VistaGen Therapeutics, Inc.
Form 10-Q
August 14, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2015
or

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to .

Commission File Number: 000-54014

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

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

343 Allerton Avenue
South San Francisco, CA 94080
(Address of principal executive offices including zip code)

(650) 577-3600
(Registrant's telephone number, including area code)

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

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

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

Large accelerated filer	[ ]	Accelerated filer	[ ]
Non-Accelerated filer	[ ]	Smaller reporting company	[X]
(do not check if a smaller reporting company)			

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

As of August 12, 2015, 1,594,461 shares of the registrant’s common stock, $0.001 par value, were issued and outstanding.

VistaGen Therapeutics, Inc.
Quarterly Report on Form 10-Q
for the Quarter Ended June 30, 2015

TABLE OF CONTENTS

	Page
PART I. FINANCIAL INFORMATION	
Item 1. Condensed Consolidated Financial Statements (Unaudited)	
Condensed Consolidated Balance Sheets at June 30, 2015 and March 31, 2015	1
Condensed Consolidated Statements of Operations and Comprehensive Loss for the three months ended June 30, 2015 and 2014	2
Condensed Consolidated Statements of Cash Flows for the three months ended June 30,2015 and 2014	3
Notes to the Condensed Consolidated Financial Statements	4
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	23
Item 4. Controls and Procedures	30
PART II. OTHER INFORMATION	
Item 1. Legal Proceedings	31
Item 1A. Risk Factors	31
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	65
Item 3. Defaults Upon Senior Secured Securities	66
Item 6. Exhibits	66
SIGNATURES	67

Table of Contents

PART I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (Unaudited)

VISTAGEN THERAPEUTICS
Consolidated Balance Sheets
(Amounts in Dollars, except share amounts)

	June 30, 2015 (Unaudited)	March 31, 2015 (Note 2)
ASSETS		
Current assets:		
Cash and cash equivalents	$121,000	$70,000
Prepaid expenses and other current assets	1,473,300	35,700
Total current assets	1,594,300	105,700
Property and equipment, net	102,600	117,100
Security deposits and other assets	46,900	46,900
Total assets	$1,743,800	$269,700
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$1,549,800	$2,251,100
Accrued expenses	1,382,200	1,206,500
Current maturities of senior secured convertible promissory notes and accrued interest	-	4,146,100
Current portion of notes payable, net of discount of $0 at June 30, 2015 and $474,500 at March 31, 2015, and accrued interest	345,700	4,117,000
Current portion of notes payable to related parties, net of discount of $0 at June 30, 2015 and $54,500 at March 31, 2015, and accrued interest	-	1,508,800
Convertible promissory notes and accrued interest, net of discount of $0 at June 30, 2015 and $180,000 at March 31, 2015, respectively	-	4,157,600
Capital lease obligations	1,000	1,000
Total current liabilities	3,278,700	17,388,100
Non-current liabilities:		
Senior secured convertible promissory notes and accrued interest	-	296,200
Notes payable	1,038,500	35,600
Warrant liability	-	3,008,500
Accrued dividends on Series B Preferred Stock	213,300	-
Deferred rent liability	78,300	83,000
Capital lease obligations	900	1,100
Total non-current liabilities	1,331,000	3,424,400
Total liabilities	4,609,700	20,812,500
Commitments and contingencies		

Stockholders' deficit:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at June 30, 2015 and March 31, 2015:		
Series A Preferred, 500,000 shares authorized and outstanding at June 30, 2015 and March 31, 2015, respectively	500	500
Series B Preferred, 4,000,000 shares and no shares authorized at June 30, 2015 and March 31, 2015, respectively; 2,995,579 shares issued and outstanding at June 30, 2015	3,000	-
Common stock, $0.001 par value; 10,000,000 shares authorized at June 30, 2015 and March 31, 2015, respectively; 1,730,126 shares and 1,677,110 shares issued at June 30, 2015 and March 31, 2015, respectively	1,700	1,700
Additional paid-in capital	115,143,800	67,945,800
Treasury stock, at cost, 135,665 shares of common stock held at June 30, 2015 and March 31, 2015, respectively	(3,968,100)	(3,968,100)
Accumulated deficit	(114,046,800)	(84,522,700)
Total stockholders' deficit	(2,865,900)	(20,542,800)
Total liabilities and stockholders' deficit	$1,743,800	$269,700

See accompanying notes to Condensed Consolidated Financial Statements.

Table of Contents

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

	Three Months Ended June 30,	
	2015	2014
Operating expenses:		
Research and development	$372,600	$473,600
General and administrative	1,448,500	797,200
Total operating expenses	1,821,100	1,270,800
Loss from operations	(1,821,100)	(1,270,800)
Other expenses, net:		
Interest expense, net	(755,100)	(784,900)
Change in warrant liability	(1,894,700)	(1,727,200)
Loss on extinguishment of debt	(25,050,900)	(768,000)
Loss before income taxes	(29,521,800)	(4,550,900)
Income taxes	(2,300)	(2,400)
Net loss and comprehensive loss	$(29,524,100)	$(4,553,300)
Accrued dividends on Series B Preferred stock	(213,300)	-
Deemed dividend on Series B Preferred Units	(256,200)	-
Net loss attributable to common stockholders	$(29,993,600)	$(4,553,300)
Basic and diluted net loss attributable to common stockholders per common share	$(19.23)	$(3.70)
Weighted average shares used in computing basic and diluted net loss attributable to common stockholders per common share	1,559,483	1,229,488

See accompanying notes to Condensed Consolidated Financial Statements.

Table of Contents

VISTAGEN THERAPEUTICS INC.
STATEMENT OF CASH FLOWS
(Unaudited)
(Amounts in Dollars)

	Three Months Ended June 30,	
	2015	2014
Cash flows from operating activities:		
Net loss	$ (29,524,100)	$ (4,553,300)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	14,500	13,100
Amortization of discounts on convertible and promissory notes	550,800	481,900
Change in warrant liability	1,894,700	1,727,200
Stock-based compensation	29,200	203,400
Expense related to modification of warrants	122,300	-
Non-cash rent and relocation expense	(4,700)	(1,400)
Interest income on note receivable for stock purchase	-	(2,500)
Fair value of common stock granted for services	500,000	134,000
Fair value of Series B Preferred stock granted for services	250,000	-
Fair value of warrants granted for services and interest	-	16,500
Foreign currency transaction loss	10,300	19,800
Loss on extinguishment of debt	25,050,900	767,900
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(8,200)	(11,900)
Accounts payable and accrued expenses, including accrued interest	291,000	193,500
Net cash used in operating activities	(823,300)	(1,011,800)
Cash flows from investing activities:		
Purchases of equipment, net	-	-
Net cash used in investing activities	-	-
Cash flows from financing activities:		
Net proceeds from issuance of common stock and warrants, including Units	280,000	1,520,000
Net proceeds from issuance of Series B Preferred Units	607,500	-
Repayment of capital lease obligations	(200)	(2,000)
Repayment of notes	(13,000)	(105,500)
Net cash provided by financing activities	874,300	1,412,500
Net increase in cash and cash equivalents	51,000	400,700
Cash and cash equivalents at beginning of period	70,000	-
Cash and cash equivalents at end of period	$ 121,000	$ 400,700
Supplemental disclosure of non-cash activites:		
Senior Secured Notes, 2014 Unit Notes, other promissory notes and related accrued interest and accounts payable, including conversion premiums, converted into Series B Preferred stock	$17,335,400	$-

See accompanying notes to Condensed Consolidated Financial Statements.

Table of Contents

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

Note 1. Description of Business

Overview

VistaGen Therapeutics, Inc., a Nevada corporation, is a clinical-stage biopharmaceutical company committed to developing and commercializing innovative product candidates for patients with depression, other diseases and various disorders related to the central nervous system (CNS), as well as cancer. Our principal executive offices are located at 343 Allerton Avenue, South San Francisco, California 94080, and our telephone number is (650) 577-3600. Our website address is www.vistagen.com. Unless the context otherwise requires, the words “VistaGen Therapeutics, Inc.” “VistaGen,” “we,” “the Company,” “us” and “our” refer to VistaGen Therapeutics, Inc., a Nevada corporation.

VistaGen Therapeutics, Inc., a California corporation incorporated on May 26, 1998 (VistaGen California), is our wholly-owned subsidiary. Pursuant to a strategic merger transaction on May 11, 2011, we acquired all outstanding shares of VistaGen California in exchange for 341,823 shares of our common stock (Merger), and assumed all of VistaGen California’s pre-Merger obligations. Our Condensed Consolidated Financial Statements in this report also include the accounts of VistaGen California’s two wholly-owned subsidiaries, Artemis Neuroscience, Inc., a Maryland corporation, and VistaStem Canada, Inc., a corporation organized under the laws of Ontario, Canada.

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

AV-101 and Major Depressive Disorder

The World Health Organization estimates that 350 million people worldwide are affected by depression. According to the U.S. National Institutes of Health (NIH), major depression is one of the most common mental disorders in the U.S. In 2012, the NIH estimated 16 million adults aged 18 or older in the U.S. had at least one major depressive episode. This represented 6.9 percent of all U.S. adults. According to the U.S. Centers for Disease Control and Prevention (CDC), one in ten Americans take an antidepressant medication. Unfortunately, approximately two-thirds of depression sufferers do not benefit from the first round treatment of currently approved antidepressant agents, including selective serotonin reuptake inhibitors (SSRIs) and serotonin-norepinephrine reuptake inhibitors (SNRIs). And, even when they do relieve depressive symptoms and induce remission of a major depressive episode, because of their mechanism of action, SSRIs and SNRIs take many weeks to achieve those therapeutic benefits. During the multiple-week lag before onset of therapeutic benefits, risks of side effects, including suicidal thoughts and behaviors, may be considerable. Ultimately, after as many as four treatment cycles involving several different antidepressant medications, approximately two-thirds of patients may find an antidepressant drug or drug combination that induces remission of depressive symptoms. This trial and error period to find an effective antidepressant medication can take many months to more than a year to achieve, with an increasing rate of potentially significant side effect risks with each successive treatment attempt.

Our lead product candidate, AV-101, is an orally available small molecule prodrug in Phase 2 clinical development for Major Depressive Disorder (MDD). AV-101’s mechanism of action (MOA), as an N-methyl-D-aspartate receptor (NMDAR) antagonist binding selectively at the glycine-binding (GlyB) co-agonist site of the NMDAR, is fundamentally different from all antidepressants approved by the U.S. Food and Drug Administration (FDA). In four

preclinical studies utilizing well-validated animal models of depression, AV-101 was shown to induce fast-acting, dose-dependent, persistent and statistically significant antidepressant-like responses, following a single treatment, which were equivalent to responses seen with a control single sub-anesthetic dose of ketamine (an FDA-approved drug sometimes used by clinicians off-label to treat suicidal behavior). In the same preclinical studies, fluoxetine (Prozac) did not induce rapid onset antidepressant-like responses. Preclinical studies also support the hypothesis that AV-101 has the potential to treat several additional CNS disorders, including chronic neuropathic pain, epilepsy and neurodegenerative diseases, such as Parkinson's disease and Huntington's disease, where modulation of the NMDAR may have therapeutic benefit.

Table of Contents

Following two successful randomized, double-blind, placebo-controlled Phase 1 safety studies funded by the NIH, in February 2015, we entered into a Cooperative Research and Development Agreement (CRADA) with the U.S. National Institute of Mental Health (NIMH), part of the NIH. Under the CRADA, we are collaborating with the NIMH on the initial Phase 2 clinical efficacy study of AV-101 in subjects with treatment-resistant MDD. Pursuant to the CRADA, the study will be conducted at the NIMH and be fully funded by the NIMH. It is contemplated that this clinical study will begin in the second half of 2015 under the direction of 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.

In addition to developing AV-101 for MDD and other CNS indications, we are applying our stem cell technology for drug rescue to identify and develop proprietary new chemical entities (NCEs) for our internal drug candidate pipeline and selected regenerative medicine opportunities. Drug rescue involves (1) using our customized in vitro bioassay systems to predict potential heart and liver toxicity of NCEs, (2) leveraging prior investments by pharmaceutical companies and others related to screening large-scale compound libraries, optimizing and testing for efficacy NCEs that were terminated before FDA approval due to heart or liver toxicity and are now available in the public domain, and (3) applying medicinal chemistry to produce safer proprietary NCEs for our internal development pipeline. Our CardioSafe 3D™ bioassay system uses our human pluripotent stem cell (hPSC)-derived cardiomyocytes, or human heart cells. We believe CardioSafe 3D is more comprehensive and clinically predictive than the hERG assay, which is currently the only in vitro cardiac safety assay required by FDA guidelines. We use our hPSC-derived hepatocytes, or human liver cells, in our LiverSafe 3D™ bioassay system to predict potential liver toxicity of NCEs, including potential drug metabolism issues and adverse drug-drug interactions. CardioSafe 3D and LiverSafe 3D offer a new paradigm for evaluating and predicting potential heart and liver toxicity of NCEs, including drug rescue NCEs, early in the development process, long before costly, high risk animal studies and human clinical trials. We intend to develop internally for our pipeline each lead drug rescue NCEs we produce. Our focus in regenerative medicine is on innovative therapeutic opportunities involving blood, cartilage, heart and liver cells.

Note 2. Basis of Presentation and Going Concern

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP) for interim financial information and with the instructions to Form 10-Q and Rule 8-03 of Regulation S-X. Accordingly, they do not contain all of the information and footnotes required for complete consolidated financial statements. In the opinion of management, the accompanying unaudited Condensed Consolidated Financial Statements reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly our interim financial information. The accompanying Condensed Consolidated Balance Sheet at March 31, 2015 has been derived from our audited consolidated financial statements at that date but does not include all disclosures required by U.S. GAAP. The operating results for the three months ended June 30, 2015 are not necessarily indicative of the operating results to be expected for our fiscal year ending March 31, 2016 or for any other interim period or any other future period.

The accompanying unaudited Condensed Consolidated Financial Statements and notes to Condensed Consolidated Financial Statements should be read in conjunction with our audited Consolidated Financial Statements for the fiscal year ended March 31, 2015 contained in our Annual Report on Form 10-K, as filed with the Securities and Exchange Commission (SEC) on June 29, 2015.

The accompanying Condensed Consolidated Financial Statements have been prepared assuming we will continue as a going concern. As an entity having not yet achieved sustainable revenues, we have experienced recurring losses and negative cash flows from operations resulting in a deficit of $114.0 million accumulated from inception through June 30, 2015. 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, other potential programs involving drug development, drug

rescue drug discovery and regenerative medicine.

Since our inception in May 1998 through June 30, 2015, we have financed our operations through (1) the issuance and sale of our common stock, preferred stock, warrants for common stock, and promissory notes for aggregate cash proceeds of approximately $30.0 million; (2) issuance of common stock and preferred stock with an approximate value at issuance of $25.2 million as consideration for, among other things, technology license payments, sponsored research, contract research, development, manufacturing and regulatory services, and legal, corporate development and financial advisory services; and, (3) receipt of aggregate non-dilutive cash proceeds of approximately $16.4 million from government research and development grant awards and strategic collaborations.

Table of Contents

As described more completely in Note 7, Convertible Promissory Notes and other Notes Payable, and Note 8, Capital Stock, in May 2015, we created a new class of Series B 10% Convertible Preferred Stock (Series B Preferred). Between March 31, 2015 and June 30, 2015, we extinguished the outstanding balances of approximately $15.4 million of promissory notes, other debt obligations and certain adjustments thereto that were either already due and payable or would have otherwise matured prior to March 31, 2016, through conversion into our Series B Preferred and, with respect to a portion of the indebtedness converted, warrants to purchase common stock. More specifically, we have converted the outstanding balances of (i) all Senior Secured Convertible Promissory Notes originally issued to Platinum Long Term Growth VII, LLC (Platinum), (ii) all 2014 Unit Notes outstanding at March 31, 2015 and those issued subsequently, and (iii) other outstanding promissory notes including those issued to Cato Research Ltd., Cato Holding Company, Morrison & Foerster (Note B), University Health Network and others, through the issuance of an aggregate of 2,363,789 shares of our Series B Preferred. Additionally, through June 30, 2015, we sold in self-placed private placement transactions with Platinum and other accredited investors, Series B Preferred Units consisting of an aggregate of 86,790 unregistered shares of Series B Preferred and five year warrants exercisable at $7.00 per share to purchase 86,790 shares of our common stock and we received cash proceeds of $607,500 therefrom. See Note 10, Subsequent Events, regarding disclosure of the conversion of the outstanding balance of additional promissory notes into Series B Preferred and self-placed private placement sales of additional Series B Preferred Units after June 30, 2015.

At June 30, 2015, we did not have sufficient cash and cash equivalents to enable us to fund our planned operations over the next twelve months, including expected cash expenditures of approximately $6.0 million. We believe that our participation in potential strategic collaborations, including potential transactions involving AV-101 such as our February 2015 CRADA with the NIH for an NIH-funded and sponsored Phase 2 study of AV-101 in MDD, may provide resources to support a portion of our future cash needs and working capital requirements, however, no assurances can be provided. When and as necessary, we have and will continue to seek to raise sufficient financing through issuance and sale of our securities, which may include both debt and equity securities, research and development collaborations, technology and drug candidate license fees, and government grant awards and collaboration revenues. Our future working capital requirements will depend on many factors, including, without limitation, the scope and nature of strategic opportunities related to our success and the success of certain other companies in clinical trials, including our future development ofAV-101 as a treatment for MDD and other conditions; our stem cell technology platform, including drug rescue and cell therapy research and development efforts and the success of such programs, our ability to obtain government grant awards and our ability to enter into strategic collaborations with institutions on terms acceptable to us. To further advance the clinical development of AV-101 and potential drug rescue and regenerative medicine applications of our stem cell technology, as well as support our operating activities, we plan to continue to carefully manage our routine operating costs, including salaries and benefits, regulatory consulting, contract research and development, legal, accounting, public company compliance and other professional services and working capital costs.

Notwithstanding the foregoing, substantial additional financing may not be available to us on a timely basis, on acceptable terms, or at all. If we are unable to obtain substantial additional financing on a timely basis in the near term, our business, financial condition, and results of operations may be harmed, the price of our stock may decline, we may be required to reduce, defer, or discontinue certain of our research and development activities and we may not be able to continue as a going concern. The accompanying Condensed Consolidated Financial Statements do not include any adjustments that might result from the outcome of this uncertainty.

Note 3. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates include those relating to revenue recognition, share-based compensation, and assumptions that have been used to value warrants, warrant modifications, and previous put option and note term extension liabilities.

Table of Contents

Revenue Recognition

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

We recognize revenue when the four basic criteria of revenue recognition are met: (1) a contractual agreement exists; (2) the transfer of technology has been completed or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured. For each source of revenue, we comply with the above revenue recognition criteria in the following manner:

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

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

Research and Development Expenses

Research and development expenses are composed of both internal and external costs. Internal costs include salaries and employment-related expenses of scientific personnel and direct project costs. External research and development expenses consist primarily of costs associated with clinical and non-clinical development of AV-101, our prodrug candidate entering late-stage clinical development for Major Depressive Disorder, sponsored stem cell research and development costs, and costs related to the application and prosecution of patents related to our stem cell technology platform and AV-101. All such costs are charged to expense as incurred.

Stock-Based Compensation

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

Table of Contents

The table below summarizes stock-based compensation expense included in the accompanying Condensed Consolidated Statements of Operations and Comprehensive Loss for the three months ended June 30, 2015 and 2014.

	Three Months Ended June 30,	
	2015	2014
Research and development expense:		
Stock option grants	$15,500	$61,500
Warrants granted to officer in March 2014	2,800	36,300
	18,300	97,800
General and administrative expense:		
Stock option grants	7,000	34,800
Warrants granted to officers and directors in March 2014	3,900	70,800
	10,900	105,600
Total stock-based compensation expense	$29,200	$203,400

We did not grant stock options to any of our employees or consultants during the three months ended June 30, 2015 or 2014. At June 30, 2015, there were stock options outstanding to purchase 206,788 shares of our common stock at a weighted average exercise price of $10.08 per share.

Warrant Liability

Between October 2012 and July 2013, we issued to Platinum warrants to purchase 176,129 unregistered shares of our common stock and, subject to Platinum's exercise of its rights to exchange shares of our Series A Preferred Stock that it holds, we are obligated to issue to Platinum an additional warrant to purchase 375,000 unregistered shares of common stock (collectively, the "Platinum Warrants"). As originally issued, the Platinum Warrants contained an exercise price adjustment feature that would reduce the exercise price of the warrants and increase the number of shares of our common stock eligible for Platinum's purchase thereunder in the event we subsequently issued equity instruments at a price lower than the exercise price of the Platinum Warrants. Prior to their amendment in May 2015, as described below, we accounted for the Platinum Warrants as non-cash liabilities and estimated their fair value at the end of each financial reporting period and recorded the change in the fair value as non-cash expense or non-cash income. The key component in determining the fair value of the Platinum Warrants and the related liability was the market price of our common stock, which is subject to significant fluctuation and is not under our control. The resulting change in the fair value of the warrant liability on our net income or loss was therefore also subject to significant fluctuation. Assuming all other fair value inputs remained generally constant, we generally recorded an increase in the warrant liability and non-cash losses when our stock price increased and a decrease in the warrant liability and non-cash gains when our stock price decreased.

As described more completely in Note 8, Capital Stock, on May 12, 2015, we entered into an agreement with Platinum pursuant to which Platinum agreed, among other things, to amend the Platinum Warrants to fix the exercise

price thereof, eliminate the exercise price reset features and fix the number of shares of our common stock issuable thereunder. This agreement and the related modifications to the Platinum Warrants resulted in the complete elimination of the warrant liability with respect to the Platinum Warrants during our fiscal quarter ended June 30, 2015.

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.

Table of Contents

Income (Loss) per Common Share

Basic income (loss) per share of common stock excludes the effect of dilution and is computed by dividing net income (loss) by the weighted-average number of shares of common stock outstanding for the period. Diluted income (loss) per share of common stock reflects the potential dilution that could occur if securities or other contracts to issue shares of common stock were exercised or converted into shares of common stock. In calculating diluted net income (loss) per share, we have historically adjusted the numerator for the change in the fair value of the warrant liability attributable to outstanding warrants, only if dilutive, and increased the denominator to include the number of potentially dilutive common shares assumed to be outstanding during the period using the treasury stock method. The change in the fair value of the warrant liability did not have an impact on the numerator in the quarter ending June 30, 2015 or 2014. As a result of our net loss for the periods presented, potentially dilutive securities were excluded from the computation, as their effect would be antidilutive. For the quarter ended June 30, 2015, the accrual for dividends on our Series B Preferred and the deemed dividend attributable to the issuance of our Series B Preferred Units represent deductions from our net loss to arrive at net loss attributable to common stockholders.

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

	As of June 30,	
	2015	2014
Series A Preferred stock issued and outstanding (1)	750,000	750,000
Series B Preferred stock issued and outstanding (2)	2,995,579	-
Warrant shares issuable to Platinum upon exercise of common stock warrants by Platinum upon exchange of Series A Preferred under the terms of the October 11, 2012 Note Exchange and Purchase Agreement, as subsequently amended	535,715	375,000
Outstanding options under the 2008 and 1999 Stock Incentive Plans	206,788	211,368
Outstanding warrants to purchase common stock	3,735,023	949,075
10% Senior Secured Convertible Notes issued to Platinum between October 2012 and July 2013, including accrued interest through June 30, 2014	-	411,810
10% convertible notes issued as a component of Unit Private Placements, including accrued interest through June 30, 2014	-	258,473
Total	8,223,105	2,955,726

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

(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

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers (Topic 606) which supersedes the revenue recognition requirements in ASC 605, Revenue Recognition. The amendment in this ASU provides guidance on revenue recognition to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The core principle of this update provides guidance to identify the performance obligations under the contract(s) with a customer and how to allocate the transaction price to the performance obligations in the contract. It further provides guidance to recognize revenue when (or as) the entity satisfies a performance obligation. The ASU is effective for public entities for annual and interim periods beginning after December 15, 2016 (the first quarter of our fiscal year ending March 31, 2018). In April 2015, the FASB proposed to defer for one year the effective date of the new revenue standard, with an option that would permit companies to adopt the standard as early as the original effective date. Early adoption prior to the original effective date is not permitted. We have not determined the potential effects of adopting this ASU on our consolidated financial statements.

Table of Contents

In August 2014, the FASB issued ASU No. 2014-15, Presentation of Financial Statements—Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. The amendments in this ASU define when and how an entity is required to disclose going concern uncertainties, which must be evaluated each interim and annual period. Specifically, the ASU requires management to determine whether substantial doubt exists regarding the entity's going concern presumption. Substantial doubt about an entity's ability to continue as a going concern exists when relevant conditions and events, considered in the aggregate, indicate that it is probable (as defined under ASC 450, Contingencies) that the entity will be unable to meet its obligations as they become due within one year after the date that the financial statements are issued or are available to be issued. If substantial doubt exists, certain disclosures are required, the extent of which depends on an evaluation of management's plans (if any) to mitigate the going concern uncertainty. This evaluation should include consideration of conditions and events that are either known or are reasonably knowable at the date the financial statements are issued or are available to be issued, as well as whether it is probable that management's plans to address the substantial doubt will be implemented and, if so, whether it is probable that the plans will alleviate the substantial doubt. ASU 2014-15 is effective for annual periods ending after December 15, 2016, and interim and annual periods thereafter. Early application is permitted. In their opinion on our audited financial statements for our fiscal year ended March 31, 2015, our auditors indicated that there was substantial doubt about our ability to continue as a going concern. Although we have not yet adopted ASU 2014-15, as we have indicated in Note 2, Basis of Presentation and Going Concern, we have taken numerous steps that have resulted in the elimination and extinguishment of a substantial portion of our indebtedness and to raise sufficient financing to permit us to continue our operations. Upon our adoption of ASU 2014-15, assuming conditions at such time indicate there is substantial doubt about our ability to continue as a going concern, or that such doubt has been alleviated, we will conform our disclosure to comply with the guidance contained in ASU 2014-15.

Note 4. Fair Value Measurements

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

Table of Contents

We do not use derivative instruments for hedging of market risks or for trading or speculative purposes. In conjunction with the issuance of the Senior Secured Convertible Promissory Notes and Platinum Warrants to Platinum between October 2012 and July 2013, and the potential issuance of the Series A Exchange Warrant pursuant to Platinum's exchange of the Series A Preferred stock that it holds into shares of our common stock, we determined that the Platinum Warrants included certain exercise price adjustment features that required the warrants to be treated as non-cash liabilities and recorded at their estimated fair value. Prior to their amendment in May 2015, as described below, we determined the initial fair value and subsequent fair value measurements of the warrant liability using a Monte Carlo simulation model with Level 3 inputs or the Black-Scholes Option Pricing model. Inputs used to determine fair value included the remaining contractual term of the Platinum Warrants, risk-free interest rates, expected volatility of the price of the underlying common stock, and the probability of a financing transaction or other equity issuance that would trigger a reset in the exercise price of the Platinum Warrants, and, in the case of the Series A Exchange Warrant, the probability of Platinum's exchange of the shares of Series A preferred stock it holds into shares of common stock. As described more completely in Note 8, Capital Stock, on May 12, 2015, we entered into an agreement with Platinum pursuant to which we amended the Platinum Warrants to fix the exercise price thereof and eliminate the anti-dilution reset features that had previously required the Platinum Warrants to be treated as liabilities and carried at fair value. As a result of the agreement with Platinum, at May 12, 2015, we adjusted the Platinum Warrants to their fair value, estimated to be $4,903,200, reflecting an increase of $1,894,700 since March 31, 2015, which was recorded as a non-cash charge to other expense, net in the accompanying Condensed Consolidated Statements of Operations and Comprehensive Loss, and subsequently eliminated the warrant liability with respect to the Platinum Warrants, with a corresponding credit to Additional Paid-in Capital.

The fair value hierarchy for the warrant liability which had been measured at fair value on a recurring basis is as follows:

		Fair Value Measurements at Reporting Date Using		
	Total Carrying Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
June 30, 2015:				
Warrant liability	$-	$-	$-	$ -
March 31, 2015:				
Warrant liability	$3,008,500	$-	$-	$ 3,008,500

During the three month period ended June 30, 2015, there was no significant change to the valuation models used for purposes of determining the fair value of the Level 3 warrant liability.

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

	Fair Value Measurements Using Significant Unobservable Inputs

	(Level 3) Warrant Liability
Balance at March 31, 2015	$ 3,008,500
Mark to market loss included in net loss	1,894,700
Elimination of liability upon modification of warrants	(4,903,200)
Balance at June 30, 2015	$ -

We carried no assets or other liabilities at fair value at June 30, 2015 or March 31, 2015.

Table of Contents

Note 5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets are composed of the following at June 30, 2015 and March 31, 2015:

	June 30, 2015	March 31, 2015
Insurance	$116,700	$27,300
Prepaid compensation under financial advisory and other consulting agreements	1,350,000	-
Legal fees	3,400	3,400
Technology license fees and all other	3,200	5,000
	$1,473,300	$35,700

Note 6. Accrued Expenses

Accrued expenses are composed of the following at June 30, 2015 and March 31, 2015:

	June 30, 2015	March 31, 2015
Accrued professional services	$389,000	$213,800
Accrued compensation	990,700	990,700
All other	2,500	2,000
	$1,382,200	$1,206,500

Table of Contents

Note 7. Convertible Promissory Notes and Other Notes Payable

The following table summarizes our secured and unsecured convertible promissory notes and other notes payable at June 30, 2015 and March 31, 2015.

	June 30, 2015			March 31, 2015		
	Principal Balance	Accrued Interest	Total	Principal Balance	Accrued Interest	Total
Senior Secured 10% Convertible Promissory Notes issued to Platinum:						
Total Senior notes issued between October 11, 2012 and July 23, 2013	$ -	$ -	$ -	$ 3,522,600	$ 919,700	$ 4,442,300
less: current portion	-	-	-	(3,272,600)	(873,500)	(4,146,100)
Senior notes - non-current portion	$ -	$ -	$ -	$ 250,000	$ 46,200	$ 296,200
10% Convertible Promissory Notes (Unit Notes)						
2014 Unit Notes, including amended notes, due 3/31/15	$ -	$ -	$ -	$ 4,066,900	$ 270,700	$ 4,337,600
Note discounts	-	-	-	(180,000)	-	(180,000)
Net convertible notes (all current)	$ -	$ -	$ -	$ 3,886,900	$ 270,700	$ 4,157,600
Notes Payable to unrelated parties:						
7.5% Notes payable to service providers for accounts payable converted to notes payable:						
Burr, Pilger, Mayer	$ -	$ -	$ -	$ 90,400	$ 13,100	$ 103,500
Desjardins	159,800	27,600	187,400	156,300	24,100	180,400
McCarthy Tetrault	-	-	-	319,700	46,000	365,700
August 2012 Morrison & Foerster Note A	918,200	221,100	1,139,300	918,200	193,200	1,111,400

August 2012 Morrison & Foerster Note B	-	-	-	1,379,400	333,100	1,712,500
University Health Network	-	-	-	549,500	101,800	651,300
	1,078,000	248,700	1,326,700	3,413,500	711,300	4,124,800
Note discount	(136,400)	-	(136,400)	(474,500)	-	(474,500)
	941,600	248,700	1,190,300	2,939,000	711,300	3,650,300
less: current portion (and discount at March 31, 2015)	(159,800)	(27,600)	(187,400)	(2,939,000)	(711,300)	(3,650,300)
non-current portion and discount	$ 781,800	$ 221,100	$ 1,002,900	$ -	$ -	$ -
5.67% and 10.25% Notes payable to insurance premium financing company (current)	$ 72,200	$ -	$ 72,200	$ 5,800	$ -	$ 5,800
10% Notes payable to vendors for accounts payable converted to notes payable	$ 44,400	$ 9,600	$ 54,000	$ 378,300	$ 51,500	$ 429,800
less: current portion	(44,400)	(9,600)	(54,000)	(378,300)	(51,500)	(429,800)
non-current portion	$ -	$ -	$ -	$ -	$ -	$ -
7.0% Note payable (August 2012)	$ 58,800	$ 8,900	$ 67,700	$ 58,800	$ 7,900	$ 66,700
less: current portion	(23,200)	(8,900)	(32,100)	(23,200)	(7,900)	(31,100)
7.0% Notes payable - non-current portion	$ 35,600	$ -	$ 35,600	$ 35,600	$ -	$ 35,600
Total notes payable to unrelated parties	$ 1,253,400	$ 267,200	$ 1,520,600	$ 3,381,900	$ 770,700	$ 4,152,600
less: current portion	(299,600)	(46,100)	(345,700)	(3,346,300)	(770,700)	(4,117,000)
non-current portion (and discount at March 31, 2015)	953,800	221,100	1,174,900	35,600	-	35,600
less: discount (non-current at June 30, 2015)	(136,400)	-	(136,400)	-	-	-
Net non-current portion	$ 817,400	$ 221,100	$ 1,038,500	$ 35,600	$ -	$ 35,600
Notes payable to related parties:						
	$ -	$ -	$ -	$ 293,600	$ 55,900	$ 349,500

October 2012 7.5% Note to Cato Holding Co.						
October 2012 7.5% Note to Cato Research Ltd.	-	-	-	1,009,000	204,800	1,213,800
	-	-	-	1,302,600	260,700	1,563,300
Note discount	-	-	-	(54,500)	-	(54,500)
Total notes payable to related parties	-	-	-	1,248,100	260,700	1,508,800
less: current portion	-	-	-	(1,248,100)	(260,700)	(1,508,800)
non-current portion and discount	$ -	$ -	$ -	$ -	$ -	$ -

Table of Contents

Between March 31, 2015 and June 30, 2015, we have eliminated the outstanding balances of approximately $15.4 million of promissory notes, other debt, and certain adjustments thereto, that were either already due and payable or would have otherwise matured prior to March 31, 2016, by converting such balances into shares of our Series B Preferred stock. Significant changes in and conversions of our convertible promissory notes and other promissory notes since March 31, 2015 are described below.

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

As described more completely in the section entitled 2014 Unit Private Placement in Note 8, Capital Stock, between April 1, 2015 and May 14, 2015, we issued to accredited investors in self-placed private placement transactions 10% convertible notes (the 2014 Unit Notes) in the aggregate face amount of $280,000. The 2014 Unit Notes issued in April and May 2015 represented a continuation of the 2014 Unit Private Placement pursuant to which we had issued an aggregate of $3,113,500 principal amount of substantially similar notes between late-March 2014 and March 31, 2015. The 2014 Unit Notes matured between April 30, 2015 and May 15, 2015 (Maturity) and the outstanding principal of the 2014 Unit Notes and their related accrued interest (the Outstanding Balance) was convertible into shares of our common stock at a conversion price of $10.00 per share at or prior to Maturity, at the option of the investor. In addition, upon our consummation of either (i) an equity or equity-based public financing registered with the SEC, or (ii) an equity or equity-based private placement, or series of private placements, not registered with the SEC, in either case resulting in gross cash proceeds to us of at least $10.0 million prior to Maturity (a Qualified Financing), the Outstanding Balance of the 2014 Unit Notes would automatically convert into securities substantially similar to those sold in the Qualified Financing, based on the following formula: (the Outstanding Balance as of the closing of the Qualified Financing) x 1.25 / (the per security price of the securities sold in the Qualified Financing).

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

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

As described more completely in Note 8, Capital Stock, effective on May 12, 2015, we entered in to an agreement with Platinum (Platinum Agreement) pursuant to which Platinum agreed, among other things, to convert the $4,489,300 outstanding balance (principal and accrued interest) of the Senior Notes having maturity dates between October 2015 and July 2016 into 641,335 shares of our Series B Preferred. We determined that the conversion of the Senior Notes into Series B Preferred should be accounted for as an extinguishment of debt. Considering the exchangeability of the Series B Preferred into our common stock, the dividend applicable to the Series B Preferred prior to such exchange and other factors, we also determined that the fair value of a share of Series B Preferred issued

pursuant to the Senior Note conversion was equal to the market value of a share of our common stock on the Senior Note conversion date. Based on the $10.00 per share fair value of the Series B Preferred at the date the Senior Notes were converted, we issued Series B Preferred having an aggregate fair value of $6,413,300 and recognized a non-cash loss on extinguishment of debt of $1,924,000 in the quarter ended June 30, 2015 in the accompanying Condensed Consolidated Statement of Operations and Comprehensive Loss.

Table of Contents

Conversion of 2014 Unit Notes into Series B Preferred

Pursuant to the Platinum Agreement, Platinum also agreed to convert the $1,345,700 outstanding balance of the 2014 Unit Notes originally issued by us to Platinum that had matured on March 31, 2015 (Platinum Unit Notes) into shares of our Series B Preferred. Platinum additionally agreed to acquire and convert into our Series B Preferred other 2014 Unit Notes that had matured on March 31, 2015 originally issued to other investors having an aggregate outstanding balance of $1,487,900 (Acquired Unit Notes). Further, effective May 20, 2015, the holders of other 2014 Unit Notes that had matured on March 31, 2015 or shortly thereafter having an aggregate outstanding balance of $1,831,200 (Investor Unit Notes) individually agreed to convert such notes into our Series B Preferred. Consequently, the outstanding balance of all 2014 Unit Notes, including those issued in April and May 2015, totaling $4,664,800, was converted into shares of our Series B Preferred. We determined that the Series B Preferred Unit Offering, as described in Note 8, Capital Stock, would be treated as a Qualified Financing applicable to the 2014 Unit Notes, entitling the 2014 Unit Note holders at the time of conversion to the 25% Qualified Financing conversion premium under the terms of the 2014 Unit Notes. Accordingly, we issued in a self-placed private placement transaction an aggregate of 833,020 shares of our Series B Preferred and warrants to purchase an aggregate of 833,020 shares of our common stock upon the conversion of the outstanding balance of all 2014 Unit Notes, including an aggregate conversion premium of $1,166,200.

We determined that the conversion of the 2014 Unit Notes into Series B Preferred should be accounted for as an extinguishment of debt. Considering the exchangeability of the Series B Preferred into our common stock, the dividend applicable to the Series B Preferred prior to such exchange and other factors, we also determined that the fair value of a share of Series B Preferred issued pursuant to the 2014 Unit Note conversions was equal to the market value of a share of our common stock on the 2014 Unit Note conversion dates. Based on the $10.00 per share fair value of the Series B Preferred at the date the Platinum Unit Notes and Acquired Unit Notes were converted and the $8.00 per share fair value of the Series B Preferred at the date the Investor Unit Notes were converted, we issued in a self-placed private placement transaction Series B Preferred having an aggregate fair value of $7,676,200 upon the conversions. We valued the warrants issued in connection with the 2014 Unit Note conversions at an aggregate of $5,168,400 using the Black Scholes option pricing model and the following assumptions:

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

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

conversion of the 2014 Unit Notes in the amount of $5,942,700 in the quarter ended June 30, 2015 in the accompanying Condensed Consolidated Statement of Operations and Comprehensive Loss.

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

On May 29, 2015, University Health Network (UHN) agreed to convert the entire $656,400 outstanding balance (principal and accrued interest) of our promissory note maturing on March 31, 2016 into 93,775 shares of our Series B Preferred. We determined that the conversion of the UHN note into Series B Preferred should be accounted for as an extinguishment of debt. Considering the exchangeability of the Series B Preferred into our common stock, the dividend applicable to the Series B Preferred prior to such exchange and other factors, we also determined that the fair value of a share of Series B Preferred issued pursuant to the UHN note conversion was equal to the market value of a share of our common stock on the UHN note conversion date. Based on the $10.00 per share fair value of the Series B Preferred at the date the UHN note was converted, we issued Series B Preferred having an aggregate fair value of $937,800 and, after eliminating the remaining $27,500 of unamortized discount on the UHN note, we recognized a non-cash loss on extinguishment of debt attributable to the conversion of the UHN Note of $308,900 in the quarter ended June 30, 2015 in the accompanying Condensed Consolidated Statement of Operations and Comprehensive Loss.

Table of Contents

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

On June 10, 2015, CHC, the parent company of CRL and a related party, agreed to convert the entire aggregate outstanding balance (principal and accrued interest) of $1,583,000 of our outstanding promissory notes issued to CHC and CRL and maturing on March 31, 2016 (together, the Cato Notes), plus an additional $171,300 of past due accounts payable to CRL and a strategic adjustment thereto (CRL Payables) into a total of 328,571 shares of our Series B Preferred. We determined that the conversion of the Cato Notes and the CRL Payables into Series B Preferred should be accounted for as an extinguishment of debt. Considering the exchangeability of the Series B Preferred into our common stock, the dividend applicable to the Series B Preferred prior to such exchange and other factors, we also determined that the fair value of a share of Series B Preferred issued pursuant to the Cato Notes and CRL Payables conversions was equal to the market value of a share of our common stock on the conversion date. Based on the $10.00 per share fair value of the Series B Preferred at the date the Cato Notes and CRL Payables were converted, we issued Series B Preferred having an aggregate fair value of $3,285,700. As additional consideration for the conversion of the Cato Notes and the CRL Payables, we amended certain outstanding warrants held by CHC and CRL to purchase 12,500 and 60,691 restricted shares of our common stock, respectively, to reduce the exercise price thereof from $30.00 and $20.00 per share, respectively, to $7.00 per share. We calculated the fair value of the warrants immediately before and after the modifications and determined that the fair value of the warrants increased by $222,700. The warrants subject to the exercise price modifications were valued using the Black-Scholes Option Pricing Model and the following assumptions:

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

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

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

On June 12, 2015, Morrison & Foerster (M&F) agreed to convert the entire aggregate outstanding balance (principal and accrued interest) of $1,735,500 of our August 2012 promissory Note B maturing on March 31, 2016 (M&F Note B) plus an agreed strategic adjustment thereto into a total of 257,143 shares of our Series B Preferred. We determined that the conversion of M&F Note B into Series B Preferred should be accounted for as an extinguishment of debt. Considering the exchangeability of the Series B Preferred into our common stock, the dividend applicable to the Series B Preferred prior to such exchange and other factors, we also determined that the fair value of a share of Series B Preferred issued pursuant to the M&F Note B conversion was equal to the market value of a share of our common stock on the conversion date. Based on the $10.00 per share fair value of the Series B Preferred at the date M&F Note B was converted, we issued Series B Preferred having an aggregate fair value of $2,571,400. As additional

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

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

Table of Contents

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

In addition to its agreement to convert M&F Note B into Series B Preferred, M&F also agreed to withhold, through the later of (i) December 31, 2016 or (ii) our consummation of a registered public offering or a strategic transaction involving AV-101 in which, in either case, we receive gross proceeds of at least $20.0 million, any and all action to collect amounts due under our past due August 2012 promissory Note A and certain past due amounts owed by us to M&F in connection with professional services previously rendered by M&F. See Note 10, Subsequent Events, regarding extinguishment of the August 2012 promissory Note A after June 30, 2015.

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

On June 18, 2015, McCarthy Tetrault (McCarthy) agreed to convert the entire $379,600 outstanding balance (principal and accrued interest) of our past due promissory note issued in May 2011 plus an additional $2,100 of past due accounts payable (together, the McCarthy Note) into 59,230 shares of our Series B Preferred. We determined that the conversion of the McCarthy Note into Series B Preferred should be accounted for as an extinguishment of debt. Considering the exchangeability of the Series B Preferred into our common stock, the dividend applicable to the Series B Preferred prior to such exchange and other factors, we also determined that the fair value of a share of Series B Preferred issued pursuant to the McCarthy Note conversion was equal to the market value of a share of our common stock on the McCarthy Note conversion date. Based on the $14.00 per share fair value of the Series B Preferred at the date the McCarthy Note was converted, we issued Series B Preferred having an aggregate fair value of $829,200 and we recognized a non-cash loss on extinguishment of debt attributable to the conversion of the McCarthy Note of $447,500 in the quarter ended June 30, 2015 in the accompanying Condensed Consolidated Statement of Operations and Comprehensive Loss.

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

On June 24, 2015, Burr Pilger & Mayer agreed to convert the entire $105,200 outstanding balance (principal and accrued interest) of our past due promissory note issued in May 2011 plus an additional $17,900 of past due accounts payable (together, the Burr Note) into 21,429 shares of our Series B Preferred. We determined that the conversion of the Burr Note into Series B Preferred should be accounted for as an extinguishment of debt. Considering the exchangeability of the Series B Preferred into our common stock, the dividend applicable to the Series B Preferred prior to such exchange and other factors, we also determined that the fair value of a share of Series B Preferred issued pursuant to the Burr Note conversion was equal to the market value of a share of our common stock on the Burr Note conversion date. Based on the $16.50 per share fair value of the Series B Preferred at the date the Burr Note was converted, we issued Series B Preferred having an aggregate fair value of $353,600 and we recognized a non-cash loss on extinguishment of debt attributable to the conversion of the Burr Note of $230,500 in the quarter ended June 30, 2015 in the accompanying Condensed Consolidated Statement of Operations and Comprehensive Loss.

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

On June 26, 2015, Icahn School of Medicine at Mount Sinai (ISMMS) agreed to convert the entire $270,400 outstanding balance (principal and accrued interest) of our past due April 2014 promissory note into a total of 40,000 shares of our Series B Preferred. We determined that the conversion of the ISMMS note into Series B Preferred should be accounted for as an extinguishment of debt. Considering the exchangeability of the Series B Preferred into our common stock, the dividend applicable to the Series B Preferred prior to such exchange and other factors, we also determined that the fair value of a share of Series B Preferred issued pursuant to the ISMMS note conversion was

equal to the market value of a share of our common stock on the conversion date. Based on the $16.00 per share fair value of the Series B Preferred at the date the ISMMS note was converted, we issued Series B Preferred having an aggregate fair value of $640,000. As additional consideration for the conversion of the ISMMS note, we amended an outstanding warrant held by ISMMS to purchase 15,000 restricted shares of our common stock to reduce the exercise price from $10.00 per share to $7.00 per share. We calculated the fair value of the warrant immediately before and after the modification and determined that the fair value of the warrant increased by $16,600. The warrant subject to the exercise price modification was valued using the Black-Scholes Option Pricing Model and the following assumptions:

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

Table of Contents

We recognized a non-cash loss on extinguishment of debt attributable to the conversion of ISMMS note of $386,200 in the quarter ended June 30, 2015 in the accompanying Condensed Consolidated Statement of Operations and Comprehensive Loss.

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

On June 29, 2015, National Jewish Health (NJH) agreed to convert the entire $115,000 outstanding balance (principal and accrued interest) of our past due promissory note into 17,857 shares of our Series B Preferred. We determined that the conversion of the NJH note into Series B Preferred should be accounted for as an extinguishment of debt. Considering the exchangeability of the Series B Preferred into our common stock, the dividend applicable to the Series B Preferred prior to such exchange and other factors, we also determined that the fair value of a share of Series B Preferred issued pursuant to the NJH note conversion was equal to the market value of a share of our common stock on the NJH note conversion date. Based on the $15.00 per share fair value of the Series B Preferred at the date the NJH note was converted, we issued Series B Preferred having an aggregate fair value of $267,900 and we recognized a non-cash loss on extinguishment of debt attributable to the conversion of the NJH note of $152,900 in the quarter ended June 30, 2015 in the accompanying Condensed Consolidated Statement of Operations and Comprehensive Loss.

Conversion of Accounts Payable to Professional Services Provider into Series B Preferred

On June 8, 2015, one of our professional service providers agreed to convert the entire $432,500 past due balance for prior services (Service Provider Payables) into 71,429 shares of our Series B Preferred. We determined that the conversion of the Service Provider Payables balance into Series B Preferred should be accounted for as an extinguishment of debt. Considering the exchangeability of the Series B Preferred into our common stock, the dividend applicable to the Series B Preferred prior to such exchange and other factors, we also determined that the fair value of a share of Series B Preferred issued pursuant to the Service Provider Payables conversion was equal to the market value of a share of our common stock on the Service Provider Payables conversion date. Based on the $10.00 per share fair value of the Series B Preferred at the date the Service Provider Payables were converted, we issued Series B Preferred having an aggregate fair value of $714,300 and we recognized a non-cash loss on extinguishment of debt attributable to the conversion of the Service Provider Payables $281,800 in the quarter ended June 30, 2015 in the accompanying Condensed Consolidated Statement of Operations and Comprehensive Loss.

See Note 10, Subsequent Events, for disclosure of additional notes and payables converted into Series B Preferred after June 30, 2015.

Note 8. Capital Stock

2014 Unit Private Placement

Between April 1, 2015 and May 14, 2015, we entered into securities purchase agreements with accredited investors pursuant to which we sold to such accredited investors, in self-placed private placement transactions, Units, for aggregate cash proceeds of $280,000, consisting of (i) 10% convertible notes in the aggregate face amount of $280,000 due between April 30, 2015 and May 15, 2015 or automatically convertible into securities issuable upon our consummation of a Qualified Financing, as defined in the note (ii) an aggregate of 33,000 restricted shares of our common stock; and (iii) warrants exercisable through December 31, 2016 to purchase an aggregate of 24,250 restricted shares of our common stock at an exercise price of $10.00 per share.

We allocated the proceeds from the private sales of the 2014 Units to the various securities based on their relative fair values on the dates of the sales. As described in Note 8, Convertible Promissory Notes and Other Notes Payable,

based on the short-term nature of the Unit Notes, we determined that fair value of the 2014 Unit Notes was equal to their face value. We determined the fair value of the 2014 Unit Stock based on the quoted market price of our common stock on the date of the 2014 Unit sale. We calculated the fair value of the 2014 Unit Warrants using the Black Scholes Option Pricing Model and the weighted average assumptions indicated in the table below. The table below also presents the aggregate allocation of the 2014 Unit sales proceeds based on the relative fair values of the 2014 Unit Stock, 2014 Unit Warrants and 2014 Unit Notes as of their respective 2014 Unit sales dates.

	Unit Warrants												
	Weighted Average Issuance Date Valuation Assumptions										Aggregate Allocation of Proceeds Based on Relative Fair Value of:		
Warrant Shares Issued	Market Price	Exercise Price	Term (Years)	Risk free Interest Rate	Volatility	Dividend Rate	Per Share Fair Value of Warrant	Aggregate Fair Value of Unit Warrants	Aggregate Proceeds of Unit Sales		Unit Stock	Unit Warrant	Unit Note
24,250	$ 10.00	$ 10.00	1.70	0.45%	73.19%	0.00%	$ 3.69	$ 89,600	$ 280,000		$ 128,900	$ 32,900	$ 118,200

Table of Contents

Between late March 2014 and May 14, 2015, in self-placed private placement transactions, we entered into securities purchase agreements with accredited investors for the 2014 Unit Private Placement pursuant to which we sold Units to such accredited investors for aggregate cash proceeds of $3,393,500, consisting of (i) 10% convertible notes in the aggregate face amount of $3,393,500 due between March 31, 2015 and May 15, 2015 or automatically convertible into securities issuable upon our consummation of a Qualified Financing, as defined in the note (ii) an aggregate of 315,850 restricted shares of our common stock; and (iii) warrants exercisable through December 31, 2016 to purchase an aggregate of 307,100 restricted shares of our common stock at an exercise price of $10.00 per share.

Creation of Series B Preferred Stock

On May 7, 2015, we filed a Certificate of Designation of the Relative Rights and Preferences of the Series B 10% Preferred Stock of VistaGen Therapeutics, Inc. (Certificate of Designation) with the Nevada Secretary of State to designate 4.0 million shares of our authorized preferred stock as Series B 10% Convertible Preferred Stock (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 at a fixed conversion price of $7.00 per share (Conversion Price). The Conversion Price is subject to adjustment, but only for customary stock dividends, reclassifications, splits and similar transactions set forth in the Certificate of Designation. All outstanding shares of Series B Preferred are also convertible automatically into shares of our common stock (Automatic Conversion) upon the closing or effective date of any of the following transactions or events: (i) a strategic transaction involving AV-101 with an initial up-front cash payment to us of at least $10.0 million; (ii) a registered public offering of our common stock with aggregate gross proceeds to us of at least $10.0 million; or (iii) for 20 consecutive trading days, our common stock trades at least 20,000 shares per day with a daily closing price of at least $12.00 per share; provided, however, that Automatic Conversion and Voluntary Conversion (collectively, Conversion) are subject to certain beneficial ownership blockers as set forth in the Certificate of Designation and/or securities purchase agreements.

Prior to Conversion, shares of Series B Preferred will accrue dividends, payable only in unregistered shares of our common stock, at a rate of 10% per annum (Accrued Dividends). The Accrued Dividends will be 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, divided by the Conversion Price. At June 30, 2015, we have recognized a liability in the amount of $213,300 for Accrued Dividends in the accompanying Condensed Consolidated Balance Sheet at June 30, 2015, based on the Series B Preferred issued and outstanding through the quarter ended June 30, 2015. This amount is also recognized in arriving at net loss attributable to common stockholders in the accompanying Condensed Consolidated Statement of Operations and Comprehensive Loss for the quarter ended June 30, 2015. The liquidation value of the Series B Preferred at June 30, 2015 is approximately $21,182,300.

Table of Contents

Agreement with Platinum

On May 5, 2015, we entered into an Agreement with Platinum, which, as modified by an Acknowledgement and Agreement, became effective on May 12, 2015 (Platinum Agreement) and pursuant to which Platinum:

- Converted all of the approximately $4.5 million outstanding balance (principal and accrued but unpaid interest) of the Senior Notes we issued to Platinum into 641,335 shares of Series B Preferred, as described previously in Note 7, Convertible Promissory Notes and Other Notes Payable; and

- Released all of its security interests in our assets and those of our subsidiaries by terminating the Amended and Restated Security Agreement, IP Security Agreement and Negative Covenant, each dated October 11, 2012 between us and Platinum; and

- Converted all of the approximately $1.3 million outstanding balance (principal and accrued but unpaid interest) of the 2014 Unit Notes that we issued to Platinum into 240,305 shares of Series B Preferred and five-year warrants to purchase 240,305 shares of our common stock at a fixed exercise price of $7.00 per share (Series B Warrants), as described previously in Note 7, Convertible Promissory Notes and Other Notes Payable; and

- Purchased approximately $1.5 million (including accrued but unpaid interest thereon) of outstanding 2014 Unit Notes we issued to various investors from the respective holders thereof (Acquired Unit Notes) and converted the entire outstanding balance of the Acquired Unit Notes into 265,699 shares of Series B Preferred and Series B Warrants to purchase 265,699 shares of our common stock, as described previously in Note 7, Convertible Promissory Notes and Other Notes Payable; and;

- Entered into a Securities Purchase Agreement (SPA) to purchase, for $1.0 million, a total of 142,857 shares of Series B Preferred and a Series B Warrant to purchase 142,857 shares of our common stock, on or before June 11, 2015 ($100,000 of which purchase was completed on June 19, 2015 and pursuant to which we issued 14,286 shares of Series B Preferred and a Series B Warrant to purchase 14,286 shares of our common stock.) See Note 10, Subsequent Events, for disclosure regarding Platinum's consummation of the remainder of this $1.0 million commitment and an agreement for $3.0 million of additional purchases of Series B Preferred and Series B Warrants under the SPA; and

- Amended the Platinum Warrants previously issued by us to Platinum in connection with the Senior Notes and the Series A Exchange Warrant to fix the exercise price thereof, eliminate the exercise price reset features and fix the number of shares of our common stock issuable thereunder, and eliminate the cashless exercise provisions from the Platinum Warrants and the Series A Exchange Warrant; and

- Agreed to refrain from the sale of any shares of our common stock held by Platinum or its affiliates until the earlier to occur of an effective registration statement relating to resale of certain specified shares of common stock under the Securities Act of 1933, as amended, or the closing price of our common stock is at least $15.00 per share.

As additional consideration for the several agreements of Platinum under the Platinum Agreement, we issued to Platinum 400,000 shares of Series B Preferred (Additional Consideration Shares) and Series B Warrants (Additional Consideration Warrants) to purchase 1.2 million shares of our common stock, and exchanged 30,000 shares of our common stock then beneficially owned or controlled by Platinum for 30,000 shares of Series B Preferred. Considering the exchangeability of the Series B Preferred into our common stock, the dividend applicable to the Series B Preferred prior to such exchange and other factors, we determined that the fair value of a share of Series B Preferred issued to Platinum pursuant to the Platinum Agreement was equal to the market value of a share of our common stock on the effective date of the Platinum Agreement. Based on the $10.00 per share fair value of the Series B Preferred at the May 12, 2015 effective date of the Platinum Agreement, we issued Additional Consideration Shares having an

aggregate fair value of $4.0 million to Platinum. We valued the Additional Consideration Warrants at an aggregate of $8,270,900 using the Black Scholes option pricing model and the same assumptions used in valuing the Series B Warrants issued to Platinum in connection with the conversion of the Platinum Unit Notes and the Acquired Unit Notes, as described previously in Note 7, Convertible Promissory Notes and Other Notes Payable. We recognized the aggregate fair value of the Additional Consideration Shares and Additional Consideration Warrants as a non-cash component of loss on debt extinguishment in the quarter ended June 30, 2015 in the accompanying Condensed Consolidated Statement of Operations and Comprehensive Loss.

Table of Contents

Series B Preferred Unit Offering

Between May 26, 2015 and June 30, 2015, in self-placed private placement transactions, we sold to accredited investors an aggregate of $607,500 of units in our Series B Preferred Unit offering, which units consist of Series B Preferred and Series B Warrants (together Series B Preferred Units), including $100,000 to Platinum. We issued 86,790 shares of Series B Preferred and Series B Warrants to purchase 86,790 shares of our common stock. Through June 30, 2015, we received an aggregate of $607,500 in cash proceeds from our self-placed private placement and sale of the Series B Preferred Units.

We allocated the proceeds from the sale of the Series B Preferred Units to the Series B Preferred and the Series B Warrants based on their relative fair values on the dates of the sales. As described in Note 7, Convertible Promissory Notes and Other Notes Payable, we determined that the fair value of a share of Series B Preferred was equal to the quoted market value of a share of our common stock on the date of a Series B Preferred Unit sale. We calculated the fair value of the Series B Warrants using the Black Scholes Option Pricing Model and the weighted average assumptions indicated in the table below. The table below also presents the aggregate allocation of the Series B Preferred Unit sales proceeds based on the relative fair values of the Series B Preferred and the Series B Warrants as of their respective Series B Preferred Unit sales dates. The difference between the relative fair value per share of the Series B Preferred, approximately $4.05 per share, and its Conversion Price (or stated value) of $7.00 per share represents a deemed dividend to the purchasers of the Series B Preferred Units. Accordingly, we have recognized a deemed dividend in the aggregate amount of $256,200 in arriving at net loss attributable to common stockholders in the accompanying Condensed Consolidated Statement of Operations and Comprehensive Loss for the quarter ended June 30, 2015.

	Series B Warrants Weighted Average Issuance Date Valuation Assumptions									Aggregate Allocation o Proceeds Based on Relative Fair Va of:	
Series B Warrant Shares Issued	Market Price	Exercise Price	Term (Years)	Risk free Interest Rate	Volatility	Dividend Rate	Per Share Fair Value of Warrant	Aggregate Fair Value of Unit Warrants	Aggregate Proceeds of Unit Sales	Series B Preferred	Series E Warrant
86,790	$ 13.22	$ 7.00	5.00	1.65%	76.22%	0.00%	$ 9.77	$ 848,000	$ 607,500	$ 351,100	$ 256

See Note 10, Subsequent Events, for disclosure regarding additional sales of Series B Preferred Units after June 30, 2015.

Issuance of Securities to Professional Service Providers

In June 2015, we issued in a private placement 25,000 shares of our Series B Preferred having a fair value of $250,000 as compensation for legal services related to our debt restructuring and other corporate finance matters. Effective on June 30, 2015, we issued an aggregate of 90,000 shares of our Series B Preferred having an aggregate value of $1,350,000 as compensation for financial advisory and corporate development service contracts with two independent contractors for services to be performed through June 30, 2016. The value of the Series B Preferred grants is recorded as a prepaid expense in the accompanying Condensed Consolidated Balance Sheet as of June 30, 2015 and will be expensed ratably over the twelve months ending June 30, 2016. During the quarter ended June 30, 2015, we also issued an aggregate of 50,000 shares of our common stock having an aggregate value of $500,000 as compensation under two corporate development service contracts. The value of the common stock grants has been expensed as a

component of general and administrative expense in the accompanying Condensed Consolidated Statement of Operations and Comprehensive Loss for the quarter ended June 30, 2015.

Modification of Warrants

In addition to warrants modified in connection with conversions of certain of our outstanding promissory notes into Series B Preferred as described earlier in Note 7, Convertible Promissory Notes and Other Notes Payable; on June 10, 2015, we modified certain other outstanding warrants to purchase an aggregate of 54,576 shares of our common stock to reduce their exercise price. We calculated the fair value of the modified warrants immediately before and after the modifications and determined that the fair value of the warrants increased by an aggregate of $122,300, which we recognized as a component of general and administrative expense in the accompanying Condensed Consolidated Statements of Operations and Comprehensive Loss for the quarter ended June 30, 2015, with a corresponding credit to additional paid-in capital. The warrants subject to the exercise price modifications were valued using the Black-Scholes Option Pricing Model and the following assumptions:

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

Table of Contents

Warrants Outstanding

Following the Series B Warrant issuances and other modifications described above, at June 30, 2015, we had outstanding warrants to purchase shares of our unregistered common stock at a weighted average exercise price of $8.58 per share as follows:

Exercise Price per Share	Expiration Date	Shares Subject to Purchase at June 30, 2015
$7.00	9/30/2017 to 6/30/2020	2,459,618
$10.00	1/31/2016 to 1/11/2020	931,468
$12.80	3/3/2023	147,000
$15.00	1/31/2016 to 3/4/2018	75,389
$20.00	7/30/2016 to 9/15/2019	115,448
$30.00	2/13/2016 to 11/20/2017	6,100
		3,735,023

Note 9. Related Party Transactions

Cato Holding Company, doing business as Cato BioVentures (CBV), the parent of Cato Research Ltd. (CRL), is one the largest institutional holders of our common stock at June 30, 2015. In October 2012, we issued a 7.5% promissory note (CHC Note) and a warrant (CHC Warrant) to CHC in settlement of prior indebtedness. As disclosed in Note 7, Convertible Promissory Notes and Other Notes Payable, during June 2015, the outstanding balance of the CHC Note was converted into shares of our Series B Preferred and we reduced the exercise price of the CHC Warrant from $30.00 per share to $7.00 per share. Total interest expense, including amortization of note discount, on the CHC Note was $4,700 and $7,600 in the three month periods ended June 30, 2015 and 2014, respectively.

During fiscal year 2007, we entered into a contract research, development and regulatory service arrangement with CRL, a contract research organization (CRO), related to the development of AV-101, our orally available small molecule prodrug candidate currently in Phase 2 clinical development for Major Depressive Disorder, and subsequent other projects under which we incurred expenses of $11,200 and $7,500 in the three month periods ended June 30, 2015 and 2014, respectively.

In October 2012, we issued to CRL (i) a 7.5% promissory note (CRL Note) as payment in full for all contract research, development and regulatory services and advice (CRO Services) rendered by CRL to us through December 31, 2012 with respect to the preclinical and clinical development of AV-101, and (ii) a warrant (CRL Warrant). As disclosed in Note 7, Convertible Promissory Notes and Other Notes Payable, during June 2015, the entire outstanding balance of the CRL Note and all other outstanding amounts owed to CRL for CRO services were converted into shares of our Series B Preferred and we reduced the exercise price of the CRL Warrant from $20.00 per share to $7.00 per share. Total interest expense, including amortization of the note discount, on the CRL Note was $23,500 and $36,800 for the three month periods ended June 30, 2015 and 2014, respectively.

Note 10. Subsequent Events

Series B Preferred Unit Offering

Between July 1, 2015 and August 11, 2015, in our self-placed private placement of Series B Preferred Units, we entered into securities purchase agreements with accredited investors pursuant to which we sold to such investors Series B Preferred Units consisting of (i) an aggregate of 206,472 shares of our Series B Preferred, including 128,574 Series B Preferred shares to Platinum; and (iii) Series B Warrants to purchase an aggregate of 206,472 shares of our common stock at an exercise price of $7.00 per share, including Series B Warrants to purchase 128,574 shares of our common stock issued to Platinum. We received cash proceeds of $1,445,300 from the private placement and sale of the Series B Preferred Units, including $900,000 from Platinum.

On August 3, 2015, we entered into an agreement with Platinum pursuant to which Platinum has agreed to purchase an additional $3.0 million of our Series B Preferred Units between August 15, 2015 and October 15, 2015 and would receive an aggregate of 458,571 shares of Series B Preferred and Series B Warrants to purchase 458,571 shares of our common stock.

Promissory Notes and Accounts Payable Converted into Series B Preferred

Between July 1, 2015 and August 12, 2015, the entire outstanding balance (principal plus accrued interest) of our outstanding promissory note payable to Desjardins Securities, our promissory note and accounts payable due to MicroConstants, our promissory Note A and accounts payable to Morrison & Foerster, and certain other amounts due to technology licensors, professional service providers and others, in the aggregate amount of $1,678,400 were extinguished and converted into an aggregate of 255,128 shares of Series B Preferred.

Table of Contents

Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q includes forward-looking statements. All statements contained in this Quarterly Report on Form 10-Q includes forward-looking statements. All statements contained in this Quarterly Report on Form 10-Q 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 in 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 our Annual Report on Form 10-K for the year ended March 31, 2015 and in our other filings with the SEC. Further, even if our product candidates appear promising at various stages of development, our share price may decrease such that we are unable to raise additional capital without significant dilution or other terms that may be unacceptable to our management, Board of Directors and stockholders.

Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the future events and trends discussed in this Quarterly Report on Form 10-Q may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. The events and circumstances reflected in the forward-looking statements may not be achieved or occur. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. We are under no duty to update any of these forward-looking statements after the date of this Quarterly Report on Form 10-Q 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

The World Health Organization estimates that 350 million people worldwide are affected by depression. According to the U.S. National Institutes of Health (NIH), major depression is one of the most common mental disorders in the U.S. In 2012, the NIH estimated 16 million adults aged 18 or older in the U.S. had at least one major depressive episode. This represented 6.9 percent of all U.S. adults. According to the U.S. Centers for Disease Control and Prevention (CDC), one in ten Americans take an antidepressant medication. Unfortunately, approximately two-thirds of depression sufferers do not benefit from the first round treatment of currently approved antidepressant agents, including selective serotonin reuptake inhibitors (SSRIs) and serotonin-norepinephrine reuptake inhibitors (SNRIs). And, even when they do relieve depressive symptoms and induce remission of a major depressive episode, because of their mechanism of action, SSRIs and SNRIs take many weeks to achieve those therapeutic benefits. During the

multiple-week lag before onset of therapeutic benefits, risks of side effects, including suicidal thoughts and behaviors, may be considerable. Ultimately, after as many as four treatment cycles involving several different antidepressant medications, approximately two-thirds of patients may find an antidepressant drug or drug combination that induces remission of depressive symptoms. This trial and error period to find an effective antidepressant medication can take many months to more than a year to achieve, with an increasing rate of potentially significant side effect risks with each successive treatment attempt.

Table of Contents

Our lead product candidate, AV-101, is an orally available small molecule prodrug in Phase 2 clinical development for Major Depressive Disorder (MDD). AV-101's mechanism of action (MOA), as an N-methyl-D-aspartate receptor (NMDAR) antagonist binding selectively at the glycine-binding (GlyB) co-agonist site of the NMDAR, is fundamentally different from all antidepressants approved by the U.S. Food and Drug Administration ("FDA"). In four preclinical studies utilizing well-validated animal models of depression, AV-101 was shown to induce fast-acting, dose-dependent, persistent and statistically significant antidepressant-like responses, following a single treatment, which were equivalent to responses seen with a control single sub-anesthetic dose of ketamine (an FDA-approved drug sometimes used by clinicians off-label to treat suicidal behavior). In the same preclinical studies, fluoxetine (Prozac) did not induce rapid onset antidepressant-like responses. Preclinical studies also support the hypothesis that AV-101 has the potential to treat several additional CNS disorders, including chronic neuropathic pain, epilepsy and neurodegenerative diseases, such as Parkinson's disease and Huntington's disease, where modulation of the NMDAR may have therapeutic benefit.

Following two successful randomized, double-blind, placebo-controlled Phase 1 safety studies funded by the NIH, in February 2015, we entered into a Cooperative Research and Development Agreement (CRADA) with the U.S. National Institute of Mental Health (NIMH), part of the NIH. Under the CRADA, we are collaborating with the NIMH on the initial Phase 2 clinical efficacy study of AV-101 in subjects with treatment-resistant MDD. Pursuant to the CRADA, the study will be conducted at the NIMH and be fully funded by the NIMH. It is contemplated that this clinical study will begin in the second half of 2015 under the direction of 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.

In addition to developing AV-101 for MDD and other CNS indications, we are applying our stem cell technology for drug rescue to identify and develop proprietary new chemical entities (NCEs) for our internal drug candidate pipeline and selected regenerative medicine opportunities. Drug rescue involves (1) using our customized in vitro bioassay systems to predict potential heart and liver toxicity of NCEs, (2) leveraging prior investments by pharmaceutical companies and others related to screening large-scale compound libraries, optimizing and testing for efficacy NCEs that were terminated before FDA approval due to heart or liver toxicity and are now available in the public domain, and (3) applying medicinal chemistry to produce safer proprietary NCEs for our internal development pipeline. Our CardioSafe 3D™ bioassay system uses our human pluripotent stem cell (hPSC)-derived cardiomyocytes, or human heart cells. We believe CardioSafe 3D is more comprehensive and clinically predictive than the hERG assay, which is currently the only in vitro cardiac safety assay required by FDA guidelines. We use our hPSC-derived hepatocytes, or human liver cells, in our LiverSafe 3D™ bioassay system to predict potential liver toxicity of NCEs, including potential drug metabolism issues and adverse drug-drug interactions. CardioSafe 3D and LiverSafe 3D offer a new paradigm for evaluating and predicting potential heart and liver toxicity of NCEs, including drug rescue NCEs, early in the development process, long before costly, high risk animal studies and human clinical trials. We intend to develop internally for our pipeline each lead drug rescue NCEs we produce. Our focus in regenerative medicine is on innovative therapeutic opportunities involving blood, cartilage, heart and liver cells.

Financial Operations Overview and Results of Operations

Our critical accounting policies and estimates and recent accounting pronouncements are disclosed in our Form 10-K for the fiscal year ended March 31, 2015, as filed with the SEC on June 29, 2015, and in Note 3 to the accompanying unaudited Condensed Consolidated Financial Statements included in Part 1, Item 1 of this Quarterly Report on Form 10-Q.

Summary

Net Loss

We have not yet achieved revenue-generating status from any of our potential products. Since inception, we have devoted substantially all of our time and efforts to development of AV-101 through its Phase 1 clinical trials and preparation for its initial Phase 2 clinical trial, stem cell research and bioassay development, small molecule drug development, and creating, protecting and patenting intellectual property in support of our drug candidate and stem cell technology platform, with the corollary initiatives of recruiting personnel and raising working capital. As of June 30, 2015, we had an accumulated deficit (including cash and non-cash charges) of approximately $114.0 million. Our net loss for the quarters ended June 30, 2015 and 2014 was $29.5 million and $4.6 million, respectively, including a non-cash loss of approximately $25.1 million attributable to converting over $15.4 million of our indebtedness into equity securities during our first quarter ended June 30, 2015. We expect losses to continue for the foreseeable future as we engage in Phase 2 clinical trials of AV-101 and its further development and increase our drug rescue and regenerative medicine activities related to our stem cell technology platform.

Table of Contents

Summary of Quarter Ended June 30, 2015

Although our financial resources have been limited, our scientific personnel and collaborators continue to explore the drug rescue opportunities related to our novel, customized bioassay systems, CardioSafe 3D™ and LiverSafe 3D™, and the multiple types of human cells we and our collaborators are able to produce from pluripotent stem cells for drug rescue and regenerative medicine applications. Additionally, as indicated previously, we have entered into a Cooperative Research and Development Agreement with the NIH providing for an NIMH-sponsored Phase 2 clinical study of AV-101 in Major Depressive Disorder that we expect to be launched shortly.

Throughout all of fiscal 2014 and 2015 and the quarter ended June 30, 2015, through self-placed private placement transactions and other corporate finance initiatives, our executive management has been focused on raising sufficient operating capital to continue to advance clinical development of AV-101 and other research and development objectives, while meeting our continuing operational needs. The most specific focus during the quarter ended June 30, 2015 was on negotiating, extinguishing and converting (in self-placed private placement transactions) a majority of our outstanding indebtedness into our equity securities.

To meet our working capital needs, between April 1, 2015 and May 14, 2015, we completed self-placed private placement transactions involving securities purchase agreements with accredited investors pursuant to which we sold to such accredited investors 2014 Private Placement Units, for aggregate cash proceeds of $280,000, consisting of (i) 10% convertible notes in the aggregate face amount of $280,000 due between April 30, 2015 and May 15, 2015; (ii) an aggregate of 33,000 restricted shares of our common stock; and (iii) warrants exercisable through December 31, 2016 to purchase an aggregate of 24,250 restricted shares of our common stock at an exercise price of $10.00 per share. Between May 26, 2015 and August 11, 2015, we entered into self-placed private placement transactions involving securities purchase agreements with accredited investors, pursuant to which we sold Series B Preferred Units consisting of an aggregate of (i) 293,262 shares of our Series B 10% Convertible Preferred Stock (Series B Preferred); and (ii) five-year warrants to purchase an aggregate of 293,262 shares of our Common Stock at a fixed exercise price of $7.00 per share. In connection with these self-placed private placement transactions, we received cash proceeds of $2,052,800 which we expect to use for general corporate purposes. The figures reported above include 142,860 shares of Series B Preferred and Series B Warrants to purchase 142,860 shares of our Common Stock sold to Montsant Partners, LLC, an affiliate of Platinum Long Term Growth VII, LLC (Platinum), for cash proceeds of $1.0 million.

Given our working capital constraints, we continue to minimize cash commitments and expenditures for both internal and external research and development and general and administrative services to the greatest extent possible. The conversion of such a substantial portion of our outstanding debt, much of which was either past due or would have matured within the next twelve months, materially reduces our cash requirement for debt service.

Comparison of Three Months Ended June 30, 2015 and 2014

The following table summarizes the results of our operations for the three months ended June 30, 2015 and 2014 (amounts in thousands).

	Three Months Ended June 30,	
	2014	2014
Operating expenses:		
Research and development	$373	$474
General and administrative	1,448	797

Total operating expenses	1,821	1,271
Loss from operations	(1,821)	(1,271)
Interest expense (net)	(755)	(785)
Change in warrant liabilities	(1,895)	(1,727)
Loss on extinguishment of debt	(25,051)	(768)
Loss before income taxes	(29,522)	(4,551)
Income taxes	(2)	(2)
Net loss	$(29,524)	$(4,553)
Accrued dividend on Series B Preferred Stock	(213)	-
Deemed dividend on Series B Preferred Stock	(256)	-
Net loss attributable to common stockholders	$(29,993)	$(4,553)

Table of Contents

Revenue

We reported no revenue for the quarters ended June 30, 2015 or 2014. We have successfully completed our Phase 1 clinical development of AV-101, our orally available, new generation prodrug candidate in Phase 2 clinical development for the treatment of Major Depressive Disorder (MDD), with additional therapeutic potential in neuropathic pain, epilepsy, Parkinson's disease and Huntington's disease. Additionally, as indicated previously, we have entered into a CRADA with the NIH providing for an NIH-sponsored Phase 2 clinical study of AV-101 in Major Depressive Disorder beginning in 2015. We presently have no revenue generating arrangements.

Research and Development Expense

Research and development expense totaled $373,000 for the quarter ended June 30, 2015, a decrease of 21% compared to $474,000 for the quarter ended June 30, 2014. The following table indicates the primary components of research and development expense for each of the periods (amounts in thousands):

	Three Months Ended June 30,	
	2015	2014
Salaries and benefits	$202	$228
Stock-based compensation	18	98
Consulting services	22	24
Technology licenses and royalties	53	41
Project-related research and supplies:		
AV-101	11	8
Stem cell and all other	2	9
	13	17
Rent	53	55
Depreciation	11	11
All other	1	-
Total Research and Development Expense	$373	$474

To conserve cash resources, during 2014, Ralph Snodgrass, Ph.D., our Chief Scientific Officer (CSO), voluntarily accepted a temporary salary reduction to substantially less than his contractual pay rate. During the quarter ended June 30, 2015, Dr. Snodgrass has received cash compensation at his contractual base salary rate. Offsetting this increase is the impact of the voluntary resignation of one member of our scientific staff at the end of September 2014 and the voluntary reduction of work hours and pay by another member of our scientific staff beginning in the last quarter of calendar 2014.

Stock based compensation expense for both 2015 and 2014 reflects the ratable amortization of option grants made to scientific staff and consultants most recently in March 2014 and October 2013 as well as amortization of grants of warrants made to our CSO in March 2014. Our stock options are generally amortized over a two-year or four-year vesting period, and warrants granted to the CSO are being amortized over a three-year vesting period. Essentially all of the option grants made prior to October 2013 and a warrant grant made to our CSO in March 2013 are now fully-vested and fully-expensed, resulting in the decrease in expense between the periods reported.

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

Stem cell technology license expense reflects both recurring annual fees as well as costs for patent prosecution and protection that we are required to fund under the terms of certain of our license agreements. We recognize the latter costs as they are invoiced to us by the licensors and they do not occur ratably throughout the year or between years.

AV-101 expenses in both periods presented reflect the costs associated with monitoring for and responding to potential feedback related to the Phase 1 clinical trial and preparing other reports required under the terms of our prior NIH grant, primarily through our contract research collaborator, Cato Research Ltd. Expenses in the quarter ended June 30, 2015 additionally include costs related to updating AV-101 documentation in preparation for the Phase 2 clinical trial to be conducted by the NIH.

Table of Contents

General and Administrative Expense

General and administrative expense was $1,448,000 for the quarter ended June 30, 2015, an 82% increase from the $797,000 reported for the quarter ended June 30, 2014. The following table indicates the primary components of general and administrative expenses for each of the periods (amounts in thousands):

	Three Months Ended June 30,	
	2015	2014
Salaries and benefits	$176	$140
Stock-based compensation	11	106
Consulting Services	28	28
Legal, accounting and other professional fees	959	373
Investor relations	34	30
Insurance	38	38
Travel and entertainment	17	15
Rent and utilities	37	39
Warrant modification expense	122	-
All other expenses	26	28
Total General and Administrative Expense	$1,448	$797

To conserve cash resources, during 2014, each of Shawn Singh, our Chief Executive Officer, and Jerrold Dotson, our Chief Financial Officer, voluntarily accepted a temporary salary reduction to substantially less than his contractual or agreed pay rate. During the quarter ended June 30, 2015, both Messrs. Singh and Dotson have received cash compensation at their respective contractual base salary rate. Pay rates and administrative employee headcount have otherwise remained stable between the periods reported.

Stock based compensation expense for both 2015 and 2014 reflects the ratable amortization of option grants made to administrative employees and consultants most recently in March 2014 and October 2013 as well as amortization of grants of warrants made to our officers and independent members of our Board of Directors in March 2014. Our stock options are generally amortized over a two-year or four-year vesting period, and warrants granted to the officers and Board members are being amortized over a three-year vesting period. Essentially all of the option grants made prior to October 2013 and a warrant grant made to an officer and our Board members in March 2013 are now fully-vested and fully-expensed, resulting in the decrease in expense between the periods reported.

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

The increase in legal, accounting and other professional fees is primarily the result of the grant of an aggregate of 50,000 shares of our common stock having a fair value of $500,000 pursuant to two corporate development contracts initiated during the quarter ended June 30, 2015 and the grant of 25,000 shares of our Series B Preferred having a fair value of $250,000 to legal counsel as compensation for services in connection with our debt restructuring and other corporate finance matters. In both years, professional services fees include the expense related to the annual audit of the prior year financial statements. Expense for 2014 also includes $169,000 attributable to a consulting agreement for strategic advisory and business development services that has now expired.

Outsourced investor relations service expenses are essentially flat between periods.

In both periods, travel expense reflects costs associated with presentations to potential investors in connection with the self-placed private placement offerings of our securities.

Warrant modification expense in 2015 reflects the impact of June 2015 strategic reductions in the exercise price of certain outstanding warrants, generally from $30.00 per share to $10.00 per share.

Table of Contents

Other Expenses, Net

Interest expense, net totaled $755,000 for the quarter ended June 30, 2015, a decrease of 4% compared to the $785,000 reported for the quarter ended June 30, 2014. The following table summarizes the primary components of interest expense for each of the periods (amounts in thousands):

	Three Months Ended June 30,	
	2015	2014
Interest expense on promissory notes	$193	$285
Amortization of discount on promissory notes	551	482
Other interest expense, including on capital leases and premium financing	1	1
	745	768
Effect of foreign currency fluctuations on notes payable	10	20
Interest income	-	(3)
Interest expense, net	$755	$785

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

Under the terms of the October 2012 Note Exchange and Purchase Agreement we entered with Platinum, we issued certain Senior Secured Convertible Promissory Notes and a related Exchange Warrant and Investment Warrants between October 2012 And July 2013. Upon Platinum's exchange of the shares of our Series A Preferred Stock held by Platinum into shares of our common stock, we will also be required to issue a Series A Exchange Warrant to Platinum. We determined that the various warrants included certain exercise price adjustment features requiring us to treat the warrants as liabilities. Accordingly, we recorded a non-cash warrant liability at its estimated fair value as of the date of warrant issuance or contract execution. As described in Note 8, Capital Stock, and Note 4, Fair Value Measurements, to the Condensed Consolidated Financial Statements included in Part 1, Item 1 of this Quarterly Report on Form 10-Q, on May 12, 2015, we entered into an agreement with Platinum pursuant to which Platinum agreed to amend the warrants to fix the exercise price thereof and eliminate the anti-dilution reset features that had previously required the warrants to be treated as liabilities and carried at fair value. Accordingly, we adjusted the Platinum Warrants to their fair value, estimated to be $4,903,200, reflecting an increase of $1,894,700 since March 31, 2015, resulting primarily from the increase in the market price of our common stock in relation to the exercise price of the warrants, and we subsequently eliminated the entire warrant liability with respect to the warrants. During the quarter ended June 30, 2014, we recognized non-cash expense of $1,727,200 related to the net increase in the estimated fair value of the warrant liabilities since March 31, 2014, which again resulted primarily from the increase in the market price of our common stock in relation to the exercise price of the warrants.

As described more completely in Note 7, Convertible Promissory Notes and other Notes Payable, and Note 8, Capital Stock, to the accompanying Condensed Consolidated Financial Statements in Part I of this Report, between May 12, 2015 and June 30, 2015, we have eliminated the outstanding balances of approximately $15.4 million of promissory notes, including our Senior Secured Notes, our 2014 Unit Notes and other debt and certain adjustments thereto that were either already due and payable or would have otherwise matured prior to March 31, 2016 by converting such

balances into shares of our Series B Preferred. We treated the conversion of the debts into Series B Preferred as extinguishments of debt for accounting purposes. Since the fair value of the Series B Preferred we negotiated in settlement of the promissory notes and other debts exceeded the carrying value of the debts, we incurred losses on each of the extinguishments. Additionally, under the terms of the Platinum Agreement, we issued to Platinum 400,000 shares of Series B Preferred having an aggregate fair value of $4.0 million and Series B Warrants to purchase 1.2 million shares of our common stock having an aggregate of fair value of $8,270,900. We recognized this aggregate fair value as an additional non-cash component of loss on debt extinguishment. Many of the 2014 Unit Notes that were converted into Series B Preferred contained a beneficial conversion feature at the time they were originally issued. We have accounted for the repurchase of the beneficial conversion feature at the time the 2014 Unit Notes were extinguished and converted, an aggregate of $2,237,100, as a reduction to the loss on extinguishment of debt. We recorded an aggregate net non-cash loss of $25.1 million attributable to the extinguishment of the debt converted into Series B Preferred.

Table of Contents

During the quarter ended June 30, 2014, we entered into agreements with substantially all holders of our 2013 Unit Notes and 2013 Unit Warrants to amend certain terms of the notes and the warrants to essentially conform them to the 2014 Unit Notes and 2014 Unit Warrants. We treated the amendments as an extinguishment of debt for accounting purposes. Accordingly, since the fair value of the amended notes and warrants exceeded the carrying amount of the original notes, we recognized non-cash losses on the extinguishment of debt in the aggregate amount of $526,200 attributable to the amendments. We also recognized an additional $241,800 as a non-cash loss on extinguishment of debt as a result of the promissory note, shares of our common stock and warrants issued to Icahn School of Medicine at Mount Sinai in settlement of stem cell technology license maintenance fees and reimbursable patent prosecution costs during the quarter ended June 30, 2014.

We allocated the proceeds from the self-placed private placement sales of Series B Preferred Units to the Series B Preferred and the Series B Warrants based on their relative fair values on the dates of the sales. The difference between the relative fair value per share of the Series B Preferred, approximately $4.05 per share, and its Conversion Price (or stated value) of $7.00 per share represents a deemed dividend to the purchasers of the Series B Preferred Units. Accordingly, we have recognized a deemed dividend in the aggregate amount of $256,200 in arriving at net loss attributable to common stockholders for the quarter ended June 30, 2015 in the accompanying Condensed Consolidated Statement of Operations and Comprehensive Loss included in Part I of this Report. Further, we have recognized $213,300 representing the 10% cumulative dividend payable on our Series B Preferred as an additional deduction in arriving at net loss attributable to common stockholders in the accompanying Condensed Consolidated Statement of Operations and Comprehensive Loss.

Liquidity and Capital Resources

Since our inception in May 1998 through June 30, 2015, we have financed our operations through (1) the issuance and sale of our common stock, preferred stock, warrants for common stock, and promissory notes for aggregate cash proceeds of approximately $30.0 million, (2) issuance of common stock and preferred stock with an approximate value at issuance of $25.2 million as consideration for, among other things, technology license payments, sponsored research, contract research, development, manufacturing and regulatory services, and legal, corporate development and financial advisory services; and (3) receipt of aggregate non-dilutive cash proceeds of approximately $16.4 million from government research and development grant awards and strategic collaborations.

As described more completely in Note 7, Convertible Promissory Notes and other Notes Payable, and Note 8, Capital Stock, to the accompanying Condensed Consolidated Financial Statements in Part I of this Report, between March 31, 2015 and June 30, 2015, we created our Series B 10% Convertible Preferred Stock (Series B Preferred) and eliminated the outstanding balances of approximately $15.4 million of promissory notes, other debt and certain adjustments thereto that was either already due and payable or would have otherwise matured prior to March 31, 2016, through conversion into our Series B Preferred and, with respect to a portion of the indebtedness converted, warrants to purchase common stock. More specifically, through the date of this report, we have converted the outstanding balances of (i) all of the Senior Secured Convertible Promissory Notes originally issued to Platinum Long Term Growth VII, LLC, our largest investor (Platinum), (ii) all of the 2014 Unit Notes outstanding at March 31, 2015 and those issued subsequently, and (iii) other outstanding promissory notes including those issued to Cato Research Ltd., Cato Holding Company, Morrison & Foerster (Note A and Note B), University Health Network, McCarthy Tetrault, Desjardins Securities, Burr Pilger & Mayer, National Jewish Health, MicroConstants and others, through the issuance of an aggregate of 2,618,917 shares of our Series B Preferred. Additionally, through August 11, 2015, in our self-placed private placement of Series B Units, we have sold additional Series B Preferred Units consisting of an aggregate of 293,262 unregistered shares of Series B Preferred and five year warrants exercisable at $7.00 per share to purchase 293,262 shares of our common stock and we have received cash proceeds of $2,052,800.

At June 30, 2015, we did not have sufficient cash and cash equivalents to enable us to fund our planned operations over the next twelve months. We believe that our participation in potential strategic collaborations, including potential transactions involving AV-101 such as our February 2015 CRADA with the NIH for an NIH-funded and sponsored Phase 2 study of AV-101 in MDD, and our self-placed private placement of Series B Units may provide resources to support a portion of our future cash needs and working capital requirements in the near term, however, no assurances can be provided. When and as necessary, we will seek to raise a material amount of financing through a combination of additional private placements and/or registered public offerings of our securities, which may include both debt and equity securities, research and development collaborations, drug candidate license or sale payments, government grant awards and revenue from collaborations. Our future working capital requirements will depend on many factors, including, without limitation, the scope and nature of strategic opportunities related to our success in clinical trials of AV-101 as a treatment for MDD and other conditions and our drug rescue and cell therapy research and development efforts, our ability to obtain government grant awards and our ability to enter into strategic collaborations with institutions on terms acceptable to us. To further advance the clinical development of AV-101 and potential drug rescue and other applications of our stem cell technology, as well as support our operating activities, we plan to continue to carefully manage our routine operating costs, including salaries and benefits, regulatory consulting, contract research and development, legal, accounting, public company compliance and other professional services and working capital costs.

Table of Contents

Notwithstanding the foregoing, substantial additional financing may not be available to us on a timely basis, on acceptable terms, or at all. If we are unable to obtain substantial additional financing on a timely basis in the near term, our business, financial condition, and results of operations may be harmed, the price of our stock may decline, we may be required to reduce, defer, or discontinue certain of our research and development activities and we may not be able to continue as a going concern.

Cash and Cash Equivalents

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

	Three Months Ended June 30,	
	2015	2014
Net cash used in operating activities	$(823)	$(1,012)
Net cash used in investing activities	-	-
Net cash provided by financing activities	874	1,413
Net increase in cash and cash equivalents	51	401
Cash and cash equivalents at beginning of period	70	-
Cash and cash equivalents at end of period	$121	$401

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements.

Item 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) as of the end of the period covered by this Report. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this Report were effective.

Internal Control over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the fiscal quarter to which this Quarterly Report on Form 10-Q relates that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

PART II: OTHER INFORMATION

Item 1. Legal Proceedings

As of the date of this Quarterly Report on Form 10-Q, we were not party to any legal matters or claims. In the future, we may become party to legal matters and claims arising in the ordinary course of business, the resolution of which we do not anticipate would have a material adverse impact on our results of operations.

Item 1A. Risk Factors

Investing in our securities involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K filed with the Securities and Exchange Commission for the fiscal year ended March 31, 2015 before investing in our securities. The risks described below are not the only risks facing our Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also materially adversely affect our business, financial condition and/or operating results. If any of the following risks are realized, our business, financial condition and results of operations could be materially and adversely affected.

Risks Related to Product Development, Regulatory Approval and Commercialization

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

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

We are not permitted to market our product candidates in the United States until we receive approval of a New Drug Application, or an NDA, from the FDA, or in any foreign countries until we receive the requisite approval from such countries. We recently received FDA clearance to initiate the initial Phase 2 clinical trial involving AV-101, to study its safety, tolerability and efficacy in patients with MDD. If our Phase 2 clinical trial of AV-101 is successful, we

expect the FDA to require us to complete at least one additional Phase 2 clinical trial and at least one pivotal Phase 3 clinical trial in order to submit an NDA for AV-101 as a treatment for MDD. However, the FDA may require that we conduct more than one additional Phase 2 clinical study and more than one Phase 3 pivotal trial of AV-101 before we can submit an NDA. The FDA may also require that we conduct additional toxicity studies and additional non-clinical studies before submitting an NDA for AV-101.

Table of Contents

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

- we may not be able to demonstrate that the product candidate is safe and effective in treating a human disease or disorder, to the satisfaction of the FDA;

- the results of our non-clinical studies and clinical trials may not meet the level of statistical or clinical significance required by the FDA for marketing approval;

- the FDA may disagree with the number, design, size, conduct or implementation of our non-clinical studies and clinical trials;

- the FDA may require that we conduct additional non-clinical studies and clinical trials;

- the FDA or the applicable foreign regulatory agency may not approve the formulation, labeling or specifications of any of our product candidates;

- the contract research organizations, or CROs, that we retain to conduct our non-clinical studies and clinical trials may take actions outside of our control that materially adversely impact our non-clinical studies and clinical trials;

- the FDA may find the data from non-clinical studies and clinical trials insufficient to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;

- the FDA may disagree with our interpretation of data from our non-clinical studies and clinical trials;

- the FDA may not accept data generated at our non-clinical studies and clinical trial sites;

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

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

- the FDA or the applicable foreign regulatory agency may determine that the manufacturing processes or facilities of third-party contract manufacturers with which we contract do not conform to applicable requirements, including current Good Manufacturing Practices, or 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 market AV-101 or any other product candidate we may develop, including drug rescue NCEs. Any such setback in our pursuit of regulatory approval would have a material adverse effect on our business and prospects.

A Fast Track designation by the FDA may not actually lead to a faster development or regulatory review or approval process.

We intend to seek FDA Fast Track designation for AV-101, and we may do so for other product candidates as well. If a product candidate is intended for the treatment of a serious or life-threatening condition and the product candidate demonstrates the potential to address unmet medical needs for this condition, the sponsor may apply for the FDA Fast Track designation. The FDA has broad discretion whether or not to grant this designation, and even if we believe AV-101 and other product candidates are eligible for this designation, we cannot be sure that the review or approval will compare to conventional FDA procedures. Even if granted, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development programs.

Table of Contents

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

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

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

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

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

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

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

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

Positive results from non-clinical studies of our product candidates, and any positive results we may obtain from early clinical trials of our product candidates, may not necessarily be predictive of the results from required later non-clinical studies and clinical trials. Similarly, even if we are able to complete our planned non-clinical studies or

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

Table of Contents

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

We and the NIH are preparing to commence an NIH-funded Phase 2 clinical trial of AV-101 as a treatment for MDD. We will need to complete at least two additional large clinical trials prior to the submission of an NDA for AV-101 as a treatment for MDD. Successful completion of our clinical trials is a prerequisite to submitting an NDA to the FDA and, consequently, the ultimate approval and commercial marketing of AV-101 for MDD and any other product candidates we may develop. We do not know whether the NIH-funded Phase 2 study of AV-101 or any of our future-planned clinical trials will begin or be completed on schedule, if at all, as the commencement and completion of clinical trials can be delayed or prevented for a number of reasons, including, among others:

- the FDA may deny permission to proceed with our planned clinical trials or any other clinical trials we may initiate, or may place a clinical trial on hold;
- delays in filing or receiving approvals of additional INDs that may be required;
- negative results from our ongoing non-clinical studies;
- delays in reaching or failing to reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- inadequate quantity or quality of a product candidate or other materials necessary to conduct clinical trials, for example delays in the manufacturing of sufficient supply of finished drug product;
- difficulties obtaining Institutional Review Board, or IRB, approval to conduct a clinical trial at a prospective site or sites;
- challenges in recruiting and enrolling patients to participate in clinical trials, including the proximity of patients to trial sites;
- eligibility criteria for the clinical trial, the nature of the clinical trial protocol, the availability of approved effective treatments for the relevant disease and competition from other clinical trial programs for similar indications;
- severe or unexpected drug-related side effects experienced by patients in a clinical trial;
- delays in validating any endpoints utilized in a clinical trial;
- the FDA may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials;
- reports from non-clinical or clinical testing of other CNS therapies that raise safety or efficacy concerns; and
- difficulties retaining patients who have enrolled in a clinical trial but may be prone to withdraw due to rigors of the clinical trials, lack of efficacy, side effects, personal issues or loss of interest.

Table of Contents

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

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

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

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

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

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

- have staffing difficulties;

- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- undergo changes in priorities or become financially distressed; or
- form relationships with other entities, some of which may be our competitors.

Table of Contents

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

Although we intend to design our clinical trials for our product candidates, we plan to have CROs, and in the case of our initial AV-101 Phase 2 study in MDD, the NIH, conduct all of the clinical trials. As a result, many important aspects of our drug development programs are outside of our direct control. In addition, the CROs or the NIH, as the case may be, may not perform all of their obligations under arrangements with us or in compliance with regulatory requirements, but we remain responsible and are subject to enforcement action that may include civil penalties up to and including criminal prosecution for any violations of FDA laws and regulations during the conduct of our clinical trials. If the NIH or CROs do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development and commercialization of AV-101 and other product candidates may be delayed or our development program materially and irreversibly harmed. We cannot control the amount and timing of resources these CROs or the NIH devote to our program or our clinical products. If we are unable to rely on clinical data collected by our CROs or the NIH, we could be required to repeat, extend the duration of, or increase the size of our clinical trials and this could significantly delay commercialization and require significantly greater expenditures.

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

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

We do not currently have, nor do we plan to acquire, the infrastructure or capability to internally manufacture our clinical drug supply of AV-101 or any other product candidates, for use in the conduct of our non-clinical studies and

clinical trials, and we lack the internal resources and the capability to manufacture any product candidates on a clinical or commercial scale. The facilities used by our contract manufacturers to manufacture the active pharmaceutical ingredient and final drug product must complete a pre-approval inspection by the FDA and other comparable foreign regulatory agencies to assess compliance with applicable requirements, including cGMPs, after we submit our NDA or relevant foreign regulatory submission to the applicable regulatory agency.

Table of Contents

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

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

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

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

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

We do not currently have an infrastructure for the sales, marketing and distribution of pharmaceutical products. In order to market our product candidates, if approved by the FDA or any other regulatory body, we must build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, 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.

Table of Contents

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

- the efficacy of our product candidates as demonstrated in clinical trials, and, if required by any applicable regulatory authority in connection with the approval for the applicable indications, to provide patients with incremental health benefits, as compared with other available CNS therapies;
- limitations or warnings contained in the labeling approved for our product candidates by the FDA or other applicable regulatory authorities;
- the clinical indications for which our product candidates are approved;
- availability of alternative treatments already approved or expected to be commercially launched in the near future;
- the potential and perceived advantages of our product candidates over current treatment options or alternative treatments, including future alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments;
- pricing and cost effectiveness;
- the effectiveness of our sales and marketing strategies;
- our ability to increase awareness of our product candidates through marketing efforts;
- our ability to obtain sufficient third-party coverage or reimbursement; or
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage.

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

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

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

Table of Contents

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

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

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

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

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

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

facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may, among other things:

- issue warning letters or untitled letters;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw marketing approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications submitted by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products, or require that we initiate a product recall.

Table of Contents

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

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

Currently, management is unaware of any FDA-approved therapy for MDD with the mechanism of action of AV-101. However, products approved for other indications, for example, the anesthetic ketamine, are being or may be used off-label for treatment of MDD, as well as other CNS indications for which AV-101 may have therapeutic potential. Additionally, other treatment options, such psychotherapy and electroconvulsive therapy, or ECT, are sometimes used before or instead of antidepressant medications to treat patients with MDD.

In the field of new generation antidepressants focused on modulation of the NMDA receptor, our principal competitor is Naurex, Inc., which is developing GLYX-13 and NRX-1074 for treatment-resistant MDD. Although each of these drug candidates is a peptide and may not be orally active in MDD patients (GLYX-13 is only administered intravenously and, we believe, NRX-1074 has not yet been administered orally to MDD patients), both are new generation NMDA modulators focused, as is AV-101, on the glycine binding site of the NMDAR.

Many of our potential competitors, alone or with their strategic partners, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of treatments and the commercialization of those treatments. We believe that a range of pharmaceutical and biotechnology companies have programs to develop small molecule drug candidates for the treatment of depression, including MDD, epilepsy, neuropathic pain, Parkinson's disease and other neurological conditions and diseases, including, but not limited to, Abbott Laboratories, Actavis, Astra Zeneca, Eli Lilly, GlaxoSmithKline, Johnson & Johnson, Lundbeck, Merck, Novartis, Otsuka, Pfizer, Roche, Sumitomo Dainippon, and Takeda. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market

We 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 a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products,

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

Table of Contents

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 collaborations 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 biopharmaceutical product candidates. Although AV-101 is in Phase 2 clinical development, our research programs, we may fail to identify other potential product candidates for clinical development for a number of reasons. Our research methodology may be unsuccessful in identifying potential product candidates or our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval.

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

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

focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful.

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

Table of Contents

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

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

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

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

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

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

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

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

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

Table of Contents

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

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as AV-101, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. For example, if we receive marketing approval for AV0-101 as a treatment for MDD, physicians may nevertheless prescribe AV-101 to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

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

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

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

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

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

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

Table of Contents

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

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

- our customers' ability to obtain reimbursement for our product candidates in foreign markets;
- our inability to directly control commercial activities because we are relying on third parties;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries;
- the existence of additional potentially relevant third party intellectual property rights;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

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

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

We are a development stage biopharmaceutical company. Although our lead drug candidate is in Phase 2 development, we currently have no approved products and generate no revenues, and we have not yet fully demonstrated an ability to overcome many of the fundamental risks and uncertainties frequently encountered by development stage companies in new and rapidly evolving fields of technology, particularly biotechnology. To

execute our business plan successfully, we will need to accomplish the following fundamental objectives, either on our own or with strategic collaborators:

- produce product candidates;
- develop and obtain required regulatory approvals for commercialization of products we produce;
- maintain, leverage and expand our intellectual property portfolio;
- establish and maintain sales, distribution and marketing capabilities, and/or enter into strategic partnering arrangements to access such capabilities;
- gain market acceptance for our products; and
- obtain adequate capital resources and manage our spending as costs and expenses increase due to research, production, development, regulatory approval and commercialization of product candidates.

Table of Contents

Our future success is highly dependent upon our ability to successfully develop and commercialize AV-101 and produce, develop and commercialize proprietary NCEs using our stem cell technology, human cells derived from stem cells, our customized human cell-based bioassay systems and medicinal chemistry, and we cannot provide any assurance that we will successfully develop and commercialize AV-101 or drug rescue NCEs , or that, if produced, AV-101 or any drug rescue NCE will be successfully commercialized.

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

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

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

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

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

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

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

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

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

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

Table of Contents

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

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

Our success is highly 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.

We have not yet fully validated LiverSafe 3D for potential drug rescue applications, and we may never do so.

We have developed proprietary protocols for controlling the differentiation of human pluripotent stem cells and producing functional, mature, adult liver cells we believe are superior to primary (cadaver) hepatocytes used in in vitro testing. However, we have not yet fully validated our ability to use the human liver cells we produce for LiverSafe 3D to predict important biological effects, both toxic and nontoxic, of reference drugs, drug rescue candidates or drug rescue NCEs on the human liver, including drug-induced liver injury and adverse drug-drug interactions. Furthermore, we may never be able to do so, which could adversely affect our business and the potential applications of LiverSafe 3D for drug discovery, drug rescue and regenerative medicine.

CardioSafe 3D, and, if validated, LiverSafe 3D may not be meaningfully more predictive of the behavior of human cells than existing methods.

The success of our drug rescue business is highly dependent, in the first instance, upon CardioSafe 3D, and, in the second instance, if validated, LiverSafe 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, and, when validated, LiverSafe 3D, will be more efficient or accurate at predicting the heart or liver safety of new drug candidates than the testing models currently used. If CardioSafe 3D and LiverSafe 3D fail to provide a meaningful difference compared to existing or new models in predicting the behavior of human heart and liver cells, 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 strategic 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.

Table of Contents

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 research and development programs related to producing and using functional, mature adult liver cells to validate LiverSafe 3D as a novel bioassay system for drug rescue, as well as exploratory nonclinical regenerative medicine programs involving blood, bone, cartilage, heart, and liver. Although we and our collaborators have developed proprietary protocols for the production of multiple differentiated cell types, we could encounter difficulties in differentiating particular cell types, even when following these proprietary protocols. These difficulties could result in delays in production of certain cells, assessment of certain drug rescue candidates and drug rescue NCEs, design and development of certain human cellular assays and performance of certain exploratory nonclinical regenerative medicine studies. In the past, our stem cell research and development projects have been significantly delayed when we encountered unanticipated difficulties in differentiating human pluripotent stem cells into heart and liver cells. Although we have overcome such difficulties in the past, we may have similar delays in the future, and we may not be able to overcome them or obtain any benefits from our future stem cell technology research and development activities. Any delay or failure by us, for example, to produce functional, mature blood, bone, cartilage, and liver cells could have a substantial and material adverse effect on our potential drug discovery, drug rescue and regenerative medicine business opportunities and results of operations.

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

Some of our ongoing and planned research and development programs 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 use hESCs derived from excess fertilized eggs that have been created for clinical use in in vitro fertilization (IVF) procedures and have been donated for research purposes with the informed consent of the donors after a successful IVF procedure because they are no longer desired or suitable for IVF. Certain academic research institutions have adopted policies regarding the ethical use of human embryonic tissue. These policies may have the effect of limiting the scope of future collaborative research opportunities with such institutions, thereby potentially impairing our ability to conduct certain research and development in this field that we believe is necessary to expand the drug rescue capabilities of our technology, which would have a material adverse effect on our business.

The use of embryonic or fetal tissue in research (including the derivation of hESCs) in other countries is regulated by the government, and varies widely from country to country. Government-imposed restrictions with respect to use of hESCs in research and development could have a material adverse effect on us by harming our ability to establish critical collaborations, delaying or preventing progress in our research and development, and causing a decrease in the market interest in our stock. These potential ethical concerns do not apply to induced pluripotent stem cells (iPSCs), or our plans to pursue studies involving human cells derived from iPSCs, because their derivation does not involve the use of embryonic tissues.

We have assumed that the biological capabilities of induced pluripotent stem cells (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 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 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.

Table of Contents

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

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

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

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

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

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

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

To the extent that our future stem cell research and development activities involve the use of iPSCs and the manipulation of human tissue and genetic information, the information we derive from such iPSC-related research and development activities could be used in a variety of applications, which may have underlying legal, social and ethical concerns, including the genetic engineering or modification of human cells, testing for genetic predisposition for certain medical conditions and stem cell banking. Governmental authorities could, for safety, social or other purposes,

call for limits on or impose regulations on the use of iPSCs and genetic testing or the manufacture or use of certain biological materials involved in our iPSC-related research and development programs. Such concerns or governmental restrictions could limit our future research and development activities, which could have a material adverse effect on our business, financial condition and results of operations.

Table of Contents

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 and LiverSafe 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 cell therapy or for other 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.

General Company-Related Risks

If we fail to attract and retain senior management and key scientific personnel, we may be unable to successfully produce, develop and commercialize AV-101, drug rescue NCEs, other potential product candidates and other commercial applications of our stem cell technology.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management and scientific and technical personnel. We are highly dependent upon our Chief Executive Officer, President and Chief Scientific Officer and Chief Financial Officer, as well as other employees, consultants and scientific collaborators. As of the date of this Quarterly Report on Form 10-Q, we have nine full-time employees, which may make us more reliant on our individual employees than companies with a greater number of employees. The loss of services of any of these individuals could delay or prevent the successful development of AV-101, drug rescue NCEs, other product candidates, and other potential applications of our stem cell technology, including our production and assessment of potential drug recuse NCEs or disrupt our administrative functions.

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

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

We may encounter difficulties in managing our growth and expanding our operations successfully.

As we seek to advance development of AV-101 for MDD and other CNS-related conditions, as well as cell production, bioassay development, drug discovery, drug rescue and development unrelated to AV-101, and stem cell

technology-related regenerative medicine programs, we will need to expand our research and development capabilities 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.

Table of Contents

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

If we develop AV-101, drug rescue NCEs, other product candidates, or regenerative medicine product candidates, either on our own or in collaboration with others, we will face an inherent risks of product liability as a result of the required clinical testing of such product candidates, and will face an even greater risk if we or our collaborators commercialize any such product candidates. For example, we may be sued if AV-101, any drug rescue NCE, other product candidate, or regenerative medicine product candidate we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for products that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- the inability to commercialize our product candidates; and
- a decline in our stock price.

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

As we continue to grow, we will need to hire additional qualified accounting and financial personnel with appropriate public company experience.

As we continue to grow our organization and seek to obtain listing of our common stock on a national securities market, we will need to establish and maintain more elaborate disclosure and financial controls and make changes in

our corporate governance practices. We will need to hire additional accounting and financial personnel with appropriate public company experience and technical accounting knowledge, and it may be difficult to recruit and retain such personnel. Even if we are able to hire appropriate personnel, our existing operating expenses and operations will increase by the direct costs of their employment and the indirect consequences related to the diversion of management resources from product development efforts.

Table of Contents

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

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

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

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

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

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

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

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

Risks Related to Our Financial Position and Need for Capital

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.

Table of Contents

We have incurred significant net losses in each fiscal year since our inception in 1998, including net losses of $13.9 million and $3.0 million during the fiscal years ending March 31, 2015 and 2014, respectively. As of June 30, 2015, we had an accumulated deficit of $114.0 million. We do not know whether or when we will become profitable. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to incur increasing levels of operating losses over the next several years and for the foreseeable future. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' deficit and working capital. We expect our research and development expenses to significantly increase in connection with non-clinical studies and clinical trials of our product candidates. In addition, if we obtain marketing approval for our product candidates, we will incur significant sales, marketing and outsourced-manufacturing expenses. As a public company, we incur additional costs associated with operating as a public company. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

Our ability to become profitable depends upon our ability to generate revenues. To date, although we have generated approximately $16.4 million in revenues, we have not commercialized any products 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 sell, AV-101, or we enter into one or more strategic development and commercialization agreements with respect to AV-101 or another product candidate. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- initiate and successfully complete clinical trials that meet their clinical endpoints;
- initiate and successfully complete all safety studies required to obtain U.S. and foreign marketing approval for our product candidates;
- commercialize our product candidates, if approved, by developing a sales force or entering into collaborations with third parties; and
- achieve market acceptance of our product candidates in the medical community and with third-party payors.
- Absent our entering into a strategic development and commercialization collaboration or partnership agreement, 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 a commercially successful drug. 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.

Our independent auditors have expressed substantial doubt about our ability to continue as a going concern.

Our consolidated financial statements for the year ended March 31, 2015 have been prepared assuming we will continue to operate as a going concern. However, due to our ongoing operating losses and our accumulated deficit, in their opinion on our audited financial statements for our fiscal year ended March 31, 2015, our auditors indicated that

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

Table of Contents

We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts or other operations.

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

At June 30, 2015, our existing cash and cash equivalents were not sufficient to fund our current operations for the next 12 months. Although, in February 2015, we entered into a Cooperative Research and Development Agreement (CRADA) with the U.S. National Institutes of Health (NIH), under which CRADA the NIH will fully fund and conduct the initial Phase 2 clinical efficacy and safety of AV-101 in Major Depressive Disorder at no cost to us, we have no current source of revenue to sustain our present activities, and we do not expect to generate revenue until, and unless, we (i) out-license or sell AV-101, a drug rescue NCE, another drug candidate unrelated to AV-101 to third-parties, (ii) enter into license arrangements involving our stem cell technology, including customized drug discovery and predictive toxicology assays and services and/or regenerative medicine opportunities with a third party, or (iii) obtain approval from the FDA or other regulatory authorities and successfully commercialize, on our own or through a future collaboration, one or more of our compounds. As the outcome of our proposed drug rescue and AV-101 development activities and future anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates, on our own or in collaboration with others. In addition, other unanticipated costs may arise. As a result of these and other factors, we will need to seek additional capital in the near term to meet our future operating requirements, including capital necessary to obtain regulatory approval for, and to commercialize, our product candidates, and may seek additional capital in the event there exists favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. We are considering a range of potential sources of funding, including public or private equity or debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or a combination of these approaches, and we intend to complete additional financing arrangements prior to the end of 2015. Raising funds in the current economic environment may present additional challenges. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations.

Our future capital requirements depend on many factors, including:

- the number and characteristics of the product candidates we pursue, including AV-101 or drug rescue NCEs;
- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical and clinical studies;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
-

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

- the cost of manufacturing our product candidates and any products we successfully commercialize;
- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- market acceptance of our products;
- the effect of competing technological and market developments;
- our ability to obtain government funding for our programs;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims necessary to preserve our freedom to operate in the stem cell industry, including litigation costs associated with any claims that we infringe third-party patents or violate other intellectual property rights and the outcome of such litigation;
- the timing, receipt and amount of potential future licensee fees, milestone payments, and sales of, or royalties on, our future products, if any; and
- the extent to which we acquire or invest in businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

Table of Contents

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

If we are unable to obtain 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.

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

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

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

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

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

As of March 31, 2015, we had federal and state net operating loss carryforwards of $58.7 million and $53.1 million, respectively, which begin to expire in fiscal 2016. Under Section 382 of the Internal Revenue Code of 1986, as amended, or 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.

Table of Contents

Risks Related to Our Intellectual Property Rights

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

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

Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce our patents, should they issue, preserve the confidentiality of our trade secrets and 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. Our owned and licensed patents and patent applications relate to AV-101 and, in general, human pluripotent stem cell technology.

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

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

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

proprietary rights in these countries. If these developments were to occur, they could have a material adverse effect on our sales.

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

Table of Contents

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

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

- any of our AV-101 or other pending patent applications, if issued, will include claims having a scope sufficient to protect AV-101 or any other products or product candidates;
- any of our pending patent applications will issue as patents at all;
- we will be able to successfully commercialize our product candidates, if approved, before our relevant patents expire;
- we were the first to make the inventions covered by each of our patents and pending patent applications;
- we were the first to file patent applications for these inventions;
- others will not develop similar or alternative technologies that do not infringe our patents;
- others will not use pre-existing technology to effectively compete against us;
- any of our patents, if issued, will be found to ultimately be valid and enforceable;
- any patents issued to us will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies or product candidates that are separately patentable; or
- that our commercial activities or products will not infringe upon the patents or proprietary rights of others.

We 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.

Table of Contents

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 which 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 were 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.

Table of Contents

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

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

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

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

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

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

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

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

If we or one of our licensing partners initiated legal proceedings against a third party to enforce a patent, if and when issued, covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include alleged failures to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for

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

Table of Contents

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

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

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

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

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

We are dependent, in part, on licensed intellectual property. If we were to lose our rights to licensed intellectual property, we may not be able to continue developing or commercializing our product candidates, if approved. If we breach any of the agreements under which we license the use, development and commercialization rights to our product candidates or technology from third parties or, in certain cases, we fail to meet certain development or payment deadlines, we could lose license rights that are important to our business.

We are a party to a number of license agreements under which we are granted rights to intellectual property that are or could become important to our business, and we expect that we may need to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose on us, various development, regulatory and/or commercial diligence obligations, payment of fees, milestones and/or royalties and other obligations. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to develop or market products which could be covered by the license. Our business could suffer, for example, if any current or future licenses terminate, if the licensors fail to abide by the terms of the license, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. See "Business—Licenses" in our Annual Report on Form 10-K for our fiscal year ended March 31, 2015, filed with the Securities and Exchange Commission on June 29, 2015, for a description of our license agreements, which includes a description of the termination provisions of these agreements.

Table of Contents

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 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 payment, 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.

Table of Contents

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

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

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

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

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

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involve both technological and

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

Table of Contents

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. However, on March 4, 2014, the U.S. PTO 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.

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

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

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

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

Numerous factors may limit any potential competitive advantage provided by our intellectual property rights.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative:

.

others may be able to develop and/or practice technology that is similar to our technology or aspects of our technology but that is not covered by the claims of patents, should such patents issue from our patent applications;

- we might not have been the first to make the inventions covered by a pending patent application that we own;
- we might not have been the first to file patent applications covering an invention;
- others may independently develop similar or alternative technologies without infringing our intellectual property rights;
- pending patent applications that we own or license may not lead to issued patents;
- patents, if issued, that we own or license may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection;
- we may not be able to obtain and/or maintain necessary or useful licenses on reasonable terms or at all;
- 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.

Table of Contents

If we seek to leverage prior discovery and development of drug rescue candidates under in-license arrangements with academic laboratories, biotechnology companies, the NIH, pharmaceutical companies or other third parties, it is uncertain what ownership rights, if any, we will obtain over intellectual property we derive from such licenses to drug rescue NCEs we may produce or develop in connection with any such third-party licenses.

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 Common Stock

There is no assurance that an active, liquid and orderly trading market will develop for our common stock or what the market price of our common stock will be and, as a result, it may be difficult for you to sell your shares of our common stock.

Since we became a publicly-traded company in May 2011, there has been a limited public market for shares of our common stock on the OTCQB Marketplace (“OTCQB”). We do not yet meet the initial listing standards of the New York Stock Exchange, the NASDAQ Capital Market, or other similar national securities exchanges. Until our common stock is listed on a broader exchange, we anticipate that it will remain quoted on the OTC Markets. In that venue, investors may find it difficult to obtain accurate quotations as to the market value of our common stock. In addition, if we fail to meet the criteria set forth in SEC regulations, various requirements would be imposed by law on broker-dealers who sell our securities to persons other than established customers and accredited investors. Consequently, such regulations may deter broker-dealers from recommending or selling our common stock, which may further affect liquidity. This could also make it more difficult to raise additional capital.

We cannot predict the extent to which investor interest in our company will lead to the development of a more active trading market on the OTC Markets, whether we will meet the initial listing standards of the New York Stock Exchange, the NASDAQ Capital Market, or other similar national securities exchanges, or how liquid that market might become. If an active trading market does not develop, you may have difficulty selling any of the shares of our common stock that you buy.

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

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

- plans for, progress of or results from non-clinical studies and clinical trials of our product candidates;
- the failure of the FDA to approve our product candidates;
- announcements of new products, technologies, commercial relationships, acquisitions or other events by us or our competitors;

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

Table of Contents

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

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

The stock market in general, and biotechnology-based companies like ours in particular, has from time to time experienced volatility in the market prices for securities that often has been unrelated to the operating performance of the underlying companies. These broad market and industry fluctuations may adversely affect the market price of our common stock, regardless of our operating performance. In certain recent situations in which the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against such company that issued the stock. If any of our stockholders were to bring a lawsuit against us, the defense and disposition of the lawsuit could be costly and divert the time and attention of our management and harm our operating results. Additionally, if the trading volume of our common stock remains low and limited there will be an increased level of volatility and you may not be able to generate a return on your investment.

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Prior to this date of this Quarterly Report on Form 10-Q, there has been a limited public market for shares of our common stock on the OTC Markets. Future sales of a substantial number of shares of our common stock in the public market, including shares issued upon the exchange of our Series A Preferred Stock and Series B Preferred Stock, and the exercise of outstanding options and warrants for common stock which are issuable upon exercise of warrants, in the public market, or the perception that these sales might, occur, could significantly reduce the market price for our common stock and impair our ability to raise adequate capital through the sale of equity securities.

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

Certain of our current institutional stockholders and their respective affiliates own a substantial portion of our outstanding capital stock, including our common stock, Series A Preferred Stock and Series B 10% Convertible Preferred Stock, which preferred stock is convertible into a substantial number of shares of common stock. Accordingly, these stockholders may exert significant influence over us and over the outcome of any corporate actions requiring approval of holders of our common stock, including the election of directors and amendments to our organizational documents, such as increases in our authorized shares of common stock, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transactions. These stockholders may also delay or prevent a change of control of us, even if such a change of control would benefit our other stockholders. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise. Furthermore, the interests of our principal institutional stockholders may not always coincide with your interests or the interests of other stockholders may act in a manner that advances its best interests and not necessarily those of other stockholders, including seeking a premium value for its common stock, which might affect the prevailing market price for our common stock.

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

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

Table of Contents

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

Following approval by our stockholders in October 2011, our Articles of Incorporation permit us to issue up to 10.0 million shares of preferred stock. Our Board of Directors has authorized the issuance of both 500,000 shares of Series A Preferred, all of which shares are currently issued and outstanding, and 4.0 million shares of Series B 10% Convertible Preferred stock, of which approximately 3.0 million shares are issued and outstanding as of June 30, 2015. Our Board of Directors could authorize the issuance of additional series of preferred stock in the future and such preferred stock could grant holders preferred rights to our assets upon liquidation, the right to receive dividends before dividends would be declared to holders of our common stock, and the right to the redemption of such shares, possibly together with a premium, prior to the redemption of the common stock. In the event and to the extent that we do issue additional preferred stock in the future, the rights of holders of our common stock could be impaired thereby, including without limitation, with respect to liquidation.

We do not intend to pay dividends on our common stock and, consequently, your ability to achieve a return on your 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 you purchased them.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Sale of Units in Series B Preferred Unit Private Placement

Between May 26, 2015 and August 11, 2015, we entered into self-placed private placement transactions involving securities purchase agreements with accredited investors, pursuant to which we sold Series B Preferred Units consisting of an aggregate of (i) 293,262 shares of our Series B 10% Convertible Preferred Stock (Series B Preferred); and (ii) five-year warrants to purchase an aggregate of 293,262 shares of our Common Stock at a fixed exercise price of $7.00 per share, subject to adjustment only for customary stock dividends, reclassifications, splits and similar transactions (Series B Warrants). We received cash proceeds of $2,052,781 which we expect to use for general corporate purposes. The figures reported above include 142,860 shares of Series B Preferred and Series B Warrants to purchase 142,860 shares of our Common Stock sold to Platinum for cash proceeds of $1.0 million in accordance with the terms of the Platinum Agreement reported in our Current Report on Form 8-K filed with the Securities and Exchange Commission on May 13, 2015. The Series B Preferred Units were offered and sold in a self-placed private placement transaction exempt from registration under the Securities Act, in reliance on Section 4(2) thereof and Rule 506 of Regulation D thereunder.

Each share of Series B Preferred is convertible, at the option of the Holder (Voluntary Conversion), into one (1) share of our Common Stock at a fixed conversion price of $7.00 per share, subject to adjustment only for customary stock dividends, reclassifications, splits and similar transactions (Fixed Conversion Price). All shares of Series B Preferred are also convertible automatically into Common Stock (Automatic Conversion) upon the closing or effective date of any of the following transactions or events: (i) a strategic transaction involving AV-101, our clinical-stage, orally-available new drug candidate for Major Depressive Disorder and other diseases and disorders of the central nervous system, with an initial up-front cash payment to us of at least $10.0 million; (ii) a registered public offering of Common Stock with aggregate gross proceeds to us of at least $10.0 million; or (iii) for 20 consecutive trading days our Common Stock trades at least 20,000 shares per day with a daily closing price of at least $12.00 per share;

provided, however, that Automatic Conversion and Voluntary Conversion (collectively, Conversion) are subject to customary beneficial ownership blockers. Prior to Conversion, shares of Series B Preferred will accrue dividends, payable only in unregistered shares of Common Stock, at a rate of 10% per annum (the Accrued Dividend). The Accrued Dividend will be payable only on the date of Conversion solely in that number of shares of Common Stock equal to the Accrued Dividend, divided by the Fixed Conversion Price.

Table of Contents

Conversion of Debt into Series B Preferred Stock

Between July 6, 2015 and August 11, 2015, the outstanding balance (principal plus accrued interest) of our outstanding promissory note and accounts payable due to MicroConstants, our promissory Note A and accounts payable to Morrison & Foerster, and certain other amounts due to technology licensors, professional service providers and others, in the aggregate amount of $1,560,895 were converted into an aggregate of 222,985 shares of Series B Preferred. The Series B Preferred was offered and sold in a private placement transaction exempt from registration under the Securities Act, in reliance on Section 4(2) thereof and Rule 506 of Regulation D thereunder.

Securities Issued for Professional Services

Between June 30, 2015 and July 13, 2015, we issued an aggregate of 100,000 shares of our Series B Preferred to four professional service providers and accredited investors as compensation for such professional services performed and to be performed for us. The Series B Preferred was issued in a self-placed private placement transaction exempt from registration under the Securities Act, in reliance on Section 4(2) thereof and Rule 506 of Regulation D thereunder.

Item 3. Defaults Upon Senior Securities

None.

Item 6. EXHIBITS

Exhibit Number	Description
31.1	Certification of the Principal Executive Officer required by Rule 13a-14(a) under the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of the Principal Financial Officer required by Rule 13a-14(a) under the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32	Certification of the Principal Executive and Financial Officers required by Rule 13a-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

Table of Contents

SIGNATURES

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

VISTAGEN THERAPEUTICS, INC.

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

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

Dated: August 14, 2015