VistaGen Therapeutics, Inc.
Form 10-K
June 26, 2018

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

Form 10-K

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

For the fiscal year ended: March 31, 2018

or

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

Commission file number: 001-37761

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

Nevada	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 No

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

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

Large accelerated filer	Accelerated filer	Non-accelerated filer	Smaller reporting company (Do not check if a smaller reporting company)	Emerging Growth Company

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

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

The aggregate market value of the common stock of the registrant held by non-affiliates of the registrant on September 30, 2017, the last business day of the registrant's second fiscal quarter, was: $18,305,024.

As of June 26, 2018, there were 23,037,615 shares of the registrant's common stock, $0.001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Items 10, 11, 12, 13 and 14 of Part III incorporate by reference certain information from VistaGen Therapeutics, Inc.'s definitive proxy statement, to be filed with the Securities and Exchange Commission on or before July 27, 2018.

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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, including our ELEVATE Study (defined below) and other clinical and non-clinical development objectives;

the accuracy of our estimates regarding expenses, future revenues and capital requirements;

our plans to develop and commercialize our lead product candidate, AV-101, initially as an adjunctive treatment for Major Depressive Disorder (MDD), and subsequently as a treatment for additional diseases and disorders involving the Central Nervous System (CNS);

our ability to initiate and complete our clinical trials, including our ELEVATE Study (defined below), and to advance AV-101 and/or other product candidates into additional clinical trials, including pivotal clinical trials, and successfully complete such clinical trials;

regulatory developments in the U.S. and foreign countries;

the performance of the U.S. National Institutes of Health (NIH), U.S. National Institute of Mental Health (NIMH), our third-party contract manufacturer(s) (CMOs), contract research organization(s) (CROs) and other third-party non-clinical and clinical drug development collaborators and regulatory service providers;

our ability to obtain and maintain intellectual property (IP) protection for our core assets, including our product candidates;

the size of the potential markets for our product candidates and our ability to serve those markets;

the rate and degree of market acceptance of our product candidates for any indication once approved;

the success of competing products and product candidates in development by others that are or become available for the indications that we are pursuing;

the loss of key scientific, clinical or non-clinical development, regulatory, and/or management personnel, internally or from one or more of our third-party collaborators; and

other risks and uncertainties, including those listed under Part I, Item 1A of this Annual Report titled “Risk Factors.”

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

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

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PART I

All brand names or trademarks appearing in this Annual Report are the property of their respective holders. Unless the context requires otherwise, references in this report to "VistaGen," the "Company," "we," "us," and "our" refer to VistaGen Therapeutics, Inc., a Nevada corporation. All references to future quarters and years in this Annual Report refer to calendar quarters and calendar years, unless reference is made otherwise.

Item 1. Business

Business Overview

We are a clinical-stage biopharmaceutical company focused on developing new generation medicines for depression and other diseases and disorders of the central nervous system (CNS) with high unmet need.

Our lead CNS product candidate, AV-101, is an oral, non-opioid and non-sedating therapy that we believe offers the potential to be a new at-home treatment for multiple CNS indications with high unmet medical need. These indications include potential use as a new generation treatment alternative for Major Depressive Disorder (MDD), as a non-addictive, non-sedating option for management of chronic neuropathic pain (CNP), to reduce dyskinesia induced by levodopa therapy for Parkinson's disease (PD LID), and additional CNS indications where modulation of NMDA (N-methyl-D-aspartate) receptor and AMPA (alpha-amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid) receptor pathways may achieve therapeutic benefit.

For MDD, we believe AV-101 has potential as a first line oral monotherapy and as an adjunctive oral therapy. As an adjunctive therapy, we believe AV-101 has potential both to displace atypical antipsychotics such as aripiprazole in the current MDD drug treatment paradigm both for patients with an inadequate response to current antidepressants approved by the U.S. Food and Drug Administration (FDA) and to prevent relapse of MDD following successful treatment with the FDA-approved anesthetic, ketamine hydrochloride, an ion-channel blocking NDMA receptor antagonist (ketamine), whether administered by intravenous (IV) injection or as an intranasal spray formulation. We believe AV-101 may have potential to deliver ketamine-like antidepressant effects on an at-home basis, without the requirement for inconvenient administration in a medical setting, and without causing psychological or other side effects and safety concerns associated with ketamine therapy.

AV-101 is in Phase 2 development in the United States. In the fourth quarter of 2017, we received authorization from the FDA to initiate ELEVATE, our Phase 2 multi-center, multi-dose, double blind, placebo-controlled clinical study to evaluate the efficacy and safety of AV-101 as an adjunctive treatment of MDD in adult patients with an inadequate therapeutic response to current FDA-approved antidepressants (the ELEVATE Study). As planned, we initiated the ELEVATE Study in the first quarter of 2018. Dr. Maurizio Fava, Professor of Psychiatry at Harvard Medical School and Director, Division of Clinical Research, Massachusetts General Hospital (MGH) Research Institute, is the Principal Investigator of the ELEVATE Study assisting our internal team, which is led by Mark Smith, MD, PhD, our Chief Medical Officer. Dr. Fava was the co-Principal Investigator with Dr. A. John Rush of the STAR*D study, the largest clinical trial conducted in depression to date, whose findings were published in journals such as the New England Journal of Medicine (NEJM) and the Journal of the American Medical Association (JAMA). We currently anticipate top line results from the ELEVATE Study in the first half of 2019.

AV-101 is also in the subject of a small Phase 2 clinical study being conducted and funded by the U.S. National Institute of Mental Health (the NIMH), pursuant to our Cooperative Research and Development Agreement (CRADA) with the NIMH (the NIMH Study). Dr. Carlos Zarate, Jr., Chief of the NIMH's Experimental Therapeutics & Pathophysiology Branch and its Section on Neurobiology and Treatment of Mood and Anxiety Disorders, is acting as

the Principal Investigator for the NIMH Study, which is focused on AV-101 monotherapy for subjects with treatment-resistant MDD and certain biomarkers. Dr. Zarate and the NIMH were among the first in the U.S. to conduct clinical studies demonstrating the robust, fast-acting antidepressant effects of ketamine in MDD patients with inadequate responses to multiple current FDA-approved antidepressants.

In addition to our CNS business, we have two additional programs through our wholly-owned subsidiary VistaStem Therapeutics (VistaStem). VistaStem is focused on applying human pluripotent stem cell (hPSC) technology to rescue, develop and commercialize (i) proprietary new chemical entities (NCEs) for CNS and other diseases and (ii) regenerative medicine (RM) involving hPSC-derived blood, cartilage, heart and liver cells. Our internal drug rescue programs are designed to utilize CardioSafe 3D, our customized cardiac bioassay system, to develop small molecule NCEs for our pipeline or out-licensing. To advance potential RM applications of VistaStem's cardiac stem cell technology, we have exclusively sublicensed to BlueRock Therapeutics LP, a next generation cell therapy and RM company established in 2016 with $225 million of committed capital from Bayer AG and Versant Ventures (BlueRock Therapeutics), rights to certain proprietary technologies relating to the production of cardiac stem cells for the treatment of heart disease (the BlueRock Agreement). In a manner similar to the BlueRock Agreement, we may pursue additional VistaStem collaborations or licensing transactions involving blood, cartilage, and/or liver cells derived from hPSCs for cell-based therapy, cell repair therapy, RM and/or tissue engineering.

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Our Strategy

Our core strategy is to independently pursue development and commercialization of our product candidates that address high unmet medical needs of patients with CNS diseases and disorders. We have assembled a management team and a team of scientific, clinical, and regulatory advisors, including recognized experts in the fields of depression and other CNS diseases and disorders, with significant pharmaceutical industry and regulatory experience to lead and execute the development and commercialization of our CNS product candidate opportunities. As we continue to build and develop our product portfolio, we may opportunistically pursue strategic partnerships that maximize the value of our product candidate pipeline.

Key elements of our strategy are to:

Develop and commercialize AV-101 for depression. The ELEVATE Study is our ongoing Phase 2 clinical development program for AV-101 focused on our initial regulatory and commercial objective for AV-101: to displace atypical antipsychotics as the primary at-home adjunctive treatment of MDD in patients with an inadequate response to current antidepressants approved by the FDA for at-home use. Following the completion of the ELEVATE Study, we intend to develop AV-101 internally and independently, through our initial pivotal Phase 3 clinical program for AV-101 focused on adjunctive treatment of MDD to augment current FDA-approved antidepressants, accompanied by submission to the FDA of our initial New Drug Application (NDA) for AV-101. In addition to adjunctive treatment of MDD with current antidepressants approved by the FDA for at-home use, we believe AV-101 may have therapeutic potential as a stand-alone first-line oral therapy for depression and as an at-home oral adjunctive treatment following in-clinic intravenous or intranasal administration of ketamine, to prevent relapse of MDD following cessation of ketamine treatment. If our initial MDD-related NDA is approved by the FDA, we may pursue strategic partnerships to maximize the commercial potential of AV-101 for these additional MDD indications and multiple other CNS indications. We may also contract for and/or establish a specialty sales force focused primarily on clinical psychiatrists and long-term care physicians who prescribe standard antidepressants, atypical antipsychotics and ketamine for treatment of their MDD patients under the current and evolving MDD drug treatment paradigm.

Develop and commercialize AV-101 for multiple additional CNS diseases and disorders. We intend to independently pursue clinical development and commercialization of AV-101 across multiple CNS-related indications beyond depression that we believe are underserved by currently available medicines and represent significant unmet medical needs. Based on AV-101 preclinical studies, our successful first-in-human NIH-funded AV-101 Phase 1 clinical safety studies, and regulatory submissions related to the ELEVATE Study, we believe AV-101 also has potential as a non-addictive, non-opioid, non-sedating treatment alternative for chronic neuropathic pain, as well as several additional CNS indications where modulation of NMDA receptors and activation of AMPA pathways may achieve therapeutic benefit, including PD LID, epilepsy and Huntington’s disease.

License and/or acquire additional CNS product candidates. While our resources are currently focused on development of AV-101 for depression and additional CNS indications, we anticipate pursuing acquisition of additional CNS-related product candidates in the future, with an emphasis on opportunities related to neuropsychiatry. We believe that a diversified CNS product candidate portfolio, combined with our internal and collaborative network of CNS drug development expertise and ecosystem, will mitigate risks inherent in drug development and increase the likelihood of our success.

Leverage VistaStem’s stem cell technology platform. We are applying VistaStem’s cardiac stem cell technology to screen and develop proprietary NCEs for our internal CNS drug development pipeline through drug rescue, without incurring many of the substantial costs and risks typically inherent in new drug discovery and nonclinical drug

development. To further capitalize on VistaStem's stem cell technology platform while supporting its CNS pipeline-enabling drug rescue programs, we may seek additional cell therapy and regenerative medicine collaborations, similar to the BlueRock Agreement, involving our intellectual property relating to blood, cartilage and/or liver cells.

Our Programs

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

Overview

AV-101 is an oral prodrug candidate (4-Cl-KYN) in development for convenient at-home use to treat multiple CNS indications with high unmet medical need. After oral administration, AV-101 readily gains access to the CNS and is rapidly converted in vivo into its active metabolite, 7-chlorokynurenic acid (7-Cl-KYNA), a well-characterized, potent and highly selective antagonist of the NMDA (N-methyl-D-aspartate) receptor at its glycine (GlyB) co-agonist binding site.

AV-101's mechanism of action (MOA) involves both NMDA and AMPA receptors in the brain responsible for fast excitatory synaptic activity throughout the CNS. AV-101's MOA is fundamentally different from all FDA-approved antidepressants, as well as all FDA-approved atypical antipsychotics, drugs such as aripiprazole, that are often used adjunctively to augment standard antidepressants. For depression, we believe AV-101 has potential both as a stand-alone first-line oral monotherapy and as an adjunctive oral therapy for at-home use. As an adjunctive therapy, we believe AV-101 has potential for at-home use to both augment current antidepressants approved by the FA for at-home use and to prevent relapse of MDD following successful treatment with ketamine hydrochloride, an ion-channel blocking NDMA receptor antagonist (ketamine), administered in a clinical setting either by intravenous (IV) injection or as an intranasal spray formulation.

Current evidence suggests that AV-101's modulation of NMDA receptor signaling may provide faster-acting antidepressant effects in the treatment of MDD than current FDA-approved antidepressants. In addition, as confirmed in our AV-101 Phase 1 clinical studies, targeting and modulating or inhibiting activity of NMDA receptors at the specific GlyB site of the NMDA receptor, rather than blocking NMDA receptor activity, does not have the negative side effects typically associated with standard antidepressants, atypical antipsychotics often used adjunctively in the current MDD drug treatment paradigm, or classic ion channel-blocking NMDA receptor antagonists, such as ketamine.

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We believe AV-101 may have potential to deliver ketamine-like antidepressant effects, without the need for inconvenient administration in a medical setting, and without causing psychological or other negative side effects and safety concerns often associated with ketamine therapy. As published in the October 2015 issue of the peer-reviewed Journal of Pharmacology and Experimental Therapeutics, in an article titled, The prodrug 4-chlorokynurenine causes ketamine-like antidepressant effects, but not side effects, by NMDA/glycineB-site inhibition, using four well-established preclinical models of depression, AV-101 was shown to induce ketamine-like fast-acting, dose-dependent, persistent and statistically significant antidepressant-like responses following a single treatment. These responses were equivalent to those seen with a single sub-anesthetic control dose of ketamine. In addition, these studies confirmed that the fast-acting antidepressant effects of AV-101 were mediated through both GlyB site inhibition of the NMDA receptor and activation of the AMPA receptor pathway in the brain.

Major Depressive Disorder

Depression is a serious medical illness and a global public health concern. The World Health Organization (WHO) estimates that 300 million people worldwide are affected by depression. According to the NIMH, major depression is one of the most common mental disorders in the U.S. The NIMH reports that, in 2016, approximately 16 million adults in the U.S. had at least one major depressive episode in the past year. According to the U.S. Centers for Disease Control and Prevention (CDC) in an August 2017 report, one in eight Americans over the age of 12 reported taking a standard, FDA-approved antidepressant in the previous month.

While most people will experience depressed mood at some point during their lifetime, MDD is different. MDD is the chronic, pervasive feeling of utter unhappiness and suffering, which impairs daily functioning. Symptoms of MDD include diminished pleasure in activities, changes in appetite that result in weight changes, insomnia or oversleeping, psychomotor agitation, loss of energy or increased fatigue, feelings of worthlessness or inappropriate guilt, difficulty thinking, concentrating or making decisions, and thoughts of death or suicide and attempts at suicide. MDD is the psychiatric diagnosis most commonly associated with suicide, with the incidence of attempted suicide approximately 20 times higher in patients with MDD compared with the general population.

Standard Antidepressants

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

Ketamine and NIMH Clinical Studies in Major Depressive Disorder

Ketamine hydrochloride (ketamine) belongs to a class of drugs that block NMDA receptors, which are neurochemical receptors in the brain found on nerve cells that respond to glutamate, which is a chemical messenger that helps form and maintain important connections between neurons. Ketamine is an FDA-approved, rapid-acting general anesthetic currently administered only by intravenous or intramuscular injection. The off-label use of ketamine to treat MDD in

treatment-resistant patients has been studied in several clinical trials conducted by depression experts at Yale University and other academic institutions, as well as at the NIMH, including by Dr. Carlos Zarate, Jr., the NIMH's Chief of Experimental Therapeutics & Pathophysiology Branch and of the Section on Neurobiology and Treatment of Mood and Anxiety Disorders. In randomized, placebo-controlled, double blind clinical trials reported by Dr. Zarate and others at the NIMH, a single sub-anesthetic dose of ketamine (0.5 mg/kg over 40 minutes) produced robust and rapid (within twenty-four hours) antidepressant effects in MDD patients who had not responded to standard antidepressants. These results were in sharp contrast to the very slow onset of standard antidepressants (SSRIs and SNRIs) that usually require many weeks of chronic usage to achieve similar antidepressant effects. The potential for widespread therapeutic use of current FDA-approved ketamine, a U.S. Drug Enforcement Agency (DEA) Schedule III drug, for MDD is limited by its potential for abuse, dissociative and other psychological side effects and by the inconvenience and practical challenges associated with the necessity of administration in a medical setting. Notwithstanding these limitations, however, the discovery of ketamine's fast-acting antidepressant effects revolutionized thinking about the current MDD drug treatment paradigm and catalyzed research and development of a new generation of antidepressant medications with a faster-acting mechanism of action (MOA) similar to ketamine's and fundamentally differentiated from all current FDA-approved antidepressants. Our oral CNS drug candidate, AV-101 is among a new generation of antidepressants with potential to deliver faster-acting antidepressant effects than current antidepressants, without the side effects typically associated with current antidepressants, atypical antipsychotics and ketamine.

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AV-101, Mechanism of Action and Major Depressive Disorder

As described above, AV-101 (4-Cl-KYN) is an orally available prodrug candidate that produces, in the brain, 7-Cl-KYNA, one of the most potent and selective antagonists of the GlyB site of the NMDA receptor, resulting in the down-regulation of NMDA receptor signaling. Growing evidence suggests that glutamatergic activation involving AMPA receptors is central to the neurobiology and treatment of MDD and other mood disorders.

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

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

Building on over $8.8 million of prior grant award funding from the NIH for preclinical and Phase 1 clinical development of AV-101, pursuant to our CRADA with the NIH, Dr. Carlos Zarate, Jr., as Principal Investigator, and his team at the NIMH are conducting, and the NIMH is funding, the NIMH Study. Among the objectives of the NIMH Study, the NIMH is evaluating the ability of AV-101 to improve overall depressive symptomatology in subjects with treatment-resistant MDD, specifically whether subjects with treatment-resistant MDD have a greater and more rapid decrease in depressive symptoms when treated with AV-101 monotherapy than with placebo, as well as assessment of multiple biomarkers.

We are conducting our ELEVATE Study to evaluate the safety and efficacy of AV-101 as an adjunctive treatment of MDD in adult patients with an inadequate response to standard, FDA-approved antidepressants. We currently anticipate that top line results of the ELEVATE Study will be available in the first half of 2019. The Principal Investigator of the ELEVATE Study is Dr. Maurizio Fava of Harvard Medical School. Dr. Fava was the co-Principal Investigator with Dr. A. John Rush of the largest clinical trial ever conducted in depression, STAR*D, whose findings were published in journals such the New England Journal of Medicine and the Journal of the American Medical Association.

AV-101 as Adjunctive Treatment to Ketamine to Prevent Post-Ketamine MDD and/or Suicidal Ideation Relapse

The use of ketamine to treat MDD has been studied in several clinical trials conducted by depression experts at numerous academic institutions and at the NIMH. In randomized, placebo-controlled, double blind clinical trials ketamine has produced robust and rapid (within twenty-four hours) antidepressant effects in MDD patients who had not responded to standard antidepressants. We believe the potential for widespread and long-term use of ketamine may be limited by its potential for abuse, dissociative and other psychological side effects and by the inconvenience and practical challenges associated with required administration in a clinical setting. In the event that ketamine's side effects, safety concerns, required in-clinic administration or other factors limit the use of ketamine and result in relapse of MDD and/or suicidal ideation, we believe AV-101 has potential to prevent relapse of MDD and/or suicidal ideation without ketamine-like side effects and safety concerns, when administered orally, on an at-home basis, following cessation of ketamine therapy. We plan to leverage our ELEVATE Study IND to conduct an exploratory Phase 2 study to assess the efficacy and safety of AV-101 as an adjunctive treatment to ketamine to prevent MDD and/or suicidal ideation relapse post-ketamine therapy.

AV-101 and Neuropathic Pain

Neuropathic pain is a complex, chronic pain state that results from problems with signals from nerves. There are various causes of neuropathic pain, including tissue injury, nerve damage or disease, diabetes, infection, toxins, certain types of drugs, such as antivirals and chemotherapeutic agents, certain cancers, and even chronic alcohol intake. With neuropathic pain, damaged, dysfunctional or injured nerve fibers send incorrect signals to other pain centers and impact nerve function both at the site of injury and areas around the injury.

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According to the WHO, about 116 million Americans were living with chronic pain in 2011.

Many neuropathic pain treatments on the market today, including prescription opioids, antidepressants, and anticonvulsants such as gabapentin and pregabalin, have side effects including anxiety, depression, dizziness, cognitive impairment and/or sedation.

The effects of AV-101 were assessed in published peer-reviewed studies involving four well-established nonclinical models of pain, both hyperalgesia and allodynia, to examine its analgesic and behavioral profile. The publication, titled: “Characterization of the effects of L-4-chlorokynurenine on nociception in rodents,” by lead author, Tony L. Yaksh, Ph.D., Professor in Anesthesiology at the University of California, San Diego, was published in The Journal of Pain in April 2017 (J Pain. 18:1184-1196, 2017)). In these studies, systemic delivery of AV-101 yielded high brain concentrations of AV-101's active metabolite, 7-Cl-KYNA that were calculated to exceed its IC50 at the NMDA receptor GlyB site and resulted in robust, dose-dependent anti-nociceptive effects, similar to gabapentin, but with no discernable negative side effects. Gabapentin, an anticonvulsant drug commonly used for neuropathic pain, causes sedation and mild cognitive impairment. Other commonly prescribed medications for neuropathic pain include drugs targeting opioid receptors in the brain. Unfortunately, misuse of such drugs can lead to a significantly increased risk of addiction, and, we believe, their therapeutic utility for neuropathic pain is unclear. Therefore, we believe AV-101, an oral drug candidate that does not target opioid receptors and is equally effective on pain, but is better tolerated than gabapentin, pregabalin or potentially addictive drugs targeting opioid receptors, could be an important treatment alternative for the millions of patients battling chronic neuropathic pain. Taken together with our successful AV-101 Phase 1a and 1b clinical safety studies, we believe the published results of these nonclinical studies support further clinical development of AV-101 in an exploratory Phase 2 clinical study to assess its potential as a non-opioid, non-addictive, non-sedating treatment to reduce debilitating neuropathic pain, especially diabetic neuropathic pain, effectively, without causing gabapentin- or pregabalin-like side effects or risk of addiction associated with pain medications targeting opioid receptors.

AV-101 and Parkinson’s Disease Levodopa-Induced Dyskinesia

Parkinson's disease (PD) is a chronic, progressive motor disorder that causes tremors, rigidity, slowed movements and postural instability. The Parkinson’s Foundation estimates that PD affects about one million people in the United States and ten million worldwide. The main finding in brains of people with PD is loss of dopaminergic neurons in the area of the brain known as the substantia nigra. The most commonly-prescribed treatments for PD are levodopa-based therapies. In the brain, levodopa is converted to dopamine to replace the dopamine loss caused by PD. Unfortunately, abnormal involuntary movements, called dyskinesias, gradually emerge as a prominent side-effect in response to previously beneficial doses of levodopa. Parkinson’s disease levodopa-induced dyskinesia (PD LID) can be severely disabling, rendering patients unable to perform routine daily tasks. It may be necessary to reduce the dose of levodopa to avoid dyskinesias, which may in turn exacerbate the core PD motor disorder. Studies published in the New England Journal of Medicine and Movement Disorders have shown PD LID develops in approximately 45% of levodopa-treated Parkinson’s disease patients after five years and 80% after 10 years of levodopa treatment. In the U.S., there are an estimated 150,000 to 200,000 people with PD who are impacted by PD LID.

AV-101 is not a dopamine-based drug candidate. Rather, it is believed to work through a different receptor in the brain that is equally important in PD, known as glutamate. We believe AV-101 has potential to reduce troublesome dyskinesia experienced by many patients with Parkinson’s disease as a result of their levodopa therapy, but without interfering with levodopa or causing side effects resulting from certain current PD LID treatments, including hallucinations, dizziness, dry mouth, swelling of legs and feet, constipation and falls.

In a monkey model of Parkinson's disease, AV-101 (250 mg/kg and 450 mg/kg) resulted in a 30% reduction of the mean dyskinesia score associated with PD LID. Maximum dyskinesia scores were also reduced by 17%. Importantly, AV-101 did not reduce the anti-parkinsonian therapeutic benefit of levodopa. Moreover, the duration of levodopa response and delay to levodopa effect were not affected by treatment with AV-101. We believe these preclinical data warrant clinical development of AV-101 in an exploratory Phase 2 clinical study to assess its potential in Parkinson's disease patients diagnosed with PD LID.

AV-101 and Epilepsy

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

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

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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 as a result of astrocytes, which are responsible for the enzymatic transamination of 4-Cl-KYN prodrug to active 7-Cl-KYNA, becoming 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 NMDA receptor agonist that causes convulsions and excitotoxic neuronal damage.

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

AV-101 and Huntington's Disease

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

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

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

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

AV-101 Phase 1 Clinical Safety Studies

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

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

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

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VistaStem Therapeutics and our Stem Cell Programs

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

Scientific Background

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

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

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

CardioSafe 3D vs. hERG Assay

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

We produce functional, non-transformed hPSC-CMs at a high level of purity and with normal ratios of all important cardiac cell types. Importantly, our hPSC-CM differentiation protocols do not involve either genetic modification or antibiotic selection. This is important because genetic modification and antibiotic selection can distort the ratio of cardiac cell types and have a direct impact on the ultimate results and clinical predictivity of assays that incorporate hPSC-CMs produced in such a manner. In addition to normal expression all of the key ion channels of the human heart (calcium, potassium and sodium) and various cardiomyocytic markers of the human heart, our CardioSafe 3D cardiac toxicity assays screening for both direct cardiomyocyte cytotoxicity and arrhythmogenesis (or development of

irregular beating patterns). We believe CardioSafe 3D is sensitive, stable, reproducible and capable of generating data enabling a more accurate prediction of the in vivo cardiac effects of NCEs than is possible with existing preclinical testing systems, particularly the hERG assay, which uses either transformed hamster ovary cells or human kidney cells and 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 – and does not assess any other clinically relevant cardiac ion channels, including calcium, non-hERG potassium and sodium ion channels. In addition, the hERG assay does not assess clinically relevant cardiac biological effects associated with cardiomyocyte viability, including apoptosis and other forms of cytotoxicity, as well as energy, mitochondria and oxidative stress. As a result of its limitations, results of the hERG assay can lead to false negative and false positive predictions regarding the cardiac safety of new drug candidates.

We believe that CardioSafe 3D provides valuable and more comprehensive bioanalytical tools for in vitro cardiac safety screening than the hERG assay.

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Using CardioSafe 3D to Develop Drug Rescue NCEs

Our drug rescue activities are focused on producing for our internal CNS pipeline or out-licensing 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 drug rescue strategy involves using CardioSafe 3D to assess the cardiac toxicity that caused certain NCEs available in the public to be terminated, and using that insight to produce and develop a new, potentially safer, and proprietary NCEs for our CNS pipeline or out-licensing. 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, insight not previously available when the NCEs were originally discovered, optimized for efficacy and developed, we believe we can demonstrate preclinical proof-of-concept (POC) as to the efficacy and safety of new, safer drug rescue NCEs in standard in vitro and in vivo models, as well as in CardioSafe 3D, earlier in development and with substantially less investment in discovery and preclinical development than was required of pharmaceutical companies and others prior to their decision to terminate the original NCE.

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

Regenerative Medicine

We believe stem cell technology-based cell therapy and regenerative medicine (RM) have the potential to transform healthcare in the U.S. and certain other large markets over the next decade by providing new approaches for treating the fundamental mechanisms of disease. We currently intend to establish strategic cell therapy- and/or RM-focused collaborations to leverage our stem cell technology platform, our expertise in human biology, differentiation of human pluripotent stem cells to develop functional adult human cells and tissues involved in human disease, including blood, bone, cartilage, heart and liver cells for cell therapy and RM purposes. In December 2016, we exclusively sublicensed to BlueRock Therapeutics, a next generation RM company established by Bayer AG and Versant Ventures, rights to certain proprietary technologies relating to the production of cardiac stem cells for the treatment of heart disease. In a manner similar to our exclusive sublicense agreement with BlueRock Therapeutics, we may pursue additional cell therapy and RM collaborations or licensing transactions involving blood, cartilage, and/or liver cells derived from hPSCs for cell-based therapy, cell repair therapy, and/or tissue engineering.

Intellectual Property

We rely upon patents as a major component of our intellectual property (IP) 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 IP and to provide certain IP rights to commercialization partners. We also rely, in part, on trade secrets for protection of some of our discoveries. We seek 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 IP rights, our employees, contractors 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 may sponsor or facilitate 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 IP rights in the results of the sponsored research.

AV-101

We have developed a portfolio of IP assets around AV-101, which involves obtaining patents and protecting trade secrets. In addition to these IP assets, we plan to seek regulatory exclusivity for the use of AV-101, with initial emphasis on treating depression as our lead indication in clinical development. These two approaches to obtaining exclusivity exist separately in the US and in several other countries and would be expected to provide complementary protection in countries where they are available.

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Although AV-101 (also known as L-4-Cl-kynurenine) is not itself patent protected as a chemical compound, as part of our strategy to seek and secure broad commercial exclusivity for AV-101, we have pursued related patents in the U.S., Europe, and other selected major pharmaceutical markets, including China, Japan and Korea. For example, some of our granted AV-101 patents and pending applications relate to the treatment of depression and others relate to the treatment of additional CNS diseases and disorders, including, among others, Parkinson's disease levodopa-induced dyskinesia and the management of certain types of neuropathic pain. Several of these patent applications were allowed or have been granted, relating to certain oral unit dose formulations of AV-101 without any restriction as to the particular medical condition, disease or disorder to be treated and, in certain countries, relating to novel therapeutic methods for treatment of depression and levodopa-induced dyskinesia. Additional granted patents and pending applications involve methods to synthesize AV-101. We expect that our granted patents will not begin to expire until 2034, and we plan to seek patent term extensions in places, such as the U.S., Europe and Japan, where they are available.

As noted elsewhere in this Annual Report, we are currently involved with the NIMH Study being conducted by the NIMH. As part of our analysis of the study results, we will be evaluating the possibility of seeking additional patent protection in the U.S., Europe, China, Japan, Korea and selected major markets based on the clinical data and on clinical observations.

As mentioned above, a complementary component of our plan is to obtain regulatory exclusivity for approved therapeutic indications for AV-101. For example, the FDA's New Drug Product Exclusivity is available for NCEs such as AV-101, which have not been previously approved by the FDA. This provides the holder of an FDA-approved NDA with up to five years of protection from competition in the U.S. marketplace from generic versions of the same product. As applicable, we will pursue similar types of regulatory exclusivity in other regions, such as Europe, and in certain other countries.

There is no guarantee that we will be successful in obtaining any additional patents related to AV-101 in the U.S., Europe, or any other country, or that if we are successful in obtaining any patents that we would also be successful in protecting those patents against challengers or in enforcing them to stop infringement. Outside the U.S. and Europe, we are pursuing patent rights in a limited number of countries that we believe are the major markets for pharmaceuticals where having patent rights should substantially facilitate commercialization of AV-101.

Stem Cell Technology

We have obtained and are pursuing IP 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 and drug discovery. It also relates to production systems of enriched populations of certain stem cell and differentiated cell types, such as cardiomyocytes, and the use of various cell types that have been differentiated from pluripotent stem cells for those and other purposes including cell-based therapy and RM. Additionally, we maintain certain trade secrets regarding our stem cell technology.

Overall, our stem cell patent portfolio includes several issued U.S. patents and pending patent applications as well as foreign counterpart patents and applications in countries of commercial interest to us such as China, Japan and Korea.

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 University Health Network (Toronto) and the Mount Sinai School of Medicine.

These license agreements generally require us to pay nominal annual license fees, and, in certain cases, 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 IP, there is also no guarantee that we will successfully obtain stem cell related patents in the countries in which we are pursuing patent rights or that we would be successful in enforcing granted patent rights against infringers.

In December 2016, we exclusively sublicensed to BlueRock Therapeutics, Inc., a company founded by Bayer AG and Versant Ventures to usher in a new era of cell-based medicine that repairs the body when it cannot repair itself, rights to certain proprietary technologies relating to the production of cardiac stem cells for the treatment of heart disease.

Strategic Transactions and Relationships

Strategic collaborations are an important cornerstone of our corporate development strategy. We believe that our highly selective outsourcing of certain research, development, manufacturing and regulatory activities gives us flexible access to a broad range of capabilities and expertise at a lower overall cost than developing and maintaining such capabilities and expertise internally on a full-time basis. In particular, we contract with third parties for certain manufacturing, nonclinical development, clinical development and regulatory affairs support. Our current strategic collaborations include our CRADA with the NIMH, pursuant to which the NIMH is conducting the NIMH Study, and our relationships with Cato Research Ltd. as our contract research organization (CRO) for the ELEVATE Study and Norac Pharma as our contract manufacturing organization (CMO) currently responsible for the production of our AV-101 drug substance.

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Manufacturing

We do not have any manufacturing facilities or personnel. We currently rely, and expect to continue to rely, on third parties for the manufacturing of our product candidates for preclinical and clinical testing, as well as for commercial manufacturing if our product candidates receive marketing approval. As a key part of our product development approach, we aim to complete formulation work at an early stage of development, such that our clinical studies are conducted with a formulation that has the potential for eventual scale-up. All of our product candidates are small molecules and are manufactured in reliable and reproducible synthetic processes from readily available starting materials. The chemistry does not require unusual equipment in the manufacturing process. We expect to continue to develop product candidates that can be produced cost-effectively at contract manufacturing facilities.

Commercialization

We intend to develop and, if approved by the FDA, to commercialize our product candidates in the United States. We may work in combination with one or more pharmaceutical partners for certain indications, where specialist capabilities are needed. Depending on the specific development path pursued, this may include larger depression and neuropathic pain indications. For other, more specialized indications, we intend to commercialize our product candidates independently. For example, we believe the patient and prescriber populations for PD LID are relatively concentrated and can be addressed with a focused sales team. We will, however, continuously review our partnering strategy in the light of new clinical data and market understanding. We may enter into development and/or commercialization arrangements for commercialization rights for other regions outside the United States.

Competition

The biopharmaceutical industry is highly competitive and subject to rapid and significant technological change. The large and growing markets for MDD, neuropathic pain, PD LID, and other CNS diseases and disorders make them attractive therapeutic areas for biopharmaceutical businesses. We face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical, and biotechnology companies, academic institutions, governmental agencies, and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. Many of our competitors may have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical studies, obtaining regulatory approvals, and marketing approved products than we do. Several of these entities have commercial products, robust drug pipelines, readily available capital, and established research and development organizations. Mergers and acquisitions in the pharmaceutical, biotechnology, and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical study sites and patient registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs. Small or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. It is probable that the number of companies seeking to develop products and therapies similar to our products will increase. The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the level of branded and generic competition, and the availability of reimbursement from government and other third-party payors.

Although currently there are no FDA-approved therapies for MDD with the mechanism of action of AV-101, we are aware of a number of pharmaceutical, biotechnology, and specialty pharmaceutical companies that are developing therapies targeting NMDA receptors. Most of the therapies being developed are broad NMDA receptor antagonists and tend to have multiple target actions, we believe AV-101 is an NMDA receptor GlyB antagonist and is truly

modulatory, without negative off-target activity in preclinical screening. We are aware of the following companies developing or commercializing NMDA receptor-targeted therapies, including but not limited to, Adamas Pharmaceuticals, Allergan, AmKor Pharma, Aptynix, Avanir Pharmaceuticals, Axsome Therapeutics, Biohaven Pharmaceutical Holding Co. Ltd., Cadent Therapeutics, Cerecor, Eli Lilly, Genentech, Immune Pharmaceuticals, Intra-Cellular Therapies, Janssen Pharmaceuticals, NeuroRx, Newron Pharmaceuticals, Otonomy, Relmada Therapeutics, Sage Therapeutics and UCB. In the field of new generation, orally available, adjunctive treatments of adult MDD patients with an inadequate response to standard antidepressants, and with an initial objective of displacing atypical antipsychotics in the current MDD drug treatment paradigm, we believe our principal competitor may be Alkermes' orally available drug candidate, ALKS-5461, an opioid modulator for which Alkermes has submitted an NDA with the FDA.

Additionally, we expect that AV-101 will have to compete with a variety of therapeutic procedures. such as psychotherapy and electroconvulsive therapy.

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

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Government Regulation

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

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

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

To establish a new product candidate’s safety and efficacy, the FDA requires companies seeking approval to market a drug product to submit extensive preclinical and clinical data, along with other information, for each indication for which the product will be labeled. The data and information are submitted to the FDA in the form of a New Drug Application (NDA), which must be accompanied by payment of a significant user fee unless a waiver or exemption applies. Generating the required data and information for an NDA takes many years and requires the expenditure of substantial resources. Information generated in this process is susceptible to varying interpretations that could delay, limit or prevent regulatory approval at any stage of the process. The failure to demonstrate adequately the quality, safety and efficacy of a product candidate under development would delay or prevent regulatory approval of the product candidate. Under applicable laws and FDA regulations, each NDA submitted for FDA approval is given an internal administrative review within 60 days following submission of the NDA. If deemed sufficiently complete to permit a substantive review, the FDA will “file” the NDA. The FDA can refuse to file any NDA that it deems

incomplete or not properly reviewable. The FDA has established internal goals of eight months from submission for priority review of NDAs that cover product candidates that offer major advances in treatment or provide a treatment where no adequate therapy exists, and 12 months from submission for the standard review of NDAs. However, the FDA is not legally required to complete its review within these periods, these performance goals may change over time and the review is often extended by FDA requests for additional information or clarification. Moreover, the outcome of the review, even if generally favorable, may not be an actual approval but a “complete response letter” that describes additional work that must be done before the NDA can be approved. Before approving an NDA, the FDA can choose to inspect the facilities at which the product is manufactured and will not approve the product unless the manufacturing facility complies with cGMPs. The FDA may also audit sites at which clinical trials have been conducted to determine compliance with GCPs and data integrity. The FDA’s review of an NDA may also involve review and recommendations by an independent FDA advisory committee, particularly for novel indications. The FDA is not bound by the recommendation of an advisory committee.

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

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

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

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

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

We and our collaborators and contract manufacturers also are required to comply with the applicable FDA cGMP regulations. cGMP regulations include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Manufacturing facilities are subject to inspection by the

FDA. These facilities must be approved before we can use them in commercial manufacturing of our potential products and must maintain ongoing compliance for commercial product manufacture. The FDA may conclude that we or our collaborators or contract manufacturers are not in compliance with applicable cGMP requirements and other FDA regulatory requirements, which may result in delay or failure to approve applications, warning letters, product recalls and/or imposition of fines or penalties.

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

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

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

Reimbursement

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

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

Healthcare Laws and Regulations

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

The federal Anti-Kickback Statute makes it illegal for any person or entity to knowingly and willfully, directly or indirectly, solicit, receive, offer, or pay any remuneration that is in exchange for or to induce the referral of business, including the purchase, order, lease of any good, facility, item or service for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. The term “remuneration” has been broadly interpreted to include anything of value.

Federal false claims and false statement laws, including the federal civil False Claims Act, prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, for payment to, or approval by, federal programs, including Medicare and Medicaid, claims for items or services, including drugs, that are false or fraudulent.

The U.S. federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) created additional federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors or making any false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH) and their implementing regulations, impose obligations on certain types of individuals and entities regarding the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information.

The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program, with specific exceptions, to report annually to CMS information related to payments or other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

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

Additionally, to the extent that our product is sold in a foreign country, we may be subject to similar foreign laws as well to compliance with the U.S Foreign Corrupt Practices Act.

Stem Cell Technology - United States

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

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

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

Subsidiaries and Inter-Corporate Relationships

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

Corporate History

VistaGen Therapeutics, Inc., a California corporation incorporated on May 26, 1998, dba VistaStem, is our wholly-owned subsidiary. Excaliber Enterprises, Ltd. (Excaliber), a publicly-held company (formerly OTCBB: EXCA) was incorporated under the laws of the State of Nevada on October 6, 2005. Pursuant to a strategic merger transaction on May 11, 2011, Excaliber acquired all outstanding shares of VistaStem in exchange for 341,823 shares

of our common stock and assumed all of VistaStem's pre-Merger obligations (the Merger). Shortly after the Merger, Excaliber's name was changed to "VistaGen Therapeutics, Inc." (a Nevada corporation).

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

The Consolidated Financial Statements included in Item 8 of this Annual Report represent the activity of VistaStem from May 26, 1998, and the consolidated activity of VistaStem and Excaliber (now VistaGen Therapeutics, Inc., a Nevada corporation), from May 11, 2011 (the date of the Merger) through March 31, 2018. The Consolidated Financial Statements also include the accounts of VistaStem's two inactive wholly-owned subsidiaries, Artemis Neuroscience, Inc., a Maryland corporation (Artemis), and VistaStem Canada, Inc., a corporation organized under the laws of Ontario, Canada (VistaStem Canada).

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Employees

As of June 26, 2018, we employed nine full-time employees, four of whom have doctorate degrees. Five full-time employees work in research and development and laboratory support services and four full-time employees work in general and administrative roles. Staffing for all other functional areas is achieved through our diverse network of strategic relationships with service providers and consultants, each of whom provides services on a real-time, as-needed basis, including human resources and payroll, information technology, facilities, legal, investor relations and website maintenance, regulatory affairs, and FDA program management.

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

Facilities

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

Legal Proceedings

None.

Environmental Regulation

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

Item 1A. Risk Factors

Investing in our securities involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all other information in this Annual Report before investing in our securities. The risks described below are not the only risks facing our Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also materially adversely affect our business, financial condition and/or operating results. If any of the following risks are realized, our business, financial condition and/or operating results could be materially and adversely affected.

Risks Related to Product Development, Regulatory Approval and Commercialization

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

We currently have no drug products for sale and may never be able to develop and commercialize marketable drug products. Our business currently depends heavily on the successful development, regulatory approval and commercialization of AV-101 for depression, including for MDD, and, potentially, various other diseases and disorders involving the CNS, as well as, but to a more limited extent, our ability to acquire, license or produce, develop and commercialize additional product candidates. AV-101 will require substantial additional nonclinical and clinical testing and regulatory approval before it may be commercialized. It is unlikely to achieve regulatory approval, if at all, until at least 2021. Each drug rescue NCE will require substantial nonclinical development, all phases of clinical development, and regulatory approval before it may be commercialized. The nonclinical and clinical development of our product candidates are, and the manufacturing and marketing of our product candidates will be,

subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and, if approved, market any product candidate. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must demonstrate through numerous nonclinical and clinical studies that the product candidate is safe and effective for use in each target indication. Research and development of product candidates in the pharmaceutical industry is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of nonclinical or clinical studies. This process takes many years and may also include post-marketing studies and surveillance obligations, which would require the expenditure of substantial resources beyond the proceeds we have raised to date. Of the large number of drug candidates in development in the United States, only a small percentage will successfully complete the FDA regulatory approval process and will be commercialized. Accordingly, we cannot assure you that AV-101, or any other future product candidate will be successfully developed or commercialized.

We are not permitted to market our product candidates in the United States until we receive approval of an NDA from the FDA, or in any foreign countries until we receive the requisite approval from such countries. We expect the FDA to require us to complete our ELEVATE study, our double-blind, placebo-controlled Phase 2 clinical study to evaluate the efficacy and safety of AV-101 as an adjunctive treatment of MDD in patients with an inadequate response to current FDA-approved antidepressants, and at least two pivotal Phase 3 clinical trials in order to submit an NDA for AV-101 as an adjunctive treatment for MDD patients with an inadequate response to standard, FDA-approved antidepressants. Also, we anticipate that the FDA will require that we conduct additional toxicology studies, additional nonclinical and certain small clinical studies before submitting an NDA for AV-101. The results of all of these studies will not be known until after the studies are concluded.

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Obtaining FDA approval of an NDA is a complex, lengthy, expensive and uncertain process. The FDA may refuse to permit the filing of our NDA, delay, limit or deny approval of an NDA for many reasons, including, among others:

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

the FDA may require development of a REMS as a condition of approval or post-approval;

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

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

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

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

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

The Fast Track designation is a program offered by the FDA pursuant to certain mandates under the FDA Modernization Act of 1997, designed to facilitate drug development and to expedite the review of new drugs that are intended to treat serious or life threatening conditions. Compounds selected must demonstrate the potential to address unmet medical needs. The 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.

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

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

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

The results of preclinical studies and early clinical trials of AV-101 and/or other product candidates, including positive results, 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.

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

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

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

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

AV-101, as a monotherapy in patients with treatment-resistant depression, is currently being tested by the NIMH in the NIMH Study and may be subjected to testing in the future for other CNS indications in additional investigator-sponsored clinical trials. If serious adverse events or other undesirable side effects or safety concerns, or unexpected characteristics attributable to AV-101 are observed in the NIMH Study, other investigator-sponsored clinical trials of AV-101, or in our clinical trials of AV-101, including our ELEVATE Study, it may adversely affect or delay our clinical development and commercialization of AV-101, and the occurrence of these events could have a material adverse effect on our business and financial prospects.

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

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

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

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

negative results from nonclinical studies;

delays in reaching or failing to reach agreement on acceptable terms with prospective CROs, investigators and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, investigators and clinical trial sites;

delays in the manufacturing of, or insufficient supply of product candidates necessary to conduct nonclinical or clinical trials, including delays in the manufacturing of sufficient supply or finished drug product;

inability to manufacture or obtain clinical supplies of a product candidate meeting required quality standards;

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

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

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

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

delays in validating any endpoints utilized in a clinical trial;

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

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

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

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

failure to conduct the clinical trial in accordance with regulatory requirements or approved clinical protocols;

inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities that reveals deficiencies or violations that require us to undertake corrective action, including the imposition of a clinical hold;

unforeseen safety issues, including any that could be identified in nonclinical carcinogenicity studies, adverse side effects or lack of effectiveness;

changes in government regulations or administrative actions;

problems with clinical supply materials that may lead to regulatory actions; and

lack of adequate funding to continue nonclinical or clinical studies.

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

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

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

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

have staffing difficulties and/or undertake obligations beyond their anticipated capabilities and resources;

fail to comply with contractual obligations;

experience regulatory compliance issues;

undergo changes in priorities or become financially distressed; or

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

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

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

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

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

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

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

With respect to AV-101, we do not yet have long-term supply agreements in place with our CMOs and each batch of AV-101 is individually contracted under a separate supply agreement. If we engage new CMOs, such contractors must complete an inspection by the FDA and other applicable foreign regulatory agencies. We plan to continue to rely upon

CMOs and, potentially, collaboration partners, to manufacture research and development scale quantities, and, if approved, commercial scale quantities of our product candidates. Although we believe our current scale of manufacturing for AV-101 and current and projected supply of AV-101 API and finished drug product will be adequate to support our planned nonclinical and clinical studies of AV-101, no assurance can be given that unanticipated AV-101 supply shortages or CMO-related delays in the manufacture and formulation of AV-101 API and/or finished drug product will not occur in the future.

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

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

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

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

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

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

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

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

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

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

number of factors, including, among others:

the efficacy and safety of our product candidates as demonstrated in clinical trials, and, if required by any applicable regulatory authority in connection with the approval for the applicable indications, to provide patients with incremental health benefits, as compared with other available therapies;

limitations or warnings contained in the labeling approved for our product candidates by the FDA or other applicable regulatory authorities;

the clinical indications for which our product candidates are approved;

availability of alternative treatments already approved or expected to be commercially launched in the near future;

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

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

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

publicity concerning our products or competing products and treatments;

pricing and cost effectiveness;

the effectiveness of our sales and marketing strategies;

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

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

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

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

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

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

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

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

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

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

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

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

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

our reputation may suffer.

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

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

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

issue warning letters or untitled letters;

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

suspend or withdraw marketing approval;

suspend any ongoing clinical trials;

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

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

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

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

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

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

In the field of new generation, oral adjunctive treatments for adult patients with MDD with an inadequate response to standard FDA-approved antidepressants, we believe our principal competitor may be Alkermes' oral opioid modulator, ALKS-5461, which adjunctive treatment product candidate is the subject of an NDA recently submitted to the FDA by Alkermes.

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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, Parkinson's disease levodopa-induced dyskinesia, neuropathic pain, epilepsy, and other neurological conditions and diseases, including, but not limited to, Abbott Laboratories, Acadia, Allergan, Alkermes, AstraZeneca, Eli Lilly, GlaxoSmithKline, IntraCellular, Johnson & Johnson/Janssen, Lundbeck, Merck, Novartis, Ono, Otsuka, Pfizer, Roche, Sage, Sumitomo Dainippon, and Takeda, as well as any affiliates of the foregoing companies. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

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

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

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

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

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

available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

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

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

The success of our business depends primarily upon our ability to identify, develop and commercialize product candidates with commercial and therapeutic potential. Although AV-101 is in Phase 2 clinical development for treatment of MDD, 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 currently have limited financial and management resources, we necessarily focus on a limited number of research and development programs and product candidates and are currently focused primarily on development of AV-101, with additional limited focus on NCE drug rescue and RM. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other potential CNS-related indications for AV-101 that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable drugs. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through future collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We may, in the future, choose to seek FDA Orphan Drug designation for one or more of our product candidates. Even if we obtain Orphan Drug designation from the FDA for a product candidate, there are limitations to the exclusivity afforded by such designation. In the U.S., the company that first obtains FDA approval for a designated orphan drug for the specified rare disease or condition receives orphan drug marketing exclusivity for that drug for a period of seven years. This orphan drug exclusivity prevents the FDA from approving another application, including a full NDA to market the same drug for the same orphan indication, except in very limited circumstances, including when the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. For purposes of small molecule drugs, the FDA defines “same drug” as a drug that contains the same active moiety and is intended for the same use as the drug in question. To obtain Orphan Drug status for a drug that shares the same active moiety as an already approved drug, it must be demonstrated to the FDA that the drug is safer or more effective than the approved orphan designated drug, or that it makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition or if another drug with the same active moiety is determined to be safer, more effective, or represents a major contribution to patient care.

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

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

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

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

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

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

import or export licensing requirements;

longer accounts receivable collection times;

longer lead times for shipping;

language barriers for technical training;

reduced protection of intellectual property rights 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 therapeutic product candidates, including conducting clinical trials and other areas

required for the successful development and commercialization of therapeutic products, which makes it difficult to assess our future viability.

We are a development stage biopharmaceutical company. Although 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 collaborators:

develop and obtain required regulatory approvals for commercialization of AV-101 and other product candidates;

maintain, leverage and expand our intellectual property portfolio;

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

gain market acceptance for our product candidates; and

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

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

Business development and research and development programs designed to identify, acquire or license additional product candidates, or, as the case may be, produce drug rescue NCEs require substantial technical, financial and human resources, whether or not any additional product candidate is acquired or licensed or NCEs are ultimately identified and produced. In particular, our drug rescue programs may initially show promise in identifying potential NCEs, yet fail to yield a lead NCE suitable for preclinical, clinical development or commercialization for many reasons, including the following:

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

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

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

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

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

In addition, we do not have a sales or marketing infrastructure, and we, including our executive officers, do not have any significant pharmaceutical sales, marketing or distribution experience. We may seek to collaborate with others to develop and commercialize AV-101, drug rescue NCEs and/or other product candidates if and when they are acquired and 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 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, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our human pluripotent stem cell technology is technically complex, and the time and resources necessary to develop various human cell types and customized bioassay systems are difficult to predict in advance. We might decide to devote significant personnel and financial resources to research and development activities designed to expand, in the case of drug rescue, and explore, in the case of drug discovery and regenerative medicine, potential applications of our stem cell technology platform. In particular, we may conduct exploratory nonclinical RM programs involving blood,

bone, cartilage, and/or liver cells. Although we and our collaborators have developed proprietary protocols to produce multiple differentiated cell types, we could encounter difficulties in differentiating and producing sufficient quantities of particular cell types, even when following these proprietary protocols. These difficulties could result in delays in production of certain cells, assessment of certain drug rescue candidates and drug rescue NCEs, design and development of certain human cellular assays and performance of certain exploratory non-clinical regenerative medicine studies. In the past, our stem cell research and development projects have been significantly delayed when we encountered unanticipated difficulties in differentiating human pluripotent stem cells into heart and liver cells. Although we have overcome such difficulties in the past, we may have similar delays in the future, and we may not be able to overcome them or obtain any benefits from our future stem cell technology research and development activities. Any delay or failure by us, for example, to produce functional, mature blood, bone, cartilage, and liver cells could have a substantial and material adverse effect on our potential drug discovery, drug rescue and regenerative medicine business opportunities and results of operations.

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

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

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

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

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

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

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these

materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

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

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

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

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

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

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

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

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

or clearance, it may not be for the uses that we believe are important or commercially attractive.

Risks Related to Our Financial Position

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

We have incurred significant net losses in each fiscal year since our inception in 1998, including net losses of $14.3 million and $10.3 million during the fiscal years ended March 31, 2018 and 2017, respectively. As of March 31, 2018, we had an accumulated deficit of approximately $156.5 million. We do not know whether or when we will become profitable. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to incur increasing levels of operating losses over the next several years and for the foreseeable future. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity (deficit) and working capital. We expect our research and development expenses to significantly increase in connection with nonclinical studies and clinical trials of our product candidates. In addition, if we obtain marketing approval for our product candidates, we may incur significant sales, marketing and outsourced-manufacturing expenses should we elect not to collaborate with one or more third parties for such services and capabilities. As a public company, we incur additional costs associated with operating as a public company. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

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Our ability to become profitable depends upon our ability to generate revenues. To date, we have generated approximately $17.7 million in revenues, including receipt of non-dilutive cash payments from collaborators, sublicense revenue, and research and development grant awards from the NIH, however not including the fair market value of the NIMH Study sponsored and conducted by the NIMH under our NIMH CRADA. 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 another product candidate, 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 nonclinical and clinical trials that meet their prescribed endpoints;

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

timely complete and compose successful regulatory submissions such as NDAs or comparable documents for both U.S. and foreign jurisdictions;

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

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

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

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

Our audited consolidated financial statements for the year ended March 31, 2018 included elsewhere in this Annual Report have been prepared assuming we will continue to operate as a going concern, although we and our auditors have indicated that our continuing losses and negative cash flows from operations raise substantial doubt about our ability to continue as such. Because we continue to experience net operating losses, our ability to continue as a going concern is subject to our ability to obtain necessary funding from outside sources, including obtaining additional funding from the sale of our securities or obtaining loans and grant awards from financial institutions and/or government agencies where possible. Our continued net operating losses increase the difficulty in completing such sales or securing alternative sources of funding, and there can be no assurances that we will be able to obtain such funding on favorable terms or at all. If we are unable to obtain sufficient financing from the sale of our securities or

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

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

At March 31, 2018, we had a cash and cash equivalents balance of approximately $10.4 million. We do not believe this amount is sufficient to enable us to fund our planned operations for at least the twelve months following the issuance of the financial statements included in this Annual Report. We expect to seek additional capital to finalize the results from our ELEVATE study, produce additional AV-101 study material, conduct Phase 3-enabling studies, conduct Phase 3 studies in MDD, conduct AV-101 Phase 2 studies in CNS indications other than MDD, acquire or license and conduct research and development of additional product candidates and to fund our internal operations in 2019 and beyond.

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

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

Our future capital requirements depend on many factors, including:

the number and characteristics of the product candidates we pursue;

the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical and clinical studies;

the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;

the cost of commercialization activities if any of our product candidates are approved for sale, including marketing, sales and distribution costs;

the cost of manufacturing our product candidates and any products we successfully commercialize;

our ability to establish and maintain strategic partnerships, licensing or other collaborative arrangements and the financial terms of such agreements;

market acceptance of our product candidates;

the effect of competing technological and market developments;

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

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

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

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

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

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

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

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

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

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

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

We intend to pursue private and public equity offerings, debt financings, strategic collaborations and licensing arrangements during 2018 and beyond. To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, or to the extent, for strategic purposes, we convert or exchange certain of our outstanding securities into common stock, our current stockholders' ownership interest in our company will be substantially diluted. In addition, the terms of any such securities may include liquidation or other preferences that materially adversely affect rights of our stockholders. Debt financing, if available, would increase our fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration, strategic partnerships and licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, our intellectual property, future revenue streams or grant licenses on terms that are not favorable to us.

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

Since inception, we have received substantial funds under grant award programs funded by state and federal governmental agencies, such as the NIH, the NIH's National Institute of Neurological Disease and Stroke (NINDS) and the NIMH, and the California Institute for Regenerative Medicine (CIRM). To fund a portion of our future research and development programs, we may apply for additional grant funding from such or similar governmental organizations. However, funding by these governmental organizations may be significantly reduced or eliminated in the future for a number of reasons. For example, some programs are subject to a yearly appropriations process in

Congress. In addition, we may not receive funds under future grants because of budgeting constraints of the agency administering the program. Therefore, we cannot assure you that we will receive any future grant funding from any government organization or otherwise. A restriction on the government funding available to us could reduce the resources that we would be able to devote to future research and development efforts. Such a reduction could delay the introduction of new products and hurt our competitive position.

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

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

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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 our product candidates.

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

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

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

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

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

As we develop our product candidates. either on our own or in collaboration with others, we will face inherent risks of product liability as a result of the required clinical testing of such product candidates, and will face an even greater risk if we or our collaborators commercialize any such product candidates. For example, we may be sued if AV-101, 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 product candidates that we may develop;

injury to our reputation;

withdrawal of clinical trial participants;

costs to defend the related litigation;

a diversion of management's time and our resources;

substantial monetary awards to trial participants or patients; or

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

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

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

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

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

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

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

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

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

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

While we have not experienced any such system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs. For example, the loss of clinical trial data for AV-101 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 product candidates, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions.

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

Risks Related to Our Intellectual Property Rights

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

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

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 and have licensed patents and patent applications related to AV-101 and human pluripotent stem cell technology.

Although we have issued patents relating to AV-101 in the U.S. and the European Union, we cannot yet provide any assurances that any of our other numerous pending U.S. and additional foreign patent applications relating to AV-101 will mature into issued patents and, if they do, that such patents will include claims with a scope sufficient to protect AV-101 or otherwise provide any competitive advantage. Moreover, other parties may have developed technologies that may be related or competitive to our approach, and may have filed or may file patent applications and may have received or may receive patents that may overlap or conflict with our patent applications, either by claiming the same methods or formulations or by claiming subject matter that could dominate our patent position. Such third-party patent positions may limit or even eliminate our ability to obtain patent protection.

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

application. In addition, such proceedings may be costly. Thus, any patents that we may own or exclusively license may not provide any protection against competitors. Furthermore, an adverse decision in an interference proceeding can result in a third party receiving the patent right sought by us, which in turn could affect our ability to develop, market or otherwise commercialize our product candidates.

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

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

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

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

any of our issued patents related to AV-101 or 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 currently held or issued to us in the future will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;

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

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.

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

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

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

cease developing, selling or otherwise commercializing our product candidates;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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.

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

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

the scope of rights granted under the license agreement and other interpretation-related issues;

whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;

our right to sublicense patent and other rights to third parties under collaborative development relationships;

our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; and

the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

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

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

prospects.

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

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

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

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

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

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

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

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

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

application of Myriad to DNA but, rather, applied the decision to other natural products. Further, in 2015, in Ariosa Diagnostics, Inc. v. Sequenom, Inc., the Court of Appeals for the Federal Circuit held that methods for detecting fetal genetic defects were not patent eligible subject matter.

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

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

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

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

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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

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

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

plans for, progress of or results from nonclinical and clinical development activities related to our product candidates;

the failure of the FDA to approve our product candidates;

announcements of new products, technologies, commercial relationships, acquisitions or other events by us or our competitors;

the success or failure of other CNS therapies;

regulatory or legal developments in the United States and other countries;

announcements regarding our intellectual property portfolio;

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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 such sales or issuances are occurring or might occur, could significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity securities.

The stock market in general, and small biopharmaceutical companies like ours in particular, have frequently experienced significant volatility in the market prices for securities that often has been unrelated to the operating performance of the underlying companies. These broad market and industry fluctuations may adversely affect the market price of our common stock, regardless of our actual operating performance. In certain situations in which the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit against us, the defense and disposition of the lawsuit could be costly and divert the time and attention of our management and harm our operating results. Additionally, if the trading volume of our common stock remains low and limited there will be an increased

level of volatility and you may not be able to generate a return on your investment.

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

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

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

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

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

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

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

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

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

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

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

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

The filing and internal control reporting requirements imposed by federal securities laws, rules and regulations on companies that are not "smaller reporting companies" under federal securities laws are rigorous and, once we are no longer a smaller reporting company, we may not be able to meet them, resulting in a possible decline in the price of

our common stock and our inability to obtain future financing. Certain of these requirements may require us to carry out activities we have not done previously and complying with such requirements may divert management's attention from other business concerns, which could have a material adverse effect on our business, results of operations, financial condition and cash flows. Any failure to adequately comply with applicable federal securities laws, rules or regulations could subject us to fines or regulatory actions, which may materially adversely affect our business, results of operations and financial condition.

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

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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, 2022. We believe that our facilities are suitable and adequate for our current and foreseeable needs.

Item 3. Legal Proceedings

None.

Item 4. Mine Safety Disclosures

Not applicable.

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

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

	High	Low
Year Ending March 31, 2018		
First quarter ending June 30, 2017	$2.40	$1.72
Second quarter ended September 30, 2017	$2.05	$1.53
Third quarter ended December 31, 2017	$2.65	$0.69
Fourth quarter ended March 31, 2018	$1.79	$0.86
Year Ending March 31, 2017		
First quarter ending June 30, 2016	$9.00	$3.40
Second quarter ended September 30, 2016	$4.69	$2.81
Third quarter ended December 31, 2016	$4.50	$3.11
Fourth quarter ended March 31, 2017	$3.90	$1.74

On June 26, 2018 the closing price of our common stock on the NASDAQ Capital Market was $1.345 per share.

As of June 26, 2018, we had 23,037,615 shares of common stock outstanding and approximately 4,500 stockholders of record. On the same date, two stockholders held all 500,000 outstanding restricted shares of our Series A Preferred Stock, which shares are convertible into 750,000 shares of common stock; two stockholders held 1,160,240 outstanding shares of our Series B 10% Convertible Preferred Stock, which shares are convertible into 1,160,240 shares of common stock; and one stockholder held all 2,318,012 outstanding shares of our Series C Preferred stock, which shares are convertible into 2,318,012 shares of common stock.

Dividend Policy

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

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.

Securities Issued for Professional Services

Between March 2018 and May 2018, we granted an aggregate of 130,000 unregistered shares of our common stock to two accredited investors and an investment banking firm as full or partial compensation for financial advisory and investor relations services. The shares of common stock were issued in private placement transactions exempt from registration under the Securities Act, in reliance on Section 4(2) thereof and Rule 506 of Regulation D thereunder.

Item 6. Selected Financial Data

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

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

Cautionary Note Regarding Forward-Looking Statements

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

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

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

Business Overview

We are a clinical-stage biopharmaceutical company focused on developing new generation medicines for depression and other diseases and disorders of the central nervous system (CNS) with high unmet need.

Our lead CNS product candidate, AV-101, is an oral, non-opioid and non-sedating therapy that we believe offers the potential to be a new at-home treatment for multiple CNS indications with high unmet medical need. These indications include potential use as a new generation treatment alternative for Major Depressive Disorder (MDD), as a non-addictive, non-sedating option for management of chronic neuropathic pain (CNP), to reduce dyskinesia induced by levodopa therapy for Parkinson's disease (PD LID), and additional CNS indications where modulation of NMDA (N-methyl-D-aspartate) receptor and AMPA (alpha-amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid) receptor pathways may achieve therapeutic benefit.

For MDD, we believe AV-101 has potential as a first line oral monotherapy and as an adjunctive oral therapy. As an adjunctive therapy, we believe AV-101 has potential both to displace atypical antipsychotics such as aripiprazole in the current MDD drug treatment paradigm both for patients with an inadequate response to current antidepressants approved by the U.S. Food and Drug Administration (FDA) and to prevent relapse of MDD following successful treatment with the FDA-approved anesthetic, ketamine hydrochloride, an ion-channel blocking NDMA receptor antagonist (ketamine), whether administered by intravenous (IV) injection or as an intranasal spray formulation. We believe AV-101 may have potential to deliver ketamine-like antidepressant effects on an at-home basis, without the requirement for inconvenient administration in a medical setting, and without causing psychological or other side effects and safety concerns associated with ketamine therapy.

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AV-101 is in Phase 2 development in the United States. In the fourth quarter of 2017, we received authorization from the FDA to initiate ELEVATE, our Phase 2 multi-center, multi-dose, double blind, placebo-controlled clinical study to evaluate the efficacy and safety of AV-101 as an adjunctive treatment of MDD in adult patients with an inadequate therapeutic response to current FDA-approved antidepressants (the ELEVATE Study). As planned, we initiated the ELEVATE Study in the first quarter of 2018. Dr. Maurizio Fava, Professor of Psychiatry at Harvard Medical School and Director, Division of Clinical Research, Massachusetts General Hospital (MGH) Research Institute, is the Principal Investigator of the ELEVATE Study assisting our internal team, which is led by Mark Smith, MD, PhD, our Chief Medical Officer. Dr. Fava was the co-Principal Investigator with Dr. A. John Rush of the STAR*D study, the largest clinical trial conducted in depression to date, whose findings were published in journals such as the New England Journal of Medicine (NEJM) and the Journal of the American Medical Association (JAMA). We currently anticipate top line results from the ELEVATE Study in the first half of 2019.

AV-101 is also in the subject of a small Phase 2 clinical study being conducted and funded by the U.S. National Institute of Mental Health (the NIMH), pursuant to our Cooperative Research and Development Agreement (CRADA) with the NIMH (the NIMH Study). Dr. Carlos Zarate, Jr., Chief of the NIMH's Experimental Therapeutics & Pathophysiology Branch and its Section on Neurobiology and Treatment of Mood and Anxiety Disorders, is acting as the Principal Investigator for the NIMH Study, which is focused on AV-101 monotherapy for subjects with treatment-resistant MDD and certain biomarkers. Dr. Zarate and the NIMH were among the first in the U.S. to conduct clinical studies demonstrating the robust, fast-acting antidepressant effects of ketamine in MDD patients with inadequate responses to multiple current FDA-approved antidepressants.

In addition to our CNS business, we have two additional programs through our wholly-owned subsidiary VistaStem Therapeutics (VistaStem). VistaStem is focused on applying human pluripotent stem cell (hPSC) technology to rescue, develop and commercialize (i) proprietary new chemical entities (NCEs) for CNS and other diseases and (ii) regenerative medicine (RM) involving hPSC-derived blood, cartilage, heart and liver cells. Our internal drug rescue programs are designed to utilize CardioSafe 3D, our customized cardiac bioassay system, to develop small molecule NCEs for our pipeline or out-licensing. To advance potential RM applications of VistaStem's cardiac stem cell technology, we have exclusively sublicensed to BlueRock Therapeutics LP, a next generation cell therapy and RM company established in 2016 with $225 million of committed capital from Bayer AG and Versant Ventures (BlueRock Therapeutics), rights to certain proprietary technologies relating to the production of cardiac stem cells for the treatment of heart disease (the BlueRock Agreement). In a manner similar to the BlueRock Agreement, we may pursue additional VistaStem collaborations or licensing transactions involving blood, cartilage, and/or liver cells derived from hPSCs for cell-based therapy, cell repair therapy, RM and/or tissue engineering.

Critical Accounting Policies and Estimates

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

Revenue Recognition

We have historically generated revenue principally from collaborative research and development arrangements, licensing and technology access fees and government grants. Through March 31, 2018, we have recognized 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 or counterparty. 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.

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

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

Technology license agreements typically consist of non-refundable upfront license fees, annual minimum access fees and/or royalty payments. Non-refundable upfront license fees and annual minimum payments received with separable stand-alone values are recognized when the technology is transferred or accessed, provided that the technology transferred or accessed is not dependent on the outcome of the continuing research and development efforts. Otherwise, revenue is recognized over the period of our continuing involvement.

Government grant awards, which support our research efforts on specific projects, generally provide for reimbursement of approved costs as defined in the terms of grant awards. We recognize grant revenue when associated project costs are incurred.

As described more completely in Note 3, Summary of Significant Accounting Policies, to the accompanying Consolidated Financial Statements contained in Item 8 of this Annual Report, the Financial Accounting Standards Board (the FASB) has issued new guidance regarding revenue recognition. This new guidance becomes effective for our fiscal year beginning April 1, 2018, and we will adopt it using the modified retrospective transition method, applying the new guidance to the most current period presented. We currently have only the BlueRock Agreement as a potential revenue generating arrangement. Upon adoption of the new guidance, we anticipate no change to the units of accounting previously identified with respect to the BlueRock Agreement under legacy GAAP, which are now considered performance obligations under the new guidance, and there was no change to the revenue recognition pattern for the performance obligation. Accordingly, we do not expect the adoption of the new standard to have a material impact on our consolidated financial statements or result in a cumulative effect change to our opening accumulated deficit balance.

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, including stock-based compensation expense, of scientific personnel and direct project costs. External research and development expenses consist primarily of costs associated with clinical and non-clinical development of AV-101, our oral NMDAR GlyB antagonist product candidate in clinical development for MDD and potentially for other CNS indications, stem cell research and development costs, and costs related to the application and prosecution of patents related to AV-101 and our stem cell technology platform. All such costs are charged to expense as incurred. We also record accruals for estimated ongoing clinical trial costs. Clinical trial costs represent costs incurred by contract research organizations (CROs) and clinical trial sites. Progress payments are generally made to CROs, clinical sites, investigators and other professional service providers. We analyze the progress of the clinical trial, including levels of subject enrollment, invoices received and contracted costs when evaluating the adequacy of accrued liabilities. Significant judgments and estimates must be made and used in determining the clinical trial accrual in any reporting period. Actual results could differ from those estimates under different assumptions. Revisions are charged to research and development expense in the period in which the facts that give rise to the revision become known.

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Stock-Based Compensation

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

We use the Black-Scholes option pricing model to estimate the fair value of stock-based awards as of the grant date. The Black-Scholes model is complex and dependent upon key data input estimates. The primary data inputs with the greatest degree of judgment are the expected term of the stock options and the estimated volatility of our stock price. The Black-Scholes model is highly sensitive to changes in these two inputs. The expected term of the options represents the period of time that options granted are expected to be outstanding. We use the simplified method in accordance with guidance provided by the Securities and Exchange Commission (SEC) 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.

Warrants Issued in Connection with Equity Financing

We generally account for warrants issued in connection with equity financings as a component of equity, unless there is a deemed possibility that we may have to settle the warrants in cash or the warrants contain other features requiring them to be treated as liabilities. For warrants issued with the possibility of cash settlement or otherwise requiring liability treatment, we record the fair value of the issued warrants as a liability at each reporting period and record changes in the estimated fair value as noncash gain or loss in the Consolidated Statements of Operations and Comprehensive Loss.

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.

Financial Operations Overview and Results of Operations

Net Loss

We have not yet achieved recurring revenue-generating status from any of our product candidates or technologies. Since inception, we have devoted substantially all of our time and efforts to developing our lead CNS product candidate, AV-101, from early nonclinical studies to our ongoing Phase 2 clinical development program in MDD, as well as stem cell technology research and development, bioassay development, small molecule drug development, and creating, protecting and patenting intellectual property (IP) related to our product candidates and technologies, with the corollary initiatives of recruiting and retaining personnel and raising working capital. As of March 31, 2018, we had an accumulated deficit of approximately $156.5 million. Our net loss for the fiscal years ended March 31, 2018 and 2017 was approximately $14.3 million and $10.3 million, respectively. We expect losses to continue for the foreseeable future, primarily as a result of our ELEVATE Study and further clinical development of AV-101 for the adjunctive treatment of MDD, as well as a range of other CNS indications.

Summary of Our Fiscal Year Ended March 31, 2018

During the fiscal year ended March 31, 2018 (Fiscal 2018), we have continued to (i) advance nonclinical, including manufacturing, and clinical development of AV-101 as a potential new generation antidepressant and as a potential new therapeutic alternative for several other CNS indications with significant unmet medical need, (ii) expand our regulatory and IP foundation to support broad clinical development and, ultimately, commercialization of AV-101 in the U.S. and major foreign markets, and (iii) on a limited basis, advance the predictive toxicology capabilities of CardioSafe 3D for small molecule NCE drug rescue and development applications and collaborative cell therapy and/or RM opportunities related to our stem cell technology platform.

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Pursuant to our CRADA with the NIMH, the NIMH continues to fund, and Dr. Carlos Zarate Jr. of the NIMH continues to conduct, the NIMH Study at no cost to us other than supplying clinical trial material.

In the fourth quarter of Fiscal 2018, we launched our ELEVATE Study. During our preparations for the launch of the ELEVATE Study, we pursued initiatives that significantly improved the efficiency of our AV-101 manufacturing processes and supplied sufficient quantities of AV-101 to enable comprehensive initiation of the ELEVATE Study.

Additionally, during Fiscal 2018, we continued to pursue initiatives to secure a broad portfolio of patent protection for AV-101, covering multiple CNS indications, unit dose formulations and chemical synthesis methods. During Fiscal 2018 and subsequently, we filed and have pursued several patent applications in the U.S., Europe, Japan and other selected countries and regions. Several of these patent applications were allowed or have been granted, including for (i) certain novel therapeutic methods for the use of AV-101, including treatment of depression (U. S. and Europe), (ii) certain unit dose formulations of AV-101 (U.S. and Europe) and (iii) treatment of levodopa-induced dyskinesia (Europe). Other patent applications have been allowed or granted for the chemical synthesis of AV-101 (U.S., Europe and Japan). We have also recently filed a new U.S. provisional patent application for the AV-101 patent portfolio. Based on our patent issuances or allowances to-date, we believe that counterpart patent applications related to AV-101 currently under review in other countries are likely to be granted, although there can be no assurance that all pending applications will ultimately be granted.

We have obtained and are pursuing patent rights to the production of several types of stem cells, including cardiomyocytes, hematopoietic cells, chondrocytes, cartilage cells and hepatocytes, as well as the use of certain cell types that have been differentiated from pluripotent stem cells for therapeutic purposes, including cell-based therapy and regenerative medicine. For example, the U.S. Patent and Trademark Office (USPTO) granted a patent during Fiscal 2018 related to methods for producing, from human pluripotent stem cells (hPSCs), hematopoietic precursor stem cells, which are stem cells that give rise to all of the blood cells and most of the bone marrow cells in the body. A related patent application was allowed in Japan and we expect this patent to be granted by the Japanese Patent Office later this year. VistaGen holds an exclusive license to this patent from the University Health Network (UHN). The technology covered by the patent has the potential to impact both direct and supportive therapy for autoimmune disorders and cancer, with CAR-T cell applications, and foundational technology which may provide approaches for producing bone marrow stem cells for bone marrow transfusions.

We were granted a U.S. patent in 2018 related to methods of producing pluripotent stem cell-derived chondrocytes, chondrocyte lineage cells, cartilage-like tissue and cartilage. Additionally, the USPTO allowed claims to the therapeutic administration of these cells and tissues to treat osteoarthritis and joint injuries affecting cartilage. VistaGen also holds an exclusive license to this patent from UHN.

In December 2017, we completed an underwritten public offering of shares of our common stock and warrants to purchase shares of our common stock at a combined public offering price of $1.50 per share and related warrant, resulting in gross proceeds of $15.0 million (the December 2017 Public Offering). We issued an aggregate of 10,000,000 shares of our common stock and warrants to purchase up to 10,000,000 shares of our common stock at an exercise price of $1.50 per share (the December 2017 Offering Warrants). The December 2017 Offering Warrants are exercisable at any time through December 13, 2022, and do not contain any cashless exercise features as long as our Registration Statement on Form S-1 (Registration No. 333-221009) (the S-1) is effective. We received net proceeds of approximately $13.6 million from the December 2017 Public Offering, after deducting underwriter’s commission and other expenses related to the offering. The common stock and the shares of common stock underlying the December 2017 Offering Warrants issued in the December 2017 Public Offering were offered, issued and sold pursuant to the S-1.

In September 2017, we completed an underwritten public offering, pursuant to which we sold 1,371,430 shares of our common stock and Series A1 Warrants to purchase up to 1,388,931 shares of common stock and Series A2 Warrants to purchase up to 503,641 shares of common stock (collectively, the Warrants), each initially exercisable for $1.82 per share to two of our existing institutional investors, resulting in net proceeds of approximately $2.0 million (the September 2017 Public Offering). The Series A1 Warrants became exercisable for a five-year period commencing on March 7, 2018, and the Series A2 Warrants were exercisable at any time through September 6, 2022. The common stock and the shares of common stock underlying the Warrants issued in the September 2017 Public Offering were sold pursuant to our effective Registration Statement on Form S-3 (Registration No. 333-215671) to cover this and potential future sales of our equity securities in one or more public offerings from time to time. Consistent with the anti-dilution protection provisions of the Series A2 Warrants, the exercise price of such warrants was reduced upon the closing of the December 2017 Public Offering. In December 2017 and January 2018, all of the Series A2 Warrants were exercised at the reset exercise price resulting from the December 2017 Public Offering and we received nominal cash proceeds. Following these exercises, none of our outstanding warrants have down round anti-dilution protection features, except as is customary with respect to a change in our capital structure in the event of a stock split or dividend.

During Fiscal 2018, we also entered into self-placed private placement transactions with individual accredited investors, pursuant to which we sold units consisting of an aggregate of 616,323 shares of our unregistered common stock and, after adjustments, warrants which are not exercisable until six months and one day following issuance and expire between April 30, 2021 and November 30, 2022, to purchase an aggregate of 616,323 unregistered shares of our common stock at a weighted average fixed exercise price of approximately $2.00 per share. We received aggregate cash proceeds of approximately $1.1 million in these self-placed private placement transactions.

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In July 2017, we appointed Mark Wallace, M.D., Distinguished Professor of Clinical Anesthesiology at the University of California, San Diego, to our Clinical and Regulatory Advisory Board to assist us in advancing development of AV-101 as a potential non-opioid, non-addictive, non-sedating oral treatment alternative for neuropathic pain. Dr. Wallace is an internationally recognized leader in the field of multi-modal pain management, with over 30 years of professional experience, board certifications, licensures, honors/awards, grants, articles and abstracts.

As a matter of course, we continue to minimize, to the greatest extent possible, cash commitments and expenditures for both internal and external research and development and general and administrative services. To further advance the nonclinical and clinical development of AV-101 and our stem cell technology platform, as well as support our operating activities, we continue to carefully manage our routine operating costs, including our internal employee related expenses, as well as external costs relating to regulatory consulting, contract research and development, investor relations and corporate development, legal, acquisition and protection of intellectual property, public company compliance and other professional services and internal costs.

Comparison of Fiscal Years Ended March 31, 2018 and 2017

The following table summarizes the results of our operations for the fiscal years ended March 31, 2018 and 2017 (amounts in thousands).

	Fiscal Year Ended March 31,	
	2018	2017
Sublicense revenue	$-	$1,250
Operating expenses:		
Research and development	7,763	5,204
General and administrative	6,437	6,295
Total operating expenses	14,200	11,499
Loss from operations	(14,200)	(10,249)
Interest expense (net)	(9)	(5)
Loss on extinguishment of accounts payable	(135)	-
Loss before income taxes	(14,344)	(10,254)
Income taxes	(2)	(2)
Net loss	(14,346)	(10,256)
Accrued dividend on Series B Preferred Stock	(1,030)	(1,257)
Deemed dividend from trigger of down round provision feature	(199)	-
Deemed dividend on Series B Preferred Stock	-	(111)

Net loss attributable to common stockholders	$(15,575)	$(11,624)

Revenue

We recognized $1.25 million in sublicense revenue pursuant to the BlueRock Agreement in the fiscal year ended March 31, 2017 (Fiscal 2017). While we may potentially receive additional payments and royalties under the BlueRock Agreement in the future, in the event certain performance-based milestones and commercial sales are achieved, we reported no revenue under the agreement in Fiscal 2018 and we presently have no recurring revenue generating arrangements with respect to AV-101 or other potential product candidates. There can be no assurance that the BlueRock Agreement will provide additional revenue to us in the near term or at all.

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Research and Development Expense

Research and development expense, including both cash and noncash components, totaled approximately $7.8 million for Fiscal 2018, an increase of approximately 49% compared to the $5.2 million reported for Fiscal 2017. Noncash expenses totaled approximately $1,595,000 and $534,000 for Fiscal 2018 and Fiscal 2017, respectively, including stock compensation, depreciation and a portion of rent expense in both periods, and a portion of AV-101 project expenses in Fiscal 2018. The increase in research and development expense in Fiscal 2018 reflects our continued focus on nonclinical and clinical development of AV-101, particularly our preparations for and fourth quarter Fiscal 2018 initiation of the ELEVATE Study. The following table indicates the primary components of research and development expense for each of the periods (amounts in thousands):

The following table indicates the primary components of research and development expense for each of the periods (amounts in thousands):

	Fiscal Years Ended March 31,	
	2018	2017
Salaries and benefits	$1,563	$1,331
Stock-based compensation	969	375
Consulting and other professional services	32	(75)
Technology licenses and royalties	433	746
Project-related research and supplies:		
AV-101	4,154	2,292
Stem cell and all other	130	185
	4,284	2,477
Rent	412	310
Depreciation	66	37
All other	3	3
Total Research and Development Expense	$7,762	$5,204

The increase in salaries and benefits reflects the hiring of our Chief Medical Officer (CMO) in June 2016, and a salary increase granted to our CMO in July 2017, as well as salary increases granted to our Chief Scientific Officer (CSO) and to the non-officer members of our scientific staff in June 2016 and June 2017, offset by the impact of a staff position terminated in April 2017. Additionally, our then-newly-hired CMO did not receive a bonus in July 2016; however, both our CMO and CSO were granted a bonus in September 2017.

Stock based compensation expense increased in the current period primarily as a result of the routine amortization of option grants made to our CSO, CMO and scientific staff in November 2016, April 2017, September 2017 and February 2018, plus the new-hire grant made to our CMO in June 2016. Grants awarded during Fiscal 2018 account for approximately $521,000 of Fiscal 2018 expense. The expense attributable to these grants is generally being

amortized over a two-year to four-year vesting period, based on the terms of the respective grants. Substantially all option grants made prior to September 2015 were fully-vested and fully-expensed prior to June 30, 2017.

Consulting services reflects fees paid or accrued for scientific, nonclinical and clinical development and regulatory advisory services rendered to us by third-parties, primarily by members of our scientific and CNS clinical and regulatory advisory boards. Fiscal 2018 expense primarily reflects payment under consulting agreements with our stem cell-related scientific advisory board members. Consulting expense in Fiscal 2017 reflected the impact of the rationalization of the agreements and accruals related to previous advisory board members.

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Technology license expense in both periods reflects both recurring annual license fees as well as legal counsel and other costs related to patent prosecution and protection pursuant to our stem cell technology license agreements or that we have elected to pursue for commercial purposes. We recognize these costs as they are invoiced to us by the licensors or counsel and they do not occur ratably throughout the year or between years. In both periods, this expense also includes legal counsel and other costs we have incurred to advance numerous pending or now-granted patent applications in the U.S. and various foreign countries with respect to AV-101 and our stem cell technology platform. Technology license-related expense for Fiscal 2017 also includes net expense of $158,000 related to the sublicense consideration paid to UHN pursuant to the BlueRock Agreement plus additional fees and expenses related to two additional stem cell technology related licenses acquired from UHN, net of amounts previously accrued in connection with our prior sponsored research agreement with UHN, as well as noncash expense of $55,000 representing the fair value of a warrant granted to intellectual property counsel as partial compensation for services.

AV-101 project expense for both periods includes costs incurred to develop more efficient and cost-effective proprietary manufacturing methods for AV-101, and to produce clinical trial material for the ELEVATE Study, and, primarily in Fiscal 2018, costs incurred for certain other nonclinical studies to facilitate further clinical development of AV-101 in MDD and potentially for other indications and to comply with applicable FDA regulations. We expect these expenses to increase significantly during fiscal 2019, as we continue to conduct and move towards completion of the ELEVATE Study. Stem cell and other project related expenses reflects costs associated with our in-house stem cell technology-related initiatives, and, to a greater extent in Fiscal 2017, our participation in the FDA’s CiPA project.

The increase in rent expense in Fiscal 2018 reflects higher commercial property rents prevalent in the South San Francisco real estate market as recognized in our November 2016 lease amendment, which extended the lease of our headquarters and laboratory facilities in South San Francisco by five years, from July 31, 2017 to July 31, 2022, and the related accounting for the extension amendment.

General and Administrative Expense

General and administrative expense, including both cash and noncash components, increased approximately 2% to $6.4 million in Fiscal 2018 from $6.3 million in Fiscal 2017. Noncash expense accounted for approximately $2.9 million and $3.1 million in Fiscal 2018 and Fiscal 2017, respectively, including, in both periods, stock compensation expense, a portion of investor relations and professional services expenses, warrant modification expense, and a portion of rent expense. The overall increase in general and administrative expenses was primarily attributable to increased salary and benefits expense and noncash stock compensation and investor relations expenses, offset by reductions in professional services and noncash warrant modification expenses. The following table indicates the primary components of general and administrative expenses, including noncash components, for each of the periods (amounts in thousands):

	Fiscal Years Ended March 31,	
	2018	2017
Salaries and benefits	$1,575	$1,206

Stock-based compensation	1,375	476
Board fees	155	140
Legal, accounting and other professional fees	785	2,093
Investor relations	1,454	1,219
Insurance	242	165
Travel expenses	131	179
Rent and utilities	279	220
Warrant modification expense	293	427
All other expenses	148	170
	$6,437	$6,295

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The increase in salaries and benefits reflects the impact of the hiring of our VP-Corporate Development in September 2016 and salary increases granted in June 2016 and July 2017 to our Chief Executive Officer (CEO) and Chief Financial Officer (CFO), and in June 2016 and June 2017 to a non-officer member of our administrative staff. Additionally, each of our administrative officers was granted a bonus in September 2017, but our VP-Corporate Development had not yet joined the Company in July 2016, when our CEO and CFO received a bonus payment.

Stock based compensation expense increased in 2017 primarily as a result of the routine amortization of option grants to independent members of our Board of Directors and our CEO, CFO, VP-Corporate Development and administrative staff in November 2016, April 2017, September 2017 and February 2018, plus the new-hire grant made to our VP-Corporate Development in September 2016. Grants awarded during Fiscal 2018 account for approximately $884,000 of Fiscal 2018 expense. The expense attributable to these grants is generally being amortized over a two-year to four-year vesting period based on the terms of the respective grants. Substantially all option grants made prior to September 2015 were fully-vested and fully-expensed prior to June 30, 2017.

Board fees includes fees recognized for the services of independent members of our Board. The Board modified its committee assignments effective in April 2017, resulting in the modest increase in expense.

Legal, accounting and other professional fees for both Fiscal 208 and Fiscal 2017 includes expense related to routine corporate legal services, the accounting expense related to the annual audit of the prior year’s financial statements, tax return preparation and the review of the financial statements for the first three quarters of each fiscal year, and various financial advisory and corporate development services. In addition to cash fees incurred, during the second quarter of Fiscal 2018, we granted an aggregate of 20,000 unregistered shares of our common stock having an aggregate grant date fair value of $30,800 to legal services providers as partial compensation for services and an aggregate of 150,000 unregistered shares of our common stock having an aggregate grant date fair value of $234,000 to two investment banking firms pursuant to financial advisory agreements. Noncash expense recognized during Fiscal 2017 includes (i) $337,500 recognized in the first quarter pursuant to the June 30, 2015 grant of an aggregate of 90,000 shares of our Series B 10% convertible preferred stock having an aggregate grant date fair value of $1,350,000 as compensation for financial advisory and corporate development service contracts with two independent providers for services to be performed through June 30, 2016; (ii) $108,500 recognized in the second quarter representing the grant date fair value of 25,000 unregistered shares of our common stock granted to a legal services provider as compensation for services; and (iii) an aggregate of $1,058,800 recognized in the third and fourth quarters of Fiscal 2017 representing the grant date fair value of 320,000 unregistered shares of our common stock granted as compensation for financial advisory, investment banking and business development services.

Investor relations expense includes the fees of our various external service providers for a broad spectrum of investor relations, market awareness and strategic advisory and support functions, as well as initiatives that included numerous meetings in multiple U.S. markets and other communication activities focused on expanding market awareness of the Company, including among registered investment professionals and investment advisors, and individual and institutional investors. During Fiscal 2018, in addition to cash fees and expenses we incurred, we granted an aggregate of 582,000 shares of our unregistered common stock to various corporate development, investor relations, market awareness and business advisory service providers as full or partial compensation for their services and recognized noncash expense totaling $886,300, representing the grant date fair value of the stock issued. During Fiscal 2017, in addition to cash fees and expenses we incurred, we granted an aggregate of 160,000 unregistered shares of our common stock to six investor relations and market awareness service providers as full or partial compensation for their services and recognized non-cash expense of $472,800, representing the grant date fair value of the stock. We also granted three-year, immediately exercisable warrants to purchase an aggregate of 75,000 shares of our unregistered common stock at exercise prices ranging from $4.50 per share to $6.00 per share to three investor relations service providers and recognized non-cash expense of $172,300 representing the grant date fair value of the

warrants.

In both fiscal years, travel expense reflects costs associated with management presentations to and meetings in multiple U.S. markets with existing and potential individual and institutional investors, investment professionals and advisors, media, and securities analysts, as well as various investor relations, market awareness and corporate development initiatives.

The increase in rent expense in Fiscal 2018 reflects higher commercial property rents prevalent in the South San Francisco real estate market as recognized in our November 2016 lease amendment, which extended the lease of our headquarters and laboratory facilities in South San Francisco by five years, from July 31, 2017 to July 31, 2022, and the related accounting for the extension amendment.

In the second quarter of Fiscal 2018, we reduced the exercise price of 247,500 warrants issued in the Spring 2017 Private Placement from a weighted average exercise price of $3.99 per share to $2.00 per share. We also issued to each of the Spring 2017 Private Placement investors additional warrants to purchase an aggregate total of 247,501 shares of common stock, each additional warrant having an exercise price of $2.00 per share. We recognized noncash expense of $279,700 in the second quarter of Fiscal 2018, representing the increase in fair value of the initially-granted warrants before and after the modification plus the fair value of the additional warrants granted. In the third quarter of Fiscal 2018, we modified outstanding warrants issued in private placement transactions between August 2017 and November 2017 to purchase an aggregate of 178,572 shares of our common stock to reduce the exercise prices from a weighted average of $2.32 per share to a weighted average of $1.58 per share. We recognized the increase in the fair value of the warrants, $13,000, as noncash warrant modification expense in the third quarter of Fiscal 2018. Between April 2016 and December 2016, we entered into warrant exchange agreements with certain warrant holders pursuant to which the warrant holders exchanged outstanding warrants to purchase an aggregate of 224,513 shares of our common stock for an aggregate of 156,246 shares of our unregistered common stock. We accounted for these transactions as warrant modifications, resulting in our recognition of an aggregate of $350,700 in noncash expense attributable to the increase in fair value related to the warrant exchanges during the first through third quarters of Fiscal 2017. Additionally, in the third quarter of Fiscal 2017, we modified an outstanding warrant to reduce the exercise price from $8.00 per share to $3.51 per share and increase the number of shares exercisable under the warrant from 25,000 shares to 50,000 shares, recognizing $76,900 in expense in the third quarter as the incremental fair value attributable to the modification.

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Interest and Other Expenses, Net

Interest expense totaled $8,900 for Fiscal 2018 compared to $4,600 for Fiscal 2017. Interest expense in both periods relates to interest paid on insurance premium financing and on a capital lease of office equipment.

During the third quarter of Fiscal 2018, we issued 500,000 unregistered shares of our common stock having a grant date fair value of $585,000 and a cash payment of $76,500 to a contract manufacturing organization in settlement of $526,500 of open accounts payable. We recognized a corresponding loss on settlement of accounts payable in the amount of $135,000 for the quarter.

We recognized $1,030,400, and $1,257,000 in Fiscal 2018 and Fiscal 2017, respectively, representing the 10% cumulative noncash dividend payable on our Series B Preferred as an additional deduction in arriving at net loss attributable to common stockholders in the Consolidated Statement of Operations and Comprehensive Loss included in Item 8 of this Annual Report. The reduction in the dividend accrual results from the automatic conversion of an aggregate of 2,403,051 shares of Series B Preferred into an equal number of shares of our common stock upon our completion of our May 2016 public offering of units consisting of common stock and warrants, and a subsequent voluntary conversion of 87,500 shares of our Series B Preferred in August 2016. There have been no conversions of outstanding shares of Series B Preferred into common shares since August 2016.

Our sale of units consisting of common stock and warrants in the December 2017 Public Offering at an offering price of $1.50 per unit triggered the anti-dilution protection provisions of the Series A2 Warrants to purchase an aggregate of 503,641 shares of our common stock issued in the September 2017 Public Offering. In accordance with the anti-dilution terms and formula contained in the Series A2 warrants, the exercise price of the Series A2 Warrants was reduced from the initial exercise price of $1.82 per share to $0.001 per share. We recognized the effect of triggering the down round feature, $199,200, as a further addition to net loss attributable to common stockholders and in our calculation of basic and fully diluted earnings per share in our Consolidated Statement of Operations and Comprehensive Loss and as a dividend in our Consolidated Statement of Stockholders' Equity included in Item 8 of this Annual Report. The holders of the Series A2 Warrants subsequently exercised them in the third and fourth quarters of Fiscal 2018 and we received minimal cash proceeds from the exercises. Following the exercise of the Series A2 Warrants, none of our outstanding warrants contain antidilution protection provisions other than is customary in the event of a change in our capital structure as a result of a stock split or dividend.

During the first quarter of Fiscal 2017, we allocated the proceeds from our self-placed private placement sales of Series B Preferred Units to the Series B Preferred stock and the Series B Warrants based on their relative fair values on the dates of the sales. The difference between the relative fair value per share of the Series B Preferred, approximately $4.20 per share, and its Conversion Price (or stated value) of $7.00 per share represented a deemed dividend to the purchasers of the Series B Preferred Units. Accordingly, we recognized a deemed dividend in the aggregate amount of $111,100 in arriving at net loss attributable to common stockholders for Fiscal 2017 in the Consolidated Statement of Operations and Comprehensive Loss included in Item 8 of this Annual Report.

Liquidity and Capital Resources

Since our inception in May 1998 through March 31, 2018, 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 $61.4 million, as well as from an aggregate of approximately $17.6 million of government research grant awards (excluding the fair market value of the NIMH Study), strategic collaboration payments, intellectual property sublicensing and other revenues. Additionally, we have issued equity securities with an approximate value at issuance of $33.6 million in non-cash settlements of certain

liabilities, including liabilities for professional services rendered to us or as compensation for such services.

In December 2017, we completed the December 2017 Public Offering pursuant to which sold shares of our common stock and warrants to purchase shares of our common stock at a combined public offering price of $1.50 per share and related warrant under our Registration Statement on Form S-1 (Registration No. 333-221009), resulting in gross proceeds of $15.0 million. In September 2017, we completed the September 2017 Public Offering pursuant to which we sold shares of our common stock and warrants resulting in gross proceeds of approximately $2.4 million under our Registration Statement on Form S-3 (Registration No. 333-215671). Subject to certain restrictions, the S-3 Registration Statement remains available for future sales of our equity securities in one or more public offerings from time to time. While we may make additional sales of our equity securities under the S-3 Registration Statement, we do not have an obligation to do so. As we have been in the past, we expect that, when and as necessary, we will be successful in raising additional capital from the sale of our equity securities either in one or more public offerings or in one or more private placement transactions with individual accredited investors or institutions.

At March 31, 2018, we had a cash and cash equivalents balance of $10.4 million. This amount was not sufficient to enable us to fund our planned operations, including expected cash expenditures of approximately $13 million for the twelve months following the date of this Annual Report, including expenditures required to satisfy a significant portion of the projected expenses associated with our ELEVATE Study.

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Our cash position at March 31, 2018 considered with our recurring and anticipated losses, negative cash flows from operations and limited stockholders' equity make it probable, in the absence of additional financing, that we will not be able to meet our obligations as they come due within one year from the date of this Report, raising substantial doubt that we can continue as a going concern. However, to alleviate that doubt, we plan, as we have numerous times in the past, to raise additional financing when and as needed, primarily through the sale of our equity securities in one or more private placements to accredited investors or public offerings.

In addition to the potential sale of our equity securities, we may also seek to enter research and development collaborations that could generate revenue and/or provide funding for development of AV-101 and additional product candidates. We may also seek additional government grant awards or agreements similar to our current CRADA with the NIMH, which provides for the NIMH to fully fund the NIMH Study. Such strategic collaborations may provide non-dilutive resources to advance our strategic initiatives while reducing a portion of our future cash outlays and working capital requirements. In a manner similar to the BlueRock Agreement, we may also pursue similar arrangements with third-parties covering other of our intellectual property. Although we may seek additional collaborations that could generate revenue and/or non-dilutive funding for development of AV-101 and other product candidates, as well as new government grant awards and/or agreements similar to our CRADA with NIMH, no assurance can be provided that any such collaborations, awards or agreements will occur in the future.

Our future working capital requirements will depend on many factors, including, without limitation, the scope and nature of opportunities related to our success and the success of certain other companies in clinical trials, including our development and commercialization of AV-101 as an adjunctive treatment for MDD and other potential CNS conditions, and various applications of our stem cell technology platform, the availability of, and our ability to obtain, government grant awards and agreements, and our ability to enter into collaborations on terms acceptable to us. To further advance the clinical development of AV-101 and our stem cell technology platform, as well as support our operating activities, we plan to continue to carefully manage our routine operating costs, including our employee headcount and related expenses, as well as costs relating to regulatory consulting, contract research and development, investor relations and corporate development, legal, acquisition and protection of intellectual property, public company compliance and other professional services and operating costs.

Notwithstanding the foregoing, there can be no assurance that future financing will be available in sufficient amounts, in a timely manner, or on terms acceptable to us, if at all. If we are unable to obtain substantial additional financing on a timely basis when needed in 2018 or 2019 and beyond, our business, financial condition, and results of operations may be harmed, the price of our stock may decline, we may be required to reduce, defer, or discontinue certain of our research and development activities and we may not be able to continue as a going concern. As noted above, these Consolidated Financial Statements do not include any adjustments that might result from the negative outcome of this uncertainty.

Cash and Cash Equivalents

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

	Fiscal Years Ended March 31,	
	2018	2017

Net cash used in operating activities	$(9,058)	$(7,262)
Net cash used in investing activities	(2)	(239)
Net cash provided by financing activities	16,517	9,994
Net increase in cash and cash equivalents	7,457	2,493
Cash and cash equivalents at beginning of period	2,921	428
Cash and cash equivalents at end of period	$10,378	$2,921

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Off-Balance Sheet Arrangements

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

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

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

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Item 8. Financial Statements and Supplementary Data

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Stockholders and Board of Directors
VistaGen Therapeutics, Inc.
South San Francisco, California

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of VistaGen Therapeutics, Inc. as of March 31, 2018 and 2017, the related consolidated statements of operations and comprehensive loss, cash flows, and stockholders' equity (deficit) for each of the two fiscal years in the period ended March 31, 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at March 31, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended March 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

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

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting 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.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ OUM & CO. LLP

San Francisco, California
June 26, 2018
We have served as the Company's auditor since 2006.

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VISTAGEN THERAPEUTICS, INC.

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

	March 31, 2018	March 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$10,378,300	$2,921,300
Prepaid expenses and other current assets	644,800	456,600
Total current assets	11,023,100	3,377,900
Property and equipment, net	207,400	286,500
Security deposits and other assets	47,800	47,800
Total assets	$11,278,300	$3,712,200
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$1,195,700	$867,300
Accrued expenses	206,300	443,000
Current notes payable	53,900	54,800
Capital lease obligations	2,600	2,400
Total current liabilities	1,458,500	1,367,500
Non-current liabilities:		
Accrued dividends on Series B Preferred Stock	2,608,300	1,577,800
Deferred rent liability	285,600	139,200
Capital lease obligations	9,300	11,900
Total non-current liabilities	2,903,200	1,728,900
Total liabilities	4,361,700	3,096,400
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at March 31, 2018 and 2017:		
Series A Preferred, 500,000 shares authorized, issued and outstanding at March 31, 2018 and 2017	500	500

Series B Preferred; 4,000,000 shares authorized at March 31, 2018 and 2017; 1,160,240 shares issued and outstanding at March 31, 2018 and 2017	1,200	1,200
Series C Preferred; 3,000,000 shares authorized at March 31, 2018 and 2017; 2,318,012 shares issued and outstanding at March 31, 2018 and 2017	2,300	2,300
Common stock, $0.001 par value; 100,000,000 and 30,000,000 shares authorized at March 31, 2018 and March 31, 2017, respectively; 23,068,280 and 8,974,386 shares issued and outstanding at March 31, 2018 and March 31, 2017, respectively	23,100	9,000
Additional paid-in capital	167,401,400	146,569,600
Treasury stock, at cost, 135,665 shares of common stock held at March 31, 2018 and 2017	(3,968,100)	(3,968,100)
Accumulated deficit	(156,543,800)	(141,998,700)
Total stockholders’ equity	6,916,600	615,800
Total liabilities and stockholders’ equity	$11,278,300	$3,712,200

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,	
	2018	2017
Revenues:		
Sublicense revenue	$-	$1,250,000
Total revenues	-	1,250,000
Operating expenses:		
Research and development	7,762,500	5,203,700
General and administrative	6,437,100	6,294,800
Total operating expenses	14,199,600	11,498,500
Loss from operations	(14,199,600)	(10,248,500)
Other expenses, net:		
Interest expense, net	(8,900)	(4,600)
Loss on extinguishment of accounts payable	(135,000)	-
Loss before income taxes	(14,343,500)	(10,253,100)
Income taxes	(2,400)	(2,400)
Net loss and comprehensive loss	(14,345,900)	(10,255,500)
Accrued dividend on Series B Preferred stock	(1,030,400)	(1,257,000)
Deemed dividend from trigger of down round provision feature	(199,200)	-
Deemed dividend on Series B Preferred Units	-	(111,100)
Net loss attributable to common stockholders	$(15,575,500)	$(11,623,600)
Basic and diluted net loss attributable to common stockholders per common share	$(1.12)	$(1.54)
Weighted average shares used in computing basic and diluted net loss attributable to common stockholders per common share	13,890,041	7,531,642

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,	
	2018	2017
Cash flows from operating activities:		
Net loss	$(14,345,900)	$(10,255,500)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	80,700	54,900
Stock-based compensation	2,344,200	851,300
Expense related to modification of warrants, including exchange of warrants for common stock	292,700	427,500
Amortization of deferred rent	146,300	83,700
Fair value of common stock granted for services	1,615,800	1,640,100
Fair value of Series B Preferred stock granted for services	-	375,000
Fair value of warrants granted for services	-	240,300
Loss on extinguishment of accounts payable	135,000	-
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	131,200	(227,700)
Accounts payable and accrued expenses, including accrued interest	541,700	(451,700)
Net cash used in operating activities	(9,058,300)	(7,262,100)
Cash flows from property and investing activities:		
Purchases of equipment	(1,600)	(239,100)
Net cash used in investing activities	(1,600)	(239,100)
Cash flows from financing activities:		
Net proceeds from issuance of common stock and warrants, including Units	16,722,300	9,899,500
Net proceeds from issuance of Series B Preferred Units	-	278,000
Repayment of capital lease obligations	(2,400)	(1,300)
Repayment of notes payable	(203,000)	(182,200)
Net cash provided by financing activities	16,516,900	9,994,000
Net increase in cash and cash equivalents	7,457,000	2,492,800
Cash and cash equivalents at beginning of period	2,921,300	428,500
Cash and cash equivalents at end of period	$10,378,300	$2,921,300
Supplemental disclosure of cash flow activities:		
Cash paid for interest	$8,900	$16,600
Cash paid for income taxes	$2,400	$2,400

Supplemental disclosure of noncash activities:		
Insurance premiums settled by issuing note payable	$202,100	$178,200
Accrued dividends on Series B Preferred	$1,030,400	$1,257,000
Accrued dividends on Series B Preferred settled upon conversion by issuance of common stock	$-	$1,768,800
Deemed dividend from trigger of down round provision feature	$199,200	$-
Acquisition of equipment under capital lease	$-	$14,700

See accompanying notes to consolidated financial statements.

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VISTAGEN THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

Fiscal Years Ended March 31, 2017 and 2018
(Amounts in dollars, except share amounts)

	Series A Preferred Stock		Series B Preferred Stock		Series C Preferred Stock		Common Stock		Additional Paid-in	Treasu
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Stock
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	$(3,96
Proceeds from sale of Series B Preferred Units for cash under Series B Preferred Unit Private Placement	-	-	39,714	-	-	-	-	-	278,000	-
Proceeds from sale of common stock and warrants for cash in May 2016 Public Offering	-	-	-	-	-	-	2,570,040	2,600	9,534,500	-
Proceeds from sale of common stock and warrants for cash in private placement offerings	-	-	-	-	-	-	124,250	100	362,300	-
Series B Preferred converted to	-	-	(2,542,551)	(2,500)	-	-	2,542,551	2,500	-	-

common stock automatically upon consummation of May 2016 Public Offering and voluntarily										
Common stock issued for dividends upon conversion of Series B Preferred	-	-	-	-	-	-	453,154	500	1,768,300	-
Accrued dividends on Series B Preferred stock	-	-	-	-	-	-	-	-	(1,257,000)	-
Share-based compensation expense	-	-	-	-	-	-			851,300	-
Exchange of outstanding warrants for common stock and other warrant modifications	-	-	-	-	-	-	156,246	200	427,300	-
Fair value of common stock and warrants granted for services	-	-	-	-	-	-	505,000	500	1,879,900	-
Net loss for fiscal year ended March 31, 2017	-	-	-	-	-	-	-	-	-	-
Balances at March 31, 2017	500,000	$500	1,160,240	$1,200	2,318,012	$2,300	8,974,386	$9,000	$146,569,600	$(3,96
Proceeds from sale of common stock and warrants for cash in September 2017 Public Offering, net of underwriting	-	-	-	-	-	-	1,371,430	1,400	2,023,000	-

discount and expenses										
Proceeds from sale of common stock and warrants for cash in December 2017 Public Offering, net of underwriting discount and expenses	-	-	-	-	-	-	10,000,000	10,000	13,614,000	-
Proceeds from sale of common stock and warrants for cash in private placement offerings	-	-	-	-	-	-	616,323	600	1,072,600	-
Proceeds from exercise of warrants	-	-	-	-	-	-	503,641	500	-	-
Accrued dividends on Series B Preferred stock	-	-	-	-	-	-	-	-	(1,030,400)	-
Stock-based compensation expense	-	-	-	-	-	-	-	-	2,344,100	-
Fair value of common stock granted for services	-	-	-	-	-	-	1,102,500	1,100	1,732,100	-
Fair value of common stock granted in settlement of accounts payable	-	-	-	-	-	-	500,000	500	584,500	-
Increase in fair value attributable to warrant modifications	-	-	-	-	-	-	-	-	292,700	-
Deemed dividend from trigger of down round	-	-	-	-	-	-	-	-	199,200	-

provision feature										
Net loss for the fiscal year ended March 31, 2018	-	-	-	-	-	-	-	-	-	-
Balances at March 31, 2018	500,000	$500	1,160,240	$1,200	2,318,012	$2,300	23,068,280	$23,100	$167,401,400	$(3,96

See accompanying notes to consolidated financial statements.

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VISTAGEN THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Description of Business

Overview

VistaGen Therapeutics. Inc., a Nevada corporation, is a clinical-stage biopharmaceutical company focused on developing new generation medicines for depression and other diseases and disorders of the central nervous system (CNS) with high unmet need.

Our lead CNS product candidate, AV-101, is an oral, non-opioid and non-sedating therapy that we believe offers the potential to be a new at-home treatment for multiple CNS indications with high unmet medical need. These indications include potential use as a new generation treatment alternative for Major Depressive Disorder (MDD), as a non-addictive, non-sedating option for management of chronic neuropathic pain (CNP), to reduce dyskinesia induced by levodopa therapy for Parkinson's disease (PD LID), and additional CNS indications where modulation of NMDA (N-methyl-D-aspartate) receptor and AMPA (alpha-amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid) receptor pathways may achieve therapeutic benefit.

For MDD, we believe AV-101 has potential as a first line oral monotherapy and as an adjunctive oral therapy. As an adjunctive therapy, we believe AV-101 has potential both to displace atypical antipsychotics such as aripiprazole in the current MDD drug treatment paradigm both for patients with an inadequate response to current antidepressants approved by the U.S. Food and Drug Administration (FDA) and to prevent relapse of MDD following successful treatment with the FDA-approved anesthetic, ketamine hydrochloride, an ion-channel blocking NDMA receptor antagonist (ketamine), whether administered by intravenous (IV) injection or as an intranasal spray formulation. We believe AV-101 may have potential to deliver ketamine-like antidepressant effects on an at-home basis, without the requirement for inconvenient administration in a medical setting, and without causing psychological or other side effects and safety concerns associated with ketamine therapy.

AV-101 is in Phase 2 development in the United States. In the fourth quarter of 2017, we received authorization from the FDA to initiate ELEVATE, our Phase 2 multi-center, multi-dose, double blind, placebo-controlled clinical study to evaluate the efficacy and safety of AV-101 as an adjunctive treatment of MDD in adult patients with an inadequate therapeutic response to current FDA-approved antidepressants (the ELEVATE Study). As planned, we initiated the ELEVATE Study in the first quarter of 2018. Dr. Maurizio Fava, Professor of Psychiatry at Harvard Medical School and Director, Division of Clinical Research, Massachusetts General Hospital (MGH) Research Institute, is the Principal Investigator of the ELEVATE Study assisting our internal team, which is led by Mark Smith, MD, PhD, our Chief Medical Officer. Dr. Fava was the co-Principal Investigator with Dr. A. John Rush of the STAR*D study, the largest clinical trial conducted in depression to date, whose findings were published in journals such as the New England Journal of Medicine (NEJM) and the Journal of the American Medical Association (JAMA). We currently anticipate top line results from the ELEVATE Study in the first half of 2019.

AV-101 is also in the subject of a small Phase 2 clinical study being conducted and funded by the U.S. National Institute of Mental Health (the NIMH), pursuant to our Cooperative Research and Development Agreement (CRADA) with the NIMH (the NIMH Study). Dr. Carlos Zarate, Jr., Chief of the NIMH's Experimental Therapeutics & Pathophysiology Branch and its Section on Neurobiology and Treatment of Mood and Anxiety Disorders, is acting as the Principal Investigator for the NIMH Study, which is focused on AV-101 monotherapy for subjects with treatment-resistant MDD and certain biomarkers. Dr. Zarate and the NIMH were among the first in the U.S. to conduct clinical studies demonstrating the robust, fast-acting antidepressant effects of ketamine in MDD patients with inadequate responses to multiple current FDA-approved antidepressants.

In addition to our CNS business, we have two additional programs through our wholly-owned subsidiary VistaGen Therapeutics, Inc., a California corporation, dba VistaStem Therapeutics (VistaStem). VistaStem is focused on applying human pluripotent stem cell (hPSC) technology to rescue, develop and commercialize (i) proprietary new chemical entities (NCEs) for CNS and other diseases and (ii) regenerative medicine (RM) involving hPSC-derived blood, cartilage, heart and liver cells. Our internal drug rescue programs are designed to utilize CardioSafe 3D, our customized cardiac bioassay system, to develop small molecule NCEs for our pipeline or out-licensing. To advance potential RM applications of VistaStem's cardiac stem cell technology, we have exclusively sublicensed to BlueRock Therapeutics LP, a next generation cell therapy and RM company established in 2016 with $225 million of committed capital from Bayer AG and Versant Ventures (BlueRock Therapeutics), rights to certain proprietary technologies relating to the production of cardiac stem cells for the treatment of heart disease (the BlueRock Agreement). In a manner similar to the BlueRock Agreement, we may pursue additional VistaStem collaborations or licensing transactions involving blood, cartilage, and/or liver cells derived from hPSCs for cell-based therapy, cell repair therapy, RM and/or tissue engineering.

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VISTAGEN THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Subsidiaries

As noted above, VistaStem is our wholly-owned subsidiary. Our Consolidated Financial Statements in this Annual Report on Form 10-K (Report) also include the accounts of VistaStem's two wholly-owned inactive subsidiaries, Artemis Neuroscience, Inc., a Maryland corporation, and VistaStem Canada, Inc., a corporation organized under the laws of Ontario, Canada.

2. Basis of Presentation and Going Concern

The accompanying Consolidated Financial Statements have been prepared assuming that we will continue as a going concern. As a clinical-stage biopharmaceutical company having not yet developed commercial products or achieved sustainable revenues, we have experienced recurring losses and negative cash flows from operations resulting in a deficit of $156.5 million accumulated from inception through March 31, 2018. We expect losses and negative cash flows from operations to continue for the foreseeable future as we engage in further potential development of AV-101, initially as an adjunctive treatment for MDD, and subsequently as a new treatment alternative for other CNS conditions, execute our drug rescue programs, and pursue potential drug development and regenerative medicine opportunities.

Since our inception in May 1998 through March 31, 2018, 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 $61.4 million, as well as from an aggregate of approximately $17.6 million of government research grant awards (excluding the fair market value of the NIMH Study), strategic collaboration payments, intellectual property sublicensing and other revenues. Additionally, we have issued equity securities with an approximate value at issuance of $33.6 million in non-cash settlements of certain liabilities, including liabilities for professional services rendered to us or as compensation for such services.

In December 2017, we completed an underwritten public offering of shares of our common stock and warrants to purchase shares of our common stock at a combined public offering price of $1.50 per share and related warrant under our Registration Statement on Form S-1 (Registration No. 333-221009), resulting in gross proceeds of $15.0 million (the December 2017 Public Offering). In September 2017, we completed an underwritten public offering pursuant to which we offered and sold shares of our common stock and warrants resulting in gross proceeds of approximately $2.4 million (the September 2017 Public Offering) under our Registration Statement on Form S-3 (Registration No. 333-215671) (the S-3 Registration Statement). (See Note 8, Capital Stock, for additional information regarding the December 2017 Public Offering and the September 2017 Public Offering.) Subject to certain restrictions, the S-3 Registration Statement remains available for future sales of our equity securities in one or more public offerings from time to time. While we may make additional sales of our equity securities under the S-3 Registration Statement, we do not have an obligation to do so. As we have been in the past, we expect that, when and as necessary, we will be successful in raising additional capital from the sale of our equity securities either in one or more public offerings or in one or more private placement transactions with individual accredited investors or institutions.

At March 31, 2018, we had a cash and cash equivalents balance of $10.4 million. This amount was not sufficient to enable us to fund our planned operations, including expected cash expenditures of approximately $13 million for the twelve months following the issuance of these financial statements, including expenditures required to satisfy a significant portion of the projected expenses associated with our ELEVATE Study.

Our cash position at March 31, 2018 considered with our recurring and anticipated losses, negative cash flows from operations and limited stockholders' equity make it probable, in the absence of additional financing, that we will not be able to meet our obligations as they come due within one year from the date of this Report, raising substantial doubt that we can continue as a going concern. However, to alleviate that doubt, we plan, as we have numerous times in the past, to raise additional financing when and as needed, primarily through the sale of our equity securities in one or more private placements to accredited investors or public offerings.

In addition to the potential sale of our equity securities, we may also seek to enter research and development collaborations that could generate revenue or provide funding for development of AV-101 and additional product candidates. We may also seek additional government grant awards or agreements similar to our current CRADA with the NIMH, which provides for the NIMH to fully fund the NIMH Study. Such strategic collaborations may provide non-dilutive resources to advance our strategic initiatives while reducing a portion of our future cash outlays and working capital requirements. In a manner similar to the BlueRock Agreement, we may also pursue similar arrangements with third-parties covering other of our intellectual property. Although we may seek additional collaborations that could generate revenue and/or non-dilutive funding for development of AV-101 and other product candidates, as well as new government grant awards and/or agreements similar to our CRADA with NIMH, no assurance can be provided that any such collaborations, awards or agreements will occur in the future.

Our future working capital requirements will depend on many factors, including, without limitation, the scope and nature of opportunities related to our success and the success of certain other companies in clinical trials, including our development and commercialization of AV-101 as an adjunctive treatment for MDD and other potential CNS conditions, and various applications of our stem cell technology platform, the availability of, and our ability to obtain, government grant awards and agreements, and our ability to enter into collaborations on terms acceptable to us. To further advance the clinical development of AV-101 and our stem cell technology platform, as well as support our operating activities, we plan to continue to carefully manage our routine operating costs, including our employee headcount and related expenses, as well as costs relating to regulatory consulting, contract research and development, investor relations and corporate development, legal, acquisition and protection of intellectual property, public company compliance and other professional services and operating costs.

Notwithstanding the foregoing, there can be no assurance that future financing will be available in sufficient amounts, in a timely manner, or on terms acceptable to us, if at all. If we are unable to obtain substantial additional financing on a timely basis when needed in 2018 or 2019 and beyond, our business, financial condition, and results of operations may be harmed, the price of our stock may decline, we may be required to reduce, defer, or discontinue certain of our research and development activities and we may not be able to continue as a going concern. As noted above, these Consolidated Financial Statements do not include any adjustments that might result from the negative outcome of this uncertainty.

3. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles (U.S. GAAP) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates include, but are not limited to, those relating to stock-based compensation, revenue recognition, research and development expenses and the assumptions used to value warrants, warrant modifications and warrant liabilities.

Principles of Consolidation

The accompanying consolidated financial statements include the Company’s accounts, VistaStem’s accounts and the accounts of VistaStem’s two wholly-owned inactive subsidiaries, Artemis Neurosciences and VistaStem Canada. All material intercompany accounts and transactions have been eliminated in consolidation.

Cash and Cash Equivalents

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

Property and Equipment

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

useful lives of property and equipment range from three to seven years.

Impairment of Long-Lived Assets

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

Revenue Recognition

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

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

Collaborative arrangements typically consist of non-refundable and/or exclusive up front technology access fees, cost reimbursements for specific research and development spending, and future product development milestone and royalty payments. If the delivered technology does not have stand-alone value, the amount of revenue allocable to the delivered technology is deferred. Non-refundable upfront fees with stand-alone value that are not dependent on future performance under these agreements are recognized as revenue when received, and are deferred if we have continuing performance obligations and have no objective and reliable evidence of the fair value of those obligations. We recognize non-refundable upfront technology access fees under agreements in which we have a continuing performance obligation ratably, on a straight-line basis, over the period during which we are obligated to provide services. Cost reimbursements for research and development spending are recognized when the related costs are incurred and when collectability is reasonably assured. Payments received related to substantive, performance-based "at-risk" milestones are recognized as revenue upon achievement of the milestone event specified in the underlying contracts, which represent the culmination of the earnings process. Amounts received in advance are recorded as deferred revenue until the technology is transferred, costs are incurred, or a milestone is reached.

Technology license agreements typically consist of non-refundable upfront license fees, annual minimum access fees, development and/or regulatory milestone payments and/or royalty payments. Non-refundable upfront license fees and annual minimum payments received with separable stand-alone values are recognized when the technology is transferred or accessed, provided that the technology transferred or accessed is not dependent on the outcome of the continuing research and development efforts. Otherwise, revenue is recognized over the period of our continuing involvement, and, in the case of development and/or regulatory milestone payments, when the applicable event triggering such a payment has occurred.

Government grants, which support our research efforts on specific projects, generally provide for reimbursement of approved costs as defined in the terms of grant awards. Grant revenue is recognized when associated project costs are incurred.

Research and Development Expenses

Research and development expenses are composed of both internal and external costs. Internal costs include salaries and employment-related expenses, including stock-based compensation expense, of scientific personnel and direct project costs. External research and development expenses consist primarily of costs associated with clinical and non-clinical development of AV-101, our oral NMDAR GlyB antagonist product candidate in clinical development for MDD and potentially for other CNS indications, stem cell research and development costs, and costs related to the application and prosecution of patents related to AV-101 and our stem cell technology platform. All such costs are charged to expense as incurred. We also record accruals for estimated ongoing clinical trial costs. Clinical trial costs represent costs incurred by contract research organizations (CROs) and clinical trial sites. Progress payments are

generally made to CROs, clinical sites, investigators and other professional service providers. We analyze the progress of the clinical trial, including levels of subject enrollment, invoices received and contracted costs when evaluating the adequacy of accrued liabilities. Significant judgments and estimates must be made and used in determining the clinical trial accrual in any reporting period. Actual results could differ from those estimates under different assumptions. Revisions are charged to research and development expense in the period in which the facts that give rise to the revision become known.

Stock-Based Compensation

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

Income Taxes

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

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Concentrations of Credit Risk

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

Fair Value Measurements

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

Level 1 — Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2 — Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 — Unobservable inputs (i.e., inputs that reflect the reporting entity's own assumptions about the assumptions that market participants would use in estimating the fair value of an asset or liability) are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

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

We carried no assets or liabilities at fair value at March 31, 2018 or 2017.

Warrants Issued in Connection with Equity Financing

We generally account for warrants issued in connection with equity financings as a component of equity, unless there is a deemed possibility that we may have to settle the warrants in cash or the warrants contain other features requiring

them to be treated as liabilities. For warrants issued with the possibility of cash settlement, or otherwise requiring liability treatment, we record the fair value of the issued warrants as a liability at each reporting period and record changes in the estimated fair value as noncash gain or loss in the Consolidated Statements of Operations and Comprehensive Loss.

Comprehensive Loss

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

Loss per Common Share Attributable to Common Stockholders

Basic net loss attributable to common stockholders per share of common stock excludes the effect of dilution and is computed by dividing net loss increased by the accrual for dividends on our Series B Preferred and, for the fiscal year ended March 31, 2018, the deemed dividend attributable to the trigger of a down-round provision feature, and, for the fiscal year ended March 31, 2017 (refer to Note 7, Capital Stock, for a description of these adjustments), the deemed dividend attributable to the issuance of our Series B Preferred Units by the weighted-average number of shares of common stock outstanding for the period. Diluted net loss attributable to common stockholders per share of common stock reflects the potential dilution that could occur if securities or other contracts to issue shares of common stock were exercised or converted into shares of common stock. In calculating diluted net loss attributable to common stockholders per share, we have generally not increased the denominator to include the number of potentially dilutive common shares assumed to be outstanding during the period using the treasury stock method because the result is antidilutive.

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

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

	Fiscal Years Ended March 31,	
	2018	2017
Numerator:		
Net loss attributable to common stockholders for basic and diluted earnings per share	$(15,575,500)	$(11,623,600)
Denominator:		
Weighted average basic and diluted common shares outstanding	13,890,041	7,531,642
Basic and diluted net loss attributable to common stockholders per common share	$(1.12)	$(1.54)

Potentially dilutive securities excluded in determining diluted net loss per common share for the fiscal years ended March 31, 2018 and 2017 are as follows:

	As of March 31,	
	2018	2017
Series A Preferred stock issued and outstanding (1)	750,000	750,000
Series B Preferred stock issued and outstanding (2)	1,160,240	1,160,240
Series C Preferred stock issued and outstanding (3)	2,318,012	2,318,012
Outstanding options under the Amended and Restated 2016 (formerly 2008) and 1999 Stock Incentive Plans (1999 Plan in 2017 only)	5,300,338	1,659,324
Outstanding warrants to purchase common stock	16,603,516	4,577,631

Total	26,132,106	10,465,207

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

Recent Accounting Pronouncements

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

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In July 2017, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2017-11, "Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): Part I: Accounting for Certain Financial Instruments with Down Round Features; Part II: Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception" (ASU 2017-11). Part I of this ASU provides that an entity will no longer have to consider "down round" features (i.e., a provision in an equity-linked financial instrument, such as a free-standing warrant, or an embedded feature, such as a conversion option in a convertible instrument, that reduces the exercise price of such instrument if the entity subsequently sells stock for a lower price or issues an equity-linked instrument with a lower exercise price) when determining whether certain equity-linked financial instruments or embedded features are indexed to its own stock. The definition of a down round feature in ASU 2017-11 excludes standard antidilution provisions related to changes in an entity's capital structure. Accounting Standards Codification Topic 815-40, "Derivatives and Hedging–Contracts in Entity's Own Equity" (ASC 815-40) requires that a freestanding equity-linked financial instrument be indexed to the issuer's own stock to be classified as equity. An equity-linked embedded feature that meets the definition of a derivative may avoid bifurcation and derivative accounting if it is indexed to the issuer's own stock. Under the terms of prior guidance, a freestanding financial instrument or embedded feature was not considered indexed to the issuer's own stock if it had a down round provision. Consequently, the freestanding financial instrument was classified as a liability (or asset), and if it met the definition of a derivative, was measured at fair value with changes in fair value recorded through earnings. Similarly, an embedded feature was bifurcated and separately accounted for as a derivative if it met all other criteria for bifurcation under ASC 815-40. The bifurcated embedded feature was also measured at fair value through earnings. Under the provisions of ASU 2017-11, an entity that presents earnings per share (EPS) under Accounting Standards Codification Topic 260, "Earnings Per Share" will recognize the effect of a down round feature in a freestanding equity-classified financial instrument only when it is triggered. The effect of triggering such a feature will be recognized as a dividend and a reduction to income available to common shareholders in basic EPS. The new guidance requires new disclosures for financial instruments with down round features and other terms that change conversion or exercise prices. Part I of ASU 2017-11 is effective for fiscal years beginning after December 15, 2018, and interim periods therein, however early adoption is permitted. We early-adopted ASU 2017-11 effective for the quarter ended September 30, 2017 and applied its guidance to certain of the warrants issued in the September 2017 Public Offering, as described more completely in Note 7, Capital Stock. No retrospective adjustments to our financial statements were required as a result of our adoption of ASU 2017-11.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), to provide guidance on revenue recognition. In August 2015 and March, April, May and December 2016, the FASB issued additional amendments to the new revenue guidance relating to reporting revenue on a gross versus net basis, identifying performance obligations, licensing arrangements, collectability, noncash consideration, presentation of sales tax, transition, and clarifying examples. Collectively these are referred to as ASC Topic 606, which replaces all legacy GAAP guidance on revenue recognition and eliminates all industry-specific guidance. The new revenue recognition guidance provides a unified model to determine how revenue is recognized. The core principal of the guidance is that an entity should recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. ASC Topic 606 defines a five-step process to achieve this core principal which may require entities to use more judgment and make more estimates than under legacy guidance. These estimates and judgments include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each distinct performance obligation. ASC Topic 606 is effective for our fiscal year beginning April 1, 2018. We will adopt ASC Topic 606 as of April 1, 2018, using the modified retrospective transition method, applying the new guidance to the most current period presented. We

currently have only the BlueRock Agreement as a potential revenue generating arrangement. Upon adoption of ASC Topic 606, we anticipate no change to the units of accounting previously identified with respect to that contract under legacy GAAP, which are now considered performance obligations under ASC Topic 606, and there was no change to the revenue recognition pattern for the performance obligation. Accordingly, we do not expect the adoption of the new standard to result in a cumulative effect change to our opening accumulated deficit balance.

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

In March 2016, the FASB issued ASU No. 2016-09, Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting which includes multiple provisions intended to simplify several aspects of accounting for share-based payment transactions, including income tax consequences, classification of awards as either equity or liabilities, an option to recognize gross stock compensation expense with actual forfeitures recognized as they occur, as well as certain classifications on the statement of cash flows. We adopted the standard effective for our fiscal year beginning April 1, 2017. Our adoption of this ASU did not have a material impact on our consolidated financial statements.

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In May 2017, the FASB issued ASU 2017-09, Compensation - Stock Compensation (Topic 718): Scope of Modification Accounting, to clarify which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting under ASC 718. Under the new guidance, an entity will not apply modification accounting to a share-based payment award if all of the following remain unchanged immediately before and after the change of terms and conditions:

The award’s fair value (or calculated value or intrinsic value, if those measurement methods are used),

The award’s vesting conditions, and

The award’s classification as an equity or liability instrument.

ASU 2017-09 is effective for our fiscal year beginning April 1, 2018 and is to be applied prospectively to awards modified on or after the adoption date. We do not believe that our adoption of ASU 2017-09 will have a material effect on our results of operations, financial condition or cash flows.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments. The standard reduces the diversity in practice of how certain cash receipts and cash payments are presented and classified in the statement of cash flows. The guidance addresses the following eight specific cash flow issues: (1) debt prepayment or debt extinguishment costs, (2) settlement of zero-coupon debt instruments or other debt instruments with coupon interest rates that are insignificant in relation to the effective interest rate of the borrowing, (3) contingent consideration payments made after a business combination, (4) proceeds from the settlement of insurance claims, (5) proceeds from settlement of corporate-owned life insurance policies, including bank-owned life insurance policies, (6) distributions received from equity method investees, (7) beneficial interests in securitization transitions and (8) separately identifiable cash flows and application of predominance principle. The guidance is effective for our fiscal year beginning April 1, 2018 and requires retrospective adoption. We do not believe that the adoption of this guidance will have a material impact on our consolidated financial statements and related disclosures.

In November 2016, the FASB issued ASU No. 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash that changes the presentation of restricted cash and cash equivalents on the statement of cash flows. Restricted cash and restricted cash equivalents must be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. This standard is effective for our fiscal year beginning April 1, 2018. As we do not currently have restricted cash or restricted cash equivalents, we do not believe that the adoption of this ASU will have a material impact on our consolidated financial statements.

4. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	March 31,	
	2018	2017

AV-101 materials and services	$505,900	$352,800
Insurance	88,300	85,800
Public offering filing fees and expenses	25,900	11,600
All other	24,700	6,400
	$644,800	$456,600

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5. Property and Equipment

Property and equipment consists of the following:

	March 31,	
	2018	2017
Laboratory equipment	$888,300	$888,300
Tenant improvements	26,900	26,900
Computers and network equipment	54,600	53,000
Office furniture and equipment	79,700	79,700
	1,049,500	1,047,900
Accumulated depreciation and amortization	(842,100)	(761,400)
Property and equipment, net	$207,400	$286,500

The following table summarizes depreciation and amortization expense attributable to owned and leased property and equipment for the fiscal years ended March 31, 2018 and 2017:

	Fiscal Years Ended March 31,	
	2018	2017
Owned assets	$77,800	$53,100
Leased assets	2,900	1,800
Total depreciation and amortization	$80,700	$54,900

Other than certain leased office equipment, none of our assets were subject to third party security interests at March 31, 2018 or 2017.

6. Accrued Expenses

Accrued expenses consist of:

	March 31,

	2018	2017
Accrued AV-101 development and related expenses	$176,600	$402,400
Accrued professional services	27,000	37,000
All other	2,700	3,600
	$206,300	$443,000

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7. Notes Payable

The following table summarizes our notes payable:

	March 31, 2018			March 31, 2017		
	Principal Balance	Accrued Interest	Total	Principal Balance	Accrued Interest	Total
7.15% (2018) and 8.25% (2017) Notes payable to insurance premium financing company (current)	$53,900	$-	$53,900	$54,800	$-	$54,800
Total notes payable to unrelated parties	$53,900	$-	$53,900	$54,800	$-	$54,800
less: current portion	(53,900)	-	(53,900)	(54,800)	-	(54,800)
Net non-current portion	$-	$-	$-	$-	$-	$-

In May 2017, we executed a promissory note in the face amount of $142,400 in connection with certain insurance policy premiums. The note was payable in monthly installments of $14,800, including principal and interest, through March 2018, when it was paid in full. In February 2018, we executed a promissory note in the face amount of $59,700 in connection with other insurance policy premiums. The note is payable in monthly installments of $6,200, including principal and interest, through December 2018, and has an outstanding balance of $53,900 at March 31, 2018.

8. Capital Stock

Common Stock

At our Annual Meeting of Stockholders on September 15, 2017, as approved by and recommended to our stockholders by our Board of Directors (Board), our stockholders approved an amendment to our Restated and Amended Articles of Incorporation to increase the authorized number of shares of common stock that we may issue from 30.0 million shares to 100.0 million shares. The amendment became effective on September 15, 2017, upon our filing of a certificate of amendment with the Nevada Secretary of State.

Series A Preferred Stock

In December 2011, our Board 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 is currently convertible at the option of the holder into one and one-half restricted shares 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 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 our affairs, 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 distributions out of our assets, if any, 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, 2018 and 2017, 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 two respective holders.

Series B Preferred Stock

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

Each share of Series B Preferred is convertible, at the option of the holder (Voluntary Conversion), into one (1) share of our Common Stock, subject to adjustment only for customary stock dividends, reclassifications, splits and similar transactions set forth in the Certificate of Designation. 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. Following the completion of the May 2016 Public Offering (defined below), which occurred concurrently with and facilitated the listing of our common stock on the NASDAQ Capital Market, approximately 2.4 million shares of Series B Preferred were converted automatically into approximately 2.4 million shares of our common stock pursuant to the Automatic Conversion provision.

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, 2018, we have recognized a liability in the amount of $2,608,300 for Accrued Dividends in the accompanying Consolidated Balance Sheet at March 31, 2018, based on the Series B Preferred issued and outstanding, net of conversions to common stock, through that date. We have recognized a deduction from net loss of $1,030,400 and $1,257,000 related to dividends on Series B Preferred in arriving at net loss attributable to common stockholders in the accompanying Consolidated Statement of Operations and Comprehensive Loss for the fiscal years ended March 31, 2018 and 2017, respectively.

In the event of the liquidation, dissolution or winding-up of our affairs, after payment or provision for payment of our debts and other liabilities, the Holders of the Series B Preferred then outstanding shall be entitled to receive distributions out of our assets, if any, of an amount equal to the Stated Value of the Series B Preferred ($7.00 per share), plus any accrued and unpaid dividends thereon, before any distribution or payment shall be made to the holders of any junior securities, including holders of our common stock. If our assets are insufficient to pay, in full, such amounts, then the entire assets to be distributed to the holders of the Series B Preferred shall be ratably distributed among the holders in accordance with the respective amounts that would be payable on such shares if all amounts payable thereon were paid in full. Upon liquidation, each share of Series B Preferred ranks pari-passu with our Series A Preferred and our Series C Preferred (defined below).The liquidation value of the Series B Preferred at March 31, 2018 is approximately $10,729,900.

At March 31, 2018 and 2017, there were 1,160,240 shares of Series B Preferred outstanding, which shares are currently subject to beneficial ownership blockers and are exchangeable at the option of the two respective holders by Voluntary Conversion, or pursuant to Automatic Conversion to the extent not otherwise subject to beneficial ownership blockers, into an aggregate of 1,160,240 shares of our common stock.

Series C Preferred Stock

In January 2016, our Board authorized the creation of and, accordingly, we filed a Certificate of Designation of the Relative Rights and Preferences of the Series C Convertible Preferred Stock of VistaGen Therapeutics, Inc. (the Series C Preferred Certificate of Designation) with the Nevada Secretary of State to designate 3.0 million shares of our preferred stock, par value $0.001 per share, as Series C Convertible Preferred Stock (Series C Preferred).

In the event of the liquidation, dissolution or winding up of our affairs, after payment or provision for payment of our debts and other liabilities, the holders of Series C Preferred then outstanding shall be entitled to receive, out of our assets, if any, an amount per share of Series C 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 C 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 C Preferred can be exchanged before any payment shall be made or any assets distributed to the holders of the common stock or any other junior stock. Upon liquidation, each share of Series C Preferred ranks pari-passu with our Series B Preferred and our Series A Preferred.

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Each share of Series C Preferred 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. At March 31, 2018 and 2017, one holder and its affiliates held all 2,318,012 outstanding shares of Series C Preferred.

Series B Preferred Unit Offering

Between May 2015 and May 2016, in self-placed private placement transactions, we sold to accredited investors an aggregate of $5,303,800 of units in our Series B Preferred Unit Offering, which units consisted of Series B Preferred and Series B Warrants (together Series B Preferred Units), including $2,650,000 to PLTG. We issued 757,692 shares of Series B Preferred and Series B Warrants to purchase 757,692 shares of our common stock. During our fiscal year ended March 31, 2017, we received an aggregate of $278,000 in cash proceeds from our self-placed private placement and sale of 39,174 Series B Preferred Units.

The warrants issued in the Series B Preferred Unit Offering have no anti-dilution or other exercise price or share reset features, except as is customary with respect to a change in our capital structure in the event of a stock split or dividend, and, accordingly, we have accounted for them as equity warrants. We allocated the proceeds from the sale of the Series B Preferred Units sold during our fiscal year ended March 31, 2017 to the Series B Preferred and the Series B Warrants based on their relative fair values on the dates of the sales. We determined that the fair value of a share of Series B Preferred was equal to the quoted market value of a share of our common stock on the date of a Series B Preferred Unit sale. We calculated the fair value of the Series B Warrants using the Black Scholes Option Pricing Model and the weighted average assumptions indicated in the table below. The table below also presents the aggregate allocation of the Series B Preferred Unit sales proceeds based on the relative fair values of the Series B Preferred and the Series B Warrants as of their respective Series B Preferred Unit sales dates. The difference between the relative fair value per share of the Series B Preferred, approximately $4.20 per share, and its Conversion Price (or stated value) of $7.00 per share represents a deemed dividend to the purchasers of the Series B Preferred Units. Accordingly, we recognized a deemed dividend in the aggregate amount of $111,100 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, 2017.

Unit Warrants

	Weighted Average Issuance Date Valuation Assumptions						Per Share	Aggregate	Aggregate	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	Fair Value of Warrant	Fair Value of Unit Warrants	Proceeds of Unit Sales	Unit Stock	Unit Warrant
39,714	$ 8.45	$ 7.00	5.00	1.27%	78.43%	0.0%	$ 5.63	$ 223,500	$ 278,000	$ 166,900	$ 61,100

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

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

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

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

Common Stock and Warrants Issued in September 2017 Public Offering

On September 6, 2017, we completed the September 2017 Public Offering, resulting in gross proceeds of approximately $2.4 million, pursuant to which we offered and sold shares of our common stock and warrants to two of our existing institutional investors. We issued an aggregate of 1,371,430 shares of our common stock, Series A1 Warrants to purchase up to 1,388,931 shares of common stock and Series A2 Warrants to purchase up to 503,641 of common stock (collectively, the Warrants), each exercisable for $1.82 per share in the September 2017 Public Offering. The Series A1 Warrants became exercisable by the investors for a five-year period commencing on March 7, 2018, and the Series A2 Warrants were immediately exercisable at any time through September 6, 2022. The common stock and the shares of common stock underlying the Warrants issued in the September 2017 Public Offering were offered, issued and sold pursuant to our S-3 Registration Statement (Registration No. 333-215671) that had previously been declared effective by the Commission to cover this and potential future sales of our equity securities in one or more public offerings from time to time. We received net proceeds of approximately $2.0 million from the September 2017 Public Offering, after deducting underwriter’s commission and other expenses related to the offering.

The Series A1 Warrants to purchase an aggregate of 1,388,931 shares of our common stock issued in the September 2017 Public Offering have no anti-dilution or other exercise price or share reset features, except as is customary with respect to a change in our capital structure in the event of a stock split or dividend, and, accordingly, we have accounted for them as equity warrants. The Series A2 Warrants to purchase an aggregate of 503,641 shares of our common stock contained anti-dilution protection provisions that would take effect upon the issuance of any common stock, securities convertible into common stock or certain other issuances at a price below the then-current ($1.82 per share) exercise price of the Series A2 Warrants, with certain exceptions; provided, however, that such anti-dilution protection would terminate automatically on the trading day following the date on which we raised at least $20.0 million in aggregate gross proceeds through one or more issuances of common stock or equity-linked securities. The anti-dilution protection provisions in the Series A2 Warrants constituted a down round feature subject to the guidance in ASU 2017-11. Since the Series A2 Warrants contained no other provisions which required their treatment as liability warrants rather than equity warrants, including exercise price or share reset features, except as is customary with respect to a change in our capital structure in the event of a stock split or dividend and which are also present in the Series A1 Warrants, we also accounted for the Series A2 Warrants as equity warrants. The anti-dilution protection provisions of the Series A2 Warrants were triggered upon our issuance of common stock and warrants in the December 2017 Public Offering (defined below) at a price below the Series A2 Warrants then-current $1.82 per share exercise price.

Common Stock and Warrants Issued in December 2017 Public Offering and Trigger of Anti-Dilution Protection Provisions of Series A2 Warrants Issued in September 2017 Public Offering

On December 13, 2017, we completed the December 2017 Public Offering, resulting in gross proceeds of $15.0 million, pursuant to which we offered and sold shares of our common stock and warrants to purchase shares of our common stock at a combined public offering price of $1.50 per shares and related warrant. We issued an aggregate of 10,000,000 shares of our common stock and warrants to purchase up to 10,000,000 shares of our common stock at an exercise price of $1.50 per share (the December 2017 Offering Warrants). The common stock and the shares of common stock underlying the December 2017 Offering Warrants issued in the December 2017 Public Offering were offered, issued and sold pursuant to our Registration Statement on Form S-1 (Registration No. 333-221009) that was declared effective by the Commission on December 11, 2017. The December 2017 Offering Warrants are exercisable at any time through December 13, 2022, have no anti-dilution or other exercise price or share reset features, except as is customary with respect to a change in our capital structure in the event of a stock split or dividend, and do not

contain any cashless exercise features as long as our Registration Statement on Form S-1 (Registration No. 333-221009) is effective. Accordingly, we accounted for the December 2017 Offering Warrants as equity warrants. We received net proceeds of approximately $13.6 million from the December 2017 Public Offering, after deducting underwriter's commission and other expenses related to the offering.

Our sale of units consisting of common stock and warrants in the December 2017 Public Offering at an offering price of $1.50 per unit triggered the anti-dilution provisions of the Series A2 Warrants. In accordance with the anti-dilution terms and formula contained in the Series A2 warrants, the exercise price of the Series A2 Warrants was reduced to $0.001 per share. In December 2017 and January 2018, the holders exercised the reset Series A2 warrants to purchase an aggregate of 503,641 shares of our common stock from which we received nominal cash proceeds. In accordance with the guidance in ASU 2017-11, we recognized the effect of triggering the down round feature as a deemed dividend in our Consolidated Statement of Stockholders' Equity for the fiscal year ended March 31, 2018 and as an addition to net loss attributable to common stockholders and in our calculation of basic and fully diluted earnings per share in our Consolidated Statement of Operations for the fiscal year ended March 31, 2018.

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We calculated the dividend from the trigger of the down round provision feature, $199,200, using the Black Scholes Option Pricing Model and the assumptions indicated in the table below:

Assumption:	Pre-reset	Post-reset
Market price per share	$1.17	$1.17
Exercise price per share	$1.82	$0.001
Risk-free interest rate	2.09%	2.09%
Remaining contractual term in years	4.73	4.73
Volatility	97.8%	97.8%
Dividend rate	0.0%	0.0%
Number of warrant shares	503,641	503,641
Fair value per share	$0.77	$1.17

Common Stock and Warrants Issued in Private Placements

During the quarter ended December 31, 2016, in self-placed private transactions, we sold to two individual accredited investors units, at a purchase price of $3.70 per unit, consisting of an aggregate of 67,000 unregistered shares of our common stock and warrants, exercisable through November 30, 2019, to purchase an aggregate of 16,750 unregistered shares of our common stock at an exercise price of $6.00 per share. The purchasers of the units have no registration rights with respect to the shares of common stock, warrants or the shares of common stock issuable upon exercise of the warrants comprising the units sold. We received aggregate cash proceeds of $247,900 in connection with this private placement, the entire amount of which was credited to stockholders' equity.

During the quarter ended March 31, 2017, in a self-placed private transaction, we sold to an accredited investor units, at a purchase price of $2.00 per unit, consisting of an aggregate of 57,250 unregistered shares of our common stock and warrants, exercisable through April 2021, to purchase an aggregate of 28,625 unregistered shares of our common stock at an exercise price of $4.00 per share. The purchaser of the units has no registration rights with respect to the shares of common stock, warrants or the shares of common stock issuable upon exercise of the warrants comprising the units sold. We received aggregate cash proceeds of $114,500 in connection with this private placement, the entire amount of which was credited to stockholders' equity.

During the quarter ended June 30, 2017, in self-placed private placement transactions, we accepted subscription agreements from individual accredited investors, pursuant to which we sold to such investors units, at a weighted average purchase price of $2.00 per unit, consisting of an aggregate of 437,751 unregistered shares of our common stock and warrants, exercisable through April 30, 2021, to purchase an aggregate of 218,875 unregistered shares of our common stock at a weighted average exercise price of $3.99 per share. The purchasers of the units have no registration rights with respect to the shares of common stock, warrants or the shares of common stock issuable upon exercise of the warrants comprising the units sold. The warrants are not exercisable until six months and one day following the date of issuance. We received aggregate cash proceeds of $873,300 in connection with these self-placed private placement transactions, and the entire amount of the proceeds was credited to stockholders' equity.

During the quarter ended September 30, 2017, in a self-placed private placement transaction, we sold to an accredited investor units consisting of 28,572 shares of our unregistered common stock and warrants exercisable through April

30, 2021 to purchase 28,572 unregistered shares of our common stock at an exercise price of $4.00 per share. The purchaser of the units has no registration rights with respect to the shares of common stock, warrants or the shares of common stock issuable upon exercise of the warrants comprising the units sold. The warrants are not exercisable until six months and one day following the date of issuance. We received cash proceeds of $50,000 from this sale of our securities, and the entire amount of the proceeds was credited to stockholders' equity.

During the quarter ended December 31, 2017, in a self-placed private placement transaction, we sold to an accredited investor units consisting of 150,000 shares of our unregistered common stock and warrants exercisable through November 30, 2021 to purchase 150,000 unregistered shares of our common stock at an exercise price of $2.00 per share. The purchaser of the units has no registration rights with respect to the shares of common stock, warrants or the shares of common stock issuable upon exercise of the warrants comprising the units sold. The warrants are not exercisable until six months and one day following the date of issuance. We received cash proceeds of $150,000 from this sale of our securities, and the entire amount of the proceeds was credited to stockholders' equity.

Issuance of Common Stock to Professional Services Providers and in Settlement of Accounts Payable

During our fiscal years ended March 31, 2018 and 2017, we issued the following securities in private placement transactions as compensation for various professional services. Unless otherwise noted, we recorded the related non-cash expense as a component of general and administrative expense in the Consolidated Statement of Operations and Comprehensive Loss for the fiscal years ended March 31, 2018 and 2017, as appropriate.

During the quarter ended September 30, 2016, we issued an aggregate of 170,000 shares of our unregistered common stock having an aggregate fair value on the date of issuance of $737,800 as compensation to various professional services providers. Of that amount, we issued 120,000 shares having a fair value of $520,800 on the date of issuance for services to be rendered from October 2016 to December 2016.

During the quarter ended December 31, 2016, we issued an aggregate of 135,000 shares of our unregistered common stock having an aggregate fair value on the respective dates of issuance of $479,800 as compensation to various professional services providers.

During the quarter ended March 31, 2017, we issued an aggregate of 200,000 unregistered shares of our common stock, of which 150,000 unregistered shares were issued from our 2016 Plan (defined below), having an aggregate fair value of $422,500 on the dates of issuance to various professional services providers.

During the quarter ended September 30, 2017, we issued an aggregate of 927,500 unregistered shares of our common stock, of which 477,500 shares were issued from our 2016 Plan, for various professional services, including contract research, legal, investor relations and financial advisory services. The common stock issued had an aggregate fair value of $1,503,600 on the dates issued, of which all but $117,300 has been recognized as noncash expense through March 31, 2018. The un-expensed portion at March 31, 2018, which is included in prepaid expenses in our accompanying Consolidated Balance Sheet, is being recognized in expense ratably through July 2019 in accordance with the terms of work orders for certain contract research services to be provided through that period.

During the quarter ended December 31, 2017, we issued an aggregate of 70,000 unregistered shares of our common stock, all of which were issued from our 2016 Plan for additional investor relations and financial advisory services. The common stock issued had an aggregate fair value of $140,800 on the dates issued.

During the quarter ended December 31, 2017, we also issued 500,000 unregistered shares of our common stock having a fair value at the time of issuance of $585,000 and a cash payment of $76,500 to our contract manufacturing organization (CMO) in exchange for and settlement of $526,500 of open accounts payable for services provided by the CMO relating to production of AV-101 drug substance. We recognized a corresponding loss on settlement of accounts payable in the amount of $135,000 for the quarter ended December 31, 2017.

During the quarter ended March 31, 2018, we issued 30,000 unregistered shares of our common stock to a provider of investor relations and financial advisory services. The common stock issued had an aggregate fair value of $39,000 on the date issued.

Warrant Exchanges into Common Stock

During our fiscal year ended March 31, 2017, we entered into Warrant Exchange Agreements with certain holders of outstanding warrants to purchase an aggregate of 224,693 shares of our common stock pursuant to which the holders agreed to cancel such warrants in exchange for the issuance of an aggregate of 156,246 unregistered shares of common stock.

We accounted for the exchanges of these warrants as warrant modifications, comparing the fair value of the warrants immediately prior to the exchanges with the fair value of the unregistered common stock issued. We calculated the weighted average fair value of the warrants prior to the respective exchanges using the Black Scholes Option Pricing

Model and the weighted average assumptions indicated in the table below. We determined the post-modification fair value based on the quoted market price of our common stock on the effective date of each exchange and the number of unregistered shares issued in the exchange, as also indicated in the table below. We recognized the incremental fair value of the unregistered common stock issued in excess of the fair value of the warrants cancelled, $350,700, as a component of warrant modification expense which is included in general and administrative expenses in our accompanying Consolidated Statement of Operations and Comprehensive Loss for the fiscal year ended March 31, 2017.

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Warrant Exchanges - FY 2017

	April - May 2016		August 2016		October 2016		December 2016	
	Pre-modification	Post-modification	Pre-modification	Post-modification	Pre-modification	Post-modification	Pre-modification	Post-modification
Market Price per share	$8.44	$8.45	$3.33	$3.33	$4.05	$4.05	$3.73	$3.73
Exercise price per share	$7.37		$8.00		$8.15		$10.00	
Risk-free interest rate	1.23%		1.10%		0.77%		0.44%	
Contractual term (years)	4.77		4.58		2.40		0.003	
Volatility	79.0%		87.0%		93.0%		100.3%	
Dividend Rate	0%		0%		0%		0%	
Weighted average fair value per share	$5.37		$1.64		$1.27		$-	
Warrant shares cancelled and exchanged	41,649		20,000		113,944		49,100	

Common shares issued in exchange		31,238		15,000		85,458		24,550
Fair Value	$223,700	$264,000	$32,900	$50,000	$144,400	$346,100	$-	$91,600
Incremental fair value recognized as warrant modification expense		$40,300		$17,100		$201,700		$91,600

Additional Warrant Modifications

In addition to warrants modified in connection with the warrant exchange transactions described immediately above, we modified other outstanding warrants during our fiscal years ended March 31, 2018 and 2017.

In December 2016, our Board authorized the modification of an outstanding warrant to both alter the exercise terms and increase the number of shares for which the warrant was exercisable. We calculated the fair value of the warrant immediately before and after the modification using the Black Scholes Option Pricing Model and the assumptions indicated in the table below. We recognized the incremental fair value, $76,900, as warrant modification expense, included as a component of general and administrative expenses, in our Consolidated Statement of Operations and Comprehensive Loss for the fiscal year ended March 31, 2017.

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Assumption:	Pre-modification	Post-modification
Market price per share	$3.51	$3.51
Exercise price per share	$8.00	$3.51
Risk-free interest rate	1.88%	2.07%
Remaining contractual term in years	4.26	5.03
Volatility	87.1%	85.8%
Dividend rate	0.0%	0.0%
Number of warrant shares	25,000	50,000
Weighted average fair value per share	$1.71	$2.39

During the quarter ended September 30, 2017, the Board authorized the modification of outstanding warrants issued in private placement transactions between March 2017 and June 2017 to reduce the exercise prices and increase the number of shares issuable thereunder. We calculated the fair value of the warrant immediately before and after the modification using the Black Scholes Option Pricing Model and the weighted average assumptions indicated in the table below. We recognized the incremental fair value, $279,700, as warrant modification expense, included as a component of general and administrative expenses, in our Consolidated Statement of Operations and Comprehensive Loss for the fiscal year ended March 31, 2018.

Assumption:	Pre-modification	Post-modification
Market price per share	$1.54	$1.54
Exercise price per share	$3.99	$2.00
Risk-free interest rate	1.62%	1.62%
Remaining contractual term in years	3.62	3.62
Volatility	95.5%	95.5%
Dividend rate	0.0%	0.0%
Number of warrant shares	247,500	495,001
Weighted average fair value per share	$0.71	$0.92

During the quarter ended December 31, 2017, the Board authorized the modification of outstanding warrants issued in private placement transactions between August 2017 and November 2017 to reduce the exercise prices of the warrants. We calculated the fair value of the warrants immediately before and after the modification using the Black Scholes Option Pricing Model and the weighted average assumptions indicated in the table below. We recognized the incremental fair value, $13,000, as warrant modification expense, included as a component of general and administrative expenses, in our Consolidated Statement of Operations and Comprehensive Loss for the fiscal year ended March 31, 2018.

Assumption:	Pre-modification	Post-modification
Market price per share	$1.14	$1.14

Exercise price per share	$2.32	$1.58
Risk-free interest rate	2.12%	2.12%
Remaining contractual term in years	3.85	3.85
Volatility	98.7%	98.7%
Dividend rate	0.0%	0.0%
Number of warrant shares	178,572	178,572
Weighted average fair value per share	$0.64	$0.71

Warrants Outstanding

The following table summarizes outstanding and exercisable warrants to purchase shares of our common stock as of March 31, 2018. The weighted average exercise price of outstanding and exercisable warrants at March 31, 2018 was $2.85 per share and $2.86 per share, respectively.

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Exercise Price per Share	Expiration Date	Warrants Outstanding at March 31, 2018	Warrants Exercisable at March 31, 2018
$1.50	11/30/2021 to 12/13/2022	10,150,000	10,000,000
$1.82	3/7/2023	1,388,931	1,388,931
$2.00	4/30/2021	523,573	523,573
$3.51	12/31/2021	50,000	50,000
$4.50	9/26/2019	25,000	25,000
$5.30	5/16/2021	2,705,883	2,705,883
$6.00	9/26/2019 to 11/30/2019	97,750	97,750
$7.00	12/11/2018 to 3/3/2023	1,346,931	1,346,931
$8.00	3/25/2021	185,000	185,000
$10.00	1/11/2020	20,000	20,000
$20.00	9/15/2019	110,448	110,448
		16,603,516	16,453,516

Reserved Shares

At March 31, 2018, we have reserved shares of our common stock for future issuance as follows:

Upon exchange of all shares of Series A Preferred Stock currently issued and outstanding (1)	750,000
Upon exchange of all shares of Series B Preferred Stock currently issued and outstanding (2)	1,823,700
Upon exchange of all shares of Series C Preferred Stock currently issued and outstanding	2,318,012
Pursuant to warrants to purchase common stock:	
Subject to outstanding warrants	16,603,516
Pursuant to stock incentive plan:	
Subject to outstanding options under the Amended and Restated 2016 Stock Incentive Plan	5,300,338
Available for future grants under the Amended and Restated 2016 Stock Incentive Plan	3,987,162
	9,287,500
Total	30,782,728

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

(2) Includes 663,460 common shares issuable in payment of accrued dividends on Series B Preferred upon conversion

At March 31, 2018, we have 46,284,657 authorized shares of our common stock not subject to reserves and available for future issuance.

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9. Research and Development Expenses

We recorded research and development expenses of approximately $7.8 million and $5.2 million in the fiscal years ended March 31, 2018 and 2017, respectively. Research and development expense is composed primarily of employee compensation expenses, including stock–based compensation, direct project expenses, notably including preparations for and the launch of our ELEVATE clinical trial, and costs to maintain and prosecute our intellectual property suite, including new patent applications for AV-101 for various indications.

10. 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.

On December 22, 2017, the Tax Cuts and Jobs Act was enacted into law, which significantly changes existing U.S. tax law. The reduction of the U.S. federal statutory tax rate from 34% to 21% is effective January 1, 2018. Income tax expense differed from the amounts computed by applying the U.S. federal income tax rate of 34% for April 1, 2017 to December 31, 2017 and 21% for January 1, 2018 to March 31, 2018 for 2018 year (prorated basis 30.75%) to pretax losses as a result of the following:

	Fiscal Years Ended March 31,	
	2018	2017
Computed expected tax benefit	(30.75)%	(34.00)%
Tax effect of warrant modifications and other non-deductible items	0.40%	1.42%
Tax effect of research and development credits	(1.44)%	-%
Effect of U.S. tax law change (federal and state)	88.09%	-%
Other losses not benefitted	(56.28)%	32.58%
Other	-%	0.02%
Income tax expense	0.02%	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 our deferred tax assets are as follows:

	March 31,

	2018	2017
Deferred tax assets:		
Net operating loss carryovers	$21,402,600	$30,184,100
Basis differences in fixed assets	(7,600)	(4,200)
Stock based compensation	2,504,500	3,673,900
Accruals and reserves	1,352,900	927,900
Total deferred tax assets	25,252,400	34,781,700
Valuation allowance	(25,252,400)	(34,781,700)
Net deferred tax assets	$-	$-

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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 decreased by $9,529,300 and increased by $3,567,000 during the fiscal years ended March 31, 2018 and 2017, respectively.

As of March 31, 2018, we had U.S. federal net operating loss carryforwards of approximately $88,477,000, which will expire in fiscal years 2019 through 2038. As of March 31, 2018, we had state net operating loss carryforwards of approximately $63,457,200, which will expire in fiscal years 2029 through 2038. The Company also has federal and state research and development tax credit carryforwards of approximately $979,900 and $826,500, respectively. The federal tax credits will expire at various dates beginning in the year 2029, unless previously utilized. The state tax credits do not expire and will carry forward indefinitely until utilized.

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

We file income tax returns in the U.S. federal, Canada and various U.S. state jurisdictions. We are subject to U.S. federal and state income tax examinations by tax authorities for tax years 1998 through 2017 due to net operating losses that are being carried forward for tax purposes, but we are not currently under examination by tax authorities in any jurisdiction.

Uncertain Tax Positions

Our unrecognized tax benefits at March 31, 2018 and 2017 relate entirely to research and development tax credits. The total amount of unrecognized tax benefits at March 31, 2018 and 2017 is $451,600 and $290,500, respectively. If recognized, none of the unrecognized tax benefits would impact our effective tax rate. The following table summarizes the activity related to our unrecognized tax benefits.

	Fiscal Years Ended March 31,	
	2018	2017
Unrecognized benefit - beginning of period	$290,500	$142,400
Current period tax position increases	102,300	77,700
Prior period tax position increases	58,800	70,400
Unrecognized benefit - end of period	$451,600	$290,500

Our policy is to recognize interest and penalties related to income taxes as components of interest expense and other expense, respectively. We incurred no interest or penalties related to unrecognized tax benefits in the years ended March 31, 2018 or 2017. We do not anticipate any significant changes of our uncertain tax positions within twelve months of this reporting date.

11. Licensing, Sublicensing and Collaborative Agreements

BlueRock Therapeutics Sublicense Agreement

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

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

U.S. National Institutes of Health

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

Cato Research Ltd.

We have built a strategic development relationship with Cato Research Ltd. (CRL), a global contract research and development organization, or CRO, and an affiliate of one of our largest institutional stockholders. CRL has provided us with access to essential CRO services and regulatory expertise supporting our AV-101 preclinical and clinical development programs and other projects. We recorded research and development expenses for CRO services provided by CRL in the amounts of $1,390,700 and $254,600 for the fiscal years ended March 31, 2018 and 2017, respectively.

University Health Network

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

In December 2016, we entered into a series of agreements with UHN pursuant to which we (i) executed two new exclusive patent license agreements related to certain cardiac stem cell technologies discovered by Dr. Gordon Keller, Director of UHN's McEwen Centre for Regenerative Medicine, under the SRCA; (ii) amended two exclusive cardiac stem cell technology patent license agreements previously entered into between us and UHN under the SRCA; (iii) terminated the SRCA to facilitate the BlueRock Therapeutics Agreement, described above; and (iv) agreed to make a

sublicense consideration payment to UHN with respect to the upfront payment we received under the BlueRock Therapeutics Agreement. All financial obligations related to these agreements with UHN, aggregating $3,600 and $233,400, are reflected in research and development expense in the accompanying Consolidated Statement of Operations and Comprehensive Loss for the fiscal years ended March 31, 2018 and 2017, respectively.

12. Stock Option Plans and 401(k) Plan

We have the following share-based compensation plans.

Amended and Restated 2016 Stock Incentive Plan

Our Board unanimously approved the Company's Amended and Restated 2016 Stock Incentive Plan, formerly titled the 2008 Stock Incentive Plan (the 2016 Plan), on July 26, 2016, and the 2016 Plan was approved by our stockholders at our 2016 Annual Meeting of Stockholders on September 26, 2016, and further amended at our 2017 Annual Meeting of Stockholders on September 15, 2017. The 2016 Plan provides for the grant of stock options, restricted shares of common stock, stock appreciation rights and dividend equivalent rights, collectively referred to as "Awards". Stock options granted under the 2016 Plan may be either incentive stock options under the provisions of Section 422 of the Internal Revenue Code of 1986, as amended (the Code), or non-qualified stock options. We may grant incentive stock options only to employees of the Company or any parent or subsidiary of the Company. Awards other than incentive stock options may be granted to employees, directors and consultants. A total of 10.0 million shares of our common stock are currently authorized for issuance under the 2016 Plan and as of March 31, 2018, approximately 4.0 million registered shares remain available for future equity grants under the plan.

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1999 Stock Incentive Plan

Our 1999 Stock Incentive Plan (the 1999 Plan) was adopted by the shareholders of VistaStem on December 6, 1999 and we assumed it in connection with our going-public transaction. We initially reserved 45,000 shares for the issuance of awards under the 1999 Plan. The 1999 Plan has terminated under its own terms and, as a result, no awards may currently be granted under the 1999 Plan. At March 31, 2018, no options granted pursuant to the 1999 Plan remain outstanding.

Description of the 2016 Plan

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

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

The exercise price of all incentive stock options granted under the 2016 Plan must be at least equal to 100% of the fair market value of the shares on the date of grant. The maximum term of an incentive stock option granted to any other participant may not exceed 10 years. The Committee determines the term and exercise or purchase price of all other Awards granted under the 2016 Plan.

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

by will and by the laws of descent and distribution; and

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

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

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

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

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

an acquisition of securities possessing more than fifty percent (50%) of the total combined voting power of our outstanding securities but excluding any such transaction or series of related transactions that the Committee determines shall not be a Corporate Transaction;

a reverse merger in which we remain the surviving entity but: (i) the shares of common stock outstanding immediately prior to such merger are converted or exchanged by virtue of the merger into other property, whether in the form of securities, cash or otherwise; or (ii) in which securities possessing more than fifty percent (50%) of the total combined voting power of our outstanding securities are transferred to a person or persons different from those who held such securities immediately prior to such merger;

a sale, transfer or other disposition of all or substantially all of the assets of the Company;

a merger or consolidation in which the Company is not the surviving entity; or

a complete liquidation or dissolution.

Under the 2016 Plan, a Change in Control is generally defined as: (i) the acquisition of more than 50% of the total combined voting power of our stock by any individual or entity which a majority of our Board (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 over a period of 12 months or less.

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

During our fiscal year ended March 31, 2018, we granted from the 2016 Plan:

options to purchase an aggregate of 880,000 shares of our common stock at an exercise price of $1.96 per share to the independent members of our Board and to our officers and all non-officer employees in April 2017;

options to purchase an aggregate of 770,000 shares of our common stock at an exercise price of $1.56 per share to the independent members of our Board, officers, non-officer employees and two consultants in September 2017;

options to purchase an aggregate of 2,000,000 shares of our common stock at an exercise price of $1.16 per share to the independent members of our Board, officers, non-officer employees and ten consultants in February 2018;

options to purchase 25,000 shares of our common stock at an exercise price of $1.21 per share to a legal services consultant in February 2018; and

an aggregate of 547,500 shares of unregistered common stock to various legal, investor relations, and financial and strategic advisory consultants in September and October 2017 pursuant to which we recognized an aggregate of $827,900 as a noncash component of general and administrative expense not included in stock compensation expense for the fiscal year.

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

options to purchase an aggregate of 655,000 shares of our common stock at an exercise price of $3.49 per share to the independent members of our Board and to our officers, including one newly-employed officer, in June 2016;

options to purchase 125,000 shares of our common stock at an exercise price of $4.27 per share to a newly-employed officer in September 2016

options to purchase an aggregate of 560,000 shares of our common stock at an exercise price of $3.80 per share to the independent members of our Board, officers, non-officer employees and a consultant in November 2016; and

an aggregate of 150,000 unregistered shares of our common stock pursuant to four consulting agreements in March 2017 pursuant to which we recognized an aggregate of $324,500 as a noncash component of general and administrative expense not included in stock compensation expense for the fiscal year.

The following table summarizes share-based compensation expense related to option grants to our officers, independent directors, consultants and service providers, included in the accompanying Consolidated Statement of Operations and Comprehensive Loss for the years ended March 31, 2018 and 2017.

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	Fiscal Years Ended March 31,	
	2018	2017
Research and development expense:		
Stock option grants	$969,200	$375,100
	969,200	375,100
General and administrative expense:		
Stock option grants	1,375,000	476,200
	1,375,000	476,200
Total stock-based compensation expense	$2,344,200	$851,300

We used the Black-Scholes Option Pricing model with the following weighted average assumptions to determine share-based compensation expense related to option grants during the fiscal years ended March 31, 2018 and 2017:

	Fiscal Years Ended March 31,	
	2018	2017
	(weighted average)	(weighted average)
Exercise price	$1.44	$3.69
Market price on date of grant	$1.44	$3.69
Risk-free interest rate	2.39%	1.51%
Expected term (years)	6.87	6.69
Volatility	90.40%	82.96%
Expected dividend yield	0.00%	0.00%
Fair value per share at grant date	$1.10	$2.68

The expected term of options represents the period that our share-based compensation awards are expected to be outstanding. We have calculated the weighted-average expected term of the options using the simplified method as prescribed by Securities and Exchange Commission Staff Accounting Bulletins No. 107 and No. 110 (SAB No. 107

and 110). The utilization of SAB No. 107 and 110 is based on the lack of relevant historical data due to both our limited historical experience as a publicly traded company as well as the historical lack of liquidity resulting from the limited number of freely-tradable shares of our common stock. Those factors also resulted in our decision to utilize the historical volatilities of a peer group of public companies' stock over the expected term of the option in determining our expected volatility assumptions. The risk-free interest rate for periods related to the expected life of the options is based on the U.S. Treasury yield curve in effect at the time of grant. The expected dividend yield is zero, as we have not paid any dividends and do not anticipate paying dividends in the near future. We recognize the effect of forfeitures as they occur.

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The following table summarizes activity for the fiscal years ended March 31, 2018 and 2017 under our stock option plans:

	Fiscal Years Ended March 31,			
	2018		2017	
	Number of Shares	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
Options outstanding at beginning of period	1,659,324	$4.76	336,987	$9.56
Options granted	3,675,000	$1.44	1,340,000	$3.69
Options exercised	-	$-	-	$-
Options forfeited	(12,154)	$5.39	-	$-
Options expired	(21,832)	$9.42	(17,663)	$15.52
Options outstanding at end of period	5,300,338	$2.43	1,659,324	$4.76
Options exercisable at end of period	1,818,962	$3.31	351,532	$8.27
Weighted average grant-date fair value of options granted during the period		$1.10		$2.69

The following table summarizes information on stock options outstanding and exercisable under our stock option plans as of March 31, 2018:

Options Outstanding		Options Exercisable	
	Weighted		

Exercise Price	Number Outstanding	Average Remaining Years until Expiration	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$1.16 to $1.21	2,025,000	9.84	$1.16	569,524	$1.16
$1.56 to $1.96	1,650,000	9.26	$1.77	384,986	$1.56
$3.49 to $4.27	1,330,000	8.41	$3.69	577,870	$3.68
$8.00 to $15.00	295,338	4.79	$9.19	286,582	$9.19
	5,300,338	9.02	$2.43	1,818,962	$3.31

At March 31, 2018, there were 3,987,162 registered shares of our common stock remaining available for grant under the 2016 Plan. There were no option exercises during the years ended March 31, 2018 or 2017.

Aggregate intrinsic value is the sum of the amount by which the fair value of the underlying common stock exceeds the aggregate exercise price of the outstanding options (in-the-money-options). Based on the $0.93 per share quoted market price of our common stock on March 31, 2018, there was no intrinsic value in any of our outstanding options at that date.

As of March 31, 2018, there was approximately $4,492,300 of unrecognized compensation cost related to non-vested share-based compensation awards from the 2016 Plan, which is expected to be recognized through September 2020.

401(k) Plan

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

13. Related Party Transactions

Cato Holding Company (CHC), doing business as Cato BioVentures (CBV), is the parent of CRL. CRL is a contract research, development and regulatory services organization (CRO) engaged by us for certain aspects of the development and regulatory affairs associated with AV-101. CBV is among our largest institutional stockholders at March 31, 2017, holding approximately 6.9% of our outstanding common stock. In October 2012, we issued certain unsecured promissory notes in the aggregate face amount of approximately $1.3 million to CBV and CRL (the Cato Notes) as payment in full for all contract research and development services and regulatory advice previously rendered to us by CRL. The Cato Notes and additional amounts payable to CRL for CRO services were extinguished in June 2015 in exchange for our issuance of an aggregate of 328,571 shares of Series B Preferred to CBV, which shares of Series B Preferred were automatically converted into an equal number of registered shares of our common stock in connection with the May 2016 Public Offering.

In July 2017, we entered into a Master Services Agreement (MSA) with CRL, which replaced a substantially similar May 2007 master services agreement, pursuant to which CRL may assist us in the evaluation, development, commercialization and marketing of our potential product candidates, including AV-101, and provide regulatory and strategic consulting services as requested from time to time. Specific projects or services are and will be delineated in individual work orders negotiated from time-to-time under the MSA. Under the terms of work orders issued pursuant to the July 2017 MSA and our May 2007 master services agreement with CRL, we incurred expenses of $1,390,700 and $254,600 during the fiscal years ended March 31, 2018 and 2017, respectively. During our fiscal year ended March 31, 2018, we issued an aggregate of 350,000 unregistered shares of our common stock to CRL under the terms of certain work orders for current and future CRO services relating to our development of AV-101 for MDD, the fair value of which represented approximately $465,000 of the reported CRO expense for the fiscal year. We anticipate periodic expenses for CRO services from CRL related to nonclinical and clinical development of, and regulatory

affairs related to, AV-101 and other potential product candidates will increase in future periods.

14. 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, 2018 or 2017.

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, 2018 or 2017.

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Leases

At March 31, 2018 and 2017, the following assets are subject to capital lease obligations and included in property and equipment:

	March 31,	
	2018	2017
Office equipment	14,700	14,700
Accumulated depreciation	(3,600)	(700)
Net book value	$11,100	$14,000

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
2019	$3,800
2020	3,800
2021	3,800
2022	3,300
Future minimum lease payments	14,700
Less imputed interest included in minimum lease payments	(2,800)
Present value of minimum lease payments	11,900
Less current portion	(2,600)
Non-current capital lease obligation	$9,300

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At March 31, 2018, future minimum payments under operating leases relate to our facility lease in South San Francisco, California through July 31, 2022 and are as follows:

Fiscal Years Ending March 31,	Amount
2019	602,800
2020	623,900
2021	645,800
2022	668,400
2023	225,300
	$2,766,200

We incurred total facility rent expense for the fiscal years ended March 31, 2018 and 2017 of $645,800 and $482,100, respectively.

Debt Repayment

At March 31, 2018, future minimum principal payments on outstanding notes related only to an insurance premium financing arrangement in the remaining principal amount of $53,900, which will be repaid in monthly principal and interest installments of $6,200 through December 2018.

15. 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, 2018:

Issuance of Common Stock to Professional Services Providers

In April 2018, we issued 25,000 unregistered shares of our common stock to a consultant pursuant to a financial advisory services contract. The common stock had a fair value of $24,000 on the date issued. In May 2018, we issued 75,000 unregistered shares of our common stock pursuant to an additional financial advisory services contract. The common stock had a fair value of $99,000 on the date issued.

16. Supplemental Financial Information (Unaudited)

The following table presents the unaudited statements of operations data for each of the eight quarters in the period ended March 31, 2018. 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.

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

	Three Months Ended				Total
	June 30, 2017	September 30, 2017	December 31, 2017	March 31, 2018	Fiscal Year 2018
Operating expenses:					
Research and development	$1,096	$2,427	$1,602	$2,638	$7,763
General and administrative	1,164	2,567	1,266	1,440	6,437
Total operating expenses	2,260	4,994	2,868	4,078	14,200
Loss from operations	(2,260)	(4,994)	(2,868)	(4,078)	(14,200)
Other expenses, net:					
Interest expense, net	(3)	(3)	(2)	(1)	(9)
Loss on extinguishment of accounts payable	-	-	(135)	-	(135)
Loss before income taxes	(2,263)	(4,997)	(3,005)	(4,079)	(14,344)
Income taxes	(2)	-	-	-	(2)
Net loss and comprehensive loss	(2,265)	(4,997)	(3,005)	(4,079)	(14,346)
Accrued dividend on Series B Preferred stock	(247)	(257)	(263)	(263)	(1,030)
Deemed dividend from trigger of down round provision feature	-	-	(199)	-	(199)
Net loss attributable to common stockholders	$(2,512)	$(5,254)	$(3,467)	$(4,342)	$(15,575)
Basic and diluted net loss per common share attributable to common stockholders	$(0.28)	$(0.53)	$(0.25)	$(0.19)	$(1.12)
Weighted average shares used in computing: Basic and diluted net loss per common share attributable to common stockholders	9,034,213	9,892,016	13,895,642	22,880,968	13,890,041

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	Three Months Ended				Total
	June 30, 2016	September 30, 2016	December 31, 2016	March 31, 2017	Fiscal Year 2017
Sublicense revenue	$-	$-	$1,250	$-	$1,250
Total revenue	-	-	1,250	-	1,250
Operating expenses:					
Research and development	826	1,606	1,611	1,161	5,204
General and administrative	1,138	1,494	2,276	1,387	6,295
Total operating expenses	1,964	3,100	3,887	2,548	11,499
Loss from operations	(1,964)	(3,100)	(2,637)	(2,548)	(10,249)
Other expenses, net:					
Interest expense, net	(2)	(1)	(1)	(1)	(5)
Loss before income taxes	(1,966)	(3,101)	(2,638)	(2,549)	(10,254)
Income taxes	(2)	-	-	-	(2)
Net loss and comprehensive loss	(1,968)	(3,101)	(2,638)	(2,549)	(10,256)
Accrued dividend on Series B Preferred stock	(540)	(241)	(238)	(238)	(1,257)
Deemed dividend on Series B Preferred stock	(111)	-	-	-	(111)
Net loss attributable to common stockholders	$(2,619)	$(3,342)	$(2,876)	$(2,787)	$(11,624)
Basic and diluted net loss per common share attributable to common stockholders	$(0.51)	$(0.42)	$(0.34)	$(0.32)	$(1.54)
Weighted average shares used in computing:					
Basic and diluted net loss per common share attributable to common stockholders	5,097,832	8,047,619	8,381,824	8,602,107	7,531,642

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

None.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures.

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

Management's Report on Internal Control Over Financial Reporting.

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

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

Management has assessed the effectiveness of our internal control over financial reporting for our fiscal year ended March 31, 2018. Management's assessment was based on criteria set forth in Internal Control - Integrated Framework (2013), issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based upon this assessment, management concluded that, as of March 31, 2018, our internal control over financial reporting was not effective, based upon those criteria, as a result of the material weaknesses identified below.

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

Specifically, management identified the following control weaknesses: (i) the size and capabilities of the Company’s staff does not permit appropriate segregation of duties to prevent one individual from overriding the internal control

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

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

As a result of the enactment of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, and the resulting amendment of Section 404 of the Sarbanes-Oxley Act of 2002, as a smaller reporting company, we are not required to provide an attestation report by our independent registered public accounting firm regarding internal control over financial reporting for the fiscal year ended March 31, 2018 or thereafter, until such time as we are no longer eligible for the exemption for smaller issuers set forth within the Sarbanes-Oxley Act.

Item 9B. Other Information

None.

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PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2018 Annual Meeting of Stockholders, which we intend to file with the Securities and Exchange Commission on or before July 27, 2018 pursuant to General Instruction G(3) of Form 10-K.

Item 11. Executive Compensation

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2018 Annual Meeting of Stockholders, which we intend to file with the Securities and Exchange Commission on or before July 27, 2018 pursuant to General Instruction G(3) of Form 10-K.

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

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2018 Annual Meeting of Stockholders, which we intend to file with the Securities and Exchange Commission on or before July 27, 2018 pursuant to General Instruction G(3) of Form 10-K.

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

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2018 Annual Meeting of Stockholders, which we intend to file with the Securities and Exchange Commission on or before July 27, 2018 pursuant to General Instruction G(3) of Form 10-K.

Item 14. Principal Accounting Fees and Services

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2018 Annual Meeting of Stockholders, which we intend to file with the Securities and Exchange Commission on or before July 27, 2018 pursuant to General Instruction G(3) of Form 10-K.

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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 65.

(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.
3.4	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.
3.9	Certificate of Designation of the Relative Rights and Preferences of the Series C Convertible Preferred Stock of VistaGen Therapeutics, Inc., dated January 25, 2016, incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K filed on January 29, 2016.
3.10	Restated Articles of Incorporation of VistaGen Therapeutics, Inc., dated August 16, 2016, incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K, filed on August 17, 2016.
3.11	Second Amended and Restated Bylaws of VistaGen Therapeutics, Inc., dated August 16, 2016, incorporated by reference from Exhibit 3.2 to the Company's Current Report on Form 8-K, filed on August 16, 2016.
3.12	Certificate of Amendment to the Restated and Amended Articles of Incorporation of VistaGen Therapeutics, Inc., dated September 15, 2017; incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K, filed on September 20, 2017.
10.1*	VistaGen's 1999 Stock Incentive Plan.
10.20*	Strategic Development Services Agreement, dated February 26, 2007, by and between VistaGen and Cato Research Ltd.
10.22*	License Agreement by and between Mount Sinai School of Medicine of New York University and the Company, dated October 1, 2004.
10.23*	

	Non-Exclusive License Agreement, dated December 5, 2008, by and between VistaGen and Wisconsin Alumni Research Foundation, as amended by that certain Wisconsin Materials Addendum, dated February 2, 2009.
10.24*	Sponsored Research Collaboration Agreement, dated September 18, 2007, between VistaGen and University Health Network, as amended by that certain Amendment No. 1 and Amendment No. 2, dated April 19, 2010 and December 15, 2010, respectively.
10.26*	License Agreement, dated October 24, 2001, by and between the University of Maryland, Baltimore, Cornell Research Foundation and Artemis Neuroscience, Inc.
10.40*	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.

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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.
10.57	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.
10.67	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.
10.73	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.
10.83	Lease between Bayside Area Development, LLC and VistaGen Therapeutics, Inc. (California) dated April 24, 2013, incorporated by reference from Exhibit 10.83 to the Company's Annual Report on Form 10-K filed July 18, 2013.
10.84	Indemnification Agreement effective May 20, 2013 between the Company and Jon S. Saxe, incorporated by reference from Exhibit 10.84 to the Company's Annual Report on Form 10-K filed on July 18, 2013.
10.85	Indemnification Agreement effective May 20, 2013 between the Company and Shawn K. Singh, incorporated by reference from Exhibit 10.85 to the Company's Annual Report on Form 10-K filed on July 18, 2013.
10.86	Indemnification Agreement effective May 20, 2013 between the Company and H. Ralph Snodgrass, incorporated by reference from Exhibit 10.86 to the Company's Annual Report on Form 10-K filed on July 18, 2013.
10.87	Indemnification Agreement effective May 20, 2013 between the Company and Brian J. Underdown, incorporated by reference from Exhibit 10.87 to the Company's Annual Report on Form 10-K filed on July 18, 2013.
10.88	Indemnification Agreement effective May 20, 2013 between the Company and Jerrold D. Dotson, incorporated by reference from Exhibit 10.88 to the Company's Annual Report on Form 10-K filed on July 18, 2013.
10.102	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 25, 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 25, 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 25, 2014.

10.111	Exchange Agreement, by and between VistaGen Therapeutics, Inc., and Platinum Long Term Growth VII, LLC and Montsant Partners, LLC, dated January 25, 2016, incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 29, 2016.
10.112	Indemnification Agreement effective April 8, 2016 between the Company and Jerry B. Gin, incorporated by reference from Exhibit 10.112 to the Company's Annual Report on Form 10-K filed on June 24, 2016.
10.113	Underwriting Agreement, by and between Chardan Capital Markets, LLC and WallachBeth Capital, LLC, as representatives of the several underwriters, and VistaGen Therapeutics, Inc., dated May 10, 2016, incorporated by reference from Exhibit 1.1 to the Company's Current Report on Form 8-K filed on May 16, 2016.
10.114	Warrant Agency Agreement, by and between Computershare, Inc. and VistaGen Therapeutics, Inc., dated May 16, 2016, incorporated by reference from Exhibit 4.1 to the Company's Current Report on Form 8-K filed on May 16, 2016.
10.115	Form of Warrant; incorporated by reference from Exhibit 4.2 to the Company's Current Report on Form 8-K filed on May 16, 2016.
10.116	Second Amendment to Employment Agreement by and between VistaGen Therapeutics, Inc. and Shawn K. Singh, dated June 22, 2016, incorporated by reference from Exhibit 10.116 to the Company's Annual Report on Form 10-K filed on June 24, 2016.
10.117	Second Amendment to Employment Agreement by and between VistaGen Therapeutics, Inc. and H. Ralph Snodgrass, Ph.D., dated June 22, 2016, incorporated by reference from Exhibit 10.117 to the Company's Annual Report on Form 10-K filed on June 24, 2016.
10.118	Second Amendment to Lease between Bayside Area Development and the Company, effective November 10, 2016, incorporated by reference from Exhibit 10.1 to the Company's Quarterly report on Form 10-Q filed on November 15, 2016.
10.119	Indemnification Agreement effective November 10, 2016 between the Company and Mark A. Smith, incorporated by reference from Exhibit 10.2 to the Company's Quarterly report on Form 10-Q filed on November 15, 2016.
10.120+	Exclusive License and Sublicense Agreement by and between VistaGen Therapeutics, Inc. and Apollo Biologics LP, effective December 9, 2016, incorporated by reference from Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on May 11, 2017.
10.121+	Patent License Amendment Agreement between VistaGen Therapeutics Inc. and University Health Network effective December 9, 2016, incorporated by reference from Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q/A filed on May 1, 2017.

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10.122	Amended and Restated 2016 Stock Incentive Plan (formerly the VistaGent Therapeutics, Inc. 2008 Stock Incentive Plan), incorporated by reference from Exhibit 10.122 to the Company's Annual Report on Form 10-K filed on June 29, 2017.
10.123	Underwriting Agreement, dated as of August 31, 2017, by and between VistaGen Therapeutics, Inc. and Oppenheimer & Co. Inc., incorporated by reference from Exhibit 1.1 to the Company's Current Report on Form 8-K filed on August 31, 2017.
10.124	Form of Series A1 Warrant, incorporated by reference from Exhibit 4.1 to the Company's Current Report on Form 8-K filed on August 31, 2017.
10.125	Form of Series A2 Warrant, incorporated by reference from Exhibit 4.2 to the Company's Current Report on Form 8-K filed on August 31, 2017.
10.126	Form of Warrant, incorporated by reference from Exhibit 4.1 to the Company's Current Report on Form 8-K filed on December 13, 2017.
21.1*	List of Subsidiaries.
23.1	Consent of Independent Registered Public Accounting Firm, filed herewith
31.1	Certification of the Company's Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, filed herewith.
31.2	Certification of the Company's Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, filed herewith.
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, filed herewith.
101.INS	XBRL Instance Document, filed herewith
101.SCH	XBRL Taxonomy Extension Schema, filed herewith
101.CAL	XBRL Taxonomy Extension Calculation Linkbase, filed herewith
101.DEF	XBRL Taxonomy Extension Definition Linkbase, filed herewith
101.LAB	XBRL Taxonomy Extension Label Linkbase, filed herewith
101.PRE	XBRL Taxonomy Extension Presentation Linkbase, filed herewith

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

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

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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 26th day of June, 2018.

VistaGen Therapeutics, Inc.

Date: June 26, 2018 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 26, 2018
/s/ Jerrold D. Dotson Jerrold D. Dotson	Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	June 26, 2018
/s/ H. Ralph Snodgrass H. Ralph Snodgrass, Ph.D	President, Chief Scientific Officer and Director	June 26, 2018
/s/ Jon S. Saxe Jon S. Saxe	Chairman of the Board of Directors	June 26, 2018
/s/ Brian J. Underdown Brian J. Underdown, Ph. D	Director	June 26, 2018
/s/ Jerry B. Gin, Ph.D Jerry B. Gin, Ph.D.	Director	June 26, 2018