended the term of 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:

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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.

Amendment of 2013 Unit Notes and 2013 Unit Warrants

Effective May 31, 2014, we entered into note and warrant amendment agreements with substantially all holders of 10% convertible promissory notes maturing on July 30, 2014 (2013 Unit Notes) and warrants exercisable through July 30, 2016 to purchase restricted shares of our common stock at an exercise price of $20.00 per share (2013 Unit Warrants) to (i) modify certain terms of their 2013 Unit Notes, including the maturity date and certain conversion features, to conform to the corresponding terms of the 2014 Unit Notes and (ii) to modify certain terms of the 2013 Unit Warrants, including the exercise price and expiration date, to conform to the corresponding terms of the 2014 Unit Warrants. Holders of 2013 Unit Notes having an aggregate initial face amount of $895,000 and warrants to purchase an aggregate of 93,250 restricted shares of our common stock agreed to the amendments. The amended 2013 Unit Notes were subsequently treated as, and referred to herein, as 2014 Unit Notes. Based on the subsequent May 2015 election by the holders of the amended 2013 Unit Notes, such notes became either a component of the Acquired Unit Notes or the Investor Unit Notes, which, as described in Note 8, Convertible Promissory Notes and Other Notes Payable, were, in either case, converted into shares of our Series B Preferred. The maturity date of 2013 Unit Notes payable to holders who did not agree to amend their 2013 Unit Note and 2013 Unit Warrant remained July 30, 2014 and the $20.00 per share exercise price and July 30, 2016 expiration date of the 2013 Unit Warrants held by such holders remained unchanged. Between April 1, 2014 and August 15, 2014, we repaid 2013 Unit Notes having an initial face value of $ 112,500 and since the later date, no un-amended 2013 Unit Notes were outstanding.

We calculated the fair value of the modified 2013 Unit Warrants immediately before and after the modifications and determined that the fair value of the warrants increased by an aggregate of $272,900, which we treated as a component of loss on extinguishment of debt for the fiscal year ended March 31, 2015 in the accompanying Consolidated Statements of Operations and Comprehensive Loss with a corresponding credit to additional paid-in capital, an equity account. 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	$ 12.60	$ 12.60
Exercise price per share	$ 20.00	$ 10.00

Risk-free interest rate	0.44%	0.62%
Remaining contractual term in years	2.17	2.59
Volatility	75.6%	76.6%
Dividend rate	0.0%	0.0%
Fair Value per share	$ 3.73	$ 6.65

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Issuance of Securities in Satisfaction of Technology License and Maintenance Fees and Patent Expenses

In April 2014, we entered into an agreement with Icahn School of Medicine at Mount Sinai (ISMMS), one of our long-term technology licensors, pursuant to which we issued to ISMMS (i) a 10% promissory note in the face amount of $300,000 due on the earlier of December 31, 2014, or the completion of a qualified financing, as defined, (ii) 15,000 restricted shares of our common stock and (iii) a warrant exercisable through March 31, 2019 to purchase 15,000 restricted shares of our common stock at an exercise price of $10.00 per share in satisfaction of $288,400 of stem cell technology license maintenance fees and reimbursable patent prosecution costs (the Icahn School Agreement). Based on the short-duration of the note, its interest rate and other terms, we determined that the fair value of the note at the date of issuance was equal to its face value. We determined the fair value of stock to be $141,000, based on the $9.40 per share quoted market price of our common stock on the date of the agreement. We calculated the fair value of the warrant to be $5.95 per share, or $89,200, using the Black Scholes Option Pricing Model and the following assumptions: market price per share: $9.40; exercise price per share: $10.00; risk-free interest rate: 1.59%; contractual term: 5.0 years; volatility: 80.3%; expected dividend rate: 0%. We recognized a loss on extinguishment of debt in the amount of $241,800 related to the Icahn School Agreement in the accompanying Statement of Operations and Comprehensive Loss for the fiscal year ended March 31, 2015. Under the terms of the Icahn School Agreement, an additional $35,800 of license maintenance fees and reimbursable patent prosecution costs were added to the principal amount of the promissory note through March 31, 2015. As described in Note 8, Convertible Promissory Notes and Other Notes Payable, this note was extinguished upon its conversion into shares of our Series B Preferred in June 2015.

Issuance of Securities to Professional Service Providers

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

In June 2015, we issued an aggregate of 25,000 shares of our Series B Preferred having a fair value of $250,000 as compensation for legal services related to our debt restructuring and other corporate finance matters.

On June 30, 2015, we issued an aggregate of 90,000 shares of our Series B Preferred having an aggregate value 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 30, 2016. The value of the Series B Preferred grants was recorded as a prepaid expense at the date of the grant and is being expensed ratably over the twelve months ending June 30, 2016, with $1,012,500 expensed during the fiscal year ended March 31, 2016.

During the quarter ended June 30, 2015, we also issued an aggregate of 50,000 shares of our common stock having an aggregate value 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 shares of our Series B Preferred having an aggregate fair value of $120,000.

In January 2016, we issued 10,000 shares of our common stock having a fair value of $90,000 in connection with legal services.

In February 2016 we issued an aggregate of 6,250 shares of our common stock in connection with legal ($25,000) and investor relations ($25,000) services;

In March 2016, we issued an aggregate of 10,375 shares of our common stock in connection with investor relations ($58,000) and legal ($25,000) services.

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As indicated in the following table, 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 the November 2015 warrant grant, we also issued 15,750 shares of unregistered common stock valued at $106,300 and, in connection with the December 11, 2015 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:	11/23/2015	12/11/2015	3/25/2016
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

In May 2014, we entered into a consulting agreement for strategic advisory and business development services pursuant to which we issued 10,000 restricted shares of our common stock as partial compensation for such professional services. We determined the fair value of stock to be $134,000, based on the $13.40 per share quoted market price of our common stock on the date of the agreement. Additionally, under the terms of the agreement, we paid an aggregate of $80,000 between May 2014 and December 31, 2014 as additional compensation for professional services rendered by the consultant. Effective January 12, 2015, we entered into a new consulting agreement with this consultant for similar services pursuant to which we issued 20,000 restricted shares of our common stock valued at $160,000, based on the $8.00 per share quoted market price of our common stock on the date of the agreement, and made cash payments of $175,000 through March 31, 2016 as compensation for such professional services.

In March 2015, we entered into a consulting agreement with another consultant for additional advisory and business development services pursuant to which we issued 25,000 restricted shares of our common stock as compensation for such professional services. We determined the fair value of stock to be $175,000, based on the $7.50 per share quoted market price of our common stock on the date of the agreement.

In March 2015, we issued 16,667 shares of our common stock valued at $166,700 to our legal counsel in settlement of direct legal fees related to services provided with respect to prospective, unconsummated public and private offerings of our equity securities during 2013 and 2014. We recognized a loss of $16,700 with respect to this settlement, which is included in Loss on Extinguishment of Debt in the accompanying Consolidated Statement of Operations and Comprehensive Loss for the year ended March 31, 2015.

Modification of Warrants

In addition to warrants modified in connection with conversions of certain of our outstanding promissory notes into Series B Preferred as described earlier in Note 8, Convertible Promissory Notes and Other Notes Payable, and the warrants modified in connection with the Warrant Exchange Agreements described earlier in this note, on June 10, 2015, we modified certain other 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 general and administrative expense for the quarter ended June 30, 2015, with a corresponding credit to additional paid-in capital. The warrants subject to the exercise price modifications were valued using the Black-Scholes Option Pricing Model and the following assumptions:

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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

Officer and Director Warrant Grants and Modifications

On September 2, 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%. 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, attributable to the warrant grants in the quarter ended September 30, 2015, which amounts are reflected in the accompanying Consolidated Statement of Operations and Comprehensive Loss for the fiscal year ended March 31, 2016.

On November 11, 2015, when the market price of our common stock was $6.50 per share, the Board authorized the modification of outstanding warrants to purchase an aggregate of 1,123,533 shares of our common stock, including the warrants to purchase an aggregate of 600,000 shares granted in September 2015, as described above, previously granted 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

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In January 2015, when the market price of our common stock was $8.00 per share, the Board authorized the grant of fully-vested five-year warrants to purchase an aggregate of 381,000 restricted shares of our common stock at an exercise price of $10.00 per share, including an aggregate of 340,000 such shares to company officers and independent members of the Board. The Board also granted one-year warrants to purchase 5,715 restricted shares of our common stock at an exercise price of $10.00 per share to consultants whose warrants had expired at December 31, 2014. Additionally, the Board extended by one year the expiration date of outstanding warrants to purchase 90,675 shares of our restricted common stock otherwise expiring during calendar 2015 and reduced the exercise price to $15.00 per share for such of those extended term warrants having exercise prices in excess of that amount.

We valued the new warrant grants at $1,756,900 using the Black Scholes Option Pricing Model and the following assumptions: market price per share: $8.00; exercise price per share: $10.00; risk-free interest rate: 1.45% for five-year warrants and 0.24% for one-year warrants; contractual term: 5 years or 1 year; volatility: 75.86% for five-year warrants and 69.74% for one-year warrants; expected dividend rate: 0%. 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 $98,400, which is reflected in general and administrative expense in the accompanying Consolidated Statement of Operations and Comprehensive Loss for the fiscal year ended March 31, 2015. The warrants subject to the exercise price modifications and term extensions were valued using the Black-Scholes Option Pricing Model and the following assumptions:

Assumption:	Pre-modification	Post-modification
Market price per share at modification date	$ 8.00	$ 8.00
Exercise price per share (weighted average)	$ 23.13	$ 13.00
Risk-free interest rate (weighted average)	0.04%	0.31%
Contractual term in years (weighted average)	0.24	1.24
Volatility (weighted average)	69.7%	69.8%
Dividend rate	0.0%	0.0%
Weighted Average Fair Value per share	$ 0.22	$ 1.31

In making our fair value determinations for both new warrant grants and warrant modifications using the Black Scholes Option Pricing Model, we utilize the following principles in selecting our input assumptions. The market price per share during the years ended March 31, 2016 and 2015 is based on the quoted market price of our common stock on the OTCQB on the date of the grant or modification. Because of our relatively short history as a public company, we estimate stock price volatility based on the historical volatilities of a peer group of public companies over the contractual or remaining contractual term of the warrant. The contractual term of the warrant is determined based on the grant or modification date and the latest date on which the warrant can be exercised under its original or modified terms. The risk-free rate of interest is based on the quoted constant maturity rate for U.S. Treasury Bills on the date of the grant or modification for the term most closely corresponding with the contractual term or remaining term of the warrant. We assume a dividend rate of zero as we have not paid and do not expect to pay dividends in the near future.

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Warrants Outstanding

The following table summarizes outstanding warrants to purchase shares of our common stock as of March 31, 2016. The weighted average exercise price of outstanding warrants at March 31, 2016 was $8.17 per share.

Exercise Price per Share	Expiration Date	Shares Subject to Purchase at March 31, 2016
$ 7.00	12/11/2018 to 3/3/2023	1,417,125
$ 8.00	3/25/2021	230,000
$ 10.00	8/31/2016 to 1/11/2020	135,384
$ 15.00	4/30/2016 to 8/31/2016	10,664
$ 20.00	9/15/2019	110,448
$ 30.00	11/20/2017	3,600
		1,907,221

Note Receivable from Sale of Common Stock

In May 2011, the Company accepted a $500,000 short-term note from an investor in payment for shares of the Company's common stock sold to the investor in a private placement transaction. On October 2, 2014 we received a cash payment of $60,000 from the maker of the note. We considered that payment to be in full satisfaction of the outstanding principal balance of the note and related accrued interest, aggregating $194,900, at the date of the payment and recognized a loss of $134,900 on the settlement of the note, which is reflected as a component of Other expenses, net in the accompanying Consolidated Statement of Operations and Comprehensive Loss for the fiscal year ended March 31, 2015.

Reserved Shares

At March 31, 2016, the Company has reserved shares of its 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	3,663,077
Reserved for potential future issuance of Series B Preferred Stock	108,105
Upon exchange of all shares of Series C Preferred Stock currently issued and outstanding	2,318,012
Reserved for potential future issuance of Series C Preferred Stock	681,988
Pursuant to warrants to purchase common stock:	
Subject to outstanding warrants	1,907,221
Pursuant to stock incentive plans:	
Subject to outstanding options under the 2008 and 1999 Stock Incentive Plans	336,987
Available for future grants under the 2008 Stock Incentive Plan	660,242
	997,229

Total	10,425,632

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

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10. Research and Development Expenses

The Company recorded research and development expenses of approximately $3.9 million and $2.4 million in the fiscal years ended March 31, 2016 and 2015, respectively. Research and development expense is composed primarily of employee compensation expenses, including stock–based compensation, direct project expenses, 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,	
	2016	2015
Computed expected tax benefit	(34.00) %	(34.00) %
Tax effect of loss on debt extinguishment	19.22 %	5.85 %
Tax effect of warrant modifications	4.38 %	0.24 %
Tax effect of Warrant Liability mark to market	1.36 %	0.08 %
Other losses not benefitted	9.04 %	27.83 %
Other	0.01 %	0.02 %
Income tax expense	0.01 %	0.02 %

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 the Company’s deferred tax assets are as follows (in thousands):

	March 31,	
	2016	2015
Deferred tax assets:		
Net operating loss carryovers	$26,606	$23,054
Basis differences in fixed assets	-	24
Accruals and reserves	4,609	2,694
Total deferred tax assets	31,215	25,772
Valuation allowance	(31,215)	(25,772)
Net deferred tax assets	$-	$-

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 $5,443,000 and $4,619,000 during the fiscal years ended March 31, 2016 and 2015,

respectively. When realized, deferred tax assets related to employee stock options will be credited to additional paid-in capital.

As of March 31, 2016, we had U.S. federal net operating loss carryforwards of $67.9 million, which will expire in fiscal years 2020 through 2036. As of March 31, 2016, we had state net operating loss carryforwards of $60.1 million, which will expire in fiscal years 2017 through 2036.

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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.

The Company files income tax returns in the U.S. federal and Canadian jurisdictions and California and Maryland state jurisdictions. The Company is subject to U.S. federal and state income tax examinations by tax authorities for tax years 2000 through 2016 due to net operating losses that are being carried forward for tax purposes.

The Company does not have any uncertain tax positions or unrecognized tax benefits at March 31, 2016 and 2015. The Company's policy is to recognize interest and penalties related to income taxes as components of interest expense and other expense, respectively.

12. Licensing and Collaborative Agreements

U.S. National Institutes of Health

During fiscal years 2006 through 2008, the U.S. National Institutes of Health (NIH) awarded VistaGen California a $4.2 million grant to support preclinical development of AV-101 for pain. In June 2009, the NIH further awarded VistaGen California 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 Major Depressive Disorder (MDD) in patients with an inadequate response to standard antidepressants. In February 2015, we entered into a Cooperative Research and Development Agreement with the National Institute of Mental Health (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 this NIMH-sponsored Phase 2a study was dosed in November 2015 and we anticipate results from the study in the second calendar quarter of 2017. 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 the Company's 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 $52,600 and $38,100 for the fiscal years ended March 31, 2016 and 2015, respectively. In October 2012, we issued an unsecured promissory note in the principal amount of $1,009,000, and a warrant exercisable for 50,450 shares of our common stock, as payment in full of all amounts owed to CRL for CRO services rendered to us through December 31, 2012. As described in Note 8, Convertible Promissory Notes and Other Notes Payable, this note and related accrued but unpaid interest was converted into shares of our Series B Preferred in June 2015.

University Health Network

On September 17, 2007, we entered into a Sponsored Research Collaboration Agreement (SRCA) with University Health Network (UHN) 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. Such pre-negotiated 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

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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 sponsored research collaboration agreement (SRCA) with UHN, as amended, has a term of ten years, ending on September 18, 2017. We did not engage in any sponsored research activities with UHN during our fiscal years ended March 31, 2016 or 2015, however, we are currently in discussions with Dr. Keller and UHN regarding the scope of potential new sponsored research projects under the SRCA. The ten-year term of the agreement is subject to renewal upon mutual agreement of the parties.

13. Stock Option Plans and 401(k) Plan

We have the following share-based compensation plans.

2008 Stock Incentive Plan

Our 2008 Stock Incentive Plan (the 2008 Plan) was adopted by the shareholders of VistaGen California on December 19, 2008 and assumed by the Company in connection with the Merger. The maximum number of shares of our common stock that may be granted pursuant to the 2008 Plan is 1,000,000 shares, subject to adjustments for stock splits, stock dividends or other similar changes in the common stock or capital structure.

1999 Stock Incentive Plan

Our 1999 Stock Incentive Plan (the 1999 Plan) was adopted by the shareholders of VistaGen California on December 6, 1999 and assumed by the Company in connection with the Merger. 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 2008 Plan

Under the terms of the 2008 Plan, the Compensation Committee of our Board of Directors may grant shares, options or similar rights having either 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, or any other security with the value derived from the value of the shares. Such awards include stock options, restricted stock, restricted stock units, stock appreciation rights and dividend equivalent rights.

The Compensation Committee may grant nonstatutory stock options under the 2008 Plan at a price of not less than 100% of the fair market value of our common stock on the date the option is granted. Incentive stock options under the 2008 Plan may be granted at a price of not less than 100% of the fair market value of our common stock on the date the option is granted. Incentive stock options granted to employees who, on the date of grant, own stock representing more than 10% of the voting power of all of our classes of stock are granted at an exercise price of not less than 110% of the fair market value of our common stock and the maximum term of such incentive stock options may not exceed five years. The maximum term of an incentive stock option granted to any other participant may not exceed ten years. The Compensation Committee determines the term and exercise or purchase price of all other awards granted under the 2008 Plan. The Compensation Committee also determines the terms and conditions of

awards, including the vesting schedule and any forfeiture provisions. Awards under the 2008 Plan may vest upon the passage of time or upon the attainment of certain performance criteria established by the Compensation Committee. We currently have no performance-based awards outstanding.

Unless terminated sooner, the 2008 Plan will automatically terminate in 2017. The Board of Directors may at any time amend, suspend or terminate our 2008 Plan.

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During September 2015, we granted 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 February 2016, we granted 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 March 2016, we granted 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. We did not grant any stock options during fiscal 2015.

The following table summarizes share-based compensation expense, including share-based expense related to grants of warrants to certain of our officers, independent directors, consultants and service providers as described in Note 9, Capital Stock, included in the accompanying Consolidated Statement of Operations and Comprehensive Loss for the years ended March 31, 2016 and 2015.

	Twelve Months Ended March 31,	
	2016	2015
Research and development expense:		
Stock option grants	$227,700	$176,200
Warrants granted to officer in March 2014 and March 2013	11,400	145,100
Fully-vested warrants granted to officer in September 2015	852,200	-
Fully-vested warrants granted to officer and consultants in January 2015	-	527,500
	1,091,300	848,800
General and administrative expense:		
Stock option grants	93,800	98,800
Warrants granted to officers and directors in March 2014 and March 2013	15,600	283,100
Fully-vested warrants granted to officers, directors and consultants in September 2015	2,840,700	-
Fully-vested warrants granted to officers, directors and consultants in January 2015	-	1,229,400
	2,950,100	1,611,300
Total stock-based compensation expense	$4,041,400	$2,460,100

We used the Black-Scholes Option Pricing model with the following assumptions to determine share-based compensation expense related to option grants during the fiscal years ended March 31, 2016 and 2015:

	Fiscal Years Ended March 31,		
	2016 (weighted average)		2015
Exercise price	$ 8.78		not applicable
Market price on date of grant	$ 8.69		not applicable
Risk-free interest rate	1.99	%	not applicable
Expected term (years)	8.45		not applicable
Volatility	93.27	%	not applicable
Expected dividend yield	0.00	%	not applicable

Fair value per share at grant date	$	7.09	not applicable

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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. Limited historical experience and lack of liquidity in our stock 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, 2016 and 2015 under our stock option plans:

	Fiscal Years Ended March 31,			
	2016		2015	
	Number of Shares	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
Options outstanding at beginning of period	207,638	$10.09	212,486	$10.09
Options granted	145,000	$8.78	-	$-
Options exercised	-	$-	-	$-
Options forfeited	(10,359)	$9.26	(2,001)	$9.25
Options expired	(5,292)	$9.42	(2,847)	$10.56
Options outstanding at end of period	336,987	$9.56	207,638	$10.09
Options exercisable at end of period	201,779	$10.11	199,013	$10.09
Weighted average grant-date fair value of options granted during the period		$7.09		$-

The following table summarizes information on stock options outstanding and exercisable under our stock option plans as of March 31, 2016:

	Options Outstanding			Options Exercisable	
Exercise Price	Number Outstanding	Weighted Average Remaining Years until Expiration	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price

$8.00	102,089	8.35	$8.00	46,881	$8.00
$9.25	80,000	9.42	$9.25	-	$9.25
$10.00	145,039	3.83	$10.00	145,039	$10.00
14.40 to $$36.00	9,859	4.04	$21.80	9,859	$21.80
	336,987	6.53	$9.56	201,779	$10.11

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At March 31, 2016, there were 660,242 shares of our common stock remaining available for grant under the 2008 Plan. There were no option exercises during the years ended March 31, 2016 or 2015.

Aggregate intrinsic value is the sum of the amounts by which the fair value of the underlying common stock exceeded the exercise price of the option (in-the-money-options). Based on the $8.75 per share quoted market price of our common stock on March 31, 2016, the aggregate intrinsic value of outstanding options at that date was $76,600, of which $35,200 related to exercisable options.

As of March 31, 2016, there was approximately $746,900 of unrecognized compensation cost related to non-vested share-based compensation awards from the 2008 Plan, which is expected to be recognized through September 2017. Additionally, at March 31, 2016, there was no remaining unrecognized compensation cost related to warrant grants to independent directors and officers, all of which grants were completely vested as of April 1, 2016.

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), the parent of CRL, is one of our largest institutional stockholders at March 31, 2016, holding common stock and Series B Preferred. 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 until August 2009. On October 10, 2012, we issued to CHC an unsecured promissory note in the principal amount of $310,400 (the 2012 CHC Note) and a five-year warrant to purchase 12,500 restricted shares of our common stock at a price of $30.00 per share (the CHC Warrant). Additionally, on October 10, 2012, we issued to CRL: (i) an unsecured promissory note in the initial principal amount of $1,009,000, which is payable solely in restricted shares of our common stock and which accrues 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, such number of shares to be adjusted in relation to accrued interest on the CRL Note (CRL Warrant). As disclosed in Note 8, Convertible Promissory Notes and Other Notes Payable, 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 CHC. CHC also participated in the February 2016 warrant exchange disclosed in Note 9, Capital 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.

Under the terms of VistaGen California's contract research organization arrangement with CRL related to the development of AV-101, we incurred expenses of $52,600 and $38,100 for the fiscal years ended March 31, 2016 and

2015, respectively. Total interest expense on notes payable to CHC and CRL was $28,200 and $175,900 for the fiscal years ended March 31, 2016 and 2015, respectively.

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Upon the approval of its Board of Directors, in December 2006, VistaGen California accepted a full-recourse promissory note in the amount of $103,400 from Mr. Shawn Singh in payment of the exercise price for options and warrants to purchase an aggregate of 6,320 restricted shares of VistaGen California's common stock. The note accrued interest at a rate of 4.90% per annum and was due and payable no later than the earlier of (i) December 1, 2016 or (ii) ten days prior to VistaGen California becoming subject to the requirements of the Securities Exchange Act of 1934, as amended (Exchange Act). On May 11, 2011, in connection with the Merger, the $128,200 outstanding balance of principal and accrued interest on this note was cancelled in accordance with Mr. Singh's employment agreement and recorded as additional compensation. In accordance with his employment agreement, Mr. Singh was also entitled to receive an income tax gross-up on the compensation related to the note cancellation. At March 31, 2015, we had accrued $101,900 as an estimate of the gross-up amount, which amount was paid to Mr. Singh during fiscal 2016.

Between September and December 2013, Mr. Singh provided short-term cash advances aggregating $64,000 to meet our short-term working capital requirements. In lieu of cash repayment of the advances, in December 2013, Mr. Singh elected to invest $50,000 of the balance due him in our private placement financing. At March 31, 2015, we had completely repaid to Mr. Singh the balance of the advances and the $50,000 promissory note issued in connection with his investment in the private placement.

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, 2016 or 2015.

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, 2016 or 2015.

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VISTAGEN THERAPEUTICS, INC.
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Leases

As of March 31, 2016 and 2015, the following assets are under capital lease obligations and included in property and equipment:

	March 31, 2016	2015
Office equipment	4,500	4,500
Accumulated depreciation	(3,400)	(2,500)
Net book value	$1,100	$2,000

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
2017	$1,200
2018	100
Future minimum lease payments	1,300
Less imputed interest included in minimum lease payments	(200)
Present value of minimum lease payments	1,100
Less current portion	(1,100)
Non-current capital lease obligation	$-

At March 31, 2016, future minimum payments under operating leases relate to our facility lease in South San Francisco, California through July 31, 2017 and are as follows:

Fiscal Years Ending March 31,	Amount
2017	$277,100
2018	93,800
	$370,900

We incurred total facility rent expense for the fiscal years ended March 31, 2016 and 2015 of $337,200 and $337,000, respectively.

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VISTAGEN THERAPEUTICS, INC.
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Long-Term Debt Repayment

At March 31, 2016, future minimum principal payments related to long-term debt were as follows:

Fiscal Years Ending March 31,	Amount
2017	$31,600
2018	10,400
2019	11,200
Thereafter through June 2019	5,600
	$58,800

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, 2016:

Series B Preferred Unit Offering

In April and May 2016, in self-placed private placement transactions, we sold to accredited investors Series B Preferred Units consisting of (i) an aggregate of 39,714 shares of our Series B Preferred and (ii) Series B Warrants to purchase an aggregate of 39,714 shares of our common stock at an exercise price of $7.00 per share. We received cash proceeds of $278,000 from these sales of Series B Preferred Units.

Conversion of Series B Preferred into Common Stock

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 such conversions, we issued an aggregate of 510 shares of our unregistered common stock in payment of $4,000 in accrued dividends on the Series B Preferred converted.

On May 19, 2016, upon the consummation of the May 2016 Public Offering, described below, 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 in payment of $1,642,100 in accrued dividends, at the rate of one share of common stock for each $3.94 of 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 in payment of $37,400 in accrued dividends, at the rate of one share of common stock for each $3.90 in accrued dividends.

May 2016 Public Offering

Effective on May 16, 2016, we consummated a fully underwritten public offering, pursuant to which we issued an aggregate of 2,570,040 registered shares of our common stock at a public sales price of $4.24 per share and five-year warrants exercisable at $5.30 per share to purchase an aggregate of 2,705,883 shares of our common stock at a public

sales price of $0.01 per warrant share, including shares and warrants issued pursuant to the exercise of the underwriters' over-allotment option (the May 2016 Public Offering). We received gross proceeds of $10,924,000 and net proceeds of approximately $9.5 million from the May 2016 Public Offering after deducting underwriters' commissions and other expenses.

Repayment of Promissory Note

On June 13, 2016, we paid in full the $71,600 outstanding balance (principal and accrued but unpaid interest) of the promissory note we issued to Progressive Medical Research in August 2012. Following this payment, we have no remaining outstanding promissory notes.

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VISTAGEN THERAPEUTICS, INC.
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17. Supplemental Financial Information

The following table presents the unaudited statements of operations data for each of the eight quarters in the period ended March 31, 2016. 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				
	June 30, 2015	September 30, 2015	December 31, 2015	March 31, 2016	Total Fiscal Year 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

	Three Months Ended				
	June 30, 2014	September 30, 2014	December 31, 2014	March 31, 2015	Total Fiscal Year 2015
Operating expenses:					
Research and development	$474	$558	$445	$956	$2,433
General and administrative	797	556	671	2,320	4,344

Total operating expenses	1,271	1,114	1,116	3,276	6,777
Loss from operations	(1,271)	(1,114)	(1,116)	(3,276)	(6,777)
Other expenses, net:					
Interest expense, net	(785)	(606)	(792)	(2,366)	(4,549)
Change in warrant liabilities	(1,727)	1,302	953	(563)	(35)
Income (loss) before income taxes	(4,551)	(2,021)	(1,090)	(6,222)	(13,884)
Income taxes	(2)	-	-	-	(2)
Net income (loss)	$(4,553)	$(2,021)	$(1,090)	$(6,222)	$(13,886)
Basic net loss per common share	$(3.70)	$(1.58)	$(0.84)	$(4.24)	$(10.53)
Diluted net loss per common share	$(3.70)	$(1.90)	$(1.08)	$(4.24)	$(10.61)
Weighted average shares used in computing:					
Basic net loss per common share	1,229,504	1,279,267	1,302,316	1,466,402	1,318,813
Diluted net loss per common share	1,229,504	1,299,115	1,302,316	1,466,402	1,318,813

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Based on their evaluation as of the end of the period covered by this report, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were effective as of the end of the period covered by this report to ensure that information that we are required to disclose in reports that management files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms.

Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives, and our chief executive officer and acting chief financial officer have concluded that these controls and procedures are effective at the “reasonable assurance” level. We believe that a control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

Management’s Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. A company’s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP.

There are inherent limitations in the effectiveness of any system of internal control, including the possibility of human error and the circumvention or overriding of controls. Accordingly, even effective internal controls can provide only reasonable assurances with respect to financial statement preparation. Further, because of changes in conditions, the effectiveness of internal control may vary over time.

Our management assessed the effectiveness of our internal control over financial reporting as of March 31, 2016. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations (COSO) of the Treadway Commission in Internal Control—Integrated Framework (2013). Based on its assessment using the COSO criteria, management concluded that our internal control over financial reporting was effective as of March 31, 2016.

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 non-accelerated filer, 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, 2016 or thereafter, until such time as we are no longer eligible for the exemption for smaller issuers set forth within the Sarbanes-Oxley Act.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial

reporting.

Item 9B. Other Information

None.

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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 22, 2016 are as follows:

Name	Age	Position
Shawn K. Singh	53	Chief Executive Officer and Director
H. Ralph Snodgrass, Ph.D.	66	Founder, President, Chief Scientific Officer and Director
Mark A. Smith, M.D., Ph.D.	60	Chief Medical Officer
Jerrold D. Dotson	62	Vice President, Chief Financial Officer and Secretary
Jon S. Saxe (1)	79	Director
Brian J. Underdown, PhD. (2)	75	Director
Jerry B. Gin, Ph.D, MBA (3)	72	Director

(1) Chairman of the audit committee and member of the compensation committee and corporate governance and nominating committee.
(2) Member of the audit committee and chairman of the compensation committee and corporate governance and nominating committee.
(3) Member of the audit committee.

Executive Officers

Shawn K. Singh has served as our Chief Executive Officer since August 2009; he joined our Board of Directors in 2000 and served on our management team (part-time) from late-2003, following our acquisition of Artemis Neuroscience, of which he was President, to August 2009. 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.

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H. Ralph Snodgrass, Ph.D. co-founded VistaGen with Dr. Gordon Keller in 1998 and served as our Chief Executive Officer until August 2009. Dr. Snodgrass has served as our President and Chief Scientific Officer since August 2009. He has served as a member of our Board of Directors since 1998. Prior to founding VistaGen, 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 23 years of experience in senior biotechnology management and over 10 years 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 Septermber 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.

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Directors

Jon S. Saxe, J.D., LL.M. has served as Chairman of our Board of Directors since 2000. 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. Dr. Underdown is currently a Venture Partner with Lumira Capital Corp. having served as a Managing Director with Lumira from September 1997-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. Formation Biologics and Osteo QC. Some of Dr. Underdown's previous board roles include: Argos Therapeutics (ARGS-Q), ID Biomedical (acquired by GSK), 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, 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.

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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. Our independent directors, Mr. Saxe, Dr. Underdown and Dr. Gin, are each members of the Audit Committee. Mr. Saxe and Dr. Underdown also currently serve as members of the Compensation Committee and the Corporate Governance and Nominating Committee.

Audit Committee

Our Audit Committee is comprised of Mr. Saxe, Dr. Underdown and Dr. Gin. Mr. Saxe is the chairman of our Audit Committee and is 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;

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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 Mr. Saxe and Dr. Underdown, who serve as the committee chairman. 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 Mr. Saxe and Dr. Underdown, who serves as the committee chairman. 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.

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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 one time and acted by unanimous written consent eight times during the fiscal year ended March 31, 2016. Our Audit Committee met four times and our Compensation Committee requested action by the entire Board of Directors for grants of warrants and the modification of certain warrants during the same period. Our Nominating and Corporate Governance Committee requested action by the entire Board of Directors with respect to the March 2016 appointment of Dr. Gin to the Board and Audit Committee. Each director serving during fiscal 2016 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. We did not hold an annual meeting of stockholders during our fiscal year ended March 31, 2016.

Compensation Committee Interlocks and Insider Participation

Our Compensation Committee consists of Dr. Underdown and Mr. Saxe, each of whom is a non-employee director. Neither member 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, 2016, all of the Reporting Persons, other than PLTG and/or its affiliate, Montsant Partners LLC, Michael Goldberg, Cato BioVentures, and Morrison & Foerster LLP, 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.

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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 at the time of hire. 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 annually and increased for merit reasons, based on the executive officers' success in meeting or exceeding individual objectives. Additionally, we 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. As indicated in the following Summary Compensation Table, to conserve our cash resources during fiscal 2015 and fiscal 2014 the cash amounts of annual base salary that we paid to our executives was significantly less than their stated annual base salary rates.

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 2012 through 2015.

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.

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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, 2016 and 2015:

Name and Principal Position	Fiscal Year	Salary ($)	Bonus ($)	Option and Warrant Awards (7) ($)	All Other Compensation ($)	Total ($)
Shawn K. Singh (1)	2016	347,500	-	1,629,574(8)	-	1,977,074
Chief Executive Officer	2015	347,500(4)	-	688,050(9)	-	1,035,550
H. Ralph Snodgrass, Ph.D. (2)	2016	305,000	-	985,025(8)	-	1,290,025
President, Chief Scientific Officer	2015	305,000 (5)	-	458,700 (9)	-	763,700
Jerrold D. Dotson (3)	2016	250,000	-	635,297(8)	-	885,297
Vice President, Chief Financial Officer, Secretary	2015	250,000 (6)	-	229,350 (9)	-	479,350

(1) Mr. Singh became VistaGen California's Chief Executive Officer on August 20, 2009 and our Chief Executive Officer in May 2011, in connection with the Merger. In our fiscal years ended March 31, 2016 and 2015, Mr. Singh's annual base cash salary, pursuant to his January 2010 employment agreement, was contractually set at $347,500. To conserve cash for our operations during fiscal 2015 and 2014, Mr. Singh voluntarily agreed to receive cash payments of less than his contractual base cash salary. The figures reported above reflect the amount of Mr. Singh's salary that we expensed for accounting purposes in our financial statements for the respective fiscal years. As discussed in note (4) below, only $82,813 was actually paid in cash to Mr. Singh in our fiscal year ended March 31, 2015. The difference between the amounts expensed in fiscal 2015 and 2014 for accounting purposes and the amounts actually paid to Mr. Singh was accrued in fiscal 2015 and 2014 for payment in the future, $153,064 of which was paid during fiscal 2016. Mr. Singh also received cash payments during fiscal 2016 of $25,242 in payment of amounts previously accrued for vacation pay and $101,936 representing a tax gross up related to the forgiveness of a loan made prior to the date the Company became public. Additionally, 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 years ended March 31, 2016 and 2015, 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, 2016 and 2015, Dr. Snodgrass' annual base cash salary, pursuant to his January 2010 employment agreement, was contractually set at $305,000. To conserve cash for our operations during fiscal 2015 and 2014, Dr. Snodgrass voluntarily agreed to receive cash payments of less than his contractual base cash salary. The figures reported above reflect the amount of Dr. Snodgrass' salary that we expensed for accounting purposes in our financial statements for the respective fiscal years. As discussed in note (5) below, only $157,292 was actually paid in cash to

Dr. Snodgrass in our fiscal year ended March 31, 2015. The difference between the amounts expensed in fiscal 2015 and 2014 for accounting purposes and the amounts actually paid to Dr. Snodgrass was accrued in fiscal 2015 and 2014 for payment in the future, $178,088 of which was paid during fiscal 2016. Dr. Snodgrass also received cash payments during fiscal 2016 of $18,088 in payment of amounts previously accrued for vacation pay. Additionally, 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.

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(3) 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, 2016 and 2015, Mr. Dotson's annual base cash salary was $250,000. To conserve cash for our operations during fiscal 2015 and 2014, Mr. Dotson voluntarily agreed to receive cash payments of less than his base cash salary. The figures reported above reflect the amount of Mr. Dotson's salary that we expensed for accounting purposes in our financial statements for the respective fiscal years. As discussed in note (6) below, only $153,917 was actually paid in cash to Mr. Dotson in our fiscal year ended March 31, 2015. The difference between the amounts expensed in fiscal 2015 and 2014 for accounting purposes and the amounts actually paid to Mr. Dotson was accrued in fiscal 2015 and 2014 for payment in the future, $144,417 of which was paid during fiscal 2016. To conserve cash for our operations, Mr. Dotson did not receive a cash bonus in either of our fiscal years ended March 31, 2016 or 2015.

(4) Mr. Singh received only $82,813 in cash compensation in our fiscal year ended March 31, 2015. The remaining balance of $264,687 was accrued at March 31, 2015 for future payment and has been paid to Mr. Singh at the date of this Annual Report on Form 10-K.

(5) Dr. Snodgrass received only $157,292 in cash compensation in our fiscal year ended March 31, 2015. The remaining balance of $147,708 was accrued at March 31, 2015 for future payment and has been repaid to Dr. Snodgrass at the date of this Annual Report on Form 10-K.

(6) Mr. Dotson received only $153,917 in cash compensation in our fiscal year ended March 31, 2015. The remaining balance of $96,083 was accrued at March 31, 2015 and was paid during fiscal 2016.

(7) The amounts in the Option and Warrant Awards column represent the aggregate grant date fair value of warrants to purchase restricted shares of our common stock awarded to Mr. Singh, Dr. Snodgrass and Mr. Dotson, and 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 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 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.

(8) 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
	$ 2,840,664	$ 409,232	$ 3,249,896

	Weighted Average (except shares)		
		Before	After
Market price per share	$ 9.11	$ 6.5	$ 6.5
Exercise price per share	$ 9.25	$ 9.99	$ 7
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

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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.

(9) We used the Black Scholes Option Pricing Model and the following assumptions for determining the grant date fair value of the warrants to purchase shares of our common stock granted in January 2015.

Market price per share	$8.00	
Exercise price per share	$10.00	
Risk-free interest rate	1.45	%
Expected Term (years)	5.0	
Volatility	75.86	%
Dividend rate	0.0	%
Grant date fair value per share	$4.59	

Mr. Singh, Dr. Snodgrass and Mr. Dotson were granted warrants to purchase 150,000, 100,000 and 50,000 restricted shares of our common stock, 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.

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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, 2016:

	Stock Options and Warrants			
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date
Shawn K. Singh	1,000	-	16.00	12/21/2016
	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(2)	-	7.00	1/11/2020
	250,000(3)	-	7.00	9/2/2020
Total:	563,178	0		
H. Ralph Snodgrass, Ph.D.	319	-	17.60	12/20/2016
	2,500	-	10.00	3/24/2019
	1,250	-	10.00	6/17/2019
	12,500	-	10.00	12/30/2019
	5,000	-	10.00	4/26/2016
	50,000	-	7.00	3/3/2023
	1,875	625(1)	7.00	3/19/2024
	5,625	1,875(1)	7.00	3/19/2024
	100,000(2)	-	7.00	1/11/2020
	150,000(3)	-	7.00	9/20/2020
Total:	329,069	2,500		
Jerrold D. Dotson	5,001	-	10.00	10/30/2022
	1,000	-	8.00	10/27/2023
	10,000	-	7.00	3/3/2023
	3,750	1,250(1)	7.00	3/19/2024
	50,000(2)	-	7.00	1/11/2020
	100,000(3)	-	7.00	9/2/2020

Total:	169,751	1,250

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(1) Represents warrant to purchase restricted shares of our common stock granted on March 19, 2014 when the market price of our common stock was $9.20 per share. The warrant became exercisable for 50% of the shares on April 1, 2014, and became exercisable for an additional 25% of the shares on April 1, 2015. The warrant became exercisable for the remaining 25% of the shares on April 1, 2016.

(2) Represents a warrant to purchase restricted shares of our common stock granted as fully exercisable on January 11, 2015 when the market price of our common stock was $8.00 per share. Warrant was modified on November 11, 2015 to reduce the exercise price to $7.00 per share.

(3) Represents a warrant to purchase restricted shares of our common stock granted as fully exercisable on September 2, 2015 when the market price of our common stock was $9.11 per share. Warrant was modified on November 11, 2015 to reduce the exercise price to $7.00 per share.

Employment or Severance Agreements

We 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 May 9, 2011, Mr. Singh's base salary is $347,500 per year. However, to conserve cash for our operations, during our fiscal year ended March 31, 2015, Mr. Singh received only $82,813 in cash. 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. 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.

In December 2006, we accepted a full-recourse promissory note in the amount of $103,411 from Mr. Singh in payment of the exercise price for options and warrants to purchase an aggregate of 6,320 shares of our common stock. On May 11, 2011, in connection with the Merger, the $128,168 outstanding balance of the principal and accrued interest on this note was cancelled in accordance with Mr. Singh's employment agreement and was treated as additional compensation. In accordance with his employment agreement, Mr. Singh is entitled to an income tax gross-up payment on the compensation related to the note cancellation. At March 31, 2016 and 2015, we had accrued $101,936 as an estimate of the gross-up amount, which amount was subsequently paid. See Note 14, Related Party Transactions, to our audited Consolidated Financial Statements for the years ended March 31, 2016 and 2015 included in Item 8 of this Annual Report on Form 10-K.

On June 22, 2016, the Compensation Committee amended Mr. Singh's employment agreement to increase his base salary to $395,000 per year, effective June 16, 2016.

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Snodgrass Agreement

We entered into an employment agreement with Dr. Snodgrass on April 28, 2010. Under the agreement, as amended on May 9, 2011, Dr. Snodgrass's base salary is $305,000 per year. However, to conserve cash for our operations, during our fiscal year ended March 31, 2015, Dr. Snodgrass received only $157,292 in cash. Dr. Snodgrass is eligible to receive an annual incentive cash bonus of up to 50% of his base salary, but he has foregone any such cash bonus payment to conserve cash for our operations. 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.

On June 22, 2016, the Compensation Committee amended Mr. Singh's employment agreement to increase his base salary to $395,000 per year, effective June 16, 2016.

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.

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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, as recently amended, 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 did not pay our independent directors any cash compensation during our fiscal years ended March 31, 2016 or 2015.

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 September 2015, we granted fully vested warrants to purchase 50,000 shares of our restricted common stock at an exercise price of $9.25 per share to each of Mr. Saxe and Dr. Underdown. In November 2015, we modified those warrants, and others granted to them previously, to reduce the exercise price to $7.00 per share. On March 30, 2016, we granted an option to purchase 25,000 shares of our common stock to Dr. Gin upon his appointment to the Board, in accordance with the director compensation policy described above. 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, 2016.

Name	Fees Earned or Paid in Cash (1) ($)	Option and Warrant Awards (2) ($)	Other Compensation ($)	Total ($)
Jon S. Saxe (3)	$ 52,500	$ 324,816(6)	$ -	$ 377,316
Brian J. Underdown, Ph.D. (4)	$ 57,500	$ 324,400(6)	$ -	$ 381,900
Jerry B. Gin, Ph.D., M.B.A (5)	$ -	$ 181,103(7)	$ -	$ 181,103

(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, 2016 which we accrued in full at that date and a portion of

which has been paid to the director through the date of this Annual Report on Form 10-K.

(2) The amounts in the Option and Warrant Awards column represent the aggregate grant date fair value of warrants or options to purchase shares of our common stock awarded to Mr. Saxe, Dr. Underdown and Dr. Gin, and the effect of modifications to prior grants of warrants to Mr. Saxe and Dr. Underdown occurring during our fiscal year ended March 31, 2016, 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, 2016. 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.

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(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, 2016. At March 31, 2016, Mr. Saxe holds: (i) 1,875 restricted shares of our common stock; (ii) fully-vested options to purchase 12,250 registered shares of our common stock; and (iii) warrants to purchase 83,250 restricted shares of our common stock, of which 82,438 shares are exercisable and of which the remaining 812 shares became exercisable on April 1, 2016.

(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, 2016. At March 31, 2016, Dr. Underdown holds: (i) fully-vested options to purchase 9,250 registered shares of our common stock and (ii) warrants to purchase 82,500 restricted shares of our common stock, of which 81,875 shares are exercisable as of March 31, 2016 and of which the remaining 625 shares became exercisable on April 1, 2016

(5) Dr. Gin was appointed to our Board of Directors and as a member of our Audit Committee on March 29, 2016. At March 31, 2016, Dr. Gin holds an option to purchase 25,000 registered shares of our common stock granted in connection with his appointment to the Board, in accordance with the director compensation policy described above.

(6) The table below provides information regarding the warrant awards and modifications we granted to Mr. Saxe and Dr. Underdown 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
Saxe	284,066	40,750	324,816
Underdown	284,066	40,334	324,400
	$ 568,132	$ 81,084	$ 649,216

		Weighted Average (except shares)	
		Before	After
Market price per share	$ 9.11	$ 6.50	6.50
Exercise price per share	$ 9.25	$ 9.80	7.00
Risk-free interest rate	1.15%	1.68%	1.72%
Volatility	77.19%	76.21%	78.56%
Expected term (years)	5.00	4.90	4.99
Dividend rate	0%	0%	0%
Fair value per share	$ 5.68	$ 3.53	4.02
Aggregate shares	100,000	165,750	165,750

Mr. Saxe and Dr. Underdown were each granted warrants to purchase 50,000 restricted shares of our common stock. We modified warrants to purchase an aggregate of 83,250 shares and 82,500 shares held by Mr. Saxe and Dr. Underdown, respectively.

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(7) The table below provides information regarding the option award we granted to Dr. Gin during fiscal 2016 and the assumptions used in the Black Scholes Option Pricing Model to determine the grant date fair value of the award as reported in the table above:

Market price per share	$	8.00
Exercise price per share	$	8.00
Risk-free interest rate		1.83%
Volatility		102.94%
Expected term (years)		10.00
Dividend rate		0%
Fair value per share	$	7.24
Option shares granted		25,000

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 and Dr. Underdown, who comprise our audit committee, compensation committee, corporate governance and nominating committee, and Dr. Gin, who serves as a member of our audit 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.

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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 22, 2016 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 7,970,705 shares of common stock outstanding at June 22, 2016. 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 22, 2016. 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 22, 2016. 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)
Executive officers and directors:		
Shawn K. Singh (2)	589,412	6.91%
H. Ralph Snodgrass, Ph.D (3)	386,793	4.66%
Mark A. Smith, M.D., Ph.D. (4)	-	*
Jerrold D. Dotson (5)	171,677	2.11%
Jon S. Saxe (6)	97,001	1.20%
Brian J. Underdown, Ph.D (7)	91,750	1.14%
Jerry B. Gin, Ph.D, MBA (8)	8,333	*
5% Stockholders:		
Platinum Long Term Growth Fund VII/Montsant Partners, LLC (9)	4,970,012	40.92%
Empery Asset Management, LP (10)	761,267	9.55%
Sabby Management, LLC (11)	761,267	9.55%
Michael Goldberg (12)	464,970	5.75%
Cato BioVentures (13)	561,775	7.05%
Morrison & Foerster LLP (14)	422,928	5.23%
All executive officers and directors as a group (7 persons) (15)	1,344,966	14.58%

* less than 1%

(1) Based on 7,970,705 shares of common stock issued and outstanding as of June 22, 2016.

(2)Includes options to purchase 85,375 registered shares of common stock exercisable within 60 days of June 22, 2016 and warrants to purchase 477,803 restricted shares of common stock exercisable

within 60 days of June 22, 2016. Excludes options to purchase 200,000 shares of registered common stock granted on June 19, 2016 not exercisable within 60 days of June 22, 2016 and of which 75,000 shares are subject to stockholder approval of an amendment to the Company's 2008 Stock Incentive Plan.

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(3) Includes options to purchase 16,569 registered shares of common stock exercisable within 60 days of June 22, 2016 and warrants to purchase 310,000 restricted shares of common stock exercisable within 60 days of June 22, 2016. Excludes options to purchase 125,000 shares of registered common stock granted on June 19, 2016 not exercisable within 60 days of June 22, 2016.

(4) Excludes options to purchase 180,000 shares of registered common stock granted on June 19, 2016 not exercisable within 60 days of June 22, 2016 and of which 30,000 shares are subject to stockholder approval of an amendment to the Company's 2008 Stock Incentive Plan.

(5) Includes options to purchase 6,677 registered shares of common stock exercisable within 60 days of June 22, 2016, including options to purchase 676 shares of common stock held by Mr. Dotson’s wife, and warrants to purchase 165,000 restricted shares of common stock exercisable within 60 days of June 22, 2016. Excludes options to purchase 75,000 shares of registered common stock granted on June 19, 2016 not exercisable within 60 days of June 22, 2016.

(6) Includes options to purchase 11,875 registered shares of common stock exercisable within 60 days of June 22, 2016 and warrants to purchase 83,250 restricted shares of common stock exercisable within 60 days of June 22, 2016. Excludes options to purchase 25,000 shares of registered common stock granted on June 19, 2016 not exercisable within 60 days of June 19, 2016.

(7) Includes options to purchase 9,250 registered shares of common stock exercisable within 60 days of June 22, 2016 and warrants to purchase 82,500 restricted shares of common stock exercisable within 60 days of June 22, 2016. Excludes options to purchase 25,000 shares of registered common stock granted on June 19, 2016 not exercisable within 60 days of June 22, 2016.

(8) Includes options to purchase 4,166 registered shares of common stock exercisable within 60 days of June 22, 2016. Excludes options to purchase 25,000 shares of registered common stock granted on June 19, 2016 not exercisable within 60 days of June 22, 2016.

(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. (PPVA), another PLTG affiliate, and us through June 22, 2016.

The number of beneficially owned shares reported includes 637,500 restricted shares of common stock that may currently be acquired by Montsant upon 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 1,219,169 shares of common stock pursuant to its ownership of 1,219,169 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.

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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 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 beneficially own 795,331 shares or 9.98% of our common stock. The primary business address of PLTG and Montsant Partners, LLC is c/o Platinum Partners, 250 West 55th Street, 14th Floor, New York, New York 10019. Mark Nordlicht has voting and investment control over the shares held by PLTG, Montsant and PPVA.

(10) Based upon information contained in Form 13G filed on May 19, 2016. 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 13G filed on May 13, 2016. 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 Sabby Management, LLC and its affiliates, Sabby Healthcare Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd. (together, Sabby) 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 Sabby 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 Sabby Mangement, LLC and its affiliates is 10 Mountainview Road, Suite 205, Upper Saddle River, New Jersey 07458. Hal Mintz has voting and investment control over the shares held by Sabby.

(12) PLTG has transferred to Michael Goldberg (Goldberg) certain of the equity securities initially issued by us to PLTG. The conversion or exercise restrictions in those securities initially applicable to PLTG remain applicable to Goldberg. The number of shares reported as beneficially owned by Goldberg includes 112,500 restricted shares of common stock that may currently be acquired by Goldberg upon exchange of 75,000 restricted shares of our Series A Preferred.

(13) Based upon information contained in Form 4 filed on January 9, 2012, as updated to give effect to transactions through June 22, 2016 as recorded on our books. Lynda Sutton has voting and investment authority over the shares held by Cato Holding Company. The primary business address of Cato BioVentures is 4364 South Alston Avenue, Durham, North Carolina 27713.

(14) Includes currently exercisable warrants to purchase 110,448 restricted shares of common stock. The primary business address of Morrison & Foerster is 555 Market Street, San Francisco, California 94105. Mark Blumenthal has voting and investment control over the shares held by Morrison & Foerster.

(15) Includes options to purchase an aggregate of 138,079 registered shares of common stock exercisable within 60 days of June 22, 2016 and warrants to purchase an aggregate of 1,118,553 restricted shares of common stock exercisable within 60 days of June 22, 2016. Excludes options to purchase an aggregate of 525,000 shares of registered common stock and warrants to purchase an aggregate of 130,000 shares of unregistered common stock granted on June 19, 2016 not exercisable within 60 days of June 22, 2016.

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Securities Authorized for Issuance Under Equity Compensation Plans

Equity Grants

As of March 31, 2016, options to purchase a total of 336,987 restricted shares of our common stock were outstanding at a weighted average exercise price of $9.56 per share, of which 201,779 options were vested and exercisable at a weighted average exercise price of $10.11 per share and 135,208 were unvested and not exercisable at a weighted average exercise price of $8.74 per share. These options were issued under our 2008 Plan and our 1999 Plan, each as described below. At March 31, 2016, an additional 660,242 shares remained available for future equity grants under our 2008 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	324,758	$ 9.48	660,242
Equity compensation plans not approved by security holders	12,229	$ 11.64	--
Total	336,987	$ 9.56	660,242

2008 Stock Incentive Plan

Stockholders of VistaGen California adopted our 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. In all cases, the maximum number of shares of common stock under the 2008 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 (the Code), is 1.0 million.

Our 2008 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 2008 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 VistaGen or any parent or subsidiary of VistaGen. Awards other than incentive stock options may be granted to employees, directors and consultants.

Our Board of Directors or the Compensation Committee of the Board of Directors, referred to as the “Administrator”, administers our 2008 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.

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The exercise price of all incentive stock options granted under our 2008 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 ten years. The Administrator determines the term and exercise or purchase price of all other awards granted under our 2008 Plan.

Under the 2008 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 Administrator by gift or pursuant to a domestic relations order to members of the participant's immediate family.

The 2008 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 participant's award that was vested at the date of such termination or such other portion of the participant's award as may be determined by the Administrator. The participant'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 participant's award was unvested at the date of termination, or if the participant does not exercise the vested portion of the participant'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 Administrator).

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 125,000 shares of common stock. In connection with a participant's commencement of service with us, a participant may be granted options and stock appreciation rights for up to an additional 25,000 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 125,000 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.

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The terms and conditions of awards are determined by the Administrator, including the vesting schedule and any forfeiture provisions. Awards under the 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 Administrator 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 2008 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 Administrator 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 2008 Plan.

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Effective upon the consummation of a Corporate Transaction (as defined below), all outstanding awards under the 2008 Plan will terminate unless the acquirer assumes or replaces such awards. The Administrator 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 2008 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 2008 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 Administrator may specify. The Administrator 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 Administrator 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 our 2008 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 Administrator 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 our Corporation;

a merger or consolidation in which our Corporation is not the surviving entity; or

a complete liquidation or dissolution.

Under our 2008 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, our 2008 Plan will automatically terminate in 2017. Our Board of Directors may at any time amend, suspend or terminate our 2008 Plan. To the extent necessary to comply with applicable provisions of U.S. federal securities laws, state corporate and securities laws, the Internal Revenue 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 2008 Stock Plan in such a manner and to such a degree as required.

As of June 22, 2016, we have options to purchase an aggregate of 974,758 registered shares of our common stock outstanding under our 2008 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.

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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 22, 2016, we have options outstanding under the 1999 Plan to purchase an aggregate of 11,854 registered shares of our common stock.

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 stockholders at March 31, 2016, holding common stock and Series B Preferred. 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 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 also 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.

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Contract Research and Development Agreement with Cato Research Ltd.

During fiscal year 2007, we entered into a contract research organization arrangement with CRL related to the development of AV-101, under which we incurred expenses of $52,600 and $38,100 for the fiscal years ended March 31, 2016 and 2015, respectively.

Advances to us by Shawn Singh

Between September 2013 and December 2013, Mr. Singh provided short-term cash advances aggregating $64,000 to meet our short-term working capital requirements. In lieu of cash repayment of the entire amount of the advances, in December 2013, Mr. Singh elected to invest $50,000 of the balance due him in the 2013 Unit Private Placement. At March 31, 2015, we had completely repaid to Mr. Singh the remaining balance of the advances and the $50,000 promissory note issued in connection with his investment in the 2013 Unit Private Placement.

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, 2016 and March 31, 2015. Information provided below includes fees for professional services provided to us by OUM for the fiscal years ended March 31, 2016 and 2015.

	Fiscal Years Ended March 31,	
	2016	2015
Audit fees	$197,180	$182,500
Audit-related fees	23,016	53,952
Tax fees	15,925	10,960
All other fees	-	-
Total fees	$236,121	$247,412

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, 2016 and 2015, 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, 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-1 that included the Company’s audited financial statements for the fiscal year ended March 31, 2015. During the fiscal year ended March 31, 2015, such fees related to accounting research projects regarding certain prospective transactions.

Tax Fees:

Tax fees include fees for professional services for tax compliance, tax advice and tax planning for the tax years ended March 31, 2016 and 2015.

All Other Fees:

All other fees include fees for products and services other than those described above. During the fiscal years ended March 31, 2016 and 2015, no such fees were billed by OUM.

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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 2016 and 2015. 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, 2016. 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, 2016.

Respectfully Submitted by:

MEMBERS OF THE AUDIT COMMITTEE

Jon S. Saxe, Audit Committee Chairman
Brian J. Underdown
Jerry B. Gin

Dated: June 22, 2016

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.

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PART IV

Item 15. Exhibits, Financial Statement Schedules

(a)(1) Financial Statements

See Index to Financial Statements under Item 8 on page 83.

(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

Exhibit No.	Description*
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.

10.1 *	VistaGen's 1999 Stock Incentive Plan.
10.2 *	Form of Option Agreement under VistaGen's 1999 Stock Incentive Plan.
10.5 *	VistaGen's 2008 Stock Incentive Plan.
10.6 *	Form of Option Agreement under VistaGen's 2008 Stock Incentive Plan.
10.20 *	Strategic Development Services Agreement, dated February 26, 2007, by and between VistaGen and Cato Research Ltd.
10.21 *	License Agreement by and between National Jewish Medical and Research Center and VistaGen, dated July 12, 1999, as amended by that certain Amendment to License Agreement dated January 25, 2001, as amended by that certain Second Amendment to License Agreement dated November 6, 2002, as amended by that certain Third Amendment to License Agreement dated March 1, 2003, and as amended by that certain Fourth Amendment to License Agreement dated April 15, 2010.

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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.
10.27 *	Non-exclusive License Agreement, dated September 1, 2010, by and between VistaGen and TET Systems GmbH & Co. KG.
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 Synterys, 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.

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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.
10.78	

	Securities Purchase Agreement between VistaGen Therapeutics, Inc., and Autilion AG dated April 8, 2013, incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 10, 2013.
10.79	Voting Agreement between VistaGen Therapeutics, Inc., and Autilion AG dated April 8, 2013, incorporated by reference from Exhibit 10.2 to the Company's Current Report on Form 8-K filed on April 10, 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.
10.81	Assignment and Assumption Agreement between Autilion AG and Bergamo Acquisition Corp. PTE LTD dated April 12, 2013, incorporated by reference from Exhibit 10.81 to the Company's Annual Report on Form 10-K filed July 18, 2013.
10.82	Amendment No. 1 to Securities Purchase Agreement dated April 30, 2013 between VistaGen Therapeutics, Inc. 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 May 1, 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.

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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.

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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, filed herewith.
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, filed herewith.
10.117	Second Amendment to Employment Agreement by and between VistaGen Therapeutics, Inc. and H. Ralph Snodgrass, Ph.D., dated June 22, 2016, filed herewith.
21.1*	List of Subsidiaries.
23.1	Consent of Independent Registered Public Accounting Firm
24.1	Power of Attorney
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
101.LAB	XBRL Taxonomy Extension Label Linkbase

101.PRE XBRL Taxonomy Extension Presentation Linkbase

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

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SIGNATURES

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 24th day of June, 2016.

VistaGen Therapeutics, Inc.

Date: June 24, 2016 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
/s/ Shawn K. Singh Shawn K. Singh, JD	Chief Executive Officer, and Director (Principal Executive Officer)	June 24, 2016
/s/ Jerrold D. Dotson Jerrold D. Dotson	Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	June 24, 2016
/s/ H. Ralph Snodgrass H. Ralph Snodgrass, Ph.D	President, Chief Scientific Officer and Director	June 24, 2016
/s/ Jon S. Saxe Jon S. Saxe	Chairman of the Board of Directors	June 24, 2016
/s/ Brian J. Underdown Brian J. Underdown, Ph. D	Director	June 24, 2016
/s/ Jerry B. Gin, Ph.D Jerry B. Gin, Ph.D.	Director	June 24, 2016